No. 23-_____

IN THE

Supreme Court of the United States

JOHN DOE, M.D., PH.D.,

Petitioner,

JOHN DOE M.D., PH.D., PLLC,

Appellee,

—v.—

JUDITH RODGERS, AS SENIOR ADVISOR IN THE DIVISION OF PRACTITIONER DATA BANKS, ET AL.,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This is the first case in 37 years since enactment of the Health Care Quality Improvement Act of 1986 (HCQIA) (42 U.S.C. §§11101–11152) to reach this Court for necessary constitutional review of the HCQIA and its mandated adverse "professional review actions" (Adverse Action Reports (AARs)) from private hospitals. These AAR's are filed and then released to would-be hospital employers, which by law must "query" the HCQIA's "databank" (NPDB) before hiring a licensed healthcare-professional. There are currently over 4-million doctors and nurses, and upwards of 21-million healthcare-professionals subject to the HCQIA. Respondents, the U.S. Department of Health & Human Services Agency (HHS) and its co-respondent division, the National Practitioner Data Bank (NPDB), have implemented the HCQIA by regulations and sub-regulatory guidance ("NPDB Guidebook"). The law and HHS regulations as enacted and applied do not require either the hospital reporting an AAR or HHS to provide physicians under review with any due process. This lack of due process at multiple levels has resulted in over-inclusive AAR reporting of skilled and competent doctors onto the NPBD, which unconstitutionally prevents them from further practice of their lawful profession.

The effect of an AAR released by Respondents against a physician is a "career-ender" because it broadly precludes re-employment anywhere in the United States due to hospitals nationwide having adopted policies not to hire physicians with an AAR. The District Court below acknowledged that effect.

Petitioner is a graduate of Harvard Medical School and holds degrees of A.B., M.D. and Ph.D. and is a Board-certified surgeon. Prior to the events giving rise

to this case, in over 11 years as a physician, Petitioner had never had any disciplinary actions against him in over 2,500 surgical cases, and in his career, had never suffered a medical malpractice judgment or payment on his behalf.

Petitioner was the victim of a false and fraudulent private hospital AAR report to the NPDB databank, without his knowledge. The AAR was for "voluntary surrender of clinical privileges" "while under, or to avoid, investigation" after the hospital told him there was no investigation. Contrary to the AAR, the NYS Dept. of Health concluded Petitioner's reported case had no deviations from the standard of care.

Petitioner sought HHS "Secretarial Review" of the AAR. Under the self-limiting regulations, and without any due process, the Secretary concluded that the AAR should be maintained, explaining:

> "The Secretary cannot conduct an independent review of the surrender or resignation, inquire whether an investigation was warranted, whether a professional review action would have been taken if the investigation had been completed, whether the 'due process' provided or to be provided by the reporting entity was adequate, or substitute his judgment for that of the entity." (Secretarial Decision, Appendix H).

Respondents have permanently maintained this AAR against Petitioner on NPDB for 14 years and released it to scores of U.S. hospitals inquiring in response to Petitioner's job applications. This has destroyed Petitioner's career as a surgeon in the United States.

The District Court dismissed all the constitutional claims and refused to find that HHS decision violated the Administrative Procedure Act. The D.C. Circuit affirmed on the opinion below without further analysis.

The questions presented are:

1. Did Congress, in enacting the HCQIA, constitutionally authorize the Secretary of HHS and its NPDB division to create rules under 42 U.S.C. §11136, "Disclosure and correction of information," to create rules broadly affecting the vast economic group of every "physician or other health care practitioner" in the United States, without any other guidance, by which HHS adopted limited, non-Due Process review "procedures in the case of disputed accuracy" of information in the Adverse Action Reports, resulting in HHS maintaining and publishing the AARs as "reviewed" by the Secretary, with the effect of broadly precluding reported physicians and other healthcare-practitioners from further employment in their chosen professions.

2. Whether the Health Care Quality Improvement Act of 1986 (HCQIA) and the HHS-adopted regulations and sub-regulatory guidance for the agency-created National Practitioner Data Bank (NPDB) are unconstitutional as written and as applied, for failing to require Due Process to licensed professionals in the reporting and review of Adverse Action Reports (AAR) made by private hospitals which are then released by HHS to future employers and broadly and permanently preclude future employment.

3. Whether Respondents violated Petitioner's constitutional rights and the Administrative Procedure Act by accepting, maintaining and releasing to all inquiring hospitals a disputed AAR against

Petitioner, under the HCQIA and HHS regulations and sub-regulatory guidance, submitted by a private hospital, for surrender of clinical privileges during an "investigation" fraudulently concealed from Petitioner, where the HSS expressly states it "cannot conduct an independent review of the surrender or resignation, inquire whether an investigation was warranted, [or] … whether the 'due process' provided or to be provided by the reporting entity was adequate."

PARTIES TO THE PROCEEDING

Petitioner, plaintiff-appellant below, is JOHN DOE, M.D., PH.D.[1]

Plaintiff-Appellee below is JOHN DOE, MD., PH.D., P.L.L.C., captioned by the D.C. Circuit on Petitioner's appeal as "Appellee".

Respondents, defendants-appellees below, are the NATIONAL PRACTITIONER DATA BANK, JUDITH RODGERS, M.H.A., in her official capacity as Senior Advisor in the Division of Practitioner Data Banks, CYNTHIA GRUBBS, J.D., in her official capacity as Director of the Division of Practitioner Data Banks, and ANASTASIA TIMOTHY, M.D., M.P.H. in her official capacity as Dispute Resolution Manager.

Former Secretary KATHLEEN SEBELIUS, M.P.A., in her official capacity as Secretary of U.S. Department of Health and Human Services was also a defendant-appellee below, but her term expired.

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[1] After 11 years, one day before the appeal was to be argued in the D.C. Circuit, the District Court entered an order granting the Government's motion, over objection, to remove pseudonymity, and then re-entered on the docket the October 20, 2020 decision, showing the plaintiff's actual name as Adam Brook, M.D., Ph.D. The D.C. Circuit Court Judgment and Orders continue to show the John Doe, M.D., Ph.D., which is used herein. (App. A and B)

CORPORATE DISCLOSURE STATEMENT

JOHN DOE, M.D. PH.D, P.L.L.C., a co-plaintiff in the District Court, was designated in the D.C. Circuit caption as "Appellee." JOHN DOE, M.D. PH.D., P.L.L.C is a New York professional limited liability company for whom the sole owner and professional is Petitioner JOHN DOE, M.D., PH.D. and has no parent corporation or other owners.

STATEMENT OF RELATED PROCEEDINGS

The following proceedings are related:

Doe v. Rodgers, No. 20-5297 (D.C. Cir) (judgment of affirmance issued February 14, 2023; petition for rehearing and petition for rehearing *en banc* denied May 12, 2023)

Doe v. Rogers (sic: Rodgers), 12 Civ. 01229 (D.D.C.) (Hogan, J.), Docket #68 sealed (June 17, 2015) and Docket #96 (unsealed, redacted filed October 9, 2015) (Memorandum Opinion granting defendants' motion to dismiss and for summary judgment on APA claims, and denying plaintiff's motion for summary judgment)

Doe v. Rogers (sic: Rodgers), 12 Civ. 01229 (D.D.C.) (Hogan, J.), Docket #130 sealed (filed September 10, 2020) and Docket #139 (unsealed signed September 10, 2020, filed October 30, 2020) (Memorandum Opinion granting defendants' motion to dismiss or in the alternative for summary judgment, denying plaintiffs' cross motion for summary judgment, and plaintiffs' motions to supplement the record and for other relief).

There are no additional proceedings in any court that are directly related to this case within the meaning of this Court's Rule 14(b)(iii).

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PETITION FOR WRIT OF CERTIORARI

This case presents recurring issues of exceptional importance to the national healthcare-system and the ability to maintain the quantity and quality of healthcare practitioners and to attract new professionals. Respondents' unconstitutional processes are causing broad preclusion of thousands of skilled, competent physicians, at a time when the Nation is experiencing a shortage of qualified healthcare-professionals and increasing medical needs due to an aging population and pandemics. This case presents the Court with a major question of economic and political importance: whether a federal agency, unguided by Congress, can enact regulations, affecting precious private rights, which provide no due process, with the result that thousands of competent healthcare-professionals are permanently removed from that needed workforce.

1. Respondents Concede No Due Process

"Secretarial Reviews" of AARs are conducted under HHS regulations and a sub-regulatory NPDB Guidebook which limit what HHS will review. They expressly provide no due process to reported physicians, as demonstrated by the boilerplate acknowledgment of the cabined scope of review. The form, issued to Dr. Doe in this case and to many others, states:

> "The Secretary cannot conduct an independent review of the surrender or resignation, inquire whether an investigation was warranted, whether a professional review action would have been taken if the investigation had been completed, whether the 'due process' provided or to be provided by the reporting entity was adequate, or

> substitute his judgment for that of the entity." (Sec. Dec. App. H, p.337).

Lacking due process review, prior reported cases and published legal literature amassed in the First Amended Complaint (FAC) confirm the widespread overbreadth of AARs to bar not only "incompetent" practitioners, but to destroy the careers of skilled, competent professionals.

2. Unconstitutional Deprivation Known to Respondents and Damaging Petitioner.

A November 2000 GAO Report criticized HHS:

> "Because NPDB information *can affect a practitioner's reputation and livelihood*, the integrity of the data bank's information has been of great concern. Since its beginning in 1990, questions have arisen about NPDB's operational efficiency and effectiveness [citing three earlier GAO Reports]." *National Practitioner Data Bank: Major Improvements Are Needed to Enhance Data Bank's Reliability,* GAO-01-130 (2000) App. G p.263 (Emphasis added.)
>
> Regarding "clinical privileging reports" (AARs), GAO reported: "We also found inaccurate information in about one-third of the 79 clinical privilege restriction reports we reviewed." (Id., App. 266, emphasis added).

Another research paper in 2012 reported that an AAR is a "career ender," and "the physician's reputation is irreparably damaged." A negative but false AAR preventing rehiring in a hospital setting renders a surgeon's license "worthless" and is referred to as "NPDB Physician Blacklisting." A negative AAR

also causes "loss of both medical insurance and the termination of managed care contracts." Van Tassel, *Blacklisted: The Constitutionality of the Federal System for Publishing Reports of "Bad Doctors" in the National Practitioner Data Bank*, 33 Cardozo Law Review 2031 (June 2012): 2053, 2057–2063. FAC ¶146 (App. I) (hereinafter "*Blacklisted*"). Respondents continue with these practices today.

Petitioner is one of many victims of this unconstitutional, non-due process career-destruction. Petitioner requests the Court grant the Petition to address the Questions Presented and find that the District Court Orders dismissing his Due Process claims and granting summary judgment on the APA claim should be reversed, with a specific finding of unconstitutionality and unlawful delegation.

3. Robust Facts on a Pleading-Stage Record

This case is a good vehicle for the Court to address the constitutional issues, since the case comes to the Court on a grant of an opening Motion to Dismiss the extensive FAC, which must be taken as true. The factual record is robust, but simple. The District Court did not so treat it, but, after 20 months, issued a 79-page Memorandum Decision, "finding facts" and with suppositions about the "possibility that the Hospital was operating under [a] mistaken belief." App. C at p.49

This case is a unique opportunity for this Court because of its unambiguous presentation of the issues to examine this national issue. In prior court challenges to HCQIA and HHS processes, the physician had written or conceded notice of the investigation and often "participated," only to quarrel with the result. In such cases, courts dismissed the claims by concluding that due process was provided at

the hospital "peer-review." Not so here. Petitioner received no notice and no due process at any level and has evidence of hospital fraud.

As more fully set forth in the FAC, Petitioner ("Doe") is a graduate of Harvard Medical School and holds degrees of A.B., M.D., and Ph. D. and is a Board-certified surgeon. Prior to the events giving rise to this case, in 11 years as a physician, Petitioner had never had any disciplinary actions against him in 2,500 surgical cases. He had never suffered a medical malpractice judgment or payment on his behalf. (FAC ¶3) His career was destroyed by the hospital's fraud, a non-due process hospital sham peer-review and AAR, and the cabined Secretarial Review permanently maintaining the AAR on his NPDB record. Scores of hospitals have rejected Doe just because of the existence of the AAR on his NPDB record which they must query. (FAC ¶51–56).

This case is a paradigm of the constitutional flaws in HCQIA and HHS's administration, affecting thousands of competent practitioners. This is a long overdue opportunity for this Court to intervene to declare these procedures unconstitutional and restore Due Process to protect millions of competent practitioners and the national healthcare-system.

4. Broad National Impact

The impact of the challenged laws and regulations on physicians and the healthcare-system cannot be overstated. Millions of healthcare-practitioners are subject to this unconstitutional process in all 50 states. HHS regulation 45 C.F.R. §60.11(a)(2022) provides:

> "Peer review organizations and private accreditation entities are required to report

> any negative actions or findings … which are taken *against a health care practitioner, health care entity, provider or supplier*…" (emphasis added).

See 45 C.F.R. §60.12(2022) (reporting review actions "of a physician or dentist"); and §60.12(a)(2)("A health care entity may report to the NPDB information … *with respect to other healthcare practitioners*.") (Emphasis added.)[2]

Published data from the Bureau of Labor Statistics and from the Kaiser Family Foundation (KFF) show over 1-million professionally active physicians, 2.9-million nurses, and 202-thousand dentists.[3] This is 4-million licensed healthcare-practitioners directly subject to "required" reporting under the Agency rule in current 45 C.F.R. §60.12. The Bureau of Labor Statistics further reports that the healthcare and social assistance sector which it views as one category, has 21.2-million employees.[4] Many of these employees

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[2] "Other healthcare practitioners" is defined in §60.3 as follows: "*Healthcare practitioner, licensed healthcare practitioner, licensed practitioner, or practitioner* means an individual who is licensed or otherwise authorized by a state to provide health care services…" (Italics in original.) That is a 50-state scope of professionals subject to the challenged system.

[3] https://www.kff.org/other/state-indicator/total-activephysicians/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D; https://www.nursingprocess.org/how-many-nurses-are-there-in-the-us.html; https://www.kff.org/other/state-indicator/total-dentists/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (accessed July 27, 2023)

[4] *See* https://www.bls.gov/iag/tgs/iag62.htm#workforce (accessed July 25, 2023)

also fall into the reportable categories. The NPDB Guidebook, Chapter C, "Subjects of Reports," Definitions contains an extensive Table C-1 of covered "health care practitioners … as used in this *Guidebook*."[5]

These millions of healthcare-providers are subject to destruction of their careers because of erroneous or maliciously inaccurate reports about their competence or resignation "while under investigation" maintained permanently on NPDB. These AAR's are released by HHS under its self-limited rules, without any Due Process. Such broad preclusion of practitioners from their lawful profession is a major question and national issue of vast economic and political significance.

In 37 years since enactment of HCQIA, this is the first case to reach this Court and provide the opportunity to correct this flawed statute and unconstitutional Agency practice. This issue has evaded this Court because healthcare-providers damaged by an NPDB Report do not have the financial resources to take such claims through three levels of federal courts. This is because the challenged conduct destroys their careers leaving them without funds to engage counsel.

OPINIONS BELOW

The Judgment in the District of Columbia Circuit Court of Appeals, No. 20-5297, is reproduced at App. A. The 2015 District Court Opinion, 139 F.Supp.3d 120 (filed October 9, 2015) is reproduced at App. C. The 2020 District Court Opinion, 498 F.Supp.3d 59 (signed

[5] https://www.npdb.hrsa.gov/guidebook/CDefinitions.jsp

September 10, 2020, filed October 30, 2020), is reproduced at App. D.

JURISDICTION

The D.C. Circuit issued Judgment on February 14, 2023, App. A, and denied Plaintiff-Appellant's timely petition for rehearing or rehearing *en banc* on May 12. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant constitutional and statutory provisions area included in Appendix E.

STATEMENT OF THE CASE

A. Legal Background

1. HCQIA Statutory Framework

The Health Care Quality Improvement Act of 1986, 42 U.S.C. §11101–11152 ("HCQIA") was enacted to address a "national 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." §11101(2) Congress believed that the problem could be remedied through "professional peer-review" in hospitals by "provid[ing] an incentive and protection for those physicians engaging in effective professional peer review." §11101(3) and (5)

"Peer-review" involves private hospitals reviewing their own physicians in cases such as "possible incompetence or improper professional conduct." §11133(a)(1)(B)(i)

Rep. Wyden, lead-sponsor of the HCQIA, said during the Congressional hearings:

> [W]e have given physicians under review full due process rights with notice and representation. Health Care Quality Improvement Act: Hearings before the Subcomm. on Civil and Constitutional Rights, 99th Cong., *52 (October 8, 1986)

In furtherance of that legislative intent, HCQIA provides immunity for peer-reviewers *if the peer-review complies with 42 U.S.C. §11112 "Standards for Professional Review Actions."* These Standards require adequate notice to the physician and proper conduct of a fair hearing, including that the review be conducted "before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved." §11112(b)(3)(A)(iii)

Crucially, HCQIA *only incentivizes* Due Process by providing such immunity if the due process standards are met but *does not require due process*. That is a fundamental constitutional flaw, because some hospitals proceed to conduct peer-review without affording the physician due process. In the case at bar, Doe's hospital has no immunity but has relied instead on a 15-million-dollar insurance policy to defend Doe's state court action for the last 11 years. (NYSCEF, Public Dkt. 957, Index No.650921/2012, Sup.Ct. N.Y. County).

HCQIA requires that hospitals report certain professional review actions to the Secretary of Health and Human Services (HHS). Physicians are reported when the hospital takes a professional review action "that adversely affects the[ir] clinical privileges … for a period longer than 30 days or accepts the surrender

of clinical privileges … (i) While the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or … (ii) In return for not conducting such an investigation or proceeding." §11133(a)(1)

With that delegation, HHS created the National Practitioner Databank (NPDB) to receive such reports ("Adverse Action Reports" (AARs)). Such reports remain permanently on the physician's NPDB record.

Congress thought it was addressing the problem of incompetent doctors identified by peer-review and reported to NPDB by mandating that each hospital must "request from the secretary" any reports before hiring, and again "every 2 years" for practitioners on the medical staff. §11135

Thus, Congress set up a national reporting system for physicians similar to a convicted sex offender registry and the No-Fly List of suspected terrorists, to permanently identify physicians reported under AARs to every future would-be hospital employer. Unlike physicians though, sex offenders and terrorists are not added to the lists until they receive due process. Absent due process for physicians, the system is flawed and does not assure that competent doctors are not wrongly reported.

2. HHS's Flawed Implementation of HCQIA and Resulting Unconstitutional Harm

Congress also directed HHS to provide by regulation "procedures in the case of disputed accuracy of the information" in AARs submitted by hospitals, §11136(2).

Despite clear legislative intent for physicians to receive due process, HHS implemented this provision

without due process protection. HHS chose administrative convenience by providing *non-due process review* of these reports under 45 C.F.R. §60.14(c)(2) (renamed 45 C.F.R. §60.21 by the May 6, 2013-C.F.R. amendment) and under the non-*Chevron* deference sub-regulatory guidance provided by the *2001 NPDB Guidebook*, which was in effect throughout the period relevant to this case (2009–2012).

§60.14 stated that in cases of physician disputes of the accuracy of the reports, HHS "will review written information submitted by both parties." HHS chose not to require adversarial proceedings, document discovery, or even sworn statements.

Thus, a hospital could, and in this case did, submit false and fraudulent documents accepted by HHS as "written information."

The Legislative History also indicated its intent to prevent hospitals and physicians accused of misconduct or incompetence from engaging in "plea bargains":

> "The purpose of requiring reports even for circumstances in which physicians surrender their privileges is to ensure that health care entities will not resort to 'plea bargains' in which a physician agrees to such a surrender in return for the health care entity's promise not to inform other health care entities about the circumstances of the physician's surrender of privileges…" H.R.Rep.99-903, at 6397–6398

But reaching such an "agreement" or "plea bargain" can only occur if the physician has knowledge of the investigation and resigns in return for a *quid pro quo*

from the hospital. In Doe's case, when the Chief Medical Officer (CMO) told Doe he was not under investigation, his resignation could not have been for a plea bargain.

Given this Congressional purpose, *resignations without knowledge* were not contemplated by the language "accepts the surrender … while … under an investigation," 42 U.S.C. §11113(a)(1)(B) Notwithstanding the above unambiguously-expressed Congressional intent that physicians receive notice and due process, HHS abolished the requirement for physician "knowledge."

HHS created a 2001 *NPDB Guidebook* with appendices totaling over 120 pages describing numerous aspects, procedures, policies, and "examples" of how it would handle various situations arising under HCQIA. HHS created this Guidebook without legally-required notice-and-comment rulemaking procedures. Guidebook Rule F-8 provides 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." This Guidebook Rule contravenes the §11112(b) Standard for Professional Review Action that the physician receives "Adequate Notice [of Investigation] and Hearing".

Rule F-8 simplifies administration by HHS to avoid any inquiry of knowledge, but impermissibly broadens HCQIA to require reporting for a surrender *even where the physician has no knowledge* that his conduct is under investigation and is not trying to "plea bargain" or escape it. FAC ¶110

If Doe had been notified of the investigation, Doe would not have resigned but "would have successfully defended [his clinical] practice." FAC ¶110 The overbroad agency F-8 Rule ensnares competent

physicians leaving for reasons having nothing to do with any unknown investigation. *A fortiori*, the Rule allows reporting even with actual fraud on the physician, as occurred here. FAC ¶54 The F-8 Rule allows HHS to maintain reports of such unknowing, innocent departures by competent doctors and ends their career without due process. (FAC ¶146)

2001 NPDB Guidebook Rule F-1 allows a physician to post a response to the AAR. As should be obvious from this "system" of permanently posting doctors on a national blacklist as if they were sex-offenders or terrorists, no physician's personal "statement" in response to the AAR serves to clear a surgeon's reputation sufficiently for a prospective employer to hire him after HHS's claimed "review."

This result follows even more so in cases of Secretarial non-due process "paper" review, which allows HHS to add to the AAR that the AAR was "maintained" after Secretarial Review, as if the physician lost a due process "appeal" to HHS. *See* Van Tassel, *Blacklisted* (Appendix I)(reporting research from an extensive study in California that "physicians who had experienced [having a negative peer-review report state that it] … was a 'career ender.'" *Id.*, 2059.) Professor Van Tassel documented that AAR reports can be misused to harm patient care, for example "to silence whistleblowers who report poor quality of care, to remove economic competition, to give vent to personal animus, or to discriminate." App. I*, Id.*, 404-405 (footnotes omitted)

Even the District Court acknowledged that hospitals virtually never hire a physician with such an adverse report: "Private hospitals are depriving Doe of employment by using the [AAR] reports in a way that

is contrary to what was contemplated by Congress." (2015 Op App. C at p.87).

As now shown by decades of reported cases and published research and legal literature, and facts in the FAC, HCQIA is unconstitutional.

HCQIA only incentivizes due process but does not require it. Defendants-Respondents conceded this in the District Court. (October 24, 2013-Transcript, Docket #57 (D.D.C.), page 36)

Congress failed to anticipate and address the unfortunately common circumstances where a hospital for its own political reasons, or out of a desire to remove an economic competitor of entrenched physicians at the hospital, would simply proceed with a peer-review without notice and due process and forego immunity under the statute.

B. Factual Background

Doe's 60-page FAC filed in the District Court (App. F) documented the facts and circumstances of Doe's excellent record, the Hospital's motives to remove him, and the fraudulent scheme employed. The resulting false AAR to NPDB destroyed Doe's career.

Doe graduated from Harvard Medical School and holds A.B., M.D. and Ph.D. degrees. He is Certified by the American Board of Surgery in surgery and the American Board of Thoracic Surgery in cardiothoracic surgery. Doe has never had any disciplinary actions against him. He had an unblemished record in 2,500 surgical cases (FAC ¶3). In October 2009, Doe had clinical privileges in thoracic and general surgery at Peconic Bay Medical Center ("PBMC").

As a highly-trained, Board-Certified surgeon, Doe's practice was growing. As a result, Doe was receiving

referrals for surgery that would have gone to others and was "competing with general surgeons at the Hospital who had long and established tenures." Doe also complained to Hospital administration when he observed substandard patient care. FAC ¶16–45 Hospital administration and competitors were looking for an opportunity to remove him.

On October 2, 2009, Doe, assisted by senior surgeon and former PBMC Surgery Chairman Dr. Rubenstein, successfully completed a laparoscopic appendectomy. A complication involved necessary transection of a diseased right Fallopian tube. The patient was discharged well from the hospital a few days later. (FAC ¶50) No malpractice claims were threatened or filed. But PBMC seized on this case in order to remove Doe as a competitor and whistleblower. (FAC ¶49, 80, 92)

Contrary to PBMC's secret sham "review" and adverse findings, the case was reviewed by the former Chairman who assisted, and by two other independent senior surgeons, including the Surgeon-in-Chief of NYU Hospitals and a senior surgeon at the New York State Department of Health Office of Professional Medical Conduct (OPMC) responsible for physician licensing. *All three surgeons found no departure from the standard of care*. (FAC ¶80) Thus, Doe's New York medical license was unaffected. *See* Administrative Record ("AR") (D.D.C. Dkt. 19) before HHS, page 226, May 11, 2011-OPMC letter; Dr. Hofstetter's March 23, 2011-letter (AR183–186)

In furtherance of the hospital's scheme, the morning of October 5, 2009 Doe was called to Chief Medical Officer Dr. Kubiak's office. Kubiak told Doe that he was "fired." Kubiak did not ask Doe anything about the operation.

Handwritten notes (AR105) that PBMC submitted to HHS document an October 5, 2009, 12-noon

meeting attended by Kubiak and three non-physician administrators. The notes state: "pts [patients] currently on his service will be reassigned *until investigation complete".* (Emphasis added.) These notes *prove that Kubiak was aware of the investigation.* The notes also state: "Dr. Kubiak to meet [with] Dr. Rubenstein at 1:30 and Dr. [Doe] at 2:30".

Shortly after 3 PM, Kubiak called Doe back and told Doe that he had just spoken with Dr. Rubenstein (the former PBMC Surgery Chairman) and that Kubiak now understood that the surgery was "just a complicated case with no malpractice". Kubiak told Doe that it would be "very unfair" for the Hospital to take any action against Doe. Kubiak also told Doe that Doe actually never had been fired because PBMC CEO Mitchell had never signed a letter stating that Doe was fired, and Kubiak had lacked authority to fire Doe. FAC ¶91 (AR0144)

The AR documents that Doe was never fired. (FAC ¶92, AR0144) The District Court erroneously concluded without citation to the AR that Doe "was told he was fired but then reinstated." 2015 Op. App. 42. To the contrary, Doe was not "reinstated" because he was never fired.

Doe knew as of September 2009 that he likely would need to attend a fellowship for his cardiothoracic surgery Board exam. Doe knew that he would have to report any resignation while under investigation on future applications for medical licensure, hospital privileges, and malpractice insurance. Therefore, prior to tendering any resignation for the fellowship, Doe specifically asked CMO Kubiak whether Doe was, or would be, under any investigation by the Hospital on account of the October 2, 2009 surgery or for any other reason. Doe told Kubiak that he would not resign if he

was under investigation but would remain on staff to defend his clinical practice. (FAC ¶53–54)

The FAC details that, despite being at the 12-noon "investigation" meeting, CMO Kubiak fraudulently told Doe, at his October 5, 2009, 3 PM meeting with Doe, and again on October 7, that Doe was not and would not be under investigation for the surgery in question (FAC ¶55). Relying on the CMO's statements to him that he was *not under investigation*, Doe believed he could leave the hospital for the unrelated fellowship. (FAC ¶53–56)

Prior to Doe's resignation on October 16, PBMC conducted in secret a biased "peer-review," with no notice to Doe, and not in compliance with the §11112 due process "Standards for Professional Review Actions". The peer-review included another surgeon who was a competitor, in direct violation of §11112(b)(3)(A)(iii). PBMC's "investigation" reached its predetermined conclusion that Doe "departed" from the standard of care. FAC ¶57

PBMC then reported Doe in an AAR to NPDB (AR2 and App. H Secretarial Dec.) for resigning "voluntarily" while under investigation, without disclosing that Kubiak told Doe that Doe was not under investigation.

Doe learned of the AAR seven months later by being rejected by another hospital for employment due to this AAR on his NPDB record. Doe requested HHS conduct administrative review of the AAR. HHS's non-Due Process review procedure, 45 C.F.R. §60.14, was limited to "written information submitted by both parties," unsworn paper documents, and hearsay letters from Hospital counsel. (AR, *passim*).

During the administrative review procedure, PBMC counsel submitted multiple documents (AR106, 109) that falsely stated that PBMC had "suspended" Doe's clinical privileges. Hospital counsel buried on page 9 of his letter that "no summary suspension or other corrective action was imposed" (AR89). But HHS relied on and quoted the "suspension" four times in its Decision to "maintain" the AAR. (App. H) The District Court failed to assess this conclusive documentary admission on the APA claim.

HHS then added to the AAR's false statements that it was maintained "after review" by HHS. NPDB has provided the AAR to scores of hospitals at which Doe sought employment and privileges. Thus, HHS's non-due process administrative review has been permanently placed in the AAR on Doe's record. For the last 13 years, this has destroyed Doe's surgical career in the United States. (FAC ¶151–156)

C. Procedural Background

This action was commenced in U.S. District Court for the District of Columbia on July 25, 2012. The Complaint was filed by the undersigned counsel for Plaintiff (now Petitioner).[6] Defendants moved to dismiss. Plaintiffs filed a First Amended Complaint

[6] Because of serious reputational harm to Doe if his name were publicly disclosed in challenging Defendants-Respondents' actions, plaintiffs moved *ex parte* for leave to file the Complaint with pseudonym "John Doe" for plaintiff, and to seal portions of the Administrative Record of HHS proceedings. Judge Bates granted these motions (D.D.C. Dkt. 6–7, 13). 11 years later, then-assigned Judge Hogan removed the pseudonym from his 2020 Memorandum Decision and identified Adam Brook. For consistency of names during most of the action, we refer to Petitioner-Plaintiff as "Doe."

(FAC) on February 22, 2013 (Dkt. 23, App. F). That remained the operative pleading. On July 13, 2013, the action was reassigned to Judge Hogan, who ultimately issued the two Memorandum Opinions rejecting all claims. Doe appealed these claims, *pro se*, to the D.C. Circuit, which affirmed on February 14, 2023 without a published opinion. (Judgment A) Petitioner retained experienced appellate counsel petition for re-argument and re-argument *en banc*. Those motions were denied May 12, 2023 (Appendix B). Petitioner brings this Petition for Certiorari with counsel admitted in this Court.

1. Claims and Pleaded Facts in the District Court

The FAC contained a challenge under the Administrative Procedure Act (APA), based on the AR before HHS, and five claims under the Constitution and Privacy Act.

The Petition for Certiorari Questions Presented relates to two constitutional claims that HCQIA and HHS regulations and procedures are unconstitutional as written and applied. Doe alleged that HHS deprived him of constitutional rights without substantive or procedural Due Process. Doe also alleged that HHS also violated APA in HHS's decision to maintain the AAR.

The District Court granted Defendants' Motion to Dismiss and for Summary Judgment in 2015 and 2020. There was no discovery in the District Court.

On March 23, 2012, Doe sued PBMC and its administrators for breach of contract, fraud, and other claims in New York state court. That action resulted in pretrial discovery of those defendants placed on the

public record, accessible via https://iapps.courts.state.ny.us/webcivil/FCASMain.

Discovery in the New York State litigation has included 17 depositions, thousands of pages of testimony, and an adverse inference order against PBMC for spoliation of documents. A Note of Issue for jury trial was filed. Appeals on the defendants' motion for summary judgment are pending.

Doe moved the District Court to consider sworn testimony from the New York State action or take judicial notice of it, which supported Doe's federal court allegations. The Court denied those motions.

The existence of public evidence from the co-pending New York State action, supporting the egregious facts alleged here, is another unique procedural aspect which further makes this a once-in-33-years-case challenging HCQIA an important opportunity for this Court and warrants granting this Petition.

On the Motion to Dismiss the constitutional and Privacy Act claims, District Court failed to accept the well-pleaded FAC allegations as true and instead improperly relied on the AR from the APA claim and accepted challenged AR documents as true. This is reviewed *infra* under Point III of Reasons to Grant the Petition. On the APA claims the District Court made its own "findings of fact" despite the above multiple issues and granted summary judgment to Respondents.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Certiorari to Decide whether Congress Constitutionally Authorized HHS to Adopt Limited, non-Due Process Procedures "in cases of disputed accuracy" of the Adverse Action Reports Allowing HHS to Maintain and Publish such AARs as "reviewed" by the Secretary, with the Effect of Broadly Precluding Physicians and other Healthcare-Practitioners from Employment in their Chosen Professions.

The U.S. Constitution, Article I, §1 (Legislative Vesting Clause) and "[t]he nondelegation doctrine ensure democratic accountability by preventing Congress from intentionally delegating its legislative powers to unelected officials. … If Congress could hand off all its legislative powers to unelected agency officials, it 'would dash the whole scheme' of our Constitution and enable intrusions into the private lives and freedoms of Americans by bare edict rather than only with the consent of their elected representatives. [Citing case.]" *NFIB v. OSHA*, 142 S.Ct.661, 669 (2022)(J. Gorsuch, concurring)

Here, Congress delegated to HHS authority to provide "by regulation … procedures in the case of disputed accuracy of the information [in AARs]." 42 U.S.C. §11136(2)

But what kind of procedures? Did Congress intend HHS to simply accept as true every narrative and document provided to HHS by a hospital?

Did Congress intend HHS to determine if the information provided to HHS was accurate by conducting some kind of hearing?

Did Congress intend HHS to determine if the Hospital had provided the physician with due process as expressed by the 42 U.S.C. §11112 "Standards for Professional Review Actions"?

Did Congress intend HHS to determine if the Hospital's accusations of malpractice, incompetence, or misconduct—such as whether the physician knowingly resigned while under investigation—were accurate?

The type of procedures chosen by HHS to determine accuracy of AARs placed permanently against doctors on the NPDB for all future hospital queries results in dramatically different outcomes for physicians and nurses. It is the difference between their careers being destroyed and being saved.

The procedure HHS chose to adjudicate accuracy of AARs is to simply accept paper submissions from hospitals and the reported physician (45 C.F.R. 60.14(c)(2)), and to assume that the information in the hospital's submissions is an "accurate" report of what occurred, without any adversarial procedures to determine the truth. That is an unacceptable "honor system" when the consequence of falsity is disastrous.

The procedural mechanism chosen by HHS to address the "disputed accuracy" of an AAR is so limited in scope by HHS's own regulations as to affirmatively *prohibit* HHS from considering "*the merits or appropriateness of the action or the due process that the subject received.*" (*NPDB Guidebook* Rule F-3 and current 45 C.F.R. §60.21(c)(1), cited with approval in the 2015 Decision (App. C at App. 52, 90–91))

This limited review procedure is unusual, because "the right to be heard before being condemned to suffer grievous loss of any kind, even though it may not

involve the stigma and hardships of a criminal conviction, is a principle basic to our society. … [W]hen Congress has given an administrative agency discretion to determine its own procedure, the agency has rarely chosen to dispose of the rights of individuals without a hearing". *Joint Anti-Fascist Refugee Comm. v. McGrath*, 341 U.S. 123, 168–169 (1951) (J. Frankfurter, concurring)

This limited review procedure is also inconsonant with Congress' promise to physicians that "we have given physicians under review full due process rights with notice and representation." Hearings (Statement, HCQIA-lead-sponsor Rep. Wyden, *52)

The limited review procedure is also inconsonant with the 42 U.S.C. §11112 "Standards for Professional Review Actions" which presume that "peer-review actions [are to be] … carried out in a manner giving the physician under review every opportunity to defend his or her record." *Id.* (Statement of Rep. Tauke, *50)

And even findings of peer-review proceedings facially compliant with §11112 are suspect, since §11112 does not ensure that hospital peer-reviewers will be impartial.

Determinations by hospital peer-review committees may be driven not by a fair assessment of the reviewed physician's competence or conduct, but by local hospital politics. And in Doe's case, there was no notice at all and participation by a competitor. Failure to allow any assessment of the impartiality of the peer-reviewers is inconsonant with the legislative history that "Congress intended that the HCQIA allow 'physicians [to] receive fair and unbiased review to protect their reputations and medical practices.'" H.R.Rep.99–903 at *11

By delegating to HHS authority to create procedures in the case of disputed accuracy of the information in AARs without placing any strictures whatsoever on what procedures HHS could create, Congress violated the Legislative Vesting Clause. Destruction of the livelihoods of American physicians and nurses is now governed by a procedure wholly determined by unelected government appointees who are unaccountable to the American people.

HHS also exceeded the authority Congress delegated to it when HHS promulgated sub-regulatory guidance which specifically provides 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". NPDB GUIDEBOOK F-8

The District Court accepted the non-due process limitations on Secretarial Review in Guidebook Rule F-3 and C.F.R., stating: "These regulatory and NPDB Guidebook interpretations of the limited scope of Secretarial Review *are in harmony* with the Health Care Quality Improvement Act…" (emphasis added), without citing any HCQIA reference for such a "limitation." This was just accepting HHS's Guidebook, which is not "in harmony" with §11112 providing for notice and due process or with the Congressional intent for due process. Requiring no notice of investigation (and in this case, worse, allowing without review or correction outright deception of the physician about the existence of an ongoing investigation) means the physician can be, as occurred here, precluded from participating at the peer-review level. This leads to the AAR being a product of a non-adversarial, one-sided, biased review by the peer-reviewers. Thus, HHS, by its convenient but narrow rules, permits creation of false reports

about competent doctors who had no notice of investigation, were excluded from their own peer-review, and were denied any opportunity to defend their clinical practices. Then HHS "will not consider … the merits … or the due process," but just publish AAR as "maintained" after HHS "review."

By interpreting the statute in a way that eliminates the due process requirement for reporting of up to 21-million healthcare-professionals who fall under one of the reportable professions under the C.F.R. and *NPDB Guidebook*, HHS's interpretation constitutes an impermissible expansion of its power to remove due process at the agency level. *See West Virginia v. EPA*, 142 S.Ct. 2587, 2607–08 (2022) ("the economic and political significance of that assertion [of agency power], provide a reason to hesitate before concluding that Congress meant to confer such authority. [Citations omitted.]").

The economic and political significance of the NPDB "blacklist" of competent healthcare-providers without due process is vast. *See Utility Air v. EPA*, 134 S.Ct. 2427, 2444 (2014) (unreasonable agency interpretation to "bring about an enormous and transformative expansion in [the agency's] regulatory authority"). By "blacklisting" innocent and qualified medical professionals without due process of law, HHS deprives the American public of the quantity and quality of medical care those same professionals would have provided, at a time when large parts of the country have critical shortages of medical and nursing professionals, especially post-COVID pandemic.

The District Court "throws the baby out with the bathwater" when it asserts that the loss of some qualified healthcare-professionals to accomplish the goal of preventing incompetent healthcare-

professionals from continuing to practice is an acceptable consequence. It is a preventable consequence if HHS imposes due process requirements at the peer-review level and Agency review level.

This Court should grant the Petition to reign-in HHS's "unheralded regulatory power over a significant portion of the American economy." *Utility Air, supra,* at 2444.

II. The Court Should Grant Certiorari to Decide Whether Petitioner's Constitutional Rights Were Violated by Respondents under HCQIA and HHS Procedures and Whether the District Court Erred in Dismissing those Due Process Claims under *Kartseva* and its progeny.

The District Court rejected Petitioner's claim that HHS is liable for action which broadly precludes Petitioner from his right to follow a chosen profession under *Kartseva v. State*, 37 F.3d 1524 (D.C. Cir. 1994) and its progeny. *Kartseva* followed this Court's decision in *Greene v. McElroy*, 360 U.S.474 (1959).

The District Court mischaracterized the AAR as merely an "unsatisfactory job performance" report, and insufficient under *Kartseva*, stating:

> 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.…
>
> [A]n 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. (*Id.*)

The court was not permitted to make its own "finding" of the impact of the AAR, rather than the broad preclusion effects pleaded in the Second and Third causes of action for the "Government's unconstitutional deprivation without due process," alleged in FAC ¶126–164. The FAC alleges that the effect of the AAR is not limited to performance of one surgery but reflects termination of employment (by the Chief Medical Officer's fraud) "while under or to avoid an investigation" of Doe. The AAR also "concluded" with an adverse finding of departures from the standard of care.

The AAR makes it appear that Doe was dishonest and resigned knowing that he was under investigation for a case which had such "departures from standard of care" rather than defend his practice.

This combination is a stigma-plus, triggering due process requirements. *See Donato v. Plainview-Old Bethpage Cent. Sch. Dist.*, 96 F.3d 623, 631 (2d Cir. 1996), *cert. denied*, 519 U.S.1150 (1997):

> Because the superintendent's comments "[went] to the very heart of Huntley's professional competence" and "drastically impaired" his chance of receiving another supervisory position, we held that the board's actions implicated a liberty interest.

The District Court citations conceded that a report that had the effect of showing "dishonesty" would be actionable stigma. (*Id.* at 61).

It was not for the District Court to decide how future hospital employers would view this AAR without discovery and trial. The court had to accept the FAC's

well-pleaded allegations that the AAR indicated an "inherent" flaw in Doe causing broad preclusion.

The FAC continued that the effect of an AAR published to all future hospitals is specifically as *intended* by HCQIA, to make the physician unemployable. Hospitals do not take an AAR as an "invit[ation to] inquiry" but use the AAR as a disqualifying "prejudgment", causing formal broad preclusion from the practice of medicine in the U.S. (*Id*. at 61)

The FAC ¶144 asserted that "mere existence of such a report with the NPDB will make it virtually impossible for the subject of the report to obtain employment," citing a 2003 publication. The FAC also cited other published reports to the same effect that the AAR causes "their professional lives [to be] ruined" FAC ¶145, that it, "has been called a 'career-ender' and a physician's reputation is thereby irreparably damaged," citing the research and examples in Van Tassel, *Blacklisted*, App. I, FAC ¶146.

The U.S. General Accounting Office ("GAO") observed that information disseminated by the defendant NPDB "can affect a practitioner's reputation and livelihood." *National Practitioner Data Bank; Major Improvements Are Needed to Enhance Data Bank's Reliability*, GAO-01-130 (2000). FAC ¶148

The FAC allegations continued that a prospective employer has "neither the time, resources nor motivation to undertake an independent investigation" of the AAR maintained and released by the government "but simply accepts it as a conclusive reason not to hire." FAC ¶150

Employers have risk of liability for "negligent hiring." FAC ¶150 Petitioner's "own experience" was

that the AAR caused rejection from every hospital he applied to FAC ¶151.

Hospital Corporation of America has a "policy" for its (then) 160 U.S. hospitals that they will not employ a provider who has an AAR on file. FAC ¶153–54 The FAC alleged that "as a result, plaintiff physician's career as a physician and surgeon in the United States has been destroyed by a false AAR, knowingly maintained by defendants, without affording Doe any due process of law." FAC ¶155

Caselaw views these allegations as sufficient at the pleading stage. *Kartseva*, 37 F.3d, at 1528 (liberty interest implicated by governmental action having the "*broad* effect of "largely precluding" plaintiff "from pursuing [her] chosen career"); *Valmonte v. Bane*, 18 F.3d 992, 999, 1001–02 (2d Cir. 1994) (listing on government database of suspected child-abusers where employers are required to check before hiring was a sufficient "plus" factor tied to likely denial of prospective employment to constitute a deprivation of liberty).

In *Lea v. District of Columbia*, 2022 WL 3153828 (D.C. Cir. 2022), the Court held that it was a sufficient allegation that the plaintiff was "completely foreclosed" from "any real prospect of pursuing employment with the District of Columbia government. … Lea submits, she was 'automatically determined to be 'unsuitable' and disqualified for any such positions."

The FAC alleges the same effect on Doe from the AAR. FAC ¶151

The District Court sought to relieve Respondents from liability their non-due process review and release of the ruinous AAR by blaming the future employers:

> [I]t 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 Doe's status. (App. C. p.84 (footnote omitted))

As the above cited cases make clear, it is *necessarily* the effect on third parties that demonstrates the broad preclusion by the government's improper disclosure. That the ultimate mechanism of injury is the reaction of third parties does not insulate the government from the denial of Due Process in requiring, and publishing, AARs in the NPDB. The government "'is responsible for the … act of a private party when the [government], by its law, has compelled the act,'" *Flagg Bros. v. Brooks*, 436 U.S.149, 164 (1978) (citation omitted), as it does here with the requirement that hospitals query NPDB and receive the AAR report of a surrender of privileges "while under or to avoid investigation," resulting in a finding of "departures".

Cases on stigmatization recognize that private reactions to government conduct can be the *mechanism* of an actionable deprivation of liberty. *See Kartseva*, 37 F.3d at 1530 (remanding to consider extent that government's action would be available to and affect "private employers in their decisions whether to employ" plaintiff). The same is true in plaintiffs' preclusion from employment in cases such as *Lea* and *Valmonte*. *See also Campbell v. District of Columbia*, 894 F.3d 281, 283, 288 (D.C. Cir. 2018*), upholding* jury's conclusion that an employee denied the opportunity to respond to false statements by her employer was "deprived of her liberty interest in

pursuing a chosen profession" even though she "found full-time employment within two years of her termination" in her chosen profession. During those two years, "she had applied to over thirty positions and secured only temporary jobs, all of which a reasonable jury could find were outside her chosen field…"

Given the FAC's extensive allegations of broad preclusion of Petitioner with multiple hospitals over many years due to Respondents' accepting, affirming, and repeatedly releasing the stigmatizing AAR, the District Court should have allowed the claim to proceed with discovery and trial for the jury to assess the scope of preclusion.

III. The Court Should Grant Certiorari to Decide Whether Petitioner's Constitutional Rights Were Violated by Respondents under the HCQIA and HHS Procedures and Whether the District Court Erred in Not Accepting the FAC Allegations as True on the Motion to Dismiss.

This case comes to the Court on a grant of a Motion to Dismiss the constitutional claims, with no separate opinion by the D.C. Circuit.

The FAC with extensive documentation including Government reports, prior cases and published literature had to be taken as true. But the District Court was also presented with an APA claim based on the AR submitted to HHS.

A fundamental error was attempting to use the disputed AR documents instead of the FAC on the constitutional claims. From the disputed AR, the court then purported make "findings" to reach conclusions about Doe and his "knowledge."

The District Court also refused to accept the FAC allegations of fraud by the Hospital but instead searched *only the AR on the APA claim*. The Court wrote:

> 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. (App. C p.58).

This was incorrect.[7] More importantly, the Court disregarded the separate, extensive, and factually-supported fraud allegations in the FAC to be considered on the constitutional claims.[8] *E.g.*, FAC ¶72:

> "[Plaintiff] was affirmatively misled by Kubiak's statements on behalf of the Hospital that there was no investigation, and that

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[7] Doe's January 6, 2011-letter (AR042–43) during Secretarial review specifically objected that PBMC was not submitting any documentation *shown to him* to advise "that there was ever an investigation" and that the "Data Bank report should be voided so that I may resume seeking employment without the *fraudulent* Adverse Action Report making it impossible for me to find work." (Emphasis added.)

[8] FAC ¶54 ("Plaintiff physician unequivocally advised Kubiak that he would not resign if such an investigation was pending or would be commenced. On October 5, 2009 and again on October 7, 2009, Kubiak responded to plaintiff physician that there was no and would be no investigation of plaintiff physician on account of his clinical practice."); FAC ¶55 ("Kubiak had superior and unique knowledge as to the status of investigations at PBMC and by reason of his special relationship as Vice President of Medical Affairs of PBMC… Accordingly, plaintiff physician accepted and reasonably relied on Kubiak's repeated and unequivocal representations that there was no and would be no investigation of plaintiff physician's clinical practice.")

> there would be no such investigation. Plaintiff physician was thus misled and defrauded by the Hospital when he tendered his resignation… and his resignation was not 'voluntary' but obtained by fraud."

The District Court needed to accept the FAC fraud allegations on the constitutional claims. AR105 clearly showed the CMO Kubiak, but not Doe, in attendance at an October 5, 2009 noon-meeting, before Kubiak met with Doe, stating there was an "investigation." Fraud was well-pleaded.

In a further effort to dispose of the fraud allegations, the District Court cited *Leal v. HHS,* 620 F.3d 1260 (11th Cir. 2010) approvingly, which it observed also had a claim of "concerns about fabrication or fraud on the part of hospitals."

Leal is distinguishable because there the physician knew that he was under investigation and received notice. Nonetheless, the District Court accepted the Eleventh Circuit's approval of HHS *following its own non-due process guidelines* without considering whether these guidelines are unconstitutional. The district court wrote:

> "[T]he Secretary's review of information in the Data Bank is limited in scope." *Id.* at 1284 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. (App. C p.53-54)

The challenge here in the FAC is that HHS adopted 45 C.F.R. §60.14(c)(2) that HHS will only "review written information submitted by both parties," which is unsworn and not subject to any adversarial process of truth-finding. Both *Leal* and the District Court failed to address Petitioner's allegation that this narrow review completely failed to meet the delegation which Congress provided in §11136 that HHS should "by regulation provide for …. procedures in the case of disputed accuracy of the information," when the legislative history expressly indicated the Congressional intent that "we have given physicians under review full due process rights with notice and representation." (Rep. Wyden, *supra*).

Further, as explained in *McGrath*, *supra,* 341 U.S., at 168–170 (J. Frankfurter, concurring):

> [W]hen Congress has given an administrative agency discretion to determine its own procedure, the agency has rarely chosen to dispose of the rights of individuals without a hearing, however informal.

The opposite has occurred here where the "entrusted agency" determined "its own procedure" to be limited to unsworn "written information submitted by the parties" no matter how challenged as fraudulent or inaccurate.

When the consequences of maintaining an AAR are the destruction of a physician's career, the agency delegated with the task of reviewing "disputed accuracy of the information" should not "dispose of the

rights of individuals without a hearing" and other due process protections.

The District Court compounded this error by quoting and accepting *dictum* from *Leal* on why such narrow review might be acceptable:

> [T]he 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. (App. C p.54).

These three suppositions in *dictum* were refuted in the FAC which had to be accepted as true.

As alleged and as the District Court found, hospitals do not "ignore" the information in the AAR. Its mere existence on the physician's NPDB record is viewed as immediately disqualifying. FAC ¶153 For that reason any further "physician statement" added to the report is disregarded, particularly if the AAR is maintained with the additional statement "after Secretarial Review", as if the agency applied some due process adjudication.

The Eleventh Circuit's suggestion that the NPDB is not designed "to provide protection for physicians" at the cost of "protecting future patients" from incompetent doctors, is a classic expression of overbreadth in the way HCQIA has been enacted and applied.

This theory implies that to protect patients from one incompetent physician, many good ones must be wrongly reported with erroneous AARs. This is an inversion of Blackstone's maxim which would be paraphrased as "Better that ten competent physicians suffer than that one incompetent escape." (*Compare* 4 William Blackstone, *Commentaries*, *358 (1769)).

The import of Blackstone's maxim is that due process procedures should be in place to ensure that the innocent are not unfairly convicted.

The District Court also stated:

> [A]t 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,* 313 F.3d 205, 211 (4th Cir.2002)(App. C p.69)

Freilich was not an action against these federal defendants challenging HCQIA as enacted or as applied by them, nor with extensive evidence of widespread broad preclusion of competent doctors. Dr. Freilich had notice and was given a hearing and was not defrauded. Her complaint was against hospital defendants which were claiming immunity for her hearing. In that case, unlike Doe's, HHS did not have to review due process because Freilich was provided with notice and hearing. Freilich sought to engage the court in a determination of *whether the immunity portion of the statute* violates the Fifth Amendment because it "authorizes and encourages the Defendants [to] act irresponsibly in matters of credentialing." 313 F. 3d at 211.

The challenge here is not a derivative objection to hospital immunity, which Doe's Hospital was never given because it failed to comply with §11112. FAC ¶128 alleges that HCQIA and HHS failing to require due process when reviewing private hospital reports, such as alleged "voluntary surrender of privileges while under, or to avoid, investigation", is "conduct by defendants under the HCQIA [which] has the effect of rendering these physicians unemployable as physicians and therefore deprives and diminishes these physicians' and plaintiff physician in particular of their liberty, property and occupation and does so without due process of law, as more fully set forth herein. This violates the Due Process Clauses of the Fifth Amendment." (FAC ¶128)

Petitioner also argued below that there is a fundamental right to practice a chosen profession which cannot be taken away without due process, citing *Schware v. Bar Examiners*, 353 U.S. 232, 239–240 (1957)("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 of the Fourteenth Amendment") and *Dent v. West Virginia,* 129 U.S. 114, 121–122 (1889)("It is undoubtedly the right of every citizen of the United States to follow any lawful calling, business, or profession he may choose… [T]he right to continue their prosecution, is often of great value to the possessors, and cannot be arbitrarily taken from them, any more than their real or personal property can be thus taken.")

The Court citing those two cases assumed, contrary to the FAC, that the actions of the NPDB were legitimately enforcing standards of "skill and competence," which is the obligation of state boards of medical licensing and professional conduct, not private hospitals acting without due process. Thus, the District Court erred when it held as a "fact":

> "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." (App. C at 70)

That conclusion would only apply if the "peer review actions" are *bona fide*, provide the due process called for in §11112, and conduct peer-reviews with Due Process.

Facially, the statute does not have that requirement, but only incentivizes such compliance with a grant of immunity if provided.

The FAC demonstrates that the delegated agency HHS under its regulations does nothing in the way of due process to ensure the accuracy of those private "peer review actions" which may be charged by the physician as false or fraudulent. HHS rubber-stamps the AAR upon any submission of any hospital unsworn "written information." 42 C.F.R. §60.14(c)(2) The District Court also questionably summed up its opinion of *Schware* and *Dent* as "there is no legal basis for the plaintiffs' assertion that the right to practice a chosen profession is a 'fundamental' right." (*Id.*)

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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Dated: August 10, 2023

APPENDIX

Appendix A

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-5297

September Term, 2022
FILED ON: FEBRUARY 14, 2023

JOHN DOE, M.D., PH.D.,
APPELLANT

JOHN DOE, M.D., PH.D., P.L.L.C.,
APPELLEE

v.

JUDITH RODGERS, M.H.A. AS SENIOR ADVISOR IN DIVISION OF PRACTITIONER DATA BANKS, ET AL.,
APPELLEES

On Appeal from the United States District Court
for the District of Columbia
(No. 1:12-cv-01229)

Before: HENDERSON and RAO, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

J U D G M E N T

The court has accorded the issues full consideration and has determined that they do not warrant a published opinion. *See* D.C. CIR. R. 36(d). It is:

ORDERED and **ADJUDGED** that the judgment of the district court be affirmed substantially for the reasons stated by the district court in its memorandum opinions signed on June 17, 2015, and September 10, 2020.

The Clerk will withhold the mandate until seven days after any timely petition for rehearing or rehearing *en banc* is resolved. *See* FED. R. APP. P. 41(b); D.C. CIR. R. 41(a)(1).

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Daniel J. Reidy
Deputy Clerk

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-5297

September Term, 2022

1:12-cv-01229-TFH

Filed On: May 12, 2023

John Doe, M.D., Ph.D.,

Appellant

John Doe, M.D., Ph.D., P.L.L.C.,

Appellee

v.

Judith Rodgers, M.H.A. as Senior Advisor in Division of Practitioner Data Banks, et al.,

Appellees

BEFORE: Srinivasan, Chief Judge; Henderson, Millett, Pillard, Wilkins, Katsas, Rao, Walker, Childs, and Pan, Circuit Judges; and Randolph, Senior Circuit Judge

O R D E R

Upon consideration of appellant's petition for rehearing en banc, and the absence of a request by any member of the court for a vote, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jordan C. Pilant
Deputy Clerk

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 20-5297

September Term, 2022

1:12-cv-01229-TFH

Filed On: May 12, 2023

John Doe, M.D., Ph.D.,

Appellant

John Doe, M.D., Ph.D., P.L.L.C.,

Appellee

v.

Judith Rodgers, M.H.A. as Senior Advisor in Division of Practitioner Data Banks, et al.,

Appellees

BEFORE: Henderson and Rao, Circuit Judges; and Randolph, Senior Circuit Judge

O R D E R

Upon consideration of appellant's petition for panel rehearing filed on May 1, 2023, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

BY: /s/
Jordan C. Pilant
Deputy Clerk

Appendix C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 12-01229 (TFH)

REDACTED

JOHN DOE, *et al.*,

Plaintiffs,

v.

Judith Rodgers, M.H.A., *et al.*,

Defendants.

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).

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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)).

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 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

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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

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

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available at http://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf.

are codified at 45 C.F.R. §§ 60.1-60.22 and "establish procedures to enable 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

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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

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. 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

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anatomy" and "the anesthesiologist's intervention prevented [Dr. Doe] from removing the patient's ovary rather than her appendix." AR 0283 [ECP No. 32-1 (Sealed)].

[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).

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 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

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[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").

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

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.

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:

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[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_thejoint_commission_main.aspx (last visited April 19, 2015).

> 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 Arn. 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 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

> 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.*

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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.

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 Guidebook, the plaintiffs maintain that the Guidebook is not entitled to the deference announced in *Chevron, US.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 Dismiss 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 of ficials. 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. US. 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 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:

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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.

> [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 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

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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.

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 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

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[13] NPDB GUIDEBOOK E-19.

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:

> 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

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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").

> October 6, but it actually happened the day before.

AR 0157 n.1 [ECF No. 19-4 (Sealed)]. In light of the plaintiff's 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).

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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 ... ").

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 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 (Sealed)]. The referenced information and record consisted of numerous adversarial filings setting forth, in detail, both the Hospital's and Dr. Doe's

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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)].

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 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

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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.

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 prof essional 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. NL.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

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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.

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 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

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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

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 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

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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.

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

[22] 42 U.S.C. §11133(c)(1).

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 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 ease 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

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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

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. 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.

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 plaintiffs assertion that the case involved the "fundamental" right to work in one's chosen profession).

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 plaintiffs] 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 plaintiffs] 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 hann 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.
>
> * * *
>
> 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." *Roehling 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-a-vis the government." *Doe v. US. 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 <u>original</u> 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 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

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

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 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

[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).

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, 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. US. 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 o,f 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

/s/ Thomas F. Hogan
THOMAS F. HOGAN
SENIOR UNITED STATES DISTRICT JUDGE

Appendix D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 12-01229 (TFH)

JOHN DOE, *et al.*,

Plaintiffs,

v.

Judith Rodgers, M.H.A., *et al.*,

Defendants.

MEMORANDUM OPINION

The Health Care Quality Improvement Act requires that hospitals file a report with the Department of Health and Human Services "whenever a physician voluntarily resigns while under investigation for reasons related to his professional competence or conduct." *Long v. HHS*, 422 F. Supp. 3d 143, 145–146 D.D.C. 2019); 42 U.S.C. §§ 11101-152. The report is then posted to the National Practitioner Data Bank, "an online database, which . . . alert[s] hospitals and other would-be employers of potential issues with the

physician's credentials." *Long*, 422 F. Supp. 3d at 145–46.

This lawsuit concerns one such report about the plaintiff, Dr. John Doe, a surgeon formerly employed by Peconic Bay Medical Center (the "Hospital"). The Hospital submitted the report (the "'Adverse Action Report"') to the National Practitioner Data Bank (the "NPBD" or the "Data Bank" in 2009 after Dr. Doe resigned while the Hospital investigated an appendectomy that he performed. Dr. Doe and his limited liability company, John Doe PLLC ("the plaintiffs"), sued the Secretary of the Department of Health and Human Services ("the Secretary", "HHS" or "the Agency"), the Data Bank, and three officials who administer the Data Bank over their maintenance and continued distribution of the Adverse Action Report.

The Court described the facts of this case in detail in *Doe v. Rogers*, 139 F. Supp. 3d 120 (D.D.C. 2015) ("*Doe*") and includes relevant excepts below:

> 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") [ECF No. 19–4 (Sealed)] . . . During the surgery, Dr. Doe removed what he characterized as an "inflamed band" AR 0101 [ECF No. 19 3 (Sealed)] . . . 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)] . . . There is no dispute

that Dr. Doe failed to recognize the anatomical identity of the "inflamed band" before he intentionally cut and removed it. Pls.' Mem. In Opp'n to Defs.' Mot. to Dismiss 3–4 [ECF No. 45 (Sealed)] . . . .

[The following Monday,] the Vice President of Medical Affairs told Dr. Doe 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 . . . filed a report that day via the New York Patient Occurrence Reporting and Tracking System ("NYPORTS") 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)]. . . .

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.
>
> 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 lubes. 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).]

> . . . . 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)].

Doe, 139 F. Supp. 3d at 129-31.

One month later, the plaintiffs filed this lawsuit alleging that the defendants violated the Administrative Procedures Act ("APA"), sections 522a(g)(1)(A) and (C) of the Privacy Act, and the plaintiffs' constitutional rights. *Doe*, 139 F. Supp. 3d at 132. After the parties filed dispositive motions (the "first round of briefing"), the Court granted the defendants' motion for summary judgment on the APA claims except as to the narrow question of whether the statement in the Adverse Action Report 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 Statement") was reportable to the Data Bank. *Id.* at 153 (quoting ECF No. 19-1 [SEALED]). The Court dismissed the plaintiffs' constitutional claims and the § 552a(g)(1)(C) Privacy Act claim, but declined to dismiss the plaintiffs' contention that the Secretary violated § 552a(g)(1)(A) of the Privacy Act because the Court remanded the reportability issue to the Agency. *Id.* at 167-68; 170.

The Agency has since issued its decision on remand, and concluded that the Statement is reportable. [ECF No. 86-1 (Sealed)]. That decision is the main subject of the motions now pending before the Court, which include the defendants' renewed motion to dismiss, or in the alternative, motion for summary judgment [ECF No. 100], and the plaintiffs' cross-motion for summary judgment and opposition to the defendants' motion [ECF No. 103]. Also pending before the Court are three additional motions filed by the plaintiffs—two motions to supplement the record, [ECF Nos. 118 & 120], and a motion for reargument and for the Court's recusal,

[ECF No. 127]. The defendants have opposed each motion. [ECF Nos. 119, 122 & 128].

I. Regulatory Background

Congress enacted the Health Care Quality Improvement Act (the "Act" or "HCQIA") to address the "increasing occurrence 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). The Act requires health care entities to report to HHS when *inter alia* they "accept[] 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." *Id*. § 11133(a)(1)(B)(i); *see also* 45 C.F.R. § 60.12(a)(1)(ii)(A).

When filing reports, the Act requires that health care entities submit "(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 acdtion or surrender as the Secretary deems appropriate." 42 U.S.C. § 11133(a)(3). According to the legislative history, this section "does not necessarily require an extensive description of the acts or omissions or other reasons for the action or, if known, for the surrender. It does, however, require sufficient specificity to enable a knowledgeable observer to determine clearly the circumstances of the action or surrender." H.R. Rep. No. 99-903 at 15 (1986), reprinted in 1986 U.S.C.C.A.N. 6384, 6398. The implementing regulations issued by the Secretary likewise require that entities report "a description of the acts or

omissions or other reasons for privilege loss, or, if known, for surrender," the "action taken, date the action was taken, and effectuve date of the action" and other information the Secretary may require "after publication in the Federal Register and after an opportunity for public comment." 45 C.F.R. § 60.12(a)(3)

II. The Plaintiffs' Remanded Administrative Procedures Act Claim

a. The Secretary Found that the Statement was Reportable.

In its decision on remand, the Secretary concluded that the Statement was reportable and denied the plaintiffs' request to strike it from the Adverse Action Report. [ECF No. 86-1 at 2 (SEALED)]. The Secretary found that the Statement "provides a more complete history of the events relevant to [Dr. Doe's] resignation while under investigation." *Id.* at 2. According to the Secretary, while Dr. Doe's "report was based on a resignation while under investigation and was not dependent on the results of the investigation," the results "are closely related to the reportable event," put queriers on "better notice of the facts and circumstances of the reported action," and "are clearly types of information that could assist further queriers in making privileging and licensing decisions." The Secretary emphasized that "[o]ne of the central purposes of the NPDB is to provide health care entities with better information on which to make licensing and privileging decisions." *Id.*

The Secretary also found that the Act and its implementing regulations require the reporting, if known, "of the reasons for the surrender," and concluded that "the results of an investigation could be useful information for future queriers in

determining the reasons for surrenders." *Id.* The Secretary went on to note that "[i]f, for instance, an investigation exonerates practitioner from any wrongdoing, a querier may determine that this provides further evidence that a practitioner's resignation was not motivated by a desire to escape punishment." *Id.*

b. Summary Judgment Standard

The plaintiffs seek review of the Secretary's decision under the Administrative Procedures Act, 5 U.S.C. § 701, *et seq.*. "Summary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review." *Chiayu Chang v. USCIS,* 289 F. Supp. 3d 177, 182 (D.D.C. 2018) (internal quotations omitted). When considering challenges to agency action under the APA, instead of appllying Federal Rule of Civil Procedure 56(a)'s summary judgment standard, "the district judge sits as an appellate tribunal. The entire case on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (internal quotations omitted).

The APA requires courts to set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "An agency action that 'entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view of the product of agency expertise' is arbitrary and capricious." *Gresham v. Azar*, 950 F.3d 93, 99 (D.C. Cir. 2020) (quoting *Motor Veh. Mfrs. Ass'n v. State*

Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). "The scope of review under the 'arbitrary and capricious' standard is narrow, and a court is not to substitute it's judgment for that of the agency." *State Farm*, 463 U.S. at 43.

c. The Secretary's Decision was not Arbitrary and Capricious.

i. The Statement is Reportable Under the Statute.

In the amended complaint and first round of briefing, the plaintiffs argued that the Statement was not reportable because the Hospital's investigation did not result in the suspension of Dr. Doe's privileges. *See Doe*, 139 F. Supp. 3d at 132 (identifying the fifth APA argument raised by the plaintiffs as the assertion that "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. ¶¶ 120-125 [ECF No. 23] Pls.' Opp'n to Defs.' Mot. to Dismiss at 47 [ECF No. 45 (SEALED)]; Pls.' Reply at 23 [ECF No. 56 (SEALED)]. The Court concluded that the Secretary did not address this argument, "likely because Dr. Doe raised it so obliquely . . . that it may not have seemed apparent," and remanded the issue for the Secretary's consideration. *Doe*, 139 F. Supp. 2d at 153; *see id.* at 170 ("remand[ing] 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.") (quoting AR 0002 [ECF No. 19-1 (Sealed)]).

The plaintiffs do not address this argument in their filings, and appear to have altogether abandoned this claim—a curious position given that it was the subject of the Court's remand to the Agency. The plaintiffs also do not respond to the Secretary's argument that the Statement is reportable pursuant to two of the Act's provisions. Defs.' Mot. Summ. J. at 9 [ECF No. 100] (citing 42 U.S.C. § 11133(a)(3)(B)-(C)). Accordingly, the Court could properly treat the plaintiffs' argument that the Statement was not reportable under the Act as conceded. *See, e.g., Wilson v. Fed. Express Corp.*, No. 18-cv-485, 2019 WL 5696874, at *1 (D.D.C. Nov. 4, 2019) ("When a party responds to some but not all arguments raised on a Motion for Summary Judgment, a court may fairly view the unacknowledged arguments as conceded.") (internal quotations marks omitted).

Even if the Court must consider whether the Act allowed the Hospital to report the results of its investigation, *cf Winston & Strawn LLP v. McLean*, 843 F.3d 503, 508 (D.C. Cir. 2016), the Court finds that it unambiguously does. The statute requires that when reporting entities "accept[] the surrender of clinical privileges of a physician while the physician is under an investigation," they submit a "description of the acts or omissions or, if known, the reason for the surrender." 42 U.S.C § 11133(a)(1)(B)(i); (a)(3). An "act" is defined as "[something done or performed, esp. voluntarity; a deed." Black's Law Dictionary (11th ed. 2019). A "description" is a "delineation or explanation of something by an account setting forth the subject's characteristics or qualities." *Id.* Putting these definitions together, the statute requires a "delineation or explanation" of "somethng done or performed"—which in this case means a delineation

or explanation of the Hospital's acceptance of Dr. Doe's resignation while he was under investigation.

This broad language indicates that the Act provides reporting entities space to include information that it does not explicitly identify in the statute, such as the results of an investigation. This interpretation is supported by the statute's purpose and legislative history. *See Doe*, 139 F. Supp. 3d at 127 (finding that the Act aims to address 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") (quoting 42 U.S.C. § 11101(1)-(2)); *Doe* 139 F. Supp. 3d at 145 (finding that the 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"); H.R. Rep. No. 99-903 (stating that § 11133(a)(3) of the Act "does not necessarily require an extensive description of the acts or omissions or other reasons for the action or, if known, for the surrender. It does, however, require sufficient specificity to enable a knowledgeable observer to determine clearly the circumstances of the action or surrender."). Providing the results of the investigation enables queriers to more fully understand the circumstances of the incident, and protects patients by providing entities with enough information to make informed hiring decisions. The statute unambiguously allows the Hospital to provide a one-sentence description of the results of their investigation.[1] *See Nat'l Ass'n of Clean Air Agencies v.*

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[1] The Secretary makes broader arguments about the Act's scope in its briefs than it did in its decision on remand. Compare Defs.' Mot. at 9 (arguing that the Statement falls under 42 U.S.C. § 11133(a)(3)(B)-(C) *with* [ECF No. 86-1 at 2 (SEALED)]

E.P.A., 489 F.3d 1221, 1228 (D.C. Cir. 2007) (*quoting Chevron v. Nat. Res. Def. Council*, 467 U.S. 837, 843 (1984)) (stating that if after "examining a statute *de novo*, 'employing traditional tools of statutory construction,'" the court finds that the "'intent of Congress is clear,'" it "accord[s] the agency's interpretation [of a statute] no deference, 'for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."

ii. The Secretary Did Not Conclude that Dr. Doe Resigned to Escape Punishment.

The plaintiffs challenge the Agency's conclusion that "[t]he results of an investigation could be useful information for future queriers in determining the reasons for surrenders." [ECF No. 86-1 at 2 (SEALED)]; *see also id.* ("[i]f, for instance, an investigation exonerates a practitioner from any wrongdoing, a querier may determine that this provides further evidence that a practitioner's resignation was not motivated by a desire to escape punishment."). The plaintiffs describe this conclusion a "classic bootstrap argument" that is "devoid of logic" because it assumes that a practitioner will know the results of a hospital's investigation before it is concluded. Pls.' Opp'n & Cross Mot. Summ. J. at 12 [ECF No. 103]. They also contend that the Secretary

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(finding the Statement reportable because the Statute requires that entities report the reasons for the surrender, if known, and "the results of an investigation could be useful information for future queries in determining" those reasons, and because the results of the investigation are "closely related to the reportable event.") Because the Act clearly allows the Hospital to report the results of the investigation, the Court does not defer to the Secretary's interpretation of the Act, and does not need to address this delta between the decision on remand and the briefs.

concluded that Dr. Doe resigned to escape punishment, even though Dr. Doe claims that he resigned before the Hospital completed its investigation to complete an additional year of surgery training in Tennessee. *Id*. at 12-13.

Contrary to the plaintiffs' assertions, the Secretary's decision on remand did not conclude that Dr. Doe left the Hospital in order to escape punishment. It did not even address Dr. Doe's reasons for resigning.[2] The Secretary's example does imply that a physician will know whether he departed from the standard of care in a given procedure, which could prompt him to resign before an investigation is complete. That is not an irrational notion, although a physician won't necessarily know what a hospital will conclude in this regard. Regardless, as the defendants note, HHS did not find that the results of an investigation are a clear indication of the reasons for a surrender, or that Dr. Doe resigned because he knew the Hospital would find that he departed from the standard of care. The Secretary simply concluded that the results "may provide further relevant information about the surrender." Defs.' Opp'n and Reply at 6 [ECF No.

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[2] The plaintiffs also allege that the Secretary accepted the Hospital's conclusion that Dr. Doe departed from the standard of care. The Secretary's decision on remand did not address that issue. In its previous decision, which is not currently before the Court, the Secretary explicitly stated that he made "no finding" concerning "whether [Dr. Doe] met the standard of care." AR 0257 [ECF No. 19-6 (SEALED)]. The Secretary did find that "it is clear from the record that PBMC determined that [Dr. Doe] departed from the "standard of care," and concluded that it was "poorly positioned to question a health care entities' conclusion" in this regard. *Id.*

105]. That conclusion does not render the Secretary's opinion arbitrary and capricious.

iii. The Court Rejected the Plaintiffs' Arguments About the Hospital's Procedures and Findings in *Doe*.

The plaintiffs spend much of their briefing challenging the Hospital s investigation and findings that he departed from the standard of care. *See, e.g.,* Pls.' Cross Mot. & Opp'n at 4-5, 7-9, 11 [ECF No. 103]. Their discontent with the Hospital's procedures and dispute with its conclusions is not grounds for finding that the Secretary's decision was arbitrary and capricious. As the Court discussed in *Doe*, "the Secretary's review of information in the Data Bank is limited in scope. *Doe*, 139 F. Supp. 3d at 149 (quoting *Leal v. Sec'y, HHS*, 620 F.3d 1280, 1284 (11th Cir. 2010)). "[T]he 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." *Doe,* 139 F. Supp. 3d at 148; *see also Leal*, 620 F.3d at 1284 ("[t]he 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.").

As the defendants contend, in *Doe*, the Court considered the plaintiffs' arguments regarding the nature of the Hospital's investigation into the surgical incident. The Court concluded that the Hospital 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 health department, and organizing a team to conduct a Root Cause Analysis." *Doe*, 139 F. Supp. 3d at 138. The Court also found that the plaintiffs' allegations that there was "no documentation of an October meeting of the Root Cause Analysis Committee" and that "individuals identified as being in attendance at the Root Cause Analysis Committee meeting were not there" were "not well founded or supported." *Id.* at 139; *see also id.* at 142-143. The Court's rulings are the law of the case; the Court will not revisit them. *See United States v. Kpodi*, 888 F.3d 486, 491 (D.C. Cir. 2018) (the law-of-the-case doctrine "prevents courts from reconsidering issues that have already been decided in the same case" and "is predicated on the premise that it would be impossible for an appellate court to perform its duties satisfactorily and efficiently and expeditiously if a question, once considered and decided by it, were to be litigated anew in the same case upon any and every subsequent appeal.") (internal quotation marks omitted and edits accepted).

III. The § 552a(g)(1)(A) Privacy Act Claim

The plaintiffs allege that the defendants have violated § 552a(g)(1)(A) of the Privacy Act by failing to amend the Adverse Action Report. They argue that the Adverse Action Report contains "errors of fact, not judgment" that should be corrected pursuant to the Privacy Act, including whether the Hospital lied about meetings and committed fraud by tricking Dr. Doe into resigning. Pls.' Cross Mot. & Opp'n at 47. The plaintiffs allege that the following facts support

their claims: 1) the Hospital submitted a redacted and incomplete document as proof of an October 2009 meeting of the Hospital's Medical Staff Performance Improvement Committee, Am. Compl. ¶ 63; 2) the Hospital misdated a memorandum documenting a review meeting on Monday, October 6, 2009, *Id.*; 3) neither the Attending Gynecology Oncology Surgeon nor the Attending General/Thoracic Surgeon attended an October 14, 2009 meeting of a Root Cause Analysis Committee, *Id.* ¶ 65; and 4) three surgeons who were not involve with the Hospital's review concluded that Dr. Doe did not depart from the standard of care, *id.* ¶ 80. According to the plaintiffs, this evidence demonstrates that the Hospital fabricated documents in support of a quality assurance review of the plaintiffs' surgical conduct that did not actually occur. *Id.* ¶ 58.

The defendants have again moved to dismiss this claim pursuant to Federal Rule of Civil Procedure 12(b)(6). They assert that the Statement was an opinion, not a fact, and that § 552a(g)(1)(A) of the Privacy Act does not provide for the amendment of opinions or judgments. According to the defendants, there "can be no plausible dispute that [the Hospital] concluded that he deviated from the standard of care, and that fact is all the [Adverse Action Report] relates." Defs.' Opp'n and Reply at 11. They also contend that the Court has already determined that the record does not support the plaintiffs' allegations that the Hospital fabricated documents or that its administrators committed fraud. *Id.* at 10.

a. Legal Standard

i. Motion to Dismiss

A complaint "must contain . . . a short and plain statement of the claim showing that the pleader is

entitled to relief." Fed. R. Civ. P. 8(a)(2). Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a party may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To survive a motion to dismiss based on Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

When ruling on a motion to dismiss, the Court must "accept all the well-pleaded factual allegations of the complaint as true and draw all reasonable inferences from those allegations in the plaintiff's favor." *Banneker Ventures v. Graham,* 798 F.3d 1119, 1129 (D.C. Cir. 2015). The Court may consider facts alleged in the complaint, as well as "any documents either attached to or incorporated in the complaint and matters of which the Court may take judicial notice." *Hurd v. District of Columbia*, 864 F.3d 671, 678 (D.C. Cir. 2017) (internal quotation marks omitted and edits accepted).

ii. § 552a(g)(1)(A) of the Privacy Act

Under the Privacy Act, an "agency that maintains a system of records" shall permit individuals "to request amendment of a record pertaining" to him or her. 5 U.S.C. § 552A(d)(2). Upon receiving such a request, an agency may either correct any portion of that record, or inform the individual of its refusal to do so, and provide, *inter alia*, the reason for the refusal. *Id.* § 552a(d)(2)(B). The Privacy Act requires that an agency "permit" an individual "who disagrees

with the refusal of the agency to amend his record" to request a review of that decision. *Id.* at § 552a(d)(3). Section 552a(g)(1)(A) of the Privacy Act—the subsection at issue here—then provides that "[w]henever an 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," the individual may "bring a civil action against the agency . . ." 5 U.S.C. § 552a(g)(1)(A)

b. The Plaintiffs have Failed to State a Claim under 5 U.S.C. § 552a(g)(1)(A).

Accepting the plaintiffs' aforementioned factual allegations as true, their Privacy Act claim does not survive a motion to dismiss because the Statement is the Hospital's judgment about Dr. Doe's conduct during the surgery.[3] "It is well-established that,

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[3] The defendants correctly note that the Court considered the plaintiffs' allegations in the context of their APA claims and found them unavailing. *See Doe*, 139 F. Supp. 3d at 139-140 (finding that 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," that the Court was "not troubled by the fact the minutes of the Medical Staff Performance Improvement Committee meeting were redacted" because "[a]s far as the Court can tell, the only thing of any consequence that was redacted in the document was the identity of Hospital employees"); *id.* at 143 (concluding that the "fact that [Dr. Ortiz] 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"). However, when considering the defendants' motion to dismiss the remaining Privacy Act claim, the Court must "accept all the well-pleaded factual allegations of the complaint as true and draw all reasonable inferences from those allegations in the plaintiff's favor." *Banneker Ventures*, 798 F.3d at 1129.

'generally speaking, the Privacy Act allows for correction of facts but not correction of opinions or judgments.'" *Mueller v. Winter*, 485 F.3d 1191, 1197 (2007) (quoting *McCready* v. *Nicholson*¸465 F.3d 1, 19 (D.C. Cir. 2006)). It is true that "[i]f a subjective judgment is 'based on a demonstrably false' factual premise . . . the Privacy Act compels the agency to correct or remove the judgment from the complaining individual's record." *Mueller*, 485 F.3d at 1197 (*quoting White v. Office of Pers. Mgmt.*, 787 F.2d 660, 662 (D.C. Cir. 1986)). But the plaintiffs do not point to a demonstratively false factual premise that would compel the Agency to correct or remove the Statement. Accepting the plaintiffs' factual allegations as true and granting reasonable inferences in their favor, the plaintiffs' allegations call into question the rigor of the Hospital's review of Dr. Doe's work, and its documentation of that review.[4] However, it would be unreasonable for the Court to infer from the plaintiffs' allegations that a review of his conduct did not occur, or that the Hospital did not conclude that he departed from the standard of care. Dr. Doe conducted an appendectomy. First Am. Compl. ¶ 49. During the course of that appendectomy, he removed an inflamed band that was identified by a subsequent pathology report as part of the patient's right Fallopian tube. *Id*. ¶ 51. The Hospital conducted a review of the procedure and reported to the Agency that it concluded that Dr. Doe's conduct departed from the standard of care. *Id*. ¶¶ 57; 61-65. That statement is a "classic statement of an author's subjective

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[4] Although the Court accepts the plaintiffs' well-plead factual allegations as true, the Court does not accept as true the plaintiff's allegations of fraud, which are legal conclusions. *Iqbal*, 556 U.S. at 678.

judgment about an individual's performance." *Mueller*, 485 F.3d at 1197. For that reason, the defendants' motion to dismiss the remaining Privacy Act claim will be granted.

IV. The Court will Not Consider the Plaintiffs' Additional Claims.

In their motion, the plaintiffs raise a slew of other issues that the Court has either already adjudicated, or that are not properly before the Court given the discrete issue on remand. The plaintiffs raise a series of constitutional claims. *See, e.g.,* Pls.' Cross Mot. & Opp'n at 15-28 (raising constitutional violations under the APA and the Fifth Amendment, including alleging that Dr. Doe has been "deprived of [his] fundamental right to practice [his] chosen profession."). The Court already adjudicated the plaintiffs' constitutional claims and will not revisit those rulings. *See Doe*, 139 F. Supp. 3d at 153-167 (considering plaintiff' Due Process claims); 168-69 (Bill of Attainer claims); 169-171 (Eight Amendment claims); *Kpodi*, 888 F.3d 486, 491 (D.C. Cir. 2018) (the law-of-the-case doctrine "prevents courts from reconsidering issues that have already been decided in the same case.") (internal quotation marks omitted).

The plaintiffs also cite three additional Privacy Act sections that are not properly before the Court and that the plaintiffs did not raise in their Amended Complaint. Pls.' Cross Mot. & Opp'n at 35-45 (citing 5 U.S.C. §§ 552a(e)(2), (e)(5) and (e)(6)). Although a court errs when it "fails to considere a *pro se* litigant's complaint in light of all filings," the plaintiffs were represented by counsel when they filed their Amended Complaint and during the first round of briefing. *Brown v. Whole Foods Mkt. Grp.,* 789 F.3d

146, 152 (D.C. Cir. 2015) (internal quotation marks omitted). Accordingly, the Court will not consider the plaintiffs' new Privacy Act arguments.

The plaintiffs also argue that the Court must accept the plaintiffs' factual allegations as true regarding all their claims and allow them to proceed to discovery. Pls.' Reply at 4-8 [ECF No. 108]. Not only do the plaintiffs seek to relitigate the standard that the Court has already applied to its APA claims in *Doe*, this argument also misstates the standard of review for APA claims, which the Court has previously discussed. *See supra* § II(b).

V. The Plaintiffs' Request to Add Extra-Record Evidence

The plaintiffs have filed two motions to supplement the record, along with a motion for reargument based on new evidence.

a. Legal Standard

"When reviewing agency action under the APA," courts "review 'the whole record or those parts of it cited by a party.'" *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1002 (D.C. Cir. 2008) (quoting 5 U.S.C. § 706). "The record consists of the order involved, any findings or reports on which that order is based, and the pleadings, evidence, and other parts of the proceedings before the agency." *Id.* (internal quotation marks omitted). It is "black-letter administrative law that in an Administrative Procedure Act case, a reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.'" *CTS Corp. v. EPA.,* 759 F.3d 52, 64 (D.C. Cir. 2014) (quoting *Hill Dermaceuticals, Inc. v. FDA,* 709 F.3d 44, 47 (D.C. Cir. 2013) (internal edits accepted). An agency is

"entitled to a strong presumption of regularity that it properly designated the administrative record." *Oceana v. Pritzker*, 217 F. Supp. 3d 310, 316 (D.D.C. 2016) (internal quotation marks omitted). For that reason, "[s]upplementation of the administrative record is the exception, not the rule." *Pac. Shores Subdivision v. U.S. Army Corps of Eng'rs*, 448 F. Supp. 2d 1, 5 (D.D.C. 2006).

There are two ways a plaintiff may seek to augment the body of materials reviewed by the district court in an APA case, both of which are often, and confusingly, referred to as "supplementing" the administrative record. *Am. Petroleum Tankers Parent v. United States*, 952 F. Supp. 2d 252, 261 (D.D.C. 2013). First, a party may seek to "add[] to the volume of the administrative record with documents the agency considered." *Earthworks v. United States Dep.'t of the Interior*, 279 F.R.D. 180, 185 (D.D.C. 2012); *see also Am. Petroleum Tankers Parent*, 952 F. Supp. 2d at 261 (describing this supplementation as seeking to "include evidence that should have been properly a part of the administrative record but was excluded by the agency.") (internal quotation marks omitted). Second, a party may seek to add extra-record evidence that was "not initially before the agency but that the plaintiff believes should nonetheless be included in the administrative record." *Am. Petroleum Tankers Parent*, 952 F. Supp. 2d at 261 (internal quotation marks omitted).

Under the first justification for supplementing the record, more accurately described as completion of the administrative record, "the moving party must rebut the presumption of administrative regularity and show that the documents to be included were before the agency decisionmaker." *Pac. Shores Subdivision,* 448 F. Supp. 2d at 6; *see also Oceana,*

217 F. Supp. 3d at 316 ("the party seeking completion must present non-speculative, concrete evidence to support their belief that the specific documents allegedly missing from the administrative record were directly or indirectly considered by the actual decision makers involved in the challenged agency action.") (internal quotation marks omitted).

Under the second justification, courts generally do not allow parties to add extra-record evidence "unless they can demonstrate unusual circumstances justifying a departure from this general rule." *Am. Wildlands*, 530 F.3d at 1002 (internal quotation marks omitted). The record "can be supplemented in three instances: (1) if the agency 'deliberately or negligently excluded documents that may have been adverse to its decision.' (2) if background information was needed 'to determine whether the agency considered all the relevant factors,' or (3) if the 'agency failed to explain administrative action so as to frustrate judicial review.'" *City of Dania Beach v. FAA*, 628 F.3d 581, 590 (D.C. Cir. 2010) (quoting *Am. Wildlands*, 530 F.3d at 1002); *see also Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010). ("The APA limits judicial review to the administrative record except when there has been a strong showing of bad faith or improper behavior or when the record is so bare that it prevents effective judicial review.") (internal quotation marks omitted). These "narrow" exceptions may "at most . . . be invoked to challenge gross procedural deficiencies." *Hill Dermaceuticals*, 709 F.3d at 47. Because the plaintiffs seek to supplement the administrative record with documents that were not before the Agency, the Court will analyze the plaintiffs' requests as requests to add extra-record evidence.

b. The Plaintiffs' Second Motion to Supplement the Record

In the plaintiffs' Second Motion to Supplement the Record, they seek to add a June 2011 letter sent by plaintiffs' then-counsel to the Data Bank attaching a complaint the plaintiffs had filed in the Eastern District of New York in 2010. Pls.' Second Mot. to Suppl. R., Ex. 1 [ECF No. 118-1]. Portions of that complaint are already in the record, AR at 140-45 [ECF No. 19-3 (SEALED)], but the plaintiffs seek to add the entire complaint to the record to demonstrate that they alleged to the Agency that the Hospital committed fraud. Pls.' Second Mot. to Suppl. R. at 5-6. In doing so, the plaintiffs seek to dispute this Court's conclusion in *Doe* 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." *Doe*, 139 F. Supp. 3d at 149. Attempting to relitigate issues that the Court has already resolved does not fall under the unusual circumstances required to add extra-record evidence. The Court will deny this motion.

c. The Plaintiffs' Third Motion to Supplement the Record

The plaintiffs also seek to supplement the administrative record with documents related to what they allege was the Hospital's improper access to the plaintiff's Data Bank file in 2010. Pls.' Third Mot. to Suppl. R. at 1 [ECF No. 120]. The first document contains email correspondence between individuals at the NPDB in 2012. *Id*. at 21-23 (Ex. 1). The correspondence indicates that when querying Dr. Doe's file in June of 2010, the Hospital selected

"Privileging or Employment" as the reason for the inquiry. *Id*. at 23. The second document is a letter dated October 12, 2012 from a staff member at the NPDB to the Vice President of Medical Affairs at the Hospital concluding that the Hospital's explanation for querying Dr. Doe's file was "supported by the record and [was] consistent with the confidentiality restrictions." *Id*. at 25 (Ex. 2). The final document contains June 2012 email correspondence between HHS employees speaking disparagingly about Dr. Doe. *Id*. at 26-27 (Ex. 3).

The Secretary's adjudication of the plaintiffs' allegations is not before the Court in this litigation. However, by seeking to supplement the record with the first two documents, the plaintiffs attempt to connect the Hospital's query of Dr. Doe's Data Bank file to the Agency's alleged bias against Dr. Doe in this litigation. Pls.' Third Mot. to Suppl. R. at 9. The plaintiffs allege that 1) the Hospital's query of Dr. Doe's Adverse Action Report was unauthorized; 2) the Hospital lied to the Data Bank when selecting its reasons for the inquiry and later asserting that it queried the file because it did not save a copy of the Adverse Action Report it submitted to the Hospital; and 3) the Data Bank's acceptance of that lie demonstrates its bias against Dr. Doe in "every single decision the [A]gency makes" despite evidence to the contrary. Pls.' Reply in Supp. of Third Mot. to Suppl. R. at 13-15 [ECF No. 123].

The plaintiffs do not demonstrate how their request falls into any of the three narrow exceptions to the presumption that the Agency has properly designated the administrative record. They do not argue that the Agency excluded documents adverse to its decision; indeed, these documents do not address the decision at issue in this case. They do not argue that these

emails provide background information to allow the Court to determine if the Agency considered relevant factors. They also do not contend that supplementing the record with these documents is appropriate because judicial review of the agency's action has been frustrated by the Agency's failure to explain its actions. *City of Dania Beach*, 628 F.3d at 590. These allegations are unsubstantiated and only tenuously relate to the issues before the Court. They do not demonstrate that the Agency is biased, and fall far short of the strong showing of bad faith necessary to support supplementation of the record with extra-record evidence. *Theodore Roosevelt Conservation P'ship,* 616 F.3d at 514.

The plaintiffs also argue that the Agency's decisions demonstrate a "practice and pattern" of bias against them. Pls.' Reply in Supp. of Third Mot. to Suppl. R. at 5. In doing so, they largely re-argue claims that this Court already considered in *Doe*, such as whether the Vice President of Medical Affairs tricked Dr. Doe into thinking he was not under investigation, and whether the Hospital fabricated the documents it submitted to the Agency. *See, e.g., id*. at 22; *Doe*, 139 F. Supp. 3d at 145 (addressing the plaintiffs' "new theory" that Dr. Doe's resignation was not voluntary because it was induced by fraud); *id*. at 139-140 (finding that the Secretary reasonably relied on ducments the plaintiffs alleged were "forged or not bona fide.") The plaintiffs disagree with the Agency's decisions. But "[d]isagreement with an agency's analysis is not enough to warrant the consideration of extra-record evidence." *Standing Rock Sioux Tribe v. U.S. Army Corp of Engineers*, 255 F. Supp. 3d 101, 125 (D.D.C. 2017).

Finally, the Court considered and denied the plaintiffs' request to supplement the administrative

record with Exhibit 3 when it denied a previous motion to supplement the record during a telephone hearing. Minute Entry, May 16, 2016. At that time, the Court expressed dismay at the unprofessional nature of the emails, but found that they did not warrant supplementing the administrated record. That ruling is the law of the case, and the Court shall not disturb it. *See LaShawn A. v. Barry,* 87 F.3d 1389, 1393 (D.C. Cir. 1996) ("the law-of-the-case doctrine[ ] [provides that] the same issue presented a second time in the same case in the same court should lead to the same result."

d. The Plaintiffs' Motion for Reargument Based on New Evidence.

The plaintiffs have moved for reargument based on what they assert is new evidence obtained in 2016 from the plaintiffs' separate litigation against the Hospital in New York state court. Pls.' Mot. for Rearg. [ECF No. 127]. They seek to add to the record the following documents: the second two pages of the Quality Management Case Report submitted to the Agency by the Hospital, *id.* Ex. 2 [ECF No. 127-3], the 2009 Summary Report for Sentinal Event, *id*. Ex. 3 [ECF No. 127-4], and deposition testimony from the Hospital's then-Vice President for Quality Management, *id.* Ex. 4 [ECF No. 127-5]. The plaintiffs rely on these documents to support their assertions that Hospital employees lied on documentation the Hospital submitted to the Agency, and that the Agency consequently relied on incomplete documents. *See, e.g., id.* at 2-12

These documents were not available to the Agency when it issued its two decisions—the plaintiffs obtained the documents in December 2016, over a year after the Agency issued its most recent decision

in this case. Defs.' Opp'n to Mot. for Rearg. at 4 [ECF No. 128]. Although Agency counsel told the plaintiffs the Agency would consider the documents, the plaintiffs declined to submit them to the Agency before filing them before the Court. *Id.* at 5. The plaintiffs contend that forcing them to present the documents to the Agency first will cause further, unnecessary delays. They also argue that the Agency will rule against them "because of its bias." Pls.' Reply in Supp. of Mot. for Rearg. at 3 [ECF No. 129].

By attempting to submit new evidence directly to the Court, the plaintiffs request that the Court bypass the Agency, review the documents they've submitted, and find that the Adverse Action Report should be struck from the Data Bank. But courts allow litigants to submit extra-record evidence in APA cases to more effectively review agency action, not to allow litigants to bypass agency review. *See Marcum v. Salazar*, 751 F. Supp. 2d 74, 79 (D.D.C. 2010) (noting that "'particularly in the procedural context, it may sometimes be appropriate to resort to extra-record information to *enable judicial review to become effective.*'") (quoting *Esch v. Yeutter,* 876 F.2d 976, 991 (D.C. Cir. 1989) (edits accepted). The Agency did not have the documents that the plaintiffs seek to add to the record when it made its decisions, and, as the Court has already emphasized, it should "have before it neither more nor less information than did the agency when it made its decision." *CTS Corp.,* 759 F.3d at 64 (quoting *Hill Dermaceuticals,* 709 F.3d at 47). The Court will not consider these documents before the Agency has reviewed them. *See Butte Cty., California v. Chaudhuri*, 197 F. Supp. 3d 82, 91 (D.D.C. 2016), *aff'd*, 887 F.3d 501 (D.C. Cir. 2018) (denying a motion to add extra-record evidence and noting that "the purpose of limiting review to the

record actually before the agency is to guard against courts using new evidence to convert the arbitrary and capricious standard into effectively de novo review.") (internal quotation marks omitted and edits accepted). For those reasons, the plaintiffs request for reargument will be denied.

VI. The Plaintiffs' Request for the Court's Recusal

Finally, the plaintiffs request that the Court recuse itself from this case. They argue that the Court has shown bias against them by making incorrect legal rulings, and because of the "unusually long time to issue decisions in this case." Pls.' Mot. for Rearg. At 31-33. The defendants oppose the request. Defs.' Opp'n to Mot. for Rearg. at 13-15.

a. Legal Standard

A judge "shall disqualify himself [or herself] in any proceeding in which his impartiality might be reasonably questioned." 28 U.S.C. § 455(a)[5]. He shall also disqualify himself "where he has personal bias or prejudice concerning a party." 28 U.S.C. § 455(b)(1). "The standard for disqualification under § 455(a) is an objective one. The question is whether a reasonable and informed observer would question the judge's impartiality." *In re Brooks*, 383 F.3d 1036, 1043 (D.C. Cir. 2004) (quoting *United States v. Microsoft*, 253 F.3d 34, 114 (D.C. Cir. 2001)).

Recusal is limited to "truly extraordinary cases" where "the judge's views have become 'so extreme as to display clear inability to render fair judgment.'"

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[5] Although they do not specifically cite this statute, the Court will evaluate the plaintiffs' request under 28 U.S.C § 455, which governs the recusal of federal judges.

Cobell v. Kempthorne, 455 F.3d 317, 332 (D.C. Cir. 2006) (quoting *Liteky v. United States*, 510 U.S. 540, 551 (1994)). "There is a presumption against disqualification and the moving party must demonstrate by clear and convincing evidence that disqualification is required by Section 455(a)." *Walsh v. FBI*, 952 F. Supp. 2d 71, 75 (D.D.C. 2013) (citation omitted). "While judicial rulings can be evidence of prejudice in certain instances . . . unfavorable judicial rulings alone almost never constitute a valid basis for reassignment." *United States v. Hite*, 769 F.3d 1154, 1172 (D.C. Cir. 2014).

b. Recusal is Not Warranted.

The plaintiffs assert that the Court made two errors in its previous rulings that demonstrate bias. First, they argue that the Court has shown bias by "holding" that "the right to practice a lawful profession has never been recognized in federal jurisprudence." Pls.' Mot. for Rearg. at 33. Second, they allege that the Court "erred in its belief" that the Hospital"s Vice President of Medical Affairs mistakenly told Dr. Doe that the Hospital commenced an investigation only to comply with the Hospital's reporting duty to state regulators. *Id*. at 32.

Not only are the plaintiffs' characterizations of the Court's findings incorrect, they do not provide any evidence to support their assertion that these supposed errors demonstrate bias.[6] Error alone "is by itself hardly a basis for imputing bias or even the appearance of partiality." *Hite,* 769 F.3d at 1172

[6] For example, the Court found that the right to practice a chosen profession was not a fundamental right that triggered the heightened review of strict scrutiny and instead applied "rational basis review" to analyze the plaintiffs' Due Process claims. *Doe*, 139 F. Supp. 3d at 157.

(citation omitted). The plaintiffs also allege, without support, that the Court has inserted its personal views in its decisions. Pls.' Reply in Supp. of Mot. for Rearg. at 2 [ECF No. 129] (asserting that the litigation's outcome "is only possible because of this Court's seeking to impose its personal view that it is better to sacrifice a few physicians who were denied due process and were victims of sham peer review than to risk subjecting the NPDB system to challenge.")[7] However, the "opinions formed by the judge on the basis of facts introduced or events occurring in the course of . . . proceedings . . . do not constitute a basis for a bias or partiality motion unless they display a deep-seated favoritism or antagonism that would make fair judgment impossible." *Liteky*, 510 U.S. at 555. Rather than demonstrating that the Court is biased against the plaintiffs, it appears instead that they are dissatisfied with the Court's rulings in this case, and conclude, without support, that the rulings stem from bias. Their dissatisfaction is "proper grounds for appeal, not recusal." *In re Kellogg Brown & Root, Inc.*, 796 F.3d 137, 151 (D.C. Cir. 2015) (quoting *Cobell*, 455 F.3d at 331).

The plaintiffs also seek the Court's recusal due to what they assert is the "unusually long time to issue decisions in this case." Pls.' Mot. for Rearg. at 33. The plaintiffs do not cite any authority supporting their request, and they do not argue that the Court is treating it differently than other litigants in the way

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[7] In other filings to the Court, the plaintiffs assert, again without support, that "it seems to me the Court used contorted reasoning to rule against me," and "the sooner this case gets before judges without indulgence towards the Government and its bureaucracy, the sooner justice will be had." Pls.' Reply in Supp. of Cross Mot. & Opp. at 10, 14.

it rules on the motions. The Court has inherent authority to manage dockets, and to balance its civil and criminal caseload. It has exercised that authority adjudicating the plaintiffs' voluminous filings, the breadth of which have far exceeded the narrow issues pending before the Court. The Court will deny the plaintiffs' request for recusal.

CONCLUSION

For the foregoing reasons, the Court will grant the defendants' motion to dismiss or, in the alternative, motion for summary judgment [ECF No. 100], and deny the plaintiffs' cross motion for summary judgment, [ECF No. 103].[8] The Court will also deny the plaintiffs second and third motions to supplement the record, and their motion for reargument based on new evidence and for the Court's recusal. [ECF Nos. 118, 120 & 127]. The Court has considered the other arguments raised by the plaintiffs and found them unavailing. An appropriate order accompanies this opinion.

September 10, 2020

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[8] As the defendants argue, because John Doe PLLC is a corporate entity, it cannot properly appear before the Court unless it is represented by counsel. LCvR 83.2; *see Greater Se. Cmty. Hosp. Found., Inc. v. Potter*, 586 F.3d 1, 4 (D.C. Cir. 2009) (quoting *Rowland v. Cal. Men's Colony*, 506 U.S. 194, 201-02 (1993)) ("'It has been the law for the better part of two centuries . . . that a corporation may apprear in the federal courts only through licensed counsel.'") *Lennon v. McClory*, 3 F. Supp. 2d 1461, 1462 n.1 (D.D.C. 1998) ("A corporation cannot represent itself and cannot appear *pro se*.") Because there are no remaining claims in this case, the Court takes no action in this regard.

/s/ Thomas F. Hogan
Thomas F. Hogan
SENIOR UNITED STATES DISTRICT JUDGE
[SEAL]
Digitally signed by Thomas F. Hogan
Date: 2020.09.10
16:00:29-04'00'

Appendix E

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Const. amend. I

Section Amendment I – Religion and Expression

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

U.S. Const. art. AMENDMENTS § Amendment I

U.S. Const. amend. V

Section Amendment V – Rights of Persons

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

US. Const. art. AMENDMENTS § Amendment V

42 U.S.C. § 11101

Section 11101 Findings

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.
(2) There is a national 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.
(3) This nationwide problem can be remedied through effective professional peer review.
(4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.
(5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.

42 U.S.C. § 11101

Pub. L. 99-660, title IV, §402, Nov. 14, 1986, 100 Stat. 3784.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SHORT TITLE *Pub. L. 99-660, title IV, §401, Nov. 14, 1986, 100 Stat. 3784, provided that: "This title [enacting this chapter and provisions set out as a note under section 11111 of this title] may be cited as the 'Health Care Quality Improvement Act of 1986'."*

Section 11111 – Professional review

(a) In general

(1) Limitation on damages for professional review actions

If a professional review action (as defined in section 11151(9) of this title) of a professional review body meets all the standards specified in section 11112(a) of this title, except as provided in subsection (b)-

(A) the professional review body,

(B) any person acting as a member or staff to the body,

(C) any person under a contract or other formal agreement with the body, and

(D) any person who participates with or assists the body with respect to the action, shall not be liable in damages under any law of the United States or of any State (or political subdivision thereof) with respect to the action. The preceding sentence shall not apply to damages under any law of the United States or any State relating to the civil rights of any person or persons, including the Civil Rights Act of 1964, 42 U.S.C. 2000e, et seq. and the Civil Rights Acts, 42 U.S.C. 1981, et seq. Nothing in this paragraph shall prevent the United States or any Attorney General of a State from bringing an action, including an action under section 15c of title 15, where such an action is otherwise authorized.

(2) Protection for those providing information to professional review bodies

Notwithstanding any other provision of law, no person (whether as a witness or otherwise) providing information to a professional review body

regarding the competence or professional conduct of a physician shall be held, by reason of having provided such information, to be liable in damages under any law of the United States or of any State (or political subdivision thereof) unless such information is false and the person providing it knew that such information was false.

(b) Exception

If the Secretary has reason to believe that a health care entity has failed to report information in accordance with section 11133(a) of this title, the Secretary shall conduct an investigation. If, after providing notice of noncompliance, an opportunity to correct the noncompliance, and an opportunity for a hearing, the Secretary determines that a health care entity has failed substantially to report information in accordance with section 11133(a) of this title, the Secretary shall publish the name of the entity in the Federal Register. The protections of subsection (a)(1) shall not apply to an entity the name of which is published in the Federal Register under the previous sentence with respect to professional review actions of the entity commenced during the 3-year period beginning 30 days after the date of publication of the name.

(c) Treatment under State laws

(1) Professional review actions taken on or after October 14, 1989

Except as provided in paragraph (2), subsection (a) shall apply to State laws in a State only for professional review actions commenced on or after October 14, 1989.

(2) Exceptions

(A) State early opt-in

Subsection (a) shall apply to State laws in a State for actions commenced before October 14, 1989, if the State by legislation elects such treatment.

(B) Effective date of election

An election under State law is not effective, for purposes of,[1] for actions commenced before the effective date of the State law, which may not be earlier than the date of the enactment of that law.

[1]So in original. Probably should be "for purposes of subparagraph (A),".

42 U.S.C. § 11111

Pub. L. 99-660, title IV, §411, Nov. 14, 1986, 100 Stat. 3784; Pub. L. 100-177, title IV, §402(c), as added Pub. L. 101-239, title VI, §6103(e)(6)(A), Dec. 19, 1989, 103 Stat. 2208.

EDITORIAL NOTES

REFERENCES IN TEXT *The Civil Rights Act of 1964, referred to in subsec. (a)(1), is Pub. L. 88-352, July 2, 1964, 78 Stat. 241, which is classified principally to subchapters II to IX (§2000a et seq.) of chapter 21 of this title. Title VII of this Act relates to equal employment opportunities, and is classified generally to subchapter VI (§2000e et seq.) of chapter 21 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of this title and Tables. The Civil Rights Acts, referred to in subsec. (a)(1), are classified generally to chapter 21 (§1981 et seq.) of this title.*

AMENDMENTS 1989*-Subsec. (c)(2)(B), (C). Pub. L. 101-239 added Pub. L. 100-177, §402(c), see 1987 Amendment note below.* ***1987****-Subsec. (c)(2)(B), (C). Pub. L. 100-177, §402(c), as added by Pub. L. 101-239 redesignated subpar. (C) as (B), struck out "subparagraphs (A) and (B)" after "for purposes of", and struck out former subpar. (B) which read as follows: "Subsection (a) of this section shall not apply to State laws in a State for actions commenced on or after October 14, 1989, if the State by legislation elects such treatment."*

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1987 AMENDMENT *Amendment by Pub. L. 100-177 effective Nov. 14, 1986, see section 402(d) of Pub. L. 100-177 as renumbered and amended, set out as a note under section 11137 of this title.*

EFFECTIVE DATE *Pub. L. 99-660 title IV, §416, Nov. 14, 1986, 100 Stat. 3788, provided that: "This part [part A (§§411-416) of title IV of Pub. L. 99-660, enacting this subchapter] shall apply to professional review actions commenced on or after the date of the enactment of this Act [Nov. 14, 1986]."*

42 U.S.C. § 11112

Section 11112 –
Standards for professional review actions

(a) In general

For purposes of the protection set forth in section 11111(a) of this title, a professional review action must be taken-

(1) in the reasonable belief that the action was in the furtherance of quality health care,

(2) after a reasonable effort to obtain the facts of the matter,

(3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and

(4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3). A professional review action shall be presumed to have met the preceding standards necessary for the protection set out in section 11111(a) of this title unless the presumption is rebutted by a preponderance of the evidence.

(b) Adequate notice and hearing

A health care entity is deemed to have met the adequate notice and hearing requirement of subsection (a)(3) with respect to a physician if the following conditions are met (or are waived voluntarily by the physician):

(1) Notice of proposed action

The physician has been given notice stating-

(A)

(i) that a professional review action has been proposed to be taken against the physician

(ii) reasons for the proposed action,

(B)

(i) that the physician has the right to request a hearing on the proposed action,

(ii) any time limit (of not less than 30 days) within which to request such a hearing, and

(C) a summary of the rights in the hearing under paragraph (3).

(2) Notice of hearing

If a hearing is requested on a timely basis under paragraph (1)(B), the physician involved must be given notice stating-

(A) the place, time, and date, of the hearing, which date shall not be less than 30 days after the date of the notice, and

(B) a list of the witnesses (if any) expected to testify at the hearing on behalf of the professional review body.

(3) Conduct of hearing and notice
If a hearing is requested on a timely basis under paragraph (1)(B)-

(A) subject to subparagraph (B), the hearing shall be held (as determined by the health care entity)-

(i) before an arbitrator mutually acceptable to the physician and the health care entity,

(ii) before a hearing officer who is appointed by the entity and who is not in direct economic competition with the physician involved, or

(iii) before a panel of individuals who are appointed by the entity and are not in direct economic competition with the physician involved;

(B) the right to the hearing may be forfeited if the physician fails, without good cause, to appear;

(C) in the hearing the physician involved has the right-

(i) to representation by an attorney or other person of the physician's choice,

(ii) to have a record made of the proceedings, copies of which may be obtained by the physician upon payment of any reasonable charges associated with the preparation thereof,

(iii) to call, examine, and cross-examine witnesses,

(iv) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and

(v) to submit a written statement at the close of the hearing; and

(D) upon completion of the hearing, the physician involved has the right-

(i) to receive the written recommendation of the arbitrator, officer, or panel, including a statement of the basis for the recommendations, and

(ii) to receive a written decision of the health care entity, including a statement of the basis for the decision.

A professional review body's failure to meet the conditions described in this subsection shall not, in itself, constitute failure to meet the standards of subsection (a)(3).

(c) Adequate procedures in investigations or health emergencies

For purposes of section 11111(a) of this title, nothing in this section shall be construed as-

(1) requiring the procedures referred to in subsection (a)(3)-

(A) where there is no adverse professional review action taken, or

(B) in the case of a suspension or restriction of clinical privileges, for a period of not longer than 14 days, during which an investigation is being conducted to determine the need for a professional review action; or

(2) precluding an immediate suspension or restriction of clinical privileges, subject to subsequent notice and hearing or other adequate procedures, where the failure to take such an action may result in an imminent danger to the health of any individual.

42 U.S.C. § 11112

Pub. L. 99-660, title IV, §412, Nov. 14, 1986, 100 Stat. 3785.

42 U.S.C. § 143

Section 11113 – Payment of reasonable attorneys' fees and costs in defense of suit

In any suit brought against a defendant, to the extent that a defendant has met the standards set forth under section 11112(a) of this title and the defendant substantially prevails, the court shall, at the conclusion of the action, award to a substantially prevailing party defending against any such claim the cost of the suit attributable to such claim, including a reasonable attorney's fee, if the claim, or the claimant's conduct during the litigation of the claim, was frivolous, unreasonable, without foundation, or in bad faith. For the purposes of this section, a defendant shall not be considered to have

substantially prevailed when the plaintiff obtains an award for damages or permanent injunctive or declaratory relief.

42 U.S.C. § 11113

Pub. L. 99-660, title IV, §413, Nov. 14, 1986, 100 Stat. 3787.

42 U.S.C. § 144

Section 11114 – Guidelines of Secretary

The Secretary may establish, after notice and opportunity for comment, such voluntary guidelines as may assist the professional review bodies in meeting the standards described in section 11112(a) of this title.

42 U.S.C. § 11114

Pub. L. 99-660, title IV, §414, Nov. 14, 1986, 100 Stat. 3787.

42 U.S.C. § 144

Section 11115 – Construction

(a) In general

Except as specifically provided in this subchapter, nothing in this subchapter shall be construed as changing the liabilities or immunities under law or as preempting or overriding any State law which provides incentives, immunities, or protection for those engaged in a professional review action that is in addition to or greater than that provided by this subchapter.

(b) Scope of clinical privileges

Nothing in this subchapter shall be construed as requiring health care entities to provide clinical

privileges to any or all classes or types of physicians or other licensed health care practitioners.

(c) Treatment of nurses and other practitioners
Nothing in this subchapter shall be construed as affecting, or modifying any provision of Federal or State law, with respect to activities of professional review bodies regarding nurses, other licensed health care practitioners, or other health professionals who are not physicians.

(d) Treatment of patient malpractice claims
Nothing in this chapter shall be construed as affecting in any manner the rights and remedies afforded patients under any provision of Federal or State law to seek redress for any harm or injury suffered as a result of negligent treatment or care by any physician, health care practitioner, or health care entity, or as limiting any defenses or immunities available to any physician, health care practitioner, or health care entity.

42 U.S.C. § 11115

Pub. L. 99-660, title IV, §415, Nov. 14, 1986, 100 Stat. 3787; Pub. L. 100-177, title IV, §402(c), as added Pub. L. 101-239, title VI, §6103(e)(6)(A), Dec. 19, 1989, 103 Stat. 2208.

EDITORIAL NOTES

AMENDMENTS 1989*-Subsec. (a). Pub. L. 101-239 added Pub. L. 100-177, §402(c), see 1987 Amendment note below.1987-Subsec. (a). Pub. L. 100-177, §402(c), as added by Pub. L. 101-239 inserted before period at end "or as preempting or overriding any State law which provides incentives, immunities, or protection for those engaged in a professional review*

action that is in addition to or greater than that provided by this subchapter".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1987 AMENDMENT
Amendment by Pub. L. 100-177 effective Nov. 14, 1986, see section 402(d) of Pub. L. 100-177 as renumbered and amended, set out as a note under section 11137 of this title.

42 U.S.C. § 146

Section 11131 – Requiring reports on medical malpractice payments

(a) In general
Each entity (including an insurance company) which makes payment under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report, in accordance with section 11134 of this title, information respecting the payment and circumstances thereof.

(b) Information to be reported
The information to be reported under subsection (a) includes-

(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made,
(2) the amount of the payment,
(3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,

(4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and

(5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.

(c) Sanctions for failure to report

Any entity that fails to report information on a payment required to be reported under this section shall be subject to a civil money penalty of not more than $10,000 for each such payment involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a-7a of this title are imposed and collected under that section.

(d) Report on treatment of small payments

The Secretary shall study and report to Congress, not later than two years after November 14, 1986, on whether information respecting small payments should continue to be required to be reported under subsection (a) and whether information respecting all claims made concerning a medical malpractice action should be required to be reported under such subsection.

42 U.S.C. § 11131

Pub. L. 99-660, title IV, §421, Nov. 14, 1986, 100 Stat. 3788.

42 U.S.C. § 148

Section 11132 – Reporting of sanctions taken by Boards of Medical Examiners

(a) In general

(1) Actions subject to reporting

Each Board of Medical Examiners-

(A) which revokes or suspends (or otherwise restricts) a physician's license or censures, reprimands, or places on probation a physician, for reasons relating to the physician's professional competence or professional conduct, or

(B) to which a physician's license is surrendered, shall report, in accordance with section 11134 of this title, the information described in paragraph (2).

(2) Information to be reported

The information to be reported under paragraph (1) is-

(A) the name of the physician involved,

(B) a description of the acts or omissions or other reasons (if known) for the revocation, suspension, or surrender of license, and

(C) such other information respecting the circumstances of the action or surrender as the Secretary deems appropriate.

(b) Failure to report

If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (a), the Secretary shall designate another

qualified entity for the reporting of information under section 11133 of this title.

42 U.S.C. § 11132

Pub. L. 99-660, title IV, §422, Nov. 14, 1986, 100 Stat. 3789.

42 U.S.C. § 149

Section 11133 – Reporting of certain professional review actions taken by health care entities

(a) Reporting by health care entities

(1) On physicians

Each health care entity which-

(A) takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;

(B) accepts the surrender of clinical privileges of a physician-

(i) while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or

(ii) in return for not conducting such an investigation or proceeding; or

(C) in the case of such an entity which is a professional society, takes a professional review action which adversely affects the membership of a physician in the society, shall report to the Board of Medical Examiners, in accordance with section 11134(a) of this title, the information described in paragraph (3).

(2) Permissive reporting on other licensed health care practitioners

A health care entity may report to the Board of Medical Examiners, in accordance with section 11134(a) of this title, the information described in paragraph (3) in the case of a licensed health care practitioner who is not a physician, if the entity would be required to report such information under paragraph (1) with respect to the practitioner if the practitioner were a physician.

(3) Information to be reported

The 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.

(b) Reporting by Board of Medical Examiners

Each Board of Medical Examiners shall report, in accordance with section 11134 of this title, the information reported to it under subsection (a) and known instances of a health care entity's failure to report information under subsection (a)(1).

(c) Sanctions

(1) Health care entities

A health care entity that fails substantially to meet the requirement of subsection (a)(1) shall lose the protections of section 11111(a)(1) of this title if the

Secretary publishes the name of the entity under section 11111(b) of this title.

(2) Board of Medical Examiners
If, after notice of noncompliance and providing an opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with subsection (b), the Secretary shall designate another qualified entity for the reporting of information under subsection (b).

(d) References to Board of Medical Examiners
Any reference in this subchapter to a Board of Medical Examiners includes, in the case of a Board in a State that fails to meet the reporting requirements of section 11132(a) of this title or subsection (b), a reference to such other qualified entity as the Secretary designates.

42 U.S.C. § 11133

Pub. L. 99-660, title IV, §423, Nov. 14, 1986, 100 Stat. 3789.

42 U.S.C. § 151

Section 11134 – Form of reporting

(a) Timing and form
The information required to be reported under sections 11131, 11132(a), and 11133 of this title shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date (not later than one year after November 14, 1986) specified by the Secretary.

(b) To whom reported

The information required to be reported under sections 11131, 11132(a), and 11133(b) of this title 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.

(c) Reporting to State licensing boards

(1) Malpractice payments

Information required to be reported under section 11131 of this title shall also be reported to the appropriate State licensing board (or boards) in the State in which the medical malpractice claim arose.

(2) Reporting to other licensing boards

Information required to be reported under section 11133(b) of this title shall also be reported to the appropriate State licensing board in the State in which the health care entity is located if it is not otherwise reported to such board under subsection (b).

42 U.S.C. § 11134

Pub. L. 99-660, title IV, §424, Nov. 14, 1986, 100 Stat. 3790.

42 U.S.C. § 152

Section 11135 – Duty of hospitals to obtain information

(a) In general

It is the duty of each hospital to request from the Secretary (or the agency designated under section 11134(b) of this title), on and after the date information is first required to be reported under section 11134(a) of this title)-[1]

(1) at the time a physician or licensed health care practitioner applies to be on the medical staff (courtesy or otherwise) of, or for clinical privileges at, the hospital, information reported under this subchapter concerning the physician or practitioner, and

(2) once every 2 years information reported under this subchapter concerning any physician or such practitioner who is on the medical staff (courtesy or otherwise) of, or has been granted clinical privileges at, the hospital.

A hospital may request such information at other times.

(b) Failure to obtain information

With respect to a medical malpractice action, a hospital which does not request information respecting a physician or practitioner as required under subsection (a) is presumed to have knowledge of any information reported under this subchapter to the Secretary with respect to the physician or practitioner.

(c) Reliance on information provided

Each hospital may rely upon information provided to the hospital under this chapter and shall not be held liable for such reliance in the absence of the hospital's knowledge that the information provided was false.

[1]So in original. The closing parenthesis probably should not appear.

42 U.S.C. § 11135

Pub. L. 99-660, title IV, §425, Nov. 14, 1986, 100 Stat. 3790.

42 U.S.C. § 154

Section 11136 – Disclosure and correction of information

With respect to the information reported to the Secretary (or the agency designated under section 11134(b) of this title) under this subchapter respecting a physician or other licensed health care practitioner, the Secretary shall, by regulation, provide for-

(1) disclosure of the information, upon request, to the physician or practitioner, and

(2) procedures in the case of disputed accuracy of the information.

42 U.S.C. § 11136

Pub. L. 99-660, title IV, §426, Nov. 14, 1986, 100 Stat. 3791.

42 U.S.C. § 154

Section 11137 – Miscellaneous provisions

(a) Providing licensing boards and other health care entities with access to information

The Secretary (or the agency designated under section 11134(b) of this title) shall, upon request, provide information reported under this subchapter with respect to a physician or other licensed health care practitioner to State licensing boards, to hospitals, and to other health care entities (including health maintenance organizations) that have entered (or may be entering) into an employment or affiliation relationship with the physician or practitioner or to which the physician or practitioner has applied for clinical privileges or appointment to the medical staff.

(b) Confidentiality of information

(1) In general

Information reported under this subchapter is considered confidential and shall not be disclosed (other than to the physician or practitioner involved) except with respect to professional review activity, as necessary to carry out subsections (b) and (c) of section 11135 of this title (as specified in regulations by the Secretary), or in accordance with regulations of the Secretary promulgated pursuant to subsection (a). Nothing in this subsection shall prevent the disclosure of such information by a party which is otherwise authorized, under applicable State law, to make such disclosure. Information reported under this subchapter that is in a form that does not permit the identification of any particular health care entity, physician, other health care practitioner, or patient shall not be considered confidential. The Secretary (or the agency designated under section 11134(b) of this title), on application by any person, shall prepare such information in such form and shall disclose such information in such form.

(2) Penalty for violations

Any person who violates paragraph (1) shall be subject to a civil money penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a-7a of this title are imposed and collected under that section.

(3) Use of information

Subject to paragraph (1), information provided under section 11135 of this title and subsection (a) is intended to be used solely with respect to activities in the furtherance of the quality of health care.

(4) Fees

The Secretary may establish or approve reasonable fees for the disclosure of information under this section or section 11136 of this title. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary (or, in the Secretary's discretion, to the agency designated under section 11134(b) of this title) to cover such costs.

(c) Relief from liability for reporting

No person or entity (including the agency designated under section 11134(b) of this title) shall be held liable in any civil action with respect to any report made under this subchapter (including information provided under subsection (a)[1] without knowledge of the falsity of the information contained in the report.

(d) Interpretation of information

In interpreting information reported under this subchapter, a payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

[1]So in original. Probably should be followed by another closing parenthesis.

42 U.S.C. § 11137

Pub. L. 99-660, title IV, §427, Nov. 14, 1986, 100 Stat. 3791; Pub. L. 100-177, title IV, §402(a), (b), Dec. 1, 1987, 101 Stat. 1007.

EDITORIAL NOTES

AMENDMENTS 1987*-Subsec. (b)(1). Pub. L. 100-177, §402(a)(1), substituted "as necessary to carry out subsections (b) and (c) of section*

11135 of this title (as specified in regulations by the Secretary)" for "with respect to medical malpractice actions" and inserted at end "Information reported under this subchapter that is in a form that does not permit the identification of any particular health care entity, physician, other health care practitioner, or patient shall not be considered confidential. The Secretary (or the agency designated under section 11134(b) of this title), on application by any person, shall prepare such information in such form and shall disclose such information in such form." Subsec. (b)(4). Pub. L. 100-177, §402(b), added par. (4).Subsec. (c). Pub. L. 100-177, §402(a)(2), inserted "(including the agency designated under section 11134(b) of this title)" after "entity" and "(including information provided under subsection (a)" after "subchapter".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1987 AMENDMENT
Pub. L. 100-177, title IV, §402(d), formerly §402(c), Dec. 1, 1987, 101 Stat. 1007, as renumbered and amended by Pub. L. 101-239, title VI, §6103(e)(6), Dec. 19, 1989, 103 Stat. 2208, provided that: "(1) IN GENERAL.-The amendments made by subsections (a) and (c) [amending this section and sections 1111 and 1115 of this title] shall become effective on November 14, 1986."(2) FEES.-The amendment made by subsection (b) [amending this section] shall become effective on the date of enactment of this Act [Dec. 1, 1987]."

42 U.S.C. § 11151

Section 11151 – Definitions

In this chapter:

(1) The term "adversely affecting" includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity.

(2) The term "Board of Medical Examiners" includes a body comparable to such a Board (as determined by the State) with responsibility for the licensing of physicians and also includes a subdivision of such a Board or body.

(3) The term "clinical privileges" includes privileges, membership on the medical staff, and the other circumstances pertaining to the furnishing of medical care under which a physician or other licensed health care practitioner is permitted to furnish such care by a health care entity.

(4)

(A) The term "health care entity" means-

(i) a hospital that is licensed to provide health care services by the State in which it is located,

(ii) an entity (including a health maintenance organization or group medical practice) that provides health care services and that follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary), and

(iii) subject to subparagraph (B), a professional society (or committee thereof) of physicians or other licensed health care practitioners that

follows a formal peer review process for the purpose of furthering quality health care (as determined under regulations of the Secretary).

(B) The term "health care entity" does not include a professional society (or committee thereof) if, within the previous 5 years, the society has been found by the Federal Trade Commission or any court to have engaged in any anti-competitive practice which had the effect of restricting the practice of licensed health care practitioners.

(5) The term "hospital" means an entity described in paragraphs (1) and (7) of section 1395x(e) of this title.

(6) The terms "licensed health care practitioner" and "practitioner" mean, with respect to a State, an individual (other than a physician) who is licensed or otherwise authorized by the State to provide health care services.

(7) The term "medical malpractice action or claim" means a written claim or demand for payment based on a health care provider's furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the law of tort, brought in any court of any State or the United States seeking monetary damages.

(8) The term "physician" means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State (or any individual who, without authority holds himself or herself out to be so authorized).

(9) The term "professional review action" means an action or recommendation of a professional review body which is taken or made in the conduct

of professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the clinical privileges, or membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action. In this chapter, an action is not considered to be based on the competence or professional conduct of a physician if the action is primarily based on-

(A) The physician's association, or lack of association, with a professional society or association,

(B) the physician's fees or the physician's advertising or engaging in other competitive acts intended to solicit or retain business,

(C) the physician's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis,

(D) a physician's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional, or

(E) any other matter that does not relate to the competence or professional conduct of a physician.

(10) The term "professional review activity" means an activity of a health care entity with respect to an individual physician-

(A) to determine whether the physician may have clinical privileges with respect to, or membership in, the entity,

(B) to determine the scope or conditions of such privileges or membership, or

(C) to change or modify such privileges or membership.

(11) The term "professional review body" means a health care entity and the governing body or any committee of a health care entity which conducts professional review activity, and includes any committee of the medical staff of such an entity when assisting the governing body in a professional review activity.

(12) The term "Secretary" means the Secretary of Health and Human Services.

(13) The term "State" means the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(14) The term "State licensing board" means, with respect to a physician or health care provider in a State, the agency of the State which is primarily responsible for the licensing of the physician or provider to furnish health care services.

42 U.S.C. § 11151

Pub. L. 99-660, title IV, §431, Nov. 14, 1986, 100 Stat. 3792.

42 U.S.C. § 11152

Section 11152 – Reports and memoranda of understanding

(a) Annual reports to Congress

The Secretary shall report to Congress, annually during the three years after November 14, 1986, on the implementation of this chapter.

(b) Memoranda of understanding

The Secretary of Health and Human Services shall seek to enter into memoranda of understanding with the Secretary of Defense and the Administrator of Veterans' Affairs to apply the provisions of subchapter II of this chapter to hospitals and other facilities and health care providers under the jurisdiction of the Secretary or Administrator, respectively. The Secretary shall report to Congress, not later than two years after November 14, 1986, on any such memoranda and on the cooperation among such officials in establishing such memoranda.

(c) Memorandum of understanding with Drug Enforcement Administration

The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Administrator of Drug Enforcement relating to providing for the reporting by the Administrator to the Secretary of information respecting physicians and other practitioners whose registration to dispense controlled substances has been suspended or revoked under section 824 of title 21. The Secretary shall report to Congress, not later than two years after November 14, 1986, on any such memorandum and on the cooperation between the Secretary and the Administrator in establishing such a memorandum.

42 U.S.C. § 11152

Pub. L. 99-660, title IV, §432, Nov. 14, 1986, 100 Stat. 3794.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME *Reference to Administrator of Veterans' Affairs deemed to refer to Secretary of Veterans Affairs pursuant to section 10 of Pub. L. 100-527 set out as a Department of Veterans Affairs Act note under section 301 of Title 38, Veterans' Benefits.*

[SEAL]
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PART 57—VOLUNTEER SERVICES

Sec.

AUTHORITY: Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539: 42 U.S.C. 217b.

SOURCE: 34 FR 13868, Aug. 29, 1969, unless otherwise noted.

§ 57.1 Applicability.

The regulations in this part apply to the acceptance of volunteer and uncompensated services for use in the operation of any health care facility of the Department or in the provision of health care.

§ 57.2 Definitions.

As used in the regulations in this part:

Secretary means the Secretary of Health and Human Services.

Department means the Department of Health and Human Services.

Volunteer services are services performed by individuals (hereafter called volunteers) whose services have been offered to the Government and accepted under a formal agreement on a without compensation basis for use in the operation of a health care facility or in the provision of health care.

Health care means services to patients in Department facilities, beneficiaries of the Federal Government, or individuals or groups for whom health services are authorized under the programs of the Department.

Health care facility means a hospital, clinic, health center, or other facility established for the purpose of providing health care.

§ 57.3 Volunteer service programs.

Programs for the use of volunteer services may be established by the Secretary, or his designee, to broaden and strengthen the delivery of health

services, contribute to the comfort and well being of patients in Department hospitals or clinics, or expand the services required in the operation of a health care facility. Volunteers may be services are obtained through the usual employment procedures.

§ 57.4 Acceptance and use of volunteer services.

The Secretary, or his designee, shall establish requirements for: Accepting volunteer services from individuals or groups of individuals, using volunteer services, giving appropriate recognition to volunteers, and maintaining records of volunteer services.

§ 57.5 Services and benefits available to volunteers.

(a) The following provisions of law may be applicable to volunteers whose services are offered and accepted under the regulations in this part:

(1) Subchapter I of Chapter 81 of Title 5 of the United States Code relating to medical services for work related injuries;
(2) Title 28 of the United States Code relating to tort claims;
(3) Section 7903 of Title 5 of the United States Code relating to protective clothing and equipment; and
(4) Section 5703 of Title 5 of the United States Code relating to travel and transportation expenses.

(b) Volunteers may also be provided such other benefits as are authorized by law or by administrative action of the Secretary or his designee.

PART 60—NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

Subpart A—General Provisions

Subpart B—Reporting of Information

Subpart C—Disclosure of Information by the National Practitioner Data Bank

AUTHORITY: Secs. 401–432 of the Health Care Quality Improvement Act of 1986, Pub. L. 99–660, 100 Stat. 3784–3794, as amended by section 402 of

Pub. L. 100–177, 101 Stat. 1007–1008 (42 U.S.C. 11101–11152).

SOURCE: 54 FR 42730, Oct. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (the Act), title IV of Pub. L. 99–660, as amended, authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners. These regulations set forth the reporting and disclosure requirements for the National Practitioner Data Bank.

§ 60.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to hospitals; health care entities; Boards of Medical Examiners; professional societies of physicians, dentists or other health care practitioners which take adverse licensure of professional review actions; and entities (including insurance companies) making payments as a result of medical malpractice actions or claims. They also establish procedures to enable individuals or entities to obtain information from the National Practitioner Data Bank or to dispute the accuracy of National Practitioner Data Bank information.

[59 FR 61555, Dec. 1, 1994]

§ 60.3 Definitions.

Act means the Health Care Quality Improvement Act of 1986, title IV of Pub. L. 99–660, as amended.

Adversely affecting means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

Board of Medical Examiners, or *Board,* means a body or subdivision of such body which is designated by a State for the purpose of licensing, monitoring and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the State. Where the Secretary, pursuant to section 423(c)(2) of the Act, has designated an alternate entity to carry out the reporting activities of § 60.9 due to a Board's failure to comply with § 60.8, the term *Board of Medical Examiners* or *Board* refers to this alternate entity.

Clinical privileges means the authorization by a health care entity to a physician, dentist or other health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

Dentist means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a State (or who, without authority, holds himself or herself out to be so authorized).

Formal peer review process means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

Health care entity means:

(a) A hospital;

(b) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or

(c) A professional society or a committee or agent thereof, including those at the national, State, or local level, of physicians, dentists, or other health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

For purposes of paragraph (b) of this definition, an entity includes: a health maintenance organization which is licensed by a State or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid medical or dental practice which meets the criteria of paragraph (b).

Health care practitioner means an individual other than a physician or dentist, who is licensed or otherwise authorized by a State to provide health care services.

Hospital means an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

Medical malpractice action or claim means a written complaint or claim demanding payment based on a physician's, dentists or other health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any State or Federal Court or other adjudicative body.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a State (or who, without authority, holds himself or herself out to be so authorized).

Professional review action means an action or recommendation of a health care entity:

(a) Taken in the course of professional review activity;

(b) Based on the professional competence or professional conduct of an individual physician, dentist or other health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(c) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the physician, dentist or other health care practitioner.

(d) This term excludes actions which are primarily based on:

(1) The physician's, dentist's or other health care practitioner's association, or lack of association, with a professional society or association;

(2) The physician's, dentist's or other health care practitioner's fees or the physician's, dentist's or other health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(3) The physician's, dentist's or other health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;

(4) A physician's, dentist's or other health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or

(5) Any other matter that does not relate to the competence or professional conduct of a physician, dentist or other health care practitioner.

Professional review activity means an activity of a health care entity with respect to an individual physician, dentist or other health care practitioner:

(a) To determine whether the physician, dentist or other health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(b) To determine the scope or conditions of such privileges or membership; or

(c) To change or modify such privileges or membership.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the Data Bank or to a Board of Medical Examiners as required under §§ 60.7, 60.8, and 60.9 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.9 must be submitted to the Data Bank within 30 days following the action to be reported, beginning with

actions occurring on or after September 1, 1990, as follows:

(a) *Malpractice Payments (§ 60.7).* Persons or entities must submit information to the Data Bank within 30 days from the date that a payment, as described in § 60.7, is made. If required under § 60.7, this information must be submitted simultaneously to the appropriate State licensing board.

(b) *Licensure Actions (§ 60.8).* The Board must submit information within 30 days from the date the licensure action was taken.

(c) *Adverse Actions (§ 60.9).* A health care entity must report an adverse action to the Board within 15 days from the date the adverse action was taken. The Board must submit the information received from a health care entity within 15 days from the date on which it received this information. If required under § 60.9, this information must be submitted by the Board simultaneously to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing Board.

[54 FR 42730, Oct. 17, 1989, as amended at 55 FR 50003, Dec. 4, 1990]

§ 60.6 Reporting errors, omissions, and revisions.

(a) Persons and entities are responsible for the accuracy of information which they report to the Data Bank. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the Data Bank or, in the case of reports made under § 60.9, to the Board of Medical Examiners, as soon as possible.

(b) An individual or entity which reports information on licensure or clinical privileges under §§ 60.8 or 60.9 must also report any revision of the action originally reported. Revisions include reversal of a professional review action or reinstatement of a license. Revisions are subject to the same time constraints and procedures of §§ 60.5, 60.8, and 60.9, as applicable to the original action which was reported.

(Approved by the Office of Management and Budget under control number 0915–0126)

[54 FR 42730, Oct. 17, 1989, as amended at 55 FR 50004, Dec. 4, 1990]

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for medical malpractice, must report information as set forth in paragraph (b) to the Data Bank and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a "payment" and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) must report the following information:

(1) With respect to the physician, dentist or other health care practitioner for whose benefit the payment is made—

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) Name of each hospital with which he or she is affiliated, if known;

(2) With respect to the reporting entity—

(i) Name and address of the entity making the payment,

(ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and

(iii) Relationship of the reporting entity of the physician, dentists, or other health care practitioner for whose benefit the payment is made;

(3) With respect to the judgment or settlement resulting in the payment—

(i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,

(ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,

(iii) Date of judgment or settlement,

(iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,

(v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,

(vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,

(vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and

(viii) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* Any entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty of up to $10,000 for each such payment involved. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

(d) *Interpretation of information.* A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

(Approved by the Office of Management and Budget under control number 0915–0126)

[54 FR 42730, Oct. 17, 1989, as amended at 59 FR 61555, Dec. 1, 1994]

§ 60.8 Reporting licensure actions taken by Boards of Medical Examiners.

(a) *What actions must be reported.* Each Board of Medical Examiners must report to the Data Bank any action based on reasons relating to a physician's or dentist's professional competence or professional conduct—

(1) Which revokes or suspends (or otherwise restricts) a physician's or dentist's license,

(2) Which censures, reprimands, or places on probation a physician or dentist, or

(3) Under which a physician's or dentist's license is surrendered.

(b) *Information that must be reported.* The Board must report the following information for each action:

(1) The physician's or dentist's name,

(2) The physician's or dentist's work address,

(3) The physician's or dentist's home address, if known,

(4) The physician's or dentist's Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(5) The physician's or dentist's date of birth,

(6) Name of each professional school attended by the physician or dentist and year of graduation,

(7) For each professional license, the physician's or dentist's license number, the field of licensure and the name of the State or Territory in which the license is held,

(8) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(9) A description of the acts or omissions or other reasons for the action taken,

(10) A description of the Board action, the date the action was taken, and its effective date,

(11) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(12) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.9.

(Approved by the Office of Management and Budget under control number 0915–0126)

§ 60.9 Reporting adverse actions on clinical privileges.

(a) *Reporting to the Board of Medical E0xaminers*—(1) *Actions that must be reported and to whom the report must be made.* Each health care entity must report to the Board of Medical Examiners in the State in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days;

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist—

(A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding; or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action concerning a physician or dentist.

(2) *Voluntary reporting on other health care practitioners.* A health care entity may report to the Board of Medical Examiners information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) *What information must be reported.* The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to the physician or dentist:

(i) Name,

(ii) Work address,

(iii) Home address, if known,

(iv) Social Security number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,

(v) Date of birth,

(vi) Name of each professional school attended and year of graduation,

(vii) For each professional license: the license number, the field of licensure, and the name of the State or Territory in which the license is held,

(viii) Drug Enforcement Administration registration number, if known,

(ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,

(x) Action taken, date the action was taken, and effective date of the action, and

(xi) Other information as required by the Secretary from time to time after publication in the

FEDERAL REGISTER and after an opportunity for public comment.

(b) *Reporting by the Board of Medical Examiners to the National Practitioner Data Bank.* Each Board must report, in accordance with §§ 60.4 and 60.5, the information reported to it by a health care entity and any known instances of a health care entity's failure to report information as required under paragraph (a)(1) of this section. In addition, each Board must simultaneously report this information to the appropriate State licensing board in the State in which the health care entity is located, if the Board is not such licensing board.

(c) *Sanctions*—(1) *Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with § 60.9, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with § 60.9, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

(i) The request for a hearing is untimely,

(ii) The health care entity does not provide a statement of material factual issues in dispute, or

(iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the FEDERAL REGISTER. In such case, the immunity protections provided under section 411(a) of the Act will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the FEDERAL REGISTER.

(d)(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

(Approved by the Office of Management and Budget under control number 0915–0126)

[54 FR 42730, Oct. 17, 1989, as amended at 59 FR 61555, Dec. 1, 1994]

Subpart C—Disclosure of Information by the National Practitioner Data Bank

§ 60.10 Information which hospitals must request from the National Practitioner Data Bank.

(a) *When information must be requested.* Each hospital, either directly or through an authorized

agent, must request information from the Data Bank concerning a physician, dentist or other health care practitioner as follows:

(1) At the time a physician, dentist or other health care practitioner applies for a position on its medical staff (courtesy or otherwise), or for clinical privileges at the hospital; and

(2) Every 2 years concerning any physician, dentist, or other health care practitioner who is on its medical staff (courtesy or otherwise), or has clinical privileges at the hospital.

(b) *Failure to request information.* Any hospital which does not request the information as required in paragraph (a) of this section is presumed to have knowledge of any information reported to the Data Bank concerning this physician, dentist or other health care practitioner.

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the Data Bank to the hospital. A hospital shall not be held liable for this reliance unless the hospital has knowledge that the information provided was false.

(Approved by the Office of Management and Budget under control number 0915–0126)

§ 60.11 Requesting information from the National Practitioner Data Bank.

(a) *Who may request information and what information may be available.* Information in the Data Bank will be available, upon request, to the persons or entities, or their authorized agents, as described below:

(1) A hospital that requests information concerning a physician, dentist or other health care

practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital,

(2) A physician, dentist, or other health care practitioner who requests information concerning himself or herself,

(3) Boards of Medical Examiners or other State licensing boards,

(4) Health care entities which have entered or may be entering employment or affiliation relationships with a physician, dentist or other health care practitioner, or to which the physician, dentist or other health care practitioner has applied for clinical privileges or appointment to the medical staff,

(5) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a State or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific physician, dentist, or other health care practitioner who is also named in the action or claim. Provided, that this information will be disclosed only upon the submission of evidence that the hospital failed to request information from the Data Bank as required by § 60.10(a), and may be used solely with respect to ligitation resulting from the action or claim against the hospital,11(6) A health care entity with respect to professional review activity, and

(7) A person or entity who requests information in a form which does not permit the identification of any particular health care entity, physician, dentist, or other health care practitioner.

(b) *Procedures for obtaining National Practitioner Data Bank information.* Persons and entities may obtain information from the Data Bank by submitting

a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.12.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989]

§ 60.12 Fees applicable to requests for information.

(a) *Policy on Fees.* The fees described in this section apply to all requests for information from the Data Bank. These fees are authorized by section 427(b)(4) of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11137). They reflect the costs of processing requests for disclosure and of providing such information. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees,

(2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used,

(3) Postage—actual cost, and

(4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.

(c) *Assessing and collecting fees.* The Secretary will announce through notice in the FEDERAL REGISTER from time to time the methods of payment of Data Bank fees. In determining these methods, the Secretary will consider efficiency, effectiveness, and convenience for the Data Bank users and the Department. Methods may include: credit card; electronic fund transfer; check; and money order.

[54 FR 42730, Oct. 17, 1989, as amended at 60 FR 27899, May 26, 1995; 64 FR 9922, Mar. 1, 1999]

§ 60.13 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the Data Bank is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in § 60.10, § 60.11 and § 60.14. Persons and entities which receive information from the Data Bank either directly or from another party must use it solely with respect to the purpose for which it was provided. Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

(b) *Penalty for violations.* Any person who violates paragraph (a) shall be subject to a civil money penalty of up to $10,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

§ 60.14 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute National Practitioner Data Bank information.* Any physician, dentist or other

health care practitioner may dispute the accuracy of information in the Data Bank concerning himself or herself. The Secretary will routinely mail a copy of any report filed in the Data Bank to the subject individual.

(b) *Procedures for filing a dispute.* A physician, dentist or other health care practitioner has 60 days from the date on which the Secretary mails the report in question to him or her in which to dispute the accuracy of the report. The procedures for disputing a report are:

(1) Informing the Secretary and the reporting entity, in writing, of the disagreement, and the basis for it,

(2) Requesting simultaneously that the disputed information be entered into a "disputed" status and be reported to inquirers as being in a "disputed" status, and

(3) Attempting to enter into discussion with the reporting entity to resolve the dispute.

(c) *Procedures for revising disputed information.* (1) If the reporting entity revises the information originally submitted to the Data Bank, the Secretary will notify all entities to whom reports have been sent that the original information has been revised.

(2) If the reporting entity does not revise the reported information, the Secretary will, upon request, review the written information submitted by both parties (the physician, dentist or other health care practitioner), and the reporting entity. After review, the Secretary will either—

(i) If the Secretary concludes that the information is accurate, include a brief statement by the physician, dentist or other health care practitioner describing the disagreement concerning

the information, and an explanation of the basis for the decision that it is accurate, or

(ii) If the Secretary concludes that the information was incorrect, send corrected information to previous inquirers.

(Approved by the Office of Management and Budget under control number 0915–0126)

[54 FR 42730, Oct. 17, 1989, as amended at 54 FR 43890, Oct. 27, 1989]

PART 61—HEALTHCARE INTEGRITY AND PROTECTION DATA BANK FOR FINAL ADVERSE INFORMATION ON HEALTH CARE PROVIDERS, SUPPLIERS AND PRACTITIONERS

Subpart A—General Provisions

Sec.

Subpart B—Reporting of Information

Subpart C—Disclosure of Information by the Healthcare Integrity and Protection Data Bank

AUTHORITY: 42 U.S.C. 1320a-7e.

SOURCE: 64 FR 57758, Oct. 26, 1999, unless otherwise noted.

Appendix F

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Case No. 12 Civ. 1229 (JDB)

JOHN DOE, M.D., PH.D.,
1479 Faxon Street, Memphis, TN 38104,
JOHN DOE, M.D., PH.D., P.L.L.C.,
350 Central Park West, New York, NY 10025,

Plaintiffs,

– vs –

JUDITH RODGERS, M.H.A., as Senior Advisor
in the Division of Practitioner Data Banks,
5600 Fischers Lane, Rockville, Md. 20857,

KATHLEEN SEBELIUS, M.P.A. Secretary,
U.S. Department of Health and Human Services, and
her Successors, 200 Independence, Ave., SW,
Washington, D.C. 20201,
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, DIVISION OF
PRACTITIONER DATA BANKS,
200 Independence, Ave., SW, Washington, D.C. 20201

NATIONAL PRACTITIONER DATA BANK,
4094 Majestic Lane, PMB 332, Fairfax, Va. 22033,

CYNTHIA GRUBBS, J.D., as the Director
of the Division of Practitioner Data Banks,
5600 Fishers Lane, Rockville, Md., 20857, and

ANASTASIA TIMOTHY, M.D., M.P.H.,
as NPDB Dispute Resolution Manager,
5600 Fishers Lane Rockville, Md.,

Defendants.

FIRST AMENDED COMPLAINT

Jurisdiction and Venue

Plaintiffs John Doe, M.D. and John Doe, M.D., PH.D., P.L.L.C. for their First Amended Complaint ("the Complaint"), pursuant to Fed. R. Civ. P. Rule 15(a), by their undersigned attorneys, allege as follows:

1. Jurisdiction in this Court is based on 5 U.S.C. §§ 701 *et seq*., the Administrative Procedure Act ("APA"), and 28 U.S.C. § 1331, federal question, in that this Complaint seeks review of final United States agency action made reviewable by statute for which there is no other adequate remedy in any court of competent jurisdiction and asserts additional claims arising under the Constitution and laws of the United States.

Parties

2. Venue is appropriate in this Court under 28 U.S.C. § 1391 in that a substantial part of the events giving rise to the underlying claims occurred in this District and the defendants Kathleen Sebelius, M.P.A., Secretary, U.S. Department of Health and Human Services, and her Successors, and the United States Department of Health and Human Services are located in and reside in this District.

3. Plaintiff, John Doe, M.D. ("Dr. Doe" or "plaintiff physician") is a physician licensed to practice medicine in the State of New York and other states, and is a citizen of the United States. Plaintiff physician graduated from Harvard Medical School and holds degrees of A.B., M.D. and Ph. D. He is a Diplomate of the American Board of Surgery, certified by that Board in general surgery, and is a Diplomate of the American Board of Thoracic Surgery, certified by that Board in cardiothoracic surgery. Prior to the events complained of herein arising from a single appendectomy surgical case in October 2009, plaintiff physician had no disciplinary actions commenced against him in over 3000 surgical cases and never suffered a medical malpractice judgment or payment on his behalf. Further, the patient in the October, 2009 case had a normal recovery and discharge, and no claims have been brought by or on behalf of the patient against plaintiffs or the hospital where plaintiff was the Director of Thoracic Surgery and had clinical privileges.

4. Plaintiff physician is a legal resident of Tennessee but currently lives and works outside the United States because he has been precluded from practice in the United States by a false and fraudulent Adverse Action Report (the "AAR") filed with defendant the National Practitioner Databank ("NPDB") in December 2010 and wrongfully maintained and repeatedly released by the NPDB and defendants, as hereinafter set forth. This improper AAR 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. On June 25,

2012, defendants issued a Secretarial Review Decision which refused to void or amend the AAR.

5. In 2009, while a citizen and resident of the United States, plaintiff physician was the subject of the wrongful AAR filed with the NPDB by Peconic Bay Medical Center ("PBMC" or the "Hospital"), a hospital located in Riverhead, New York. Prior to the filing of the AAR, plaintiff had clinical privileges as a thoracic surgeon and general surgeon at PBMC.

6. Plaintiff physician is the sole owner of a New York professional limited liability company John Doe, M.D., Ph.D., P.L.L.C. ("the PLLC") with a principal place of business in New York, NY. Plaintiff PLLC bills for and collects professional fees solely for plaintiff physician's surgical services, rendered in the United States. By reason of the wrongful AAR and defendants' failure to void the AAR as hereinafter set forth, plaintiff PLLC has not been able to bill for or collect professional fees for services that would have been provided had the defendants' wrongful conduct hereinafter alleged not prevented plaintiff physician from obtaining hospital privileges in the United States and has therefore suffered substantial economic injury.

7. Defendant Judy Rodgers, M.H.A. ("Rodgers"), is a Senior Advisor in the Division of Practitioner Data Banks. As such, she is responsible in part for the acts of the NPDB in receiving and assisting in the administration and review of Adverse Action Reports filed with the NPDB pursuant to the Health Care Quality Improvement Act of 1986 ("HCQIA"), including the Secretarial Review Decision issued by the United States Department of Health and Human Services ("HHS") on June 25, 2012.

8. Defendant the HHS is the federal agency designated under the HCQIA as amended, 42 U.S.C. §§ 11101 *et seq.* to oversee and administer the filing, receipt and voiding of reports from health care entities such as PBMC, and others, as prescribed in the HCQIA. Such reports include Adverse Action Reports which are mandatory under HCQIA if meeting the statutory and regulatory conditions for filing.

9. Defendant Kathleen Sebelius, M.P.A. is the Secretary of HHS (the "Secretary"), duly appointed, qualified and acting as the administrative head of such agency/department. As such, she is responsible in whole or in part for its acts including the Secretarial Review Decision issued by HHS on June 25, 2012.

10. Defendant Division of Practitioner Data Banks ("DPDB") is an entity of, administered and operated by HHS, and has offices in Rockville, Maryland whereby information purportedly as to physicians' competence and conduct is received, maintained and disseminated in response to queries from hospitals and other authorized entities.

11. Defendant National Practitioner Data Bank ("NPDB") is an entity of, administered and operated by HHS, and has offices in Fairfax, Virginia whereby information purportedly as to physicians' competence is received, maintained and disseminated in response to queries from hospitals and other authorized entities.

12. Defendant Cynthia Grubbs, J.D., ("Grubbs") is the Director of the Division of Practitioner Data Banks. As such, she is responsible in part for the acts of the NPDB in receiving and assisting in the administration and review of Adverse Action Reports

filed with the NPDB pursuant to the HCQIA, including the Secretarial Review Decision issued by HHS on June 25, 2012.

13. Defendant Anastasia Timothy, M.D., M.P.H., is the "Dispute Resolution Manager" at the NPDB who functioned on defendants' Secretarial Review of the AAR and is responsible in part for the acts of the NPDB in receiving and assisting in the administration and review of Adverse Action Reports filed with the NPDB pursuant to the HCQIA, including the Secretarial Review Decision issued by HHS on June 25, 2012.

Facts

14. Pursuant to the HCQIA, certain information and reports relating to a physician's licensure, clinical privileges and credentials, among other things, must be reported to the NPDB. The NPDB functions as an administrative arm of the HHS to receive, record, administer and disseminate information received under the HCQIA, including Adverse Action Reports filed concerning physicians.

15. In May 2009, plaintiff commenced employment and his clinical practice at PBMC as Director of Thoracic Surgery.

Dr. Doe's Efforts to Improve Conditions and Overall Patient Safety at the Hospital and Competition with Entrenched Physicians

16. PBMC is a small "acute care" hospital on the eastern end of Long Island, located in Riverhead, New York. The nearest tertiary care hospital, Stony Brook University Hospital, is an about an hour's drive from PBMC.

17. When Dr. Doe joined PBMC's medical staff in 2009, upon information and belief, the Hospital was suffering from negative reviews, and a number of its physicians, had had very serious medical malpractice cases against them.

18. Against this background, Dr. Doe joined PBMC and sought to improve the quality of patient care it provided to ensure that the local communities in eastern Long Island had immediate access to quality health care. From the inception of his tenure at PBMC, as documented by his emails to PBMC's administration, Dr. Doe set to work to improve the conditions under which he and other surgeons operated so as to provide patients with the highest level of patient care. However, Dr. Doe's laudable efforts to improve patient care were seen by PBMC and certain of its doctors as upsetting their established way of practicing medicine and interfering with the established medical practices and relationships of the doctors on staff. As a result, upon information and belief, PBMC and certain its doctors set out to eliminate Dr. Doe from their hospital and maliciously to retaliate and punish him. They accomplished these ends by presenting false peer review charges designed to prevent him from ever practicing medicine again anywhere. As hereinafter alleged, with the complicity of the defendants and unless remedied by this Court, this scheme has so far been successful and has removed plaintiff physician, a highly qualified surgeon, from practice in the United States, to the detriment of patients needing his skilled surgical care and causing substantial injury to plaintiffs in their business, reputation and resulting in a deprivation of a fundamental constitutional right to practice the chosen profession, as alleged in greater detail below.

19. The following are illustrative examples of Dr. Doe's efforts to improve conditions at PBMC.

20. **Sternal Saws:** PBMC's lack of certain basic thoracic surgical equipment was of great concern to Dr. Doe, even before he started working at the Hospital. In particular, Dr. Doe was concerned that PBMC did not own any sternal saws, which are critical for opening the chest during surgery to expose the heart, if such access was or became indicated. In addition to numerous phone calls and emails to the Hospital's administration, Dr. Doe worked with the representative of the sternal saw manufacturer to determine which model sternal saws would be appropriate for the Hospital.

21. At first, Dr. Doe's efforts to improve patient care appeared successful. The Hospital's Operating Room Coordinator told Dr. Doe that PBMC had obtained two sternal saws, and Dr. Doe even went so far as to call the Hospital's Operating Room Coordinator personally to let him know that the saws had arrived. PBMC's lack of sternal saws was of such critical importance that Dr. Doe immediately went to the Operating Room ("OR") to see the saws. Upon confirming that the saws had arrived, Dr. Doe was relieved that he could perform chest surgery with a saw to cut the sternum, and was encouraged by PBMC's cooperation in his efforts to improve patient care.

22. Shortly thereafter, Dr. Doe was preparing to operate on a patient who presented to the PBMC emergency room in shock caused by a pericardial effusion, and requiring an operation to create a pericardial window.

23. Recognizing that he might need to open the patient's sternum in the event of a complication, Dr.

Doe sought to confirm that the sternal saws were available for use during this emergent operation. Dr. Doe learned that they were not. Dr. Doe learned that the PBMC administration had decided not to purchase the saws, sent them back to the manufacturer and did not notify Dr. Doe, even though Dr. Doe was the Director of Thoracic Surgery, had spearheaded the efforts to purchase the saws, and had been intimately involved in the decision to do so. Dr. Doe, on the other hand, remained committed to improving the quality of patient care at PBMC. He was undeterred by the Hospital's recalcitrance, and continued to press PBMC to purchase the much needed sternal saws. Dr. Doe raised the issue directly with the Hospital's CEO. The request was not acted on as of Dr. Doe's departure from PBMC.

24. **Inadequate PACU Care:** Dr. Doe was also concerned about, and sought to modify, PBMC's policy of not sending critically ill post-operative patients directly to the Intensive Care Unit (the "ICU"), but to send them instead to the Post-Anesthesia Care Unit ("PACU"). In Dr. Doe's experience and professional judgment, the PACU staff did not have the expertise and experience required to administer care to critically ill post-operative patients, a judgment generally shared throughout the medical community. For example, at every other hospital at which Dr. Doe had practiced, critically ill patients went directly from the operating room ("OR") to the ICU without stopping in the PACU. Moreover, prior to coming to PBMC, Dr. Doe had never heard of a surgeon being told they were ***not*** allowed to send their patients directly to the ICU.

25. Upon information and belief, PBMC's policy had little to do with what was best for the patients,

and everything to do with what was best for the certain doctors at the Hospital. Upon information and belief, one critical care physician (the "CC Physician"), told Dr. Doe that he did not want the responsibility of caring for patients in the immediate post-operative period, and so, for that reason, insisted that these patients spend those critical hours in the PACU.

26. Gravely concerned for the well-being of his patients, Dr. Doe offered to take care of his patients personally in the ICU if they could be sent there directly from the OR if the CC Physician was unwilling or unable to care for Dr. Doe's patient. However, the CC Physician expressly told Dr. Doe that he was not permitted to transfer critically ill patients directly from the OR to the ICU because he did not want to care for them himself – though he is a critical care physician, and did not want another physician caring for patients in the ICU.

27. Dr. Doe's fears concerning PBMC's misguided policy were soon realized. Dr. Doe had a septic patient on whom he had operated for perforated diverticulitis who, because of PBMC's policy, was sent post-operatively to the PACU instead of to the ICU where he belonged. The patient was hemodynamically stable when he arrived in the PACU. After Dr. Doe completed his next case in the OR, he discovered that his patient was obtunded from low blood pressure. Dr. Doe immediately resuscitated the patient with a favorable clinical response of recovery of normal blood pressure and mental status.

28. Dr. Doe then asked for a central line (a type of intravenous catheter), to place in the patient. Dr. Doe was told that a central line had not been placed in patients in the PACU in years, and was not

available. Eventually a central line was located in the emergency room, which Dr. Doe inserted. The patient was then was transferred to the ICU, where he should have been from the outset.

29. Later, the ICU nurse reported to told Dr. Doe that she had had to spend 1 ½ hours untangling the patient's intravascular lines because of the disorganized manner in which the PACU nurse had left the patient.

30. On July 27, 2009, Dr. Doe e-mailed PBMC's Vice President of Medical Affairs, Dr. Richard Kubiak ("Dr. Kubiak" or "Kubiak"), and stated:

> Simply put, recovery room nurses are not experienced in treating critically ill patients. The ICU nurse for my patient tonight told me she had to spend an hour and a half straightening everything out. Please do not take this as a criticism of the recovery room nurses.

31. Dr. Doe's patient was very angry at the Hospital and told Dr. Doe's office that he wanted to sue everyone at PBMC except for Dr. Doe. The patient told Dr. Doe's office, "Dr. [Doe] saved my life."

32. **Patient Fall:** Dr. Doe also was concerned that certain members of PBMC's medical staff failed to properly administer even the most basic care to patients. Upon information and belief, a patient of Dr. Kubiak's was paralyzed in both legs and one arm, leaving her with only the use of her left arm. The patient also was very confused. In spite of this, the floor nursing staff failed to adequately secure and restrain the patient so that she would not injure herself, which is exactly what happened when the patient fell out of bed.

33. Dr. Kubiak's physician assistant immediately sought help from Dr. Doe, who happened to be on medical ward at the time. The patient's temperature was 90 degree, and the patient was minutes away from having a cardiac arrest. Dr. Doe got the patient over to the ICU, contacted another physician in the ICU, and helped stabilize the patient.

34. **Failure to Consult Surgeon Concerning Withdrawal of Care.:** Dr. Doe was also quite troubled about the breaches in protocol exhibited by certain PBMC doctors. For example, during his PBMC tenure, Dr. Doe was confronted with a high risk patient with advanced lung cancer in need of a palliative operation. Dr. Doe was concerned about the physical condition of his patient, and consulted anesthesia and cardiology attending physicians as to the wisdom of proceeding with an operation on such a high risk patient. Both doctors consulted concurred that the operation was necessary, because, otherwise, according to the cardiologist, without surgery the patient would become increasingly short of breath and die a miserable death.

35. Dr. Doe operated on the patient. The operation went satisfactorily although, not surprisingly, the patient needed to remain on the ventilator for a few days after surgery, under the care of both Dr. Doe and a pulmonologist.

36. On post-operative day 1, another doctor was covering for the pulmonologist. In addition to being a pulmonologist, the covering doctor also was the medical director of the ICU and had been at PBMC for 25 years. Without Dr. Doe's knowledge or prior consultation, this ICU director spoke with the family members of Dr. Doe's patient and convinced them to withdraw care for the patient. The ICU director made

this recommendation even though Dr. Doe believed his patient was likely to survive the operation and successfully come off the ventilator in a few days. Upon information and belief, the ICU director started a morphine drip on the patient with the intention of causing the patient to die. Even after the decision to withdraw care had been made, the ICU director failed to advise Dr. Doe of this critical decision concerning his surgical patient.

37. Dr. Doe is unaware of any case where a physician has made the unilateral decision to withdraw support on a surgeon's patient without first notifying the surgeon. Dr. Doe complained to Dr. Kubiak about this grievous breach of protocol by the ICU director.

38. **Dispute with Critical Care Physician:** Dr. Doe and his physician assistant attended an elderly patient in the emergency room who had become completely obtunded. Dr. Doe was unable to rouse the patient and was concerned about this acute onset of obtundation. Dr. Doe's primary concern was that the patient was in danger of being unable to protect his airway and was at risk for an aspiration event that could cause suffocation or overwhelming pneumonia. Dr. Doe made the decision to intubate the patient, and proceeded to insert a laryngoscope in the patient's throat to permit insertion of an endotracheal tube to provide oxygen and maintain the airway.

39. Once the patient was admitted to Dr. Doe's service, Dr. Doe sought a critical care consult with pulmonology. When the regular pulmonologist was not available, Dr. Doe called the CC Physician, and presented the case to him. This doctor then agreed to provide the critical care consult. After this physician

arrived, he criticized Dr. Doe in a raised tone of voice, for intubating the patient despite Dr. Doe's observation that the patient had become obtunded.

40. The CC Physician also asserted that the ER nursing staff knew better than Dr. Doe that the patient was not obtunded and he started yelling at Dr. Doe, and pointing his finger at Dr. Doe, stating in words or substance: "I have been watching you. I am going to report this to the medical staff."

41. Dr. Doe immediately called Dr. Kubiak to report the CC Physician's inappropriate conduct. After Dr. Doe and Dr. Kubiak finished their call, the CC Physician continued yelling at Dr. Doe and pointing his finger at him, and stated "You don't know who you're messing with," and "we are never going to talk about this again."

42. **Anticompetitive Conduct by Competing Physicians:** In addition to his efforts to improve care, soon after his arrival at PBMC, Dr. Doe became quite successful. As such, he became an immediate competitive threat to several of the existing PBMC physician defendants. As Dr. Doe was doing general surgery in addition to thoracic surgery, he was competing with general surgeons at the Hospital who had long and established tenures. In addition, Dr. Doe was competing with the pulmonologist/intensive care specialists, including the CC Physician, since the primary care physicians were sending lung cancer patients directly to Dr. Doe, bypassing these pulmonologists. Thus, Dr. Doe's presence not only highlighted the poor patient care provided by certain of his colleagues, but also threatened the loss of patients and income for several of these established physicians.

43. For example, soon after his arrival at PBMC, Dr. Doe met with several primary care physicians. These doctors started sending their patients to Dr. Doe. Within three months, Dr. Doe on an office day was seeing 15 patients in his private office and eight patients at PBMC.

44. Moreover, a number of the individual defendants with administrative positions at PBMC viewed Dr. Doe's efforts to improve equipment and processes to upgrade patient care at the Hospital as disruptive of their entrenched status quo.

45. As a result, these incumbent physician competitor defendants and their administrative allies combined and conspired to eliminate Dr. Doe as a competitor and advocate, regardless of his value to patients, to PBMC and his efforts to improve patient care. In furtherance of the conspiracy, the defendants took a series of actions first outside of the context of any peer-review, to make life miserable for Dr. Doe and dangerous for his patients in an attempt to drive him from PBMC and eliminate the competitive threat that Dr. Doe represented. Ironically, defendants ultimately seized upon a fraudulent claim of substandard care and fraudulent Quality Assurance ("QA") review to drive Dr. Doe from PBMC.

Dr. Doe Is Called to the University of Tennessee

46. Unrelated to these events, in mid-September 2009, Ms. Patricia Watson of the American Board of Thoracic Surgery advised Dr. Doe that if he wanted to become Board Certified in thoracic surgery, it was likely that he would be required to complete an additional year of training at the University of Tennessee, to include an additional 125 cases. She also told plaintiff physician that the Credentials Committee of the American Board of Thoracic

Surgery (the "ABTS Credentials Committee") would be meeting on October 3, 2009, and would make its final decision during that meeting. Thus plaintiff physician expected he might have to leave PBMC in 2009 to resume fellowship training in preparation for Board certification.

47. On October 3, 2009, the ABTS Credentials Committee did in fact decide that plaintiff physician would need to return to the University of Tennessee for one year to obtain more senior-level experience in cardiac surgery.

Plaintiff's October 2, 2009 Emergency Case

48. While plaintiff physician was waiting for the outcome of the ABTS Credential Committee's October 3, 2009 meeting, on October 2, 2009, an adolescent girl presented to PBMC's emergency room, where plaintiff physician was on call, with acute appendicitis. The patient's condition was serious, exhibiting symptoms of severe abdominal pain, peritoneal inflammation and elevated white blood cell count.

49. Despite preoperative and intraoperative complications, including severe inflammation from a perforated appendix and location of the appendix in a retrocecal position and an inflamed band adherent to the cecum, plaintiff physician, assisted by a senior surgeon who was the Hospital's former Chairman of Surgery, successfully completed an emergency laparoscopic appendectomy on the patient.

50. In the course of the procedure with these complications, the surgeons encountered an inflammatory band overlying the lateral peritoneal reflection and adherent to the cecum. They determined it was necessary and appropriate to

divide the inflammatory band in order to complete the surgical removal of the perforated appendix and save the patient's life. Thus, removal of the band was not inadvertent, but was a considered medical judgment as to the appropriate and necessary procedure to address the intraoperative complication. The procedure was completed successfully and the patient was discharged from the hospital a few days later.

51. On October 5, 2009, the pathology report confirmed that the removed structures were the perforated appendix and that the inflammatory band was part of the right Fallopian tube, which was notable for "serosal adhesions and marked vascular congestion" and a 1 cm cyst. "Marked vascular congestion" is an indication of severe inflammation.

52. On October 5, 2009, plaintiff physician and the senior assistant surgeon met with the patient's parents and explained the operation and the pathology. The surgeons assured both parents that their daughter would be able to have children because of the presence of a healthy left Fallopian tube. In response, the patient's parents expressed their gratitude to Dr. Doe for having saved their daughter's life. In addition, the patient's mother recounted to Dr. Doe her own experience with a perforated appendicitis at age 15, which initially had been misdiagnosed. Years later, the mother suffered a potentially life threatening ectopic pregnancy in the Fallopian tube that was caused by the scar tissue associated with the perforated appendix. The parents and the patient filed no claims against plaintiffs, the other doctors, or the Hospital.

53. In or about this time, plaintiff physician learned 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. On October 5, 2009, plaintiff physician advised Kubiak, PBMC's Vice President of Medical Affairs, that he would likely need to resign his position at PBMC to return to Tennessee to complete the fellowship.

54. Plaintiff physician knew that a resignation while under or to avoid investigation relating to professional conduct or competence would be a reportable event. Therefore, prior to tendering any resignation, plaintiff physician specifically inquired of Kubiak whether plaintiff physician was under any investigation by PBMC on account of the October 2, 2009 surgery or for any other reason. Plaintiff physician unequivocally advised Kubiak that he would not resign if such an investigation was pending or would be commenced. On October 5, 2009 and again on October 7, 2009, Kubiak responded to plaintiff physician that there was no and would be no investigation of plaintiff physician on account of his clinical practice.

55. Kubiak had superior and unique knowledge as to the status of investigations at PBMC and by reason of his special relationship as Vice President of Medical Affairs of PBMC, both to the medical staff members themselves and to the public with respect to the granting, renewing or suspension of privileges of medical staff members in the hospital. Accordingly, plaintiff physician accepted and reasonably relied on Kubiak's repeated and unequivocal representations that there was no and would be no investigation of plaintiff physician's clinical practice.

56. On October 7, 2009, in reliance on Kubiak's affirmative representations that there was no and

would be no investigation by PBMC of his clinical practice, plaintiff physician submitted his resignation to PBMC to be effective October 16, 2009, and soon thereafter left Riverhead, New York to pursue his fellowship at the University of Tennessee.

57. However, contrary to Kubiak's affirmative representations, and unknown to plaintiffs at the time, Kubiak and PBMC two months later, in December, 2009 took the position that plaintiff physician had surrendered clinical privileges while under investigation, an event reportable in an AAR filed with defendant NPDB. However, in furtherance of the malicious purposes of PBMC and the doctors retaliating against Dr. Doe for his efforts to improve patient care and to eliminate a competitor as hereinabove alleged, the untimely AAR did not just report a claimed resignation while under investigation. Even though concededly no action was taken by the Hospital as to Dr. Doe's hospital privileges and the AAR stated that "the Hospital took no further action regarding the physician's privileges or employment," the AAR maliciously added the gratuitous 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." In fact, as more fully alleged herein, there was no *bona fide* peer review or quality assurance review of Dr. Doe's case.

58. The AAR filed with NPDB was based on a sham peer review riddled with fabricated meetings and documents designed to give the appearance that PBMC had conducted a proper peer review of Dr. Doe and his practice. For example, as hereinafter alleged, the documentation of the "investigation" described meetings that did not occur and described people as

having attended those meetings when, in fact, they did not attend because those meetings did not happen.

59. In fact, plaintiff physician was never "under investigation" within the meaning of the Act or the regulations issued by defendants thereunder. The PBMC By-Laws prescribe detailed procedures for "summary suspension" and commencement of an investigation of a practitioner by the hospital's Credentials Committee. As hereinafter set forth, these By-Law procedures require written notices to request such action with a Special Notice (defined as a written notification sent by certified mail, return receipt requested) to the physician in writing and giving the opportunity to request a hearing. PBMC never complied with these requirements, never informed plaintiff physician of an investigation, and no *bona fide* investigation was commenced prior to plaintiff physician's resignation. Therefore, plaintiff physician had no knowledge of and no opportunity to contest or participate in any alleged "investigation." Prior to the defendants' actions challenged in this case, defendants were made aware of these Hospital By Law requirements and that they were not complied with. Defendants also knew that Dr. Doe received no "due process," as conceded in the letters submitted by the Hospital to the NPDB (e.g., March 24, 2011 letter, p. 9) (admitting that physician was entitled to "request a hearing" in the event of "recommended adverse action" and stating that Hospital had "no reason" to provide due process). Defendants' disregard of the admitted Hospital procedures requiring notice for an investigation and notice to the physician while accepting the Hospital AAR that such an investigation existed is arbitrary,

capricious, an abuse of discretion, or otherwise not in accordance with law.

60. Likewise, Dr. Doe never voluntarily agreed to refrain from exercising his clinical privileges pending any investigation, and which he was told did not exist. Defendants had Dr. Doe's letter of resignation from the Hospital's submission (March 24, 2011 letter, Tab. 10) which stated he would not be doing further operations (because he was leaving) but did not say "pending the Hospital's investigation" and never used the word "investigation." Therefore, the defendants' acceptance of the contrary statement by the Hospital, without undertaking due process to determine the truth, was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

61. After plaintiff physician's resignation, PBMC asserted to defendants that an Incident Report had been prepared concerning the October 2, 2009 surgery for submission to the State of New York Department of Health ("NYDOH") and that this "qualified" as an "investigation" by the Hospital under the HCQIA. As a matter of law, the Incident Report was to report an incident under state law, and was not an "investigation" of the physician. Further, upon information and belief, Kubiak knew of this alleged Incident Report at the time of his representations to plaintiff physician that there was no investigation. Inconsistently, and with malicious intent, Kubiak and PBMC took the position two months after the fact that the Incident Report was part of the "investigation" by the Hospital of Dr. Doe's clinical practice as of October 5, 2012 and as of plaintiff's letter of resignation submitted October 7, 2009.

62. The Incident Report is not a document identified in the PBMC By-Laws as a step in the entity initiating any "investigation" of a physician's practice, which must be done by written notice to the Credentials Committee. Moreover, the Incident Report as provided to defendants was incomplete, redacted, showed no signature and one page showed a fax header of a New York City law firm marked page "003," raising issues as to completeness and authenticity. Despite the foregoing deficiencies, and the admitted lack of contemporaneous notice of any investigation to Dr. Doe as required by the Hospital By Laws, the defendants improperly accepted the Hospital's alleged Incident Report without review as to its genuineness, as "evidence" of an entity investigation under the HCQIA, inconsistent with Dr. Kubiak's statements to Dr. Doe that there was no investigation. No affidavit or statement of Dr. Kubiak was submitted to refute Dr. Doe's submission. This determination by defendants was therefore arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

63. In addition, PBMC later advised defendant NPDB that in October, 2009 on an unspecified date but prior to a Root Cause Analysis ("RCA") Committee meeting and prior to the October 16, 2009 effective date of plaintiff physician's resignation, the care provided by plaintiff physician during the laparoscopic appendectomy case was reviewed at a Hospital Medical Staff Performance Improvement Committee meeting. The document the Hospital actually submitted to the defendant NPDB and accepted by the NPDB as "proof" of that meeting was redacted and incomplete, and dated "September 2009," a date false and backdated on its face since the events in question did not begin until October 2, 2009

(Hospital letter to NPDB, March 24, 2011, Tab 13). Likewise, the Hospital's memorandum of an alleged review meeting stated it took place "on Monday, October 6, 2009" when as defendants here had to know, October 6 was in fact a Tuesday, casting doubt on the authenticity of the document. (Hospital letter to NPDB, March 24, 2011, Tab 7). Moreover, the PBMC By-Laws require investigations to be commenced at the request "in writing" of specified individuals to the "Credentials Committee," not a "Medical Staff Performance Improvement Committee." Defendants' acceptance and maintenance of the AAR, despite submission of the above documents false and backdated on their face was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

64. Likewise, PBMC later advised defendant NPDB that on October 14, 2009 and again prior to the October 16, 2009 effective date of plaintiff's resignation, the RCA Committee allegedly met to consider plaintiff physician's case, with personnel identified as including the "Vice President of Nursing" and an "Attending Gynecology Oncology Surgeon," and an "Attending General/Thoracic Surgeon," among others. (Hospital letter to NPDB, March 24, 2011 at p. 5). No documentation was submitted by PBMC to defendants concerning this alleged meeting.

65. During defendants' Secretarial Review of the AAR, plaintiff physician submitted evidence that neither the Attending Gynecology Oncology Surgeon referred to, nor the Attending General/Thoracic Surgeon referred to, attended the alleged October 14, 2009 meeting. This evidence includes a letter signed by the Attending Gynecologic Oncology Surgeon, dated June 14, 2011, submitted to defendants

expressly stating that she had not attended an RCA meeting concerning plaintiff's case, and in which she stated "Let me assure you that you are a competent physician and will excel in your field. It was a pleasure working with you . . . ." Plaintiff physician also informed the NPDB that the Attending General/ Thoracic Surgeon did not attend the purported RCA meeting.

66. Defendants' acceptance and maintenance of the AAR, despite submission of this uncontradicted documentary evidence that there was no RCA meeting with these individuals, was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

67. Despite the fact that plaintiff physician's resignation was not yet effective, through all these events, PBMC also never complied with its By-Laws to conduct an investigation by the Credentials Committee of the Hospital "which shall include a Special Notice to the Practitioner involved about the investigation." The PBMC By-Laws define "Special Notice" as "written notification sent by certified mail, return receipt requested." (Definition 22.) No such Special Notice was ever provided to plaintiff physician or submitted by PBMC to the defendants, despite the purported investigation allegedly commencing and continuing for at least 11 days prior to the effective date of plaintiff physician's resignation and thereafter. PBMC's submissions to defendants conceded these facts.

68. Defendants knew that plaintiff physician never received such a written Special Notice either prior to or after the effective date of his resignation. Accordingly, defendants' acceptance and maintenance of the AAR despite the lack of such written evidence

required under the Hospital By-Laws was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of the APA.

69. The defendant NPDB Guidebook at page E-19 states that an "investigation must be carried out by the health care entity, not an individual on staff." The evidence before the defendants showed that the entity PBMC did not conduct an investigation in accordance with its own By-Laws. Nor did PBMC ever issue either a written request for investigation to the Credentials Committee or notice to the physician, or otherwise institute or carry out an investigation as required by the Hospital's By-Laws.

70. The defendant NPDB Guidebook at page E-19 further states that a health care entity that submits an AAR based on surrender of privileges while under investigation "should have contemporaneous evidence of an ongoing investigation at the time of surrender . . . [and] 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 of excerpts from committee meetings, orders from hospital officials directing an investigation, and notices to practitioners of an investigation." (Emphasis added.) Upon information and belief, defendants never received such evidence, and there were no minutes of any investigation by the "Credentials Committee" prior to the October 7, 2009 resignation letter, as required by the By-Laws. Instead, the defendants accepted documents showing actions of individuals "on staff" not instituting an investigation by the entity in accordance with any of its By-Laws prior to October 7, 2009.

71. Defendants concededly received no "minutes" of a Credentials Committee meeting, no "orders" directing an investigation, and no "notice" to the practitioner, prior to the alleged resignation, as specified in the NPDB Guidebook. Accordingly, defendants' acceptance and maintenance of the AAR despite the lack of contemporaneous evidence as specified in the NPDB Guidebook of an investigation commenced "prior" to plaintiff physician's resignation, was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of the APA.

72. In addition, since plaintiff physician had unequivocally advised Kubiak that he would not resign if such an investigation was pending or to be commenced, plaintiff physician was affirmatively misled by Kubiak's statements on behalf of the Hospital that there was no investigation, and that there would be no such investigation. Plaintiff physician was thus misled and defrauded by the Hospital when he tendered his resignation prior to completion of any purported PBMC investigation into his professional competence and his resignation was not "voluntary" but obtained by fraud. But for those affirmative misrepresentations, plaintiff physician would not have tendered his resignation and would have maintained his position at PBMC and defended the quality of his surgical practice, and he would not and could not have been reported to the defendant NPDB as the Hospital did, for "voluntary surrender of clinical privileges while under, or to avoid, investigation relating to professional competence or conduct."

73. Thus Dr. Doe did not "voluntarily resign" from PBMC and there was no reportable event under the HCQIA or 45 C.F.R. § 60.11(a)(2). Defendants

nevertheless accepted the AAR as stating on its face a "voluntary surrender of clinical privileges." The Hospital never disputed that Dr. Doe was told by Kubiak that there was "no investigation." The defendants acceptance of the AAR under these admitted facts was arbitrary and capricious, an abuse of discretion and not in accordance with law.

74. PBMC did not report its "acceptance of [plaintiff physician's] surrender of clinical privileges while under investigation for possible professional incompetence" to the NPDB within 15 days as PBMC would have been required to do by the NPDB Guidebook (page E-17) had plaintiff physician actually been under investigation "for possible professional incompetence." Instead, PBMC waited two months to file the alleged reportable event. Instead, PBMC waited two months to file the alleged reportable event. This is further evidence that Dr. Doe was not under investigation as of his involuntary resignation letter of October 7, 2009.

75. Nor did PBMC submit information regarding the "acceptance of the surrender of [plaintiff physician's] clinical privileges" "while under investigation relating to possible incompetence" "to the NPDB within 30 days following" PBMC's "acceptance of the surrender of clinical privileges" as PBMC would have been required to do by NPDB regulations 45 C.F.R. §§ 60.5 and 60.11(a)(1)(ii) had plaintiff physician actually been under investigation by PBMC "relating to possible incompetence." This is further evidence that Dr. Doe was not under investigation as of his involuntary resignation letter of October 7, 2009.

76. Nor did PBMC report its "acceptance of the surrender of [plaintiff physician's] clinical privileges"

"while under investigation relating to possible incompetence" "to the [New York] Board [of Medical Examiners] within 15 days" from the date of the "acceptance of the surrender" as PBMC would have been required to do by NPDB regulations 45 C.F.R. §§ 60.5(d) and 60.11(a)(1)(ii) had plaintiff physician actually been under investigation "relating to possible incompetence." This is further evidence that Dr. Doe was not under investigation as of his involuntary resignation letter of October 7, 2009.

77. Defendants' acceptance and maintenance of the AAR with knowledge of these failures to timely report by PBMC was arbitrary, capricious, an abuse of discretion and not in accordance with law.

78. Long after the alleged resignation, two months later, on December 3, 2009, PBMC filed the AAR with the NPDB in which PBMC claimed for the first time that plaintiff physician had surrendered his clinical privileges at PBMC two months earlier "while under, or to avoid, investigation relating to professional competence of conduct." This statement, in addition to being untimely under NPDB regulations, was either false because there was no investigation or was a resignation fraudulently induced by Kubiak's and PBMC's affirmative misrepresentations to plaintiff physician that there was no investigation. Accordingly, such a resignation was not "voluntary" and defendants despite all this evidence in the administrative record failed and refused to make that necessary factual determination. Further defendants relied instead on an NPDB Guidebook rule that a physician's lack of knowledge of the investigation does not affect reporting a resignation. As hereinafter alleged, the Guidebook rule is contrary to the expressed legislative purpose and intent of the HCQIA and

should be voided. Moreover, the issue was not mere lack of knowledge but affirmative misrepresentation of no investigation, which the defendants failed and refused to determine in assessing whether there was a "voluntary surrender."

79. The AAR contained the further statement that since plaintiff resigned,

> [a]ccordingly, 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.

80. Contrary to this statement in the AAR that plaintiff's practice departed from the standard of care, three senior, distinguished surgeons reached the opposite conclusion and found that plaintiff physician's practice in the case was within or exceeded the standard of care. These surgeons were (i) Dr. Richard Rubenstein, the former Chairman of Surgery at PBMC, with over 30 years' experience, (ii) the senior surgeon at the NY Office of Professional Medical Conduct ("OPMC") which in May, 2011 closed its review of plaintiff physician's October 2, 2009 surgical case with no further action and no restriction on his license to practice, and (iii) Dr. Steven Hofstetter, one of the leading abdominal surgeons in the world with 35 years of experience, having performed thousands of operations and chaired many surgical review committees. Dr. Hofstetter is the Surgeon-in-Chief at New York University ("NYU") Hospitals Center and the Vice-Chairman of the Department of Surgery NYU School

of Medicine in New York City. Defendants were fully informed of these facts but failed and refused to consider them or Dr. Doe's request that this portion of the AAR was erroneous, irrelevant to the alleged basis for reporting and should be stricken.

81. The AAR was assigned number is 5500000059633157 by the NPDB and placed in its files for access by all queriers concerning the Dr. Doe.

82. When submitting the AAR in December, 2009, PBMC provided a knowingly false address for the plaintiff physician as being at the Hospital's address, when PBMC knew that he had left PBMC and left Riverhead, New York in order to participate in the fellowship at the University of Tennessee. Defendants never informed plaintiff physician of the filing of the AAR. As a result, Dr. Doe had no knowledge of or reason to know of the false AAR at or near the time it was filed or for almost six months later.

83. Over the following months, plaintiff physician was successfully completing his fellowship in thoracic surgery at the University of Tennessee and was preparing to take the ABTS examination to become Board Certified in Thoracic Surgery. In or about May, 2010, plaintiff physician sought future employment as a thoracic surgeon at Reston Hospital Center in Reston, Virginia, still unaware that a false AAR report had been filed with the NPDB.

84. On May 12, 2010, Ms. Cindy Markwell, Director of Medical Staff Development at Reston Hospital Center in Reston, Virginia, informed plaintiff physician that Reston Hospital Center wished to interview him. Reston Hospital Center is operated by Hospital Corporation of America ("HCA"). Upon information and belief, HCA, operates

over 160 hospitals and is one of the largest private operators of health care facilities in the United States.

85. On June 1, 2010, Ms. Markwell e-mailed plaintiff physician as follows:

> 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.

86. This advice from Reston Hospital Center was the first time that Plaintiff physician learned of the filing of the false AAR with the NPDB. On or about June 3, 2010, he requested by self-query and later received a copy of the AAR from defendant NPDB and first read the AAR filed against him.

87. On June 1, 2010, the Vice-President for Medical Staff Affairs at Reston Hospital Center told plaintiff physician that not only was it HCA policy not to interview any healthcare provider with an NPDB AAR privileges report, but that Reston Hospital Center would be sending a copy of the NPDB report on Dr. Doe to HCA headquarters in Nashville, TN. As a result, the plaintiff is forever barred from employment at every HCA hospital in the world.

88. On June 1, 2010 and again on June 4, 2010, Dr. Doe asked Kubiak and PBMC to void the AAR.

89. On July 3, 2010, plaintiff physician submitted a responsive Subject Statement to the Databank and placed Report 5500000059633157 in disputed status challenging both the factual accuracy of the report and whether the report was submitted in accordance with the NPDB's reporting requirements.

90. On August 4, 2010, an attorney for PBMC, sent a fax to plaintiff's then attorney stating that "the Medical Center declines to void its report to the NPDB [National Practitioner Data Bank]."

91. After PBMC refused to void the Adverse Action Report, on August 20, 2010, plaintiff physician sought Secretarial Review of the disputed report.

92. Thereafter, PBMC and Dr. Doe submitted papers and written arguments to the NPDB as part of the Secretarial Review process. In a letter to the NPDB dated March 24, 2011, at pp. 8-9, the Hospital's attorney stated that Dr. Doe's statements to the NPDB that he was "unaware of any investigation" and "never notified of an investigation" were "irrelevant" facts because the NPDB Guidelines to not require the "practitioner's awareness" of an investigation. Accordingly, unlike other cases where a hospital purports to provide notice and due process, PBMC did not do so here and defendants knew it before rendering their Secretarial Review Decision accepting the AAR as a "voluntary surrender" of privileges while "under investigation." This decision is therefore arbitrary, capricious, an abuse of discretion and not in accordance with law.

93. On March 5, 2012, plaintiff submitted a supplemental Subject Statement further contesting the allegations in the AAR.

94. The defendants took nearly two years from the date the review was requested before rendering a decision on the Secretarial Review on June 25, 2012. From the time of filing of the false AAR and during the almost two years of the defendant Secretary's review without a decision, plaintiff physician's reputation and career were severely damaged by the maintenance of the false AAR on the NPDB database, where it was accessed and reviewed by United States hospitals where plaintiff physician subsequently sought to obtain employment and clinical privileges. Plaintiff physician's livelihood as a surgeon is necessarily dependent on acquiring and maintaining hospital staff privileges in order to perform surgery. Upon information and belief, in every case, his applications for employment and privileges would have been accepted but for defendants' maintenance of the false AAR report. Because of the AAR and defendants' improper refusal to void it, plaintiff physician to date has been unable to obtain hospital privileges or employment in the United States. This has resulted in severe economic harm to both plaintiffs.

95. During this same period, as a direct result of plaintiff physician being rejected from every United States hospital where he sought employment or privileges due, upon information and belief, to defendants' acceptance and maintenance of the false AAR on the defendant NPDB database, plaintiff PLLC has been unable to bill for or collect any revenue for surgery which plaintiff physician would have performed had he been able to obtain hospital privileges.

96. Prospective employer hospitals which queried the NPDB on plaintiff physician, and subsequently refused to employ plaintiff physician, include on June

27, 2011 Baptist Regional Medical Center in Kentucky, on July 25, 2011 Natchez Regional Medical Center in Mississippi, and on August 21, 2011 Muskogee Regional Medical Center in Oklahoma. These rejections occurred prior to completion of the Secretarial Review.

97. On June 25, 2012, almost two years after Dr. Doe's request, the Secretary finally issued her Secretarial Review Decision on Report 5500000059633157 finding "that there no basis to conclude that the report should not have been filed" or that "for agency purposes it is not accurate, complete, timely or relevant." Plaintiff physician's request that Report 5500000059633157 be voided was denied. Said Secretarial Review Decision constitutes the agency's final order. Plaintiff physician was informed of the decision by a confidential letter and explanation sent to him by defendant Rodgers dated June 25, 2012. By reason of the detailed facts recited above, the Secretarial Review Decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of the APA.

98. The June 25, 2012 Secretarial Review Decision of the defendants expressly asserted that there were five (5) disputes it could not decide, including:

a) "The Secretary cannot conduct an independent review of the surrender or resignation;"

b) "inquire whether an investigation was warranted;"

c) "whether a professional review action would have been taken if the investigation had been completed"

d) "whether the 'due process' provided or to be provided by the reporting entity was adequate;" and

e) "substitute [the Secretary's] judgment for that of the entity."

99. As a result of the foregoing arbitrary and capricious action by the defendant Secretary and other defendants, the false AAR, and the later filed Subject Statement, and the Secretarial Review Decision have been entered and maintained in the NPDB database for dissemination to all entities which queried and received a copy of the AAR concerning the plaintiff physician in the past three years. The language of the Secretarial Review Decision purports to tell inquirers that the report is "accurate, complete, timely and relevant" when in fact it is not. Further, unless voided and enjoined by this Court, these materials and the Secretarial Review Decision will be disseminated to all future entities who request a NPDB report on the plaintiff physician.

100. As a result of the dissemination of the foregoing AAR and the Secretarial Review Decision, and unless the AAR, Decision and NPDB record are voided and enjoined from dissemination by this Court, plaintiffs have and will suffer great and irreparable harm to their reputation, property, business, trade, profession, and occupation, as well as harm to their present and future business and professional relationships with hospitals, clinics, PPO/HMO credentialing entities, and other such individuals and entities.

101. Plaintiffs have exhausted all administrative remedies available to them, and no further right of

agency review or appeal is available to plaintiffs before HHS or the NPDB.

FIRST CAUSE OF ACTION TO SET ASIDE REPORT AS ARBITRARY, CAPRICIOUS, ABUSE OF DISCRETION AND NOT IN ACCORDANCE WITH LAW

102. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 101 of this Complaint.

103. 5 U.S.C. § 706 states in relevant part:

> The reviewing court shall . . .
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

104. As hereinabove alleged, defendants' actions with regard to Adverse Action Report 5500000059633157, and the acceptance and maintenance of same, were unlawful in that said actions were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law as herein more fully set forth.

There Was No Investigation by the Entity

105. Among other things, the defendants accepted and refused to void the AAR claiming plaintiff physician resigned while under investigation when there was no contemporaneous evidence of such an investigation as required by the HCQIA, and the report was untimely filed with NPDB.

106. As hereinabove alleged, the defendants' NPDB Guidebook at page E-19 states that a health care entity that submits an AAR based on surrender of privileges while under investigation "should have contemporaneous evidence of an ongoing investigation at the time of surrender . . . [and] 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 of excerpts from committee meetings, orders from hospital officials directing an investigation, and notices to practitioners of an investigation." Upon information and belief, defendants never received such evidence and as of the alleged resignation on October 7, 2009, there were no "minutes" of any *bone fide* Hospital committee meeting, no "orders" directing an investigation, and no "notices" to the practitioner plaintiff.

107. Accordingly, defendants acceptance and maintenance of the AAR despite the lack of such contemporaneous evidence of an investigation commenced "by the entity" and in accordance with its By Laws "prior" to plaintiff's resignation was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of the APA.

Resignation Was Obtained by Fraud, Not Voluntary

108. Alternatively, if there was an investigation of plaintiff physician, he was affirmatively misled as to its existence, thus procuring his resignation by fraud when he would otherwise not have resigned and not have been reported. Therefore, 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.

109. Further, since the AAR was classified not as a suspension of privileges but as a "voluntary surrender of clinical privileges" while under investigation, defendants were obligated under the statute to determine if such "voluntary surrender" "while under investigation" actually occurred. Defendants' disregard of the unrefuted evidence that Dr. Doe was misled as to the status of any claimed investigation and disregard of the lack of evidence of the kind required by the NPDB to prove an entity investigation prior to the alleged "voluntary resignation" were arbitrary, capricious actions, an abuse of discretion and not in accordance with law.

The Defendants' Guidebook Rule Disregarding Physician Knowledge is Contrary to Law.

110. The defendant NPDB Guidebook at page F-8 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." ("F-8 Rule.") Defendants relied on this F-8 Rule at page 4 of the Secretarial Review Decision. This Guidebook provision is not contained in the HCQIA as enacted into law, or the regulations adopted thereunder, and upon information and belief, was not adopted with any public notice or comment. On its face, this administrative Guidebook interpretation is overbroad, over-inclusive and contrary to the purposes of the HCQIA because it makes reportable and thereby brands as "incompetent" practitioners who are competent and who would have not surrendered clinical privileges but would have successfully defended their practice

under investigation if they were "aware" of the investigation. Defendants' Guidebook interpretation that a physician can be reported for a resignation without knowledge of an investigation is also contrary to the express legislative history and House Report of the HCQIA. The House Report states that requiring reports for resignation or surrender of privileges "while under investigation" was included in the law "to ensure that health care entities will not resort to 'plea bargains' in which a physician agrees to such a surrender in return for the health care entity's" not informing others about the circumstances of the surrender. Such a risk of plea bargain or surrender to avoid investigation necessarily requires that the physician had knowledge of the investigation, or there would be no need for concern over a possible "plea bargain."

111. Accordingly, defendants' adoption and application of this Guidebook Rule is arbitrary and capricious, an abuse of discretion, and not in accordance with law. Even if the interpretation were proper, it should not have been applied by defendants in this case, where plaintiff was not merely "not aware" of an alleged investigation, but was affirmatively misled by the reporting Hospital that there was no investigation, in order for the Hospital to obtain his resignation, a fact the defendants knew and which the Hospital did not even deny in its submissions to defendants.

112. Specifically, the defendant's Guidebook interpretation that the defendants will accept an AAR even if the physician was not "aware" of an investigation at the time of surrender of clinical privileges is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law as applied in this case by defendants to accept and

maintain the AAR, when plaintiffs have alleged and submitted evidence that there was fraud and affirmative misrepresentation by the reporting entity, PBMC, but for which plaintiff would not have resigned. Therefore, there was no "voluntary resignation while under or to avoid such an investigation," but a resignation obtained by fraud and deceit perpetrated on a physician who was prepared to defend his practice. This is contrary to the purpose of the HCQIA, which is to protect the public by preventing incompetent physicians from voluntarily resigning to avoid investigations in order to practice elsewhere. The HCQIA may not be applied by defendants to accept damaging reports on competent physicians who are deceived to resign during an alleged investigation. Defendants failed to discharge their duty to determine if plaintiff physician was deceived so that his resignation was not "voluntary."

113. In view of these allegations of fraud and affirmative misrepresentation, which the Hospital did not dispute, but which defendants expressly declined to consider, defendants' acceptance and maintenance of an AAR based on a fraudulently obtained "resignation," is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

The AAR Report Was Untimely as Matter of Law

114. Furthermore, the AAR was manifestly untimely. Since plaintiff physician submitted his fraudulently obtained resignation letter to Kubiak on October 7, 2009 effective October 16, 2009, and since Kubiak accepted the letter on October 7, 2009, under 45 C.F.R. § 60.11(a) the acceptance of the surrender

of clinical privileges occurred on October 7, 2009 or at the latest October 16, 2009. Under applicable law and regulations, 45 C.F.R. §§ 60.5(d) and 60.11(a), PBMC was required to report the Adverse Action Report to the NPDB "within 30 days following the action to be reported" *i.e.* by November 6, 2009, and to the New York State Board for Medicine "within 15 days from the date the adverse action was taken or clinical privileges were voluntarily surrendered" *i.e.* by October 22, 2009. PBMC failed to do so and accordingly the report of surrender of privileges, in addition to being false and fraudulently obtained, was untimely as a matter of law. Defendants also failed to consider this two-month filing delay by the Hospital as evidence that there was no investigation at the time of resignation, or the report would have been timely made, especially when combined with the lack of "contemporaneous" evidence of an investigation as specified by the By-Laws.

115. The NPDB Guidebook at page E-17 states:

> Reporting Adverse Clinical Privileges Actions [to the NPDB]
>
> Health care entities must report adverse actions within 15 days from the date the adverse action was taken or clinical privileges were voluntarily surrendered. The health care entity must print a copy of each report submitted to the NPDB and mail it to the appropriate State licensing board for its use. The Report Verification Document that health care entities receive after a report is successfully processed by the NPDB should be used for submission to the appropriate State licensing board.

116. Upon information and belief, PBMC did not report the Adverse Action Report to an appropriate New York State licensing board and the NPDB as above required within 15 days of October 7, 2009, which would have been by October 22, 2009. Accordingly, the Report is improper and unlawful and should have been rejected or thereafter declared untimely and voided by defendants during the Secretarial Review process.

117. As per 45 C.F.R. § 60.5, PBMC was required to submit the Adverse Action Report ("information required under §§ 60.7, 60.8, and 60.11") to the NPDB "within 30 days following the action to be reported" *i.e.* by November 6, 2009.

118. Since PBMC did not submit the Adverse Action Report to the NPDB until December 3, 2009, the Report was untimely, improper and unlawful and should have been rejected or thereafter declared untimely and voided by the defendants during the Secretarial Review process.

119. The failure of the NPDB and the other defendants to follow the Code of Federal Regulations and NPDB's own Guidebook with regard to these issues, including the lack of evidence of an investigation and the untimeliness of PBMC's submissions, was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

The Hospital's Subsequent *Ex Parte* "Review" Was Not a Reportable Event

120. In addition, the applicable law and regulations require reporting as an adverse action a "professional review action" that adversely affects the physician's clinical privileges and only if lasting "longer than 30 days." 42 U.S.C. § 11133(a), 42 U.S.C.

§ 11151(9), 45 C.F.R. § 60.11 and the NPDB Guidebook at page E-19 ("summary suspensions" for more than 30 days), page E-17 (actions that "adversely affect" clinical privileges for more than 30 days).

121. The NPDB's own Guidebook at page E-19 states:

> Investigations should not be reported to the NPDB; only the surrender or restriction of clinical privileges while under investigation or to avoid investigation is reportable."

122. However, the last two sentences of the AAR which PBMC submitted to the defendant NPDB stated that because plaintiff resigned,

> [a]ccordingly, 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.

123. Since the AAR acknowledged that there was no actual "restriction," "suspension," or "effect on" plaintiff's clinical privileges on account of the alleged quality assurance review, this was not a reportable event. Thus, the AAR report as to the "results" of the alleged investigation was not a suspension of privileges and therefore as a matter of law, was not a reportable event and should not have been accepted by defendants and should have been stricken upon Secretarial Review.

124. As a factual matter, the AAR stated that because of the resignation, the Hospital could take

"no further action regarding the physician's privileges or employment." Therefore, the AAR statement of what the alleged quality assurance review "indicat[ed]" without an actual restriction of privileges occurring was a non-reportable event and should have been neither reported nor accepted by defendants but should have been voided.

125. Defendants' acceptance of the AAR with this improper statement of a non-reportable event, and the failure on Secretarial Review to void it or strike it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

SECOND CAUSE OF ACTION TO DECLARE THE HCQIA AS INTERPRETED AND APPLIED BY DEFENDANTS AS AN UNCONSTITUTIONAL DEPRIVATION WITHOUT DUE PROCESS

126. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 125 of the Complaint.

127. Plaintiff and other physicians, who are granted a professional license to practice medicine by a State of the United States have thereby obtained a valuable property right. Plaintiff physician and other physicians who have, or have had, clinical and hospital staff privileges also have a valuable property right. Plaintiff's and other physicians' right to engage in a profession of their choice is a valuable liberty interest. These property rights and liberty interests are protected under the United States Constitution. The right to practice one's lawful profession is a fundamental right under the United States Constitution.

128. Defendants' acceptance, maintenance and dissemination of an AAR against practitioners, and Dr. Doe in particular, on account of alleged surrender of privileges, arises from particular action involving their prior employment. As hereinafter alleged in detail, such an AAR has the actual adverse effect of automatically (a) excluding such Dr. Doe and similarly situated physicians from a definite range of their constitutionally-protected property and liberty rights and right to employment in their chosen profession, and (b) altering or extinguishing their right to engage in the practice of medicine under their state-granted professional licenses. Such conduct by the defendants under the HCQIA 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. Such conduct by defendants under the HCQIA has the effect of rendering these physicians unemployable as physicians and therefore deprives and diminishes these physicians' and plaintiff physician in particular of their liberty, property and occupation and does so without due process of law, as more fully set forth herein. This violates the Due Process Clauses of the Fifth Amendment, causes irreparable harm, and should be enjoined by this Court.

129. More specifically, the HCQIA requires that prospective employers query the NPDB before hiring a new physician. 42 U.S.C. § 11135(1). This is for the ostensible purpose of preventing incompetent physicians from obtaining new employment by alerting subsequent employers to the existence of an

AAR on the NPDB. However, the defendants accept and disseminate adverse information about a physician in these AAR's without any procedurally-safeguarded opportunity to contest the accuracy of the facts alleged in the reports. Further, defendants' acceptance of such AAR's without a prior opportunity to challenge the accuracy and dissemination of the information is a violation of due process and constitutionally-protected rights.

130. In addition, defendants' acceptance of such AAR's without a subsequent prompt and meaningful due process opportunity to challenge the accuracy and dissemination of the information is a violation of due process and constitutionally-protected rights.

Unconstitutionality and Illegality of the Defendants' Guidebook Rule F-8 Accepting AAR despite Physician's Lack Of Knowledge of Any Investigation

131. Defendants' NPDB Guidebook Rule at page F-8 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" (the "F-8 Rule"). This F-8 Rule is not contained in the HCQIA or Code of Federal Regulations implementing the HCQIA. Upon information and belief, defendants adopted the F-8 Rule and apply it as an administrative convenience for themselves and to avoid having to determine factual issues as to a physician's knowledge, even though such knowledge is directly relevant to the purposes of the HCQIA.

132. As hereinabove alleged from the legislative history of the HCQIA, the House Report states that requiring reports for resignation or surrender of privileges "while under investigation" was included in

the law "to ensure that health care entities will not resort to 'plea bargains' in which a physician agrees to such a surrender in return for the health care entity's" not informing others about the circumstances of the surrender. (Emphasis added.) Such a risk of plea bargain or surrender to avoid investigation necessarily requires that the physician had knowledge of the investigation, or there would be no need for concern over a possible "plea bargain."

133. Defendants' acceptance of AAR's under Rule F-8 in cases where the physician had no knowledge of the alleged investigation, as is the case here for Dr. Doe, places the physician on the NPDB database with an AAR for all subsequent queriers. As hereinafter alleged, the effect of being so placed on the NPDB database brands resigning physicians as "incompetent" and makes them unemployable. In cases such as this when the resignation is accepted without the physician's knowledge of the investigation, upon information and belief, many of the reported physicians are competent and would not have surrendered clinical privileges and would have successfully defended their practice under investigation if given notice of the investigation. And the effect of the F-8 Rule is particularly pernicious where, as here, it is alleged that reporting entity acted fraudulently and out of malice to harm a competent physician who never knew of the alleged investigation. Here, for example, Dr. Doe had no knowledge of the alleged investigation and was exonerated in the surgical case at issue by the New York State Office of Professional Medical Conduct ("OPMC"), a neutral fact finder charged with protecting patients and maintaining the quality of healthcare in New York State. Unlike defendants and

the Hospital, the OPMC conducts its review of competence with due process.

134. The F-8 Rule thus effects a deprivation of fundamental constitutional rights not only without due process, but without the physician's knowledge that such a filing and deprivation will occur. Accordingly, defendants' adoption and implementation of this self-serving administrative F-8 Rule is contrary to the purposes of the HCQIA, is unauthorized, illegal and is unconstitutional.

Unconstitutionality of the Defendants' Practice of Accepting and Maintaining AAR's on the NPDB Database Without Due Process to Determine if the Asserted Facts are True

135. The HCQIA does not specify the procedures and the scope of defendants' review in the case of "disputed accuracy of the information" reported but leaves this to the Secretary. 42 U.S.C. § 11136. According to defendants, and as set forth in the NPDB Guidebook at E-19 and F-6, the defendants will only review whether the entity reporting a surrender of privileges while under investigation or for a restriction of privileges had a basis to make the report based on "contemporaneous" documentary evidence of an investigation. Defendants will not review whether the submitted documents are *bona fide* or forged, whether the alleged investigation was warranted, whether it was carried out fairly or with due process, and whether any resulting restriction on privileges was warranted, claiming these matters are "outside the scope of review." See examples of what the NPDB will not consider in NPDB Guidebook pp. F-3 to F-6. Moreover, the limited opportunity afforded by defendants under 45 C.F.R. § 60.16 for plaintiff to submit a letter "in writing, of the disagreement [with

the report] and the basis for it" is wholly inadequate to provide due process to refute the veracity and accuracy of the reporting entity's paper record when it is "accepted" by defendants and maintained on the NPDB database for inquiring hospitals.

136. In the present case, defendants in accordance with this improper and unconstitutional application of the law, specifically followed their above stated procedure of failing to make any of the determinations relevant "whether the due process . . . was adequate" or as to the merits of plaintiff physician's competence as a physician, which is the ostensible purpose of the HCQIA.

137. The defendants' express statement in this very case of what they could not and did not consider under the HCQIA and their own regulations is a paradigm of the lack of due process. Thus, the Secretarial Review Decision here expressly advised plaintiffs that

> a) "The Secretary cannot conduct an independent review of the surrender or resignation;"
>
> b) "inquire whether an investigation was warranted;"
>
> c) "whether a professional review action would have been taken if the investigation had been completed;"
>
> d) "whether the 'due process' provided or to be provided by the reporting entity was adequate;" and
>
> e) "substitute [the Secretary's] judgment for that of the entity."

138. The effect of the law and regulations under which defendants employ such a limited scope of review (and they provide no prior notice, hearing, or trial) and profess lack of authority to determine anything other than that the reporting entity has what it claims is "contemporaneous" paperwork to support the report is to effect an unconstitutional deprivation of plaintiff physician's rights and the rights of any physician who is reported in an AAR. Defendants can, and did, accept such self-serving documents without affording or conducting any due process into their veracity. As hereinabove alleged, such paperwork may in fact be, as alleged herein, fabricated, backdated, not contemporaneous, false, malicious and refutable by due process. But defendants have stated that these issues are "outside the scope" of the defendants' review, and in any event, no procedures are in place to enable such truth-finding. Defendants' failure to afford due process protections to Dr. Doe, or to insure that the reporting hospital has done so, results in an unconstitutional deprivation of the rights of plaintiffs and similarly-situated physicians.

139. Defendants' aforesaid procedures admittedly without affording any due process, of accepting and maintaining an AAR against a physician for resigning while under, or to avoid, investigation, as in this case, or alternatively for having privileges restricted for more than 30 days due to alleged incompetence, as implied by the AAR in this case indicating a "departure from the standard of care," renders a physician, and the plaintiff physician here, unemployable and deprives both plaintiffs of their right to property, liberty and practice of profession without due process of law, as more fully alleged herein.

Unconstitutional Effects of Defendants' Conduct

140. The HCQIA and Code of Federal Regulations thereunder as administered by defendants are unconstitutionally over-inclusive of the purposes of the HCQIA because they make reportable and thereby brand as "incompetent" practitioners who are competent and who could have successfully defended their practice and/or who are victims of false and malicious reporters, which would not occur had they been afforded due process. There is substantial evidence of these effects and upon information and belief, these effects of deprivation of constitutional rights are known to defendants.

141. The defendant NPDB's published Annual Report for 2010 admits at p. 68 that in 2008, in 2009, and in 2010, the NPDB did not void a single Adverse Action Report in over 150 AAR's under review, submitted by any hospital anywhere in the United States. Upon information and belief, "Secretarial Review" conducted by defendants in the fashion hereinabove alleged is just a "rubber stamp" approval. Accordingly, the defendants' level of review, as hereinabove alleged, is factually and constitutionally inadequate to determine if the AAR is true and should be maintained. Defendants should be required to void the AAR in this case and so notify all inquirers.

142. For example, in one reported case, upon information and belief, a physician in California was reported to the NPDB for resigning while under investigation, but ultimately prevailed before the California state medical board in proving the charges in the investigation were unfounded. Defendants, informed of these facts, still refused to remove the

report of resignation while under investigation, thereby depriving an adjudicated competent doctor, and his potential patients, of his constitutionally-protected right to practice. This is entirely inconsistent with the purposes of the HCQIA. Testimony of presidents of two California medical associations on behalf of that physician in that case was to "it will be virtually impossible" for that physician to find work in a U.S. hospital with that report in the NPDB database.

143. The same unconstitutional deprivation has occurred here to plaintiff physician Dr. Doe, whose practice in the subject surgical case was examined by the NY Office of Professional Medical Conduct and found not to warrant any discipline or restriction on his practice. Yet plaintiff physician remains reported and unemployable for resigning during an alleged investigation about which he had no knowledge. Moreover, prior to resigning, the plaintiff physician was affirmatively told by the Hospital's Vice President of Medical Affairs that he was not "under investigation" and that nothing would be reported. This demonstrates that the HCQIA and regulations as enacted and administered by defendants effectuate an erroneous and unconstitutional deprivation of plaintiff's fundamental constitutional rights.

144. Further, upon information and belief, officials of numerous U.S. medical associations have stated that mere existence of such a report with the NPDB will make it "virtually impossible" for the subject of the report to obtain employment as a physician at any U.S. hospital, and "can essentially make you unemployable." Twedt, *A Negative Data Bank Listing Isn't Easy To Erase*, Pittsburgh Post-Gazette, October 27, 2003.

145. An extensive study in California concluded that a physician subject to a negative peer review report has "their professional lives . . . ruined." Lumetra, *Comprehensive Study of Peer Review in California, Final Report*, July 31, 2008 at 65, 94. Where the report is false or malicious, the defendants' acceptance and maintenance of it without affording due process is therefore unconstitutional.

146. An adverse AAR report has been called a "career-ender," and a physician's reputation is thereby "irreparably damaged." This is particularly true of surgeons, such as Dr. Doe, who can only practice their profession in a hospital setting and thus must have hospital privileges. A negative but false AAR preventing rehiring in a hospital setting thus renders a surgeon's license "worthless," and therefore has been referred to as "NPDB Physician Blacklisting." A negative AAR can also cause "loss of both medical insurance and termination of managed care rights." Van Tassel, *Blacklisted: The Constitutionality of the Federal System for Publishing Reports of "Bad Doctors" in the National Practitioner Data Bank*, 33 Cardozo Law Review 2031 (June 2012) at 2053, 2057-2063. Under the HCQIA as applied by defendants, these constitutional deprivations can be imposed without due process and were so imposed on Dr. Doe.

147. A reported analysis of NPDB public files from 1990 to 2009 concluded that of 10,672 physicians reported for termination or restriction of hospital privileges, 3,218 lost their privileges permanently. Public Citizen, *State Medical Boards Fail to Discipline Doctors with Hospital Actions Against Them* (March 2011). Upon information and belief, a substantial number of physicians who are competent

are suffering constitutional deprivation from defendants' implementation of the HCQIA.

148. The U.S. General Accounting Office ("GAO") in a report concerned with the accuracy of data contained in the NPDB records observed that information disseminated by the defendant NPDB "can affect a practitioner's reputation and livelihood." *National Practitioner DataBank; Major Improvements Are Needed to Enhance Data Bank's Reliability*, GAO-01-130 (2000) available at http://www.semmelweis.org/ref/8b4.pdf.

149. By reason of the foregoing published reports and otherwise, upon information and belief, defendants are, and have been aware for some time prior to the events complained of herein, of the extent of deprivation and harm to Dr. Doe's and other similarly situated physician's rights of property, liberty and to practice of profession resulting from defendants' erroneous application and implementation of the HCQIA without affording due process.

150. Such unconstitutional deprivation is inevitable, given that the purported purpose of the HCQIA is to alert prospective employers that a reported physician is a risk because of issues as to his or her clinical competence. However, upon information and belief, prospective employers in the vast majority of cases choose not to hire a physician who has an AAR report on file with the NPDB, because the prospective employer has neither the time, resources nor motivation to undertake an independent investigation as to the veracity of and accuracy of the information contained in the AAR maintained by defendants but simply accepts it as a conclusive reason not to hire. Such employers have

available to them other applicants with no such adverse AAR reports, who, upon information and belief, will therefore be hired without the prospective employer fearing risk to its patients or itself from hiring a physician even wrongly reported as having been investigated or having had privileges suspended, and the further risk to the prospective employer of liability to any patients who might be injured by such a physician under a tort theory such as negligent hiring. Upon information and belief, defendants know this.

151. Here, plaintiff physician's own experience as alleged is direct evidence of this effect of unconstitutional deprivation, since every hospital in the United States to which plaintiff physician has since applied, and to which he had to disclose the AAR, has refused to hire or grant clinical privileges to plaintiff physician. Some of these hospitals have expressly stated that the AAR on file with defendants against Dr. Doe prevents them from considering his application as a matter of company policy.

152. Dr. Doe was told directly by several of the hospitals at which he has attempted to obtain privileges that, but for the Adverse Action Report they would be very interested in hiring him, but that, because of the Adverse Action Report, they are unable to grant him privileges *as a matter of policy*. The effect of the defendants' refusal to employ due process review of the *bona fides* of the Adverse Action Report thereby deprives plaintiff physician of his right to practice his profession without due process.

153. Since being the subject of the AAR filed with the defendant NPDB in December 2009, plaintiff physician has been rejected by more than five U.S. hospitals. A credentialing doctor at Reston Hospital

in Virginia, one of over 160 U.S. hospitals operated by Hospital Corporation of America ("HCA"), told Dr. Doe that as a matter of policy, HCA hospitals will not consider or employ a provider who has an AAR on file with the NPDB database. As heretofore alleged, the Director of Medical Staff Development at that hospital emailed Dr. Doe as follows:

> 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.

154. Such prospective employer rejections of plaintiff physician include the following hospitals which accessed the NPDB report on Dr. Doe in or about the following dates: May 24, 2010 and June 1, 2010 by Reston Hospital Center in Virginia; June 27, 2011 by Baptist Regional Medical Center in Kentucky; July 25, 2011 by Natchez Regional Medical Center in Mississippi; and August 21, 2011 and March 5, 2012 by Muskogee Regional Medical Center in Oklahoma. Thus, despite Dr. Doe's excellent training, education and experience, as hereinabove alleged in ¶ 3, and despite an otherwise unblemished record in over 3000 surgeries, Dr. Doe has not been able to obtain employment as a physician in the United States and has been out of work in the United States for over two and a half years.

155. As a result, plaintiff physician's career as a physician and surgeon in the United States has been destroyed by a false AAR, knowingly maintained by defendants, without affording Dr. Doe any due process of law. Plaintiff's property and liberty interests and his right to practice medicine have been severely diminished and destroyed.

156. Accordingly, under the statutes and regulations as applied to plaintiff physician in this case, plaintiffs have been deprived of their liberty and property interests in plaintiff physician's career and income and right to practice of Dr. Doe's lawful profession by the federal defendants, in violation of the Due Process Clause of the Fifth Amendment of the United States Constitution. Accordingly, the AAR filed with and maintained by defendants as to Dr. Doe should be ordered voided, as hereinafter requested.

THIRD CAUSE OF ACTION TO DECLARE THE HCQIA AND REGULATIONS AS AN UNCONSTITUTIONAL DEPRIVATION WITHOUT DUE PROCESS

157. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 156 of the Complaint.

158. As hereinabove alleged, Dr. Doe and other physicians who have been granted a license to practice medicine under state laws have valuable rights of property, liberty and a fundamental right to practice their profession under the United States Constitution. Such rights may not be taken without due process of law.

159. The HCQIA does not require due process prior to or after an AAR is filed with defendants. The HCQIA only provides that reporting entities and persons involved in professional review actions under the HCQIA, who voluntarily choose to follow certain due process requirements as set forth in 42 U.S.C. §§ 11111-11112 "shall not be liable in damages." There is no affirmative requirement that such entities provide due process before making reports to the NPDB database under the HCQIA. The HCQIA is therefore constitutionally infirm.

160. The legislative history of HCQIA, and as explained in defendants' Guidebook, indicates that Congress intended the reports to NPDB to serve only as "an alert or flagging system" and "should serve only to alert" subsequent hiring hospitals to investigate the reported physician before hiring him or her. NPDB Guidebook at A-3. However, as hereinabove alleged, many hospitals have no time, resources nor motivation to undertake an independent investigation as to the veracity of and accuracy of the information contained in the AAR maintained by defendants but simply accept it as a matter of policy or practice to impose an absolute and strict rule not hire any physician who has an AAR on file with the NPDB database. Likewise, the defendants concede that under the HCQIA, they have no obligation to and do not provide due process review of any alleged reportable actions. Accordingly, and as hereinabove alleged, such reports made to the NPDB under the HCQIA without ever affording due process have the actual effect of depriving the reported physicians of constitutionally protected rights without due process of law.

161. Because the HCQIA has the effect of impinging on fundamental constitutional rights, it

had to be narrowly tailored and is subject to strict constitutional scrutiny, not a mere rational relationship to the purposes sought to be achieved. As hereinabove alleged, the HCQIA is unconstitutional under this test because it does not require due process by reporting hospitals or by the Government defendants and results in both overinclusive and underinclusive deprivation of fundamental constitutional rights.

162. The HCQIA is overinclusive in cases such as Dr. Doe and others, who are in fact competent doctors wrongly reported without knowledge of any investigation and/or without due process by reporting entities who choose not to afford themselves the immunity offered under the HCQIA or who report falsely and maliciously.

163. The HCQIA is underinclusive because, upon information and belief, some hospitals will discriminate in their peer review and reporting responsibilities to not report physicians who have particular political or financial power at the reporting entity. In addition, the aforesaid GAO Report, *National Practitioner Data Bank: Major Improvements Are Needed to Enhance Data Bank's Reliability*, GAO-01-130 (2000) at pages 10-14 under "Efforts to Address Underreporting Have Been Unsuccessful" details numerous instances of underinclusiveness. These include practitioners using a "corporate shield" to avoid reporting of their names when an entity settles a medical malpractice case, and that a comparison of medical malpractice insurers' reports to the National Association of Insurance Commissioners with the insurers' reports to NPDB identified 18 of 24 companies failing to properly report to the NPDB. (GAO Report at 12). Thus, of an estimated 850,000 or more licensed

physicians in the United States in 2010, in that year only 935 clinical privilege AAR reports were made to the NPDB, and from 1990-2010, 2,832 of 5,980 (or 47.4%) non-federal hospitals in 50 states, with active registrations with NPDB, had "never reported" a physician to the NPDB. See NPDB Annual Report for 2010 at 49 and 66-67. As the GAO Report concluded at p. 13: "While early estimates projected as many as 10,000 clinical privilege restrictions would be reported annually, fewer than 9000 reports were submitted [in the entire 10 years] from 1990-1999." HCQIA is accordingly grossly underinclusive with respect to its purpose as well as overinclusive in wrongly maintaining reports on competent physicians, many without due process.

164. Since the HCQIA permits the deprivation of fundamental constitutional rights without due process and is both overinclusive and underinclusive of its intended purpose, it cannot be justified by its intended purpose and fails the strict scrutiny test and should be declared unconstitutional by this Court.

FOURTH CAUSE OF ACTION FOR DEFENDANTS' VIOLATION OF THE FEDERAL PRIVACY ACT

165. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 164 of the Complaint.

166. Section 552a (g)(1) of Title 5 of the United States Code provides that:

> [w]henever any agency, (A) makes a determination ... not to amend an individual's record in accordance with his request, or fails to make such review in conformity with that

> subsection; (B) refuses to comply with an individual request under subsection (d)(1) of this section; (C) 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, or; (D) fails to comply with any other provision of this section, or any rule promulgated thereunder, in such a way as to have an adverse effect on an 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.

167. The law in this District is settled that the requirements of Section 552(g)(1) supersede the regulations adopted under the HCQIA. Accordingly, plaintiff physician was entitled to the protections of the Privacy Act from defendants.

168. Based on all the facts as hereinabove alleged, defendants violated Section 552a(g)(1)(C) by failing to maintain any the AAR report on Dr. Doe "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." Specifically, defendants maintained and actually released to inquiring hospitals the AAR during the entire period of Dr. Doe's requested review, without making adequate

determinations "necessary to assure fairness" as to Dr. Doe. Moreover, defendants ultimately simply accepted without any hearing the challenged documentation from the Hospital, even though it included on its face fabricated, backdated, not contemporaneous and false information and in material respects was refuted by documentary evidence submitted by Dr. Doe, such as signed statements from other physicians that they never attended the peer review meetings the Hospital claimed they attended. See Complaint ¶¶ 62-80, *supra*.

169. When comparing the Privacy Act to the procedures promulgated by defendants for challenging a record submitted to the NPDB, it is readily apparent that the NPDB procedures provide less protection than the procedures required by the Privacy Act. For example, the Privacy Act requires that "prior to disseminating any record about an individual to any person other than an agency ... [, the agency must] make reasonable efforts to assure that such records are accurate, complete, timely, and relevant for agency purposes." 5 U.S.C. § 552a (e)(6) (emphasis added). On the other hand, the NPDB regulations only require the defendant Secretary to place the information into a "disputed status" on any report if information it contains is in dispute, and do not require a "reasonable" effort to check for, among other requirements, accuracy prior to its dissemination. 45 C.F.R. § 60.16.

170. Moreover, when reviewing a disputed record pursuant to the NPDB regulations, the Secretary only purports to consider whether "the information is accurate" 45 C.F.R. § 60.16(c)(2)(i), not its completeness, timeliness and relevance as required by the Privacy Act. Further, the extent of defendants

determining "accuracy" is limited by the NPDB Guidebook at p. E-19 to determine only whether the reporting entity has "contemporaneous evidence of an ongoing investigation at the time of surrender . . . [and] should be able to produce evidence that an investigation was initiated **prior** to the surrender of clinical privileges by a practitioner." No provision is made to resolve discrepancies in the entity's submitted papers or inconsistencies with the physician's evidence submitted to the NPDB, and defendants expressly concede they did not do so. For example, the June 25, 2012 Secretarial Review Decision stated that "the Secretary cannot conduct an independent review of the surrender or resignation;" such as whether it was truly voluntary or "inquire whether an investigation was warranted," which is relevant to accuracy and the purpose of the agency and the HQCIA.

171. Thus, the NPDB regulations and Guidebook fall far short of providing plaintiff physician with the same level of protection afforded by the Privacy Act in three respects: first, by authorizing the dissemination of the record while information it contains is being disputed; second, by not requiring that the record be reviewed for completeness, timeliness and relevance; and third by not containing adequate procedures to resolve disputes as to "accuracy."

172. Plaintiffs also are entitled to review by this Court of defendants' actions under Section 552a(g)(1)(A) in that the Secretarial Review Decision made no change in the AAR and accordingly, the defendants made "a determination . . . not to amend an individual's record in accordance with his request." For the reasons hereinabove alleged, plaintiffs request that the AAR filed with and

maintained by defendants as to Dr. Doe should be ordered voided, as hereinafter requested and for an award of costs and reasonable attorneys fees under Section 552a(g)(2)(B).

FIFTH CAUSE OF ACTION TO DECLARE THE HCQIA AS INTERPRETED AND APPLIED BY DEFENDANTS AS AN UNCONSTITUTIONAL BILL OF ATTAINDER

173. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 172 of the Complaint.

174. By reason of the foregoing facts as alleged, the HCQIA as enacted and administered by defendants singles out and effectively deprives a readily ascertainable group of physicians from future professional employment. This group is all those physicians who are reported for nothing more than having resigned or surrendered clinical privileges without knowledge that they were under investigation, or were affirmatively misled as not being under investigation, when in fact they are fully competent, qualified physicians who would prove such had they been informed of the investigation, not misled and given opportunity to contest the charges. Such an enactment and conduct amounts to a Bill of Pains and Penalties and Bill of Attainder, in that the legislation as enacted and implemented inflicts punishment on this ascertainable group of physicians, without a judicial trial, and is therefore prohibited by Article I, § 9 clause 3 of the Constitution.

175. By reason of the foregoing, the HCQIA as enacted by the Congress and administered by defendants singles out and effectively deprives this

readily ascertainable group of physicians, which includes competent physicians, and lists them in a manner which in purpose and effect deprives them of future employment without any notice, hearing or due process. This group of competent physicians, who have done no more than resign without knowing of an investigation, or by being affirmatively misled prior to resignation that there was no investigation, is thereby "blacklisted" from further employment in their chosen field by act of the Congress and by the defendants as they have chosen to implement the law, subjecting plaintiff and similarly situated physicians to severe punishment and constitutional deprivation without a trial or other due process. The blacklist can be facilitated by persons who are economic rivals or private enemies of the subjected physicians, like plaintiff Dr. Doe, who are added to the NPDB blacklist by private parties for reasons of personal dislike, malice, discrimination, and economic competition. In cases of resignation without knowledge that they were under investigation, or by being affirmatively misled that there is no investigation, this group of physicians are penalized by the legislation and receive no due process.

176. In such cases of being blacklisted by the defendant NPDB for resigning while under an alleged investigation of which the physician was not aware or the existence of which he was misled about, the HCQIA as implemented by defendants does not afford the blacklisted physician any pre-listing notice, nor any trial or a hearing at which to prove that the charges of incompetence are false. As hereinabove alleged, this group of competent physicians suffer the elimination, or severe curtailment, of the physicians' ability and constitutional right to practice their chosen occupation as a consequence of being on the

blacklist. Upon information and belief, the federal defendants are aware of this effect and punishment of physicians reported to the NPDB under such circumstances. Accordingly, the HCQIA as enacted and implemented by defendants should be declared an unconstitutional legislative and executive action in violation of the Constitution, Art. I, Sec. 9 clause 3 and defendants are liable to plaintiff for damages to be determined at trial for on the claim for blacklisting.

SIXTH CAUSE OF ACTION TO DECLARE THE HCQIA AS APPLIED BY DEFENDANTS TO PLAINTIFF A VIOLATION OF THE EIGHTH AMENDMENT

177. Plaintiffs reallege and incorporate herein as if fully set forth, the allegations contained in paragraphs 1 through 176 of the Complaint.

178. The Eighth Amendment prohibits the infliction of cruel and unusual punishments. As a matter of law, this prohibition in the Eighth Amendment is not confined to criminal proceedings but includes civil penalties and punishments, even if the punishment imposed in a civil sanction also serves a remedial purpose, as asserted in provisions of the HCQIA.

179. As hereinabove alleged, the effect of the HCQIA as implemented by defendants against Dr. Doe in this case is to effectively deprive him of his practice of medicine on account of the reporting of a single surgical case wherein he was unaware that there was any alleged investigation, unaware that any report would be made and unaware that he would be deprived of the right and opportunity to defend his practice in that case. In such

circumstances, the HCQIA and defendants' conduct, as applied in this case, is not merely remedial, but was punitive and excessively so.

180. Accordingly, in the circumstances of this case, the civil sanction of being reported in the allegedly false and deceptively obtained AAR, accepted and maintained by defendants without reasonable review or due process, served not solely any remedial purpose but also served as excessive, cruel and unusual punishment of Dr. Doe by permanently depriving him of his right to practice his profession for the rest of his life, unless relief is provided by this Court.

181. The acts of defendants in accepting, maintaining and republishing the AAR against Dr. Doe now and in the future to all inquiring hospitals and containing the assertion that he "voluntarily surrendered" clinical privileges "while under or to avoid investigation relating to professional competence" and further that the Hospital's quality review, of which Dr. Doe was not aware of and had no opportunity to participate in, "indicate[d] departures by the physician from the standard of care" in a surgical procedure, is tantamount to asserting that the accused surgeon is an incompetent surgeon, to each and every hospital to which the surgeon applies to for medical staff privileges. Since as hereinabove alleged, the effect of defendants' conduct has been and will continue to be to make Dr. Doe unemployable in his chosen profession and to earn his livelihood, the defendants' conduct is punishment that is both cruel and unusual.

182. Further, this punishment is grossly disproportionate to the alleged "offense" committed, consisting either of surrender of privileges while

under investigation or as alleged in the AAR "departure from the standard of care" in a single case wherein the patient made a full recovery and made no claims against Dr. Doe or the Hospital.

183. Furthermore, releasing such information, and including in the AAR informing the hospitals to which the information is being sent that the NPDB has determined in the Secretarial Review Decision that the AAR should not be stricken and that in words and substance it is "accurate, complete timely [and] relevant" for "agency purposes" and will be maintained in the NPDB database forever, is the Government imposing a cruel and unusual punishment.

184. Accordingly the AAR filed with and maintained by defendants as to Dr. Doe should be ordered voided, as hereinafter requested, as a violation of the Eighth Amendment.

WHEREFORE, plaintiffs pray for an order and judgment against defendants:

A. Finding and declaring that the actions of defendants were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

B. Finding and declaring that the actions of defendants in accepting and maintaining the AAR number 5500000059633157 filed against plaintiff physician without affording plaintiff physician adequate notice and opportunity to be heard on all the merits before the defendant agency is unconstitutional as being without Due Process and in violation of the Fifth Amendment, and in violation of Article I § 9 clause 3 of the United States Constitution as a Bill of Attainder and in violation of

the Eighth Amendment as a cruel and unusual punishment;

C. Finding and declaring that the actions of defendants in accepting and maintaining the AAR number 5500000059633157 filed against plaintiff physician is in violation of the Privacy Act;

D. Finding and declaring that all the materials accessible on the NPDB database concerning the plaintiff physician, including the AAR number 5500000059633157, plaintiff's Subject Statement and the Secretarial Review Decision are ordered voided and removed from the NPDB records and that all past queriers be notified of such removal and that the AAR has been withdrawn and nullified;

E. Permanently enjoining defendants, their officers, agents, servants, employees and attorneys, and their successors, and all persons in active concert or participation with any of them, from disseminating in any way any of the information previously contained in the aforesaid materials previously accessible on the NPDB database;

F. Awarding plaintiffs damages in an amount to be determined at trial for defendants' blacklisting of Dr. Doe;

G. Awarding plaintiffs their costs and attorneys' fees to the extent allowed by law; and

H. Granting plaintiffs such other and further relief as the Court deems just and proper.

Dated: New York, New York
February 22, 2013

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Certificate of Service

I hereby certify that on the 22nd day of February, 2012, I caused a true copy of the foregoing to be served upon all counsel of record in this proceeding via the Court's electronic filing system.

/s/ Barry Coburn

Appendix G

United States General Accounting Office
GAO

Report to the Chairman, Subcommittee on National Economic Growth, Natural Resources and Regulatory Affairs, Committee on Government Reform, House of Representatives

November 2000

NATIONAL PRACTITIONER DATA BANK

Major Improvements Are Needed to Enhance Data Bank's Reliability

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Contents

Abbreviations

DEA	Drug Enforcement Administration
DFO	Division of Financial Operations
EFT	electronic funds transfer
HIPDB	Healthcare Integrity Protection Data Bank
HHS	Department of Health and Human Services
HHS/OIG	HHS/Office of Inspector General
HRSA	Health Resources and Services Administration

NAIC	National Association of Insurance Commissioners
NPDB	National Practitioner Data Bank

United States General Accounting Office
Washington, D.C. 20548

November 17, 2000

The Honorable David M. McIntosh

Chairman, Subcommittee on National Economic
Growth, Natural Resources and Regulatory Affairs
Committee on Government Reform
House of Representatives

Dear Mr. Chairman:

To address concerns that states were hampered in their ability to protect the public from incompetent health care practitioners who cross state lines to continue the practice of medicine, the Health Care Quality Improvement Act of 1986 authorized the Secretary of Health and Human Services (HHS) to create the National Practitioner Data Bank (NPDB).[1] Administered by HHS' Health Resources and Services Administration (HRSA), NPDB is the nation's only central source of information on physicians, dentists, and other health care practitioners who either have been disciplined by a state licensing board, professional society, or health care provider or have been named in a medical malpractice settlement or judgment. Hospitals and other health care providers periodically access NPDB, for a fee, to obtain information on practitioners who are currently on staff, under contract, or who have

[1] P. L. 99-660, title IV.

applied for clinical privileges. Because NPDB information can affect a practitioner's reputation and livelihood, the integrity of the data bank's information has been of great concern.

Since its beginning in 1990, questions have arisen about NPDB's operational efficiency and effectiveness. We studied NPDB's early development and recommended operational and security-related improvements.[2] HRSA officials responsible for ensuring that the data bank has comprehensive information have questioned whether medical malpractice insurers and health care providers report all practitioners, as required. Officials from HHS' Office of Inspector General (HHS/OIG), who have studied and reported on the data bank, determined that a relatively small number of disciplinary actions were reported by hospitals and other health care providers and recommended that HRSA do more to address potential underreporting. In addition, various organizations representing the health care industry have periodically questioned the accuracy of information submitted to NPDB. The industry has also questioned the appropriateness of fees charged to access data and HRSA's use of these fees. Accordingly, you asked that we (1) assess HRSA's efforts to address potential underreporting to the data bank, (2) evaluate the accuracy, completeness, and timeliness of NPDB data, and (3) assess the adequacy of internal controls over user fees and

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[2] *Information System: National Health Practitioner Data Bank Has Not Been Well Managed* (GAO/IMTEC-90-68, Aug. 21, 1990), *Practitioner Data Bank: Information on Small Medical Malpractice Payments* (GAO/IMTEC-92-56, July 7, 1992), and *Health Information Systems: National Practitioner Data Bank Continues to Experience Problems* (GAO/IMTEC-93-1, Jan. 29, 1993).

expenditures to determine whether these fees are set at the appropriate level.

To address issues related to underreporting, we reviewed HRSA's operational and research plans for NPDB, related studies and documentation, and interviewed officials from HRSA, HHS/OIG, and selected health care industry representatives. To assess the accuracy, completeness, and timeliness of reported data, we worked with HRSA officials and chose September 1999 as a typical reporting period. We analyzed the reports submitted to NPDB during that month. Additionally, we obtained and analyzed information from NPDB on 34 practitioners who were reported to NPDB during September 1999. Finally, to assess the adequacy of internal controls over user fees and expenditures, we interviewed HRSA officials to understand how NPDB's user fees are determined, collected, and disbursed. We also reviewed applicable laws, regulations, and other guidance concerning user fees, and tested a sample of the data bank's disbursements made between October 1994 and May 2000. We conducted our audit work between January 2000 and September 2000 in accordance with generally accepted government auditing standards. (See app. I for more detailed information on our scope and methodology.)

Results in Brief

Although HRSA has long been concerned that underreporting weakens NPDB's reliability, steps for addressing such issues are not part of the agency's strategic plan. As a result, HRSA's efforts to quantify or minimize underreporting have been unsuccessful. For example, the agency has focused on the underreporting of malpractice payments even though

HHS/OIG and HRSA-sponsored studies conclude that underreporting of clinical privilege restrictions by hospitals and other health care providers is a more pressing issue. Industry experts also agree, pointing out that disciplinary actions taken by health care providers and states are better indicators of professional competence than medical malpractice. However, HRSA has made little progress in addressing suspected underreporting by health care providers. HRSA officials said that additional resources and skills are needed to monitor and sanction nonreporters effectively. Also, HRSA has not implemented a 13-year-old law that expanded NPDB to include information on nurses and other health care practitioners. As a result, disciplinary actions taken against nurses and other practitioners are not reported to NPDB, despite these individuals' increasing importance in the delivery of health care.

Problems that we identified in the data submitted to NPDB during September 1999 raise concerns about the effectiveness of HRSA's management of the data bank and of the two mechanisms—practitioner notification and dispute resolution—that are intended to ensure the quality of reported information. We identified problems particular to each of the three types of reports we reviewed. The data in medical malpractice payment reports—representing about 80 percent of the information in NPDB—generally did not meet HRSA's criteria for completeness. For example, over 95 percent of the medical malpractice reports we reviewed did not note whether the standard of patient care had been considered when the claim was settled or adjudicated. Further, our analysis of 252 reports of state licensure actions revealed that about 30 percent were submitted late and 11 percent contained inaccurate or misleading

information on the severity or number of times practitioners had been disciplined. We also found inaccurate information in about one-third of the 79 clinical privilege restriction reports we reviewed.

Finally, our review disclosed that HRSA has not adequately examined whether the level of user fees used to finance NPDB operations is appropriate. HRSA does not have a plan that projects cash flows such as revenue, disbursements, and capital investments. Such a plan is needed to determine if the level of fees is appropriate and if HRSA's long-standing policy of maintaining a cash balance of 4 to 6 months of operating expenses is still reasonable. HRSA has not reassessed the amount needed to cover operating expenses since 1994. As of the end of fiscal year 1999, it had a $6.8 million cash balance. We also found that controls over NPDB transactions did not ensure that all collections were received and that disbursements were for authorized purposes. For example, HRSA and HHS' Division of Financial Operations (DFO), which performs the accounting functions, do not have adequate controls to ensure that all assessed user fees are collected and properly recorded in HRSA's general ledger. HRSA and DFO also could not ensure that user fees collected electronically—presently about 30 percent of NPDB's receipts—were properly allocated between NPDB and another data bank the agency also manages. Additionally, we found that controls over disbursements were not effective, as supporting documentation was sometimes missing or inadequate.

We are making several recommendations to the Secretary of HHS, the Administrator of HRSA, and the Director of HHS/DFO to improve both the operation and the financial management of the data bank. In its written comments on a draft of this

report, HHS concurred with our recommendations to improve compliance monitoring and enforcement, allocate user fees appropriately, and develop criteria for the narrative section of disciplinary action reports. HHS also described actions it is taking or plans to take. HHS did not concur with our specific recommendations to improve the reliability of reported information and to strengthen its internal controls over NPDB user fee collections and disbursements. However, we believe that actions on these recommendations are necessary to enhance the accuracy, completeness, and timeliness of NPDB's information and to improve internal controls and financial operations.

Background

In 1986, the Congress found that there was a need nationally to restrict the ability of incompetent practitioners to move between states without disclosure or discovery of their professional histories. Moreover, it was determined that states and individual organizations, acting independently, might not be able to do so. While there were several private and nonprofit organizations that collected data on state disciplinary actions, these groups did not have access to information either on the disciplinary actions taken by health care providers or on medical malpractice cases. As a result, the Congress created NPDB as the nation's central source of such information on health care practitioners.

HRSA has federal oversight responsibility for NPDB. As such, it has developed rules and regulations for reporting information and accessing NPDB. The instructions for reporting practitioner information to NPDB and for accessing the data bank, which is known

as querying, are spelled out in the *NPDB Guidebook*, updated January 1999. HRSA is also responsible for ensuring health care industry compliance with reporting and querying requirements. A private contractor operates the data bank for HRSA.[3]

In 1988, HRSA commissioned a group of health care industry representatives and advocates to provide continual advice to its contractor on NPDB operational issues. This group, the NPDB Executive Committee, includes various health care industry representatives from organizations such as accrediting bodies and licensing boards, hospitals and other providers, malpractice insurers, professional societies, and others. With the advice of the NPDB Executive Committee, HRSA and its contractors developed and customized the software applications used to collect reports on practitioners and respond to user queries.

The Health Care Quality Improvement Act of 1986 also established criteria for reporting practitioners to NPDB. The requirements for reporters—malpractice insurers, health care providers, state licensing boards, and federal agencies—essentially parallel their areas of responsibility. Entities such as insurance companies must report practitioners on whose behalf medical malpractice payments are made. State licensing boards must report practitioners whom they have disciplined.[4] Health care providers such as hospitals and health plans

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[3] Several different private contractors have operated and maintained NPDB since it began operations Sept. 1, 1990. The current contractor has been operating NPDB since June 1995.

[4] According to the *NPDB Guidebook*, state licensing boards are required to report disciplinary actions such as revocations, suspensions, reprimands, and fines associated with license restrictions.

must report disciplinary actions restricting practitioners' clinical privileges for more than 30 days. In addition, professional societies such as the American Medical Association and the American Dental Association must report actions that adversely affect a practitioner's membership in the society. Finally, the law directed HRSA to negotiate Memorandums of Understanding with selected federal agencies, outlining the terms for reporting practitioners that they employ, insure, or regulate.[5]

Time frames for reporting the required information are set in the law, regulation, or *NPDB Guidebook*. Medical malpractice payments must be reported to NPDB within 30 days of the date of the initial payment. Health care providers that report electronically have up to 15 days to report simultaneously to NPDB and the applicable state licensing board. Providers submitting paper reports have up to 15 days to send reports to the applicable state licensing board. State boards have 15 days to forward paper reports to NPDB. State licensing actions against practitioners must be reported within 30 days. Professional societies must report actions taken against practitioners' memberships within 15 days. Some federal agencies, in their Memorandums of Understanding with HRSA, also agreed to report malpractice payments and disciplinary actions within 30 days of the payment or action.

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[5] The law specifically directed HRSA to negotiate Memorandums of Understanding with the Department of Defense, the Department of Veterans Affairs, and the Drug Enforcement Administration (DEA). HRSA also has agreements with the Department of Transportation (U.S. Coast Guard), the Bureau of Prisons, and with the U.S. Public Health Service for reporting its physicians and dentists, including those working in community health centers or the Indian Health Service.

Since 1986, NPDB has been expanded to include additional information and other categories of health care practitioners who must be reported. The Medicare and Medicaid Patient and Program Protection Act of 1987, as amended, requires that states have a system for reporting licensure actions taken against nurses and other state-licensed health care practitioners such as chiropractors, emergency medical technicians, and physical therapists to NPDB.[6] Since 1997, under an agreement among the HHS/OIG, HRSA, and the Health Care Financing Administration, practitioners who are excluded from participation in the Medicare and Medicaid federal health care programs due to fraudulent or abusive activities or who default on federal loan agreements are also reported to NPDB.[7]

The law also has provisions regarding access to and use of information contained in the data bank. Hospitals are required to query NPDB whenever a practitioner applies for clinical privileges and every 2 years for practitioners already on staff. State licensing boards, professional societies, and certain other types of health care providers are permitted to query but are not required to do so. Individual practitioners can query NPDB but only to obtain

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[6] P. L. 100-93.

[7] The HHS/OIG's exclusion list provides information on individuals and organizations that are excluded from participation in Medicare, Medicaid, and other federal health care programs because of criminal convictions related to Medicare or state health programs, patient abuse or neglect, felony convictions related to controlled substances, health care fraud, and other criteria such as defaulting on federal loans and license revocations. As of January 1999, there were more than 15,000 individuals and entities excluded from program participation.

information on themselves.[8] Under current law, malpractice insurers, advocacy groups, and the public cannot query NPDB; however, selected information that does not identify individual practitioners is available for purchase in a public use data file.[9]

NPDB's operations are to be completely funded by the fees charged to users. Fees are imposed for each practitioner's name queried and must be sufficient to cover the cost of collecting reports and releasing query information.[10] HRSA is responsible for setting these fees.[11] In fiscal year 1999, HRSA collected about $14 million in user fees, disbursed about $12 million for NPDB expenses, and had a cash balance of $6.8 million.

Civil penalties can be assessed for nonreporting and for unauthorized use of NPDB information. Entities failing to report medical malpractice payments can be assessed up to $11,000 for each unreported payment.

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[8] Practitioners who query the data bank for information about themselves are charged $10. They complete an Internet-based form that can be accessed from NPDB's home page. The completed form must be notarized and mailed to the NPDB contractor for processing.

[9] Plaintiffs' attorneys or plaintiffs acting on their own behalf may query NPDB only if they can independently prove that a hospital did not perform the query, as required by law, and a medical malpractice suit against that hospital, naming the specific practitioner among the defendants, has been filed in court. However, they may not query for information when suing practitioners.

[10] Users who submit queries via the Internet are charged $4 per practitioner name, while those submitting queries on diskette are charged $7 per practitioner.

[11] The Secretary of Health and Human Services approves user fees for NPDB queries and publishes these fees periodically in the *Federal Register*.

HRSA can also impose penalties of up to $11,000 for each instance of unauthorized access or improper distribution of NPDB information. There are no financial penalties for states, health care providers, or federal agencies that do not report practitioners to NPDB. HRSA officials said that several organizations have been fined for unauthorized access but none for not reporting to the data bank. HRSA cannot penalize organizations that do not report the required information on time.

Efforts to Address Underreporting Have Been Unsuccessful

Although HRSA has long suspected that some organizations do not report practitioners as required, the agency has not included steps for addressing underreporting in its strategic plan, nor has it taken a systematic approach to the problem. Most of HRSA's efforts to address underreporting have focused on medical malpractice insurers, while HHS/OIG and HRSA-sponsored studies have concluded that underreporting of clinical privilege restrictions by hospitals and other health care providers is a larger and more pressing issue. Moreover, experts widely agree that disciplinary actions taken by state licensing boards and health care providers are better indicators of professional competence than malpractice settlements. Yet, very little has been done to address suspected underreporting among health care providers. Further, disciplinary actions taken against nurses and other health care practitioners are not being reported to NPDB because HRSA has not yet implemented the law. According to HRSA's management, additional staff and resources would be needed for the agency to identify and take effective

action against organizations suspected of underreporting to the data bank.

Medical Malpractice Underreporting is a Long-Standing Problem

Although HRSA has been concerned that malpractice payments are underreported, it has not been able to determine the magnitude of the problem despite many years of effort. Medical malpractice payments can be underreported in two ways, neither of which has been successfully quantified. First, agency officials believe that some insurers may be using a technicality in NPDB's reporting requirements to avoid reporting some practitioners. Second, agency officials believe that some insurers and self-insured organizations such as HMOs and other health plans should report to NPDB but do not. However, HRSA has not yet identified or fined any organizations for failing to report the required information. Agency officials told us that they are reluctant to impose fines because they believe that the cost of levying and collecting civil penalties often exceeds the $11,000 maximum amount that can be assessed.

Soon after NPDB began operating in 1990, HRSA officials became aware that under the data bank's regulations, some practitioners, who may have committed malpractice, were not being reported because of what has become known as the "corporate shield." NPDB regulations require that only the practitioners named in final malpractice settlements be reported to the data bank. The corporate shield occurs when individuals filing malpractice claims remove the practitioner's name from the claim, leaving only the hospital or another corporate entity identified as the responsible party. When this

happens, no report is submitted to NPDB. HRSA officials believe that practitioners who have committed malpractice use the corporate shield to avoid being reported. However, they have not been able to quantify the extent to which the corporate shield is used for such purposes. In addition, the agency has not found a means of successfully addressing this issue in a way that would also have the support of industry representatives on NPDB's Executive Committee, who could facilitate compliance by persuading member organizations to adopt this policy change.

In December 1998, HRSA proposed changing NPDB's malpractice payment reporting regulations. The proposal would have required that insurers report all practitioners for whose benefit a payment is made, including those practitioners who might not have been named in the final settlement or even in the initial malpractice claim. The health care industry—including those organizations on NPDB's Executive Committee—overwhelmingly opposed the proposal, arguing that it would interfere with settlement negotiations between the insurer and the claimant. The industry also argued that reporting all initially named practitioners would deny due process to those not found liable by the court. HRSA subsequently withdrew the proposal and initiated other strategies to solve this problem while working to gain NPDB Executive Committee support for a change in medical malpractice reporting requirements.

HRSA officials have begun to work more closely with the NPDB Executive Committee to obtain its input and gain consensus before finalizing a new proposal. Two proposals have recently emerged from this collaboration and will be circulated within HRSA and the full Executive Committee for comment. The first

proposal would require insurers to report to NPDB the names of corporations and individual practitioners named in malpractice settlements or judgments. HRSA officials told us that by collecting information on corporations, they will have more complete data on the total number of claims settled or adjudicated, which will help them identify specific instances when the corporate shield has been used. However, they acknowledge that the proposal to report corporations does not fully solve the problem.

The second proposal would permit peer review organizations to determine which practitioners involved in malpractice settlements should be reported to NPDB. The Department of Defense and the Department of Veterans Affairs—two large federal health care providers—both have peer review processes for reporting practitioners to NPDB. As outlined in their Memorandums of Understanding with HRSA, only those identified by their agencies' peer review processes as responsible for injuring a patient or violating standards of patient care are reported. However, HRSA officials told us that they are presently concerned about the limited quantity and timeliness of reports that are submitted following the federal agencies' peer review processes. Further, this proposed alternative might require congressional action because NPDB's authorizing legislation does not provide for peer review of malpractice settlements or specify that HRSA can use the fees it collects for queries to fund this activity.

In addition to these efforts to alleviate the use of the corporate shield, HRSA officials told us that, since early 2000, they have been trying to identify insurers that have paid medical malpractice claims but have not reported the involved practitioners to NPDB. Using malpractice claims data that insurance

companies voluntarily report to the National Association of Insurance Commissioners (NAIC), the agency identified 41 insurers that reported payments to NAIC but not to NPDB. HRSA contacted these companies seeking explanations regarding the differences in the reported payments. As of September 2000, 17 of the 41 companies have adequately explained the discrepancies to HRSA. For instance, NAIC data, for some companies, reflect total payments made by their corporations—combining payments made on behalf of individual practitioners with payments made on behalf of organizations. NPDB data only represent payments made on behalf of individual practitioners. Of the remaining 24 companies, 18 recognized their omissions and agreed to file the delinquent reports. The other six companies have not responded to HRSA's inquiries and have been warned by the agency that they will be reported to HHS/OIG for possible enforcement action.

Although HRSA has had some success in identifying nonreporters using NAIC data, agency officials acknowledged that these data have some significant limitations. NAIC's medical malpractice data are not comprehensive because companies report this information voluntarily. Moreover, they do not include payments made by self-insured organizations, such as health maintenance organizations and other health plans that do not report to NAIC. Also, as previously noted, NAIC data combine the payments made on behalf of practitioners with those made on behalf of institutions. Because HRSA could not independently reconcile NAIC and NPDB data, agency officials had to rely on insurers' explanations as to whether reports should have been submitted or not.

Underreporting of Clinical Privilege Restrictions Is Another Long-Standing Concern

HRSA and the HHS/OIG have been concerned about the relatively low number of reported clinical privilege restrictions since NPDB's early years of operation. While early estimates projected that as many as 10,000 clinical privilege restrictions would be reported annually, fewer than 9,000 reports were submitted from 1990 through 1999. Concerned with the contrast between the early estimates and the number of clinical privilege restrictions being reported, HRSA management asked HHS/OIG and others to study the issue. HHS/OIG concluded that providers are more likely to report if there are penalties for nonreporting and recommended that HRSA seek legislative authority to fine nonreporting providers, comparable to its authority to fine malpractice insurers. Although HRSA generally concurred with HHS/OIG's July 1999 recommendation, the agency did not act on it until late July 2000.

HRSA officials acknowledge that the agency has not been successful in encouraging provider compliance with clinical privilege reporting requirements. HRSA officials believe that to improve compliance significantly, the agency needs more than the ability to fine providers. They noted that the states report licensure actions, as required, but providers' reporting of clinical privilege restrictions have always fallen far short of the agency's projections. Before NPDB began operations, the Public Health Service projected that about 5,000 clinical privilege restrictions would be reported annually. The American Medical Association estimated there would be as many as 10,000 reports per year. As of the end of

calendar year 1999—after 9 years of operation—NPDB had received fewer than 8,600 clinical privilege restriction reports.

HRSA officials told us that the original estimates may have been too high and that, over time, changes in industry practices may have resulted in different approaches to disciplining practitioners. Industry representatives told us that hospitals now provide more monitoring and training to address performance problems than at the time the Public Health Service and the American Medical Association estimates were made. This new approach to disciplining practitioners may reduce the number of restrictions that hospitals impose for more than 30 days and thus reduce the number of individuals who would be reported to NPDB. NPDB's authorizing legislation does not require that the data bank collect information on practitioners targeted for special monitoring or training.

In July 1999, an HHS/OIG study recommended that HRSA seek authority to fine nonreporting providers. HRSA officials told us that in late July 2000, they asked HHS to pursue legislation allowing the agency to fine health care providers up to $25,000 when specific instances of noncompliance are identified. However, HRSA does not currently have the authority to access the confidential peer review records that hospitals and other health care providers maintain on practitioner performance. HRSA officials told us that the agency would need this additional authority and staff skilled in investigating specific instances of noncompliance to monitor and sanction nonreporters effectively. Recognizing that additional funding and skilled staff might not be forthcoming, agency officials have begun to develop a compliance monitoring plan that less specialized personnel could

perform. Agency officials said they are hopeful that the plan would be implemented in fiscal year 2001.

13-Year-Old Law Awaits Implementation

HRSA has not implemented a law passed in 1987 that would have significantly increased the information reported to NPDB. The Medicare and Medicaid Patient and Program Protection Act of 1987 directed the states to have systems of reporting licensure actions taken against nurses and other licensed health care practitioners. Today, nurses and other licensed practitioners play an even more important role in the provision of health care. The law was amended in 1990 to include state reporting of adverse actions taken by peer review and accrediting organizations against nurses and other practitioners. HRSA officials told us that they did not implement this law when NPDB began operating in 1990 because the agency lacked the funding to include information on these additional practitioners in the data bank. According to HRSA officials, the HHS General Counsel initially advised the agency that it could not impose user fees to cover the cost of collecting and disseminating this additional information, but it has since reversed that opinion.

By July 1998, HRSA had drafted reporting regulations and had modified the data bank's software to accommodate additional categories of practitioners. Nonetheless, implementation was postponed pending start-up of a new fraud and abuse data bank, the Healthcare Integrity Protection Data Bank (HIPDB), which HRSA manages for HHS/OIG.[12] HRSA officials told us that they made

[12] As authorized by the Health Insurance Portability and Accountability Act of 1996, HIPDB is a central source of

this decision because, in their opinion, expanding NPDB at the same time the agency initiated HIPDB might have confused the data banks' users. For instance, some state actions, such as denied licensure renewals, are reported to both data banks. Other actions, such as denied initial licenses, are only reported to HIPDB.

Recognizing the potential burden and confusion that users might face, the Congress directed that duplicative reporting requirements be avoided. As a result, HRSA developed a single system for users to access both data banks. This Internet-based system became operational in November 1999 and by October 2000 was the only way authorized organizations could report to or query the data banks.[13] With this system, users only need to report information once. Information is automatically distributed to one or both data banks, as appropriate. For example, state licensure actions taken against physicians and dentists are routed to both data banks, while actions taken against nurses and other licensed practitioners are presently routed only to HIPDB.

Currently, hospitals are not authorized access to HIPDB. As a result, they cannot obtain information on licensure actions that states take against nurses and other licensed practitioners. For instance, while

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information on final actions that states and courts have taken against individuals and companies found guilty of health care fraud or abuse. It contains data on health-care-related criminal convictions and civil judgments, as well as the names of individuals and companies excluded from participation in federal health programs. NPDB, on the other hand, collects information on individuals whose professional competence may be at issue.

[13] Individual practitioners, who can only access information about themselves, must submit their queries on paper.

the state of Illinois reports at least 15 such actions each month, hospitals cannot obtain that information from HIPDB. HRSA officials told us that they have suggested a technical modification to HIPDB's authorizing legislation that would allow hospitals to access the data bank. While this would provide hospitals access to information on licensing actions, we believe that this is only a partial solution because the actions taken by peer review and accrediting organizations are not reported to HIPDB.

HRSA officials told us that they support HHS/OIG's suggestion that NPDB and HIPDB be combined into a single data bank and are working with members of HHS/OIG General Counsel's office to develop a legislative proposal. However, work on the legislative proposal has just begun and, if enacted, may take several years before a combined data bank would be available to users. In the interim, HHS/OIG officials have informed HRSA that they are concerned that the agency might again delay implementing the 1987 law. HRSA management officials told us that aside from seeking statutory changes—allowing hospital access to HIPDB and combining the two data banks—they do not have any other immediate plans for including actions taken against nurses and other practitioners in NPDB.

Weaknesses in NPDB Data Limit Their Usefulness

The quality of some of the reports we reviewed suggests weaknesses in the data bank's reliability. We found problems with each of three types of reports we analyzed—malpractice payments, state licensure actions, and clinical privilege restrictions. Medical malpractice payment reports, which comprise 80

percent of the data bank, generally did not meet HRSA's criteria for completeness. We also found that reports from state licensing boards and health care providers were, at times, untimely, inaccurate, or submitted in duplicate, which made it appear that twice the number of disciplinary actions against a practitioner had been taken. Moreover, when mistakes were made, practitioners had difficulty getting the reported information corrected.

HRSA officials acknowledged that there are problems with the accuracy and completeness of the data and that they have been working with consultants to revise the way information reported to the data bank is coded. Agency officials said they are considering revisions to the coding scheme to improve the accuracy and completeness of reports. They have also begun working with the NPDB contractor to remove duplicate reports from the data bank. They also acknowledged that some reports are submitted late, but they have not sought the additional authority to fine late reporters. Agency officials also realize that practitioners can face difficulties in correcting reported information. However, they said that NPDB's practitioner notification and dispute resolution processes adequately address individual concerns while maintaining the data bank's integrity.

Test Results Revealed Lags and Gaps in NPDB Submissions

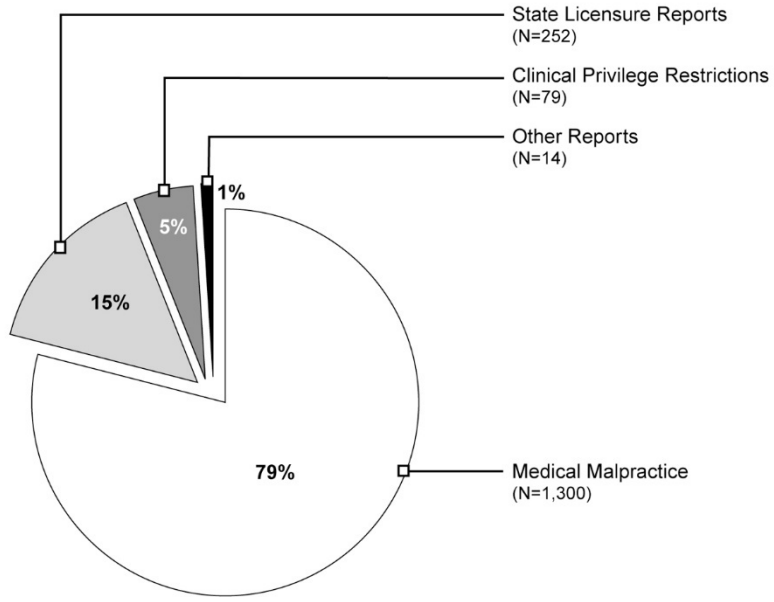
To evaluate the reliability of NPDB information, we obtained electronic copies of the 1,645 reports submitted to the data bank during September 1999. In general, we analyzed the timeliness of reports by comparing the dates they were submitted with NPDB's reporting time frames. We assessed the

completeness of reports by comparing information in them with NPDB's criteria for the items of information that should be reported. Because NPDB is the only central source for much of the information it contains, we assessed accuracy by determining the internal consistency of the narrative and coded information in individual reports. (See app. I for a more detailed description of the types of reports submitted in September 1999.)

As figure 1 indicates, nearly 80 percent of the reports submitted to NPDB during September 1999 were related to medical malpractice payments. This percentage is somewhat comparable to the data bank's cumulative totals. Since 1990, almost 173,000 out of approximately 228,000 NPDB reports—or 76 percent—involved malpractice.

Clinical privilege restrictions comprise 5 percent of the September 1999 reports and less than 4 percent of NPDB's cumulative totals. On average, fewer than 1,000 such reports are submitted annually. HRSA officials estimate that about 60 percent of the nation's hospitals had never reported a practitioner to NPDB. Officials arrived at this figure by comparing the list of authorized reporters with those entities that have submitted at least one report to NPDB since it began operating in 1990. While the estimate may include entities that may no longer exist or that may have more than one authorization number, it appears that many of the nation's hospitals have never reported to NPDB.

Figure 1: Percentage of Report Types Submitted to NPDB, September 1999



Source: GAO analysis of September 1999 NPDB reports.

Our analysis revealed weaknesses in the timeliness and currency of medical malpractice payment reports. About 25 percent (331) of the 1,300 malpractice reports received in September 1999 were not submitted to NPDB within 30 days of the initial payment, as required. On average, these reports were about 85 days late. About 30 percent (76) of the state licensure reports submitted during September 1999 were late by an average of 61 days. As noted in figure 2, our analysis of these late submissions showed that one-third of state licensure reports and almost one-half of medical malpractice reports were 31 or more days late. We did not measure the timeliness of

reports submitted by hospitals and other health care providers.[14]

HRSA does not track the timeliness of reports submitted and does not have the authority to sanction late reporters. Agency officials told us that penalizing late reporters may have a chilling effect on submissions.

The timely submission of information does not necessarily ensure that information about practitioners is quickly available. The malpractice payments reported in September 1999 involved incidents that occurred, on average, 4-1/2 years earlier. The median time was 4 years, which is not an unusual length of time to resolve malpractice claims. During the time it takes to resolve claims and report malpractice payment information, practitioners could move between states or change health care providers.

In addition to the lateness and dated nature of reported information, our analysis also revealed some delays in getting reports into NPDB. For 512 reports, or more than 30 percent of the September reports, we noted delays between the date the report was submitted to NPDB and the date that the information was incorporated into the data bank. These delays ranged from 5 days to more than 1 year. The median processing delay was about 13 days. HRSA officials were unaware of the lengthier delays. They explained

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[14] Health care providers have two options for submitting reports to NPDB, with different reporting deadlines for each. Electronic submissions have a 15-day deadline, while paper submissions pass through the state licensing board and are allowed up to 30 days to reach NPDB. From the information we obtained from NPDB, we could not determine which reporting option was used. As a result, we could not measure the timeliness of clinical privilege restrictions.

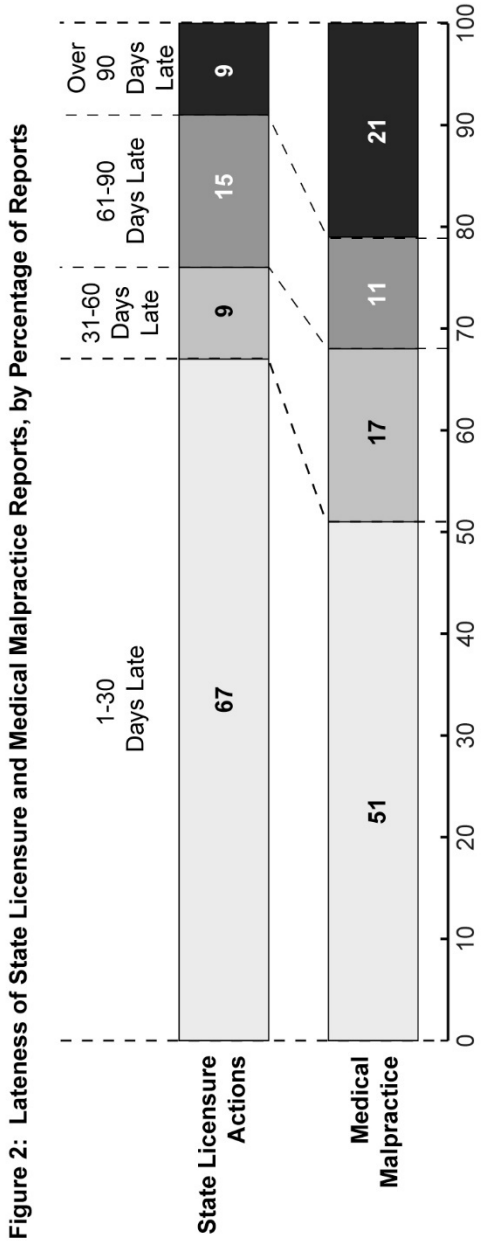

Figure 2: Lateness of State Licensure and Medical Malpractice Reports, by Percentage of Reports

Source: GAO analysis of 331 medical malpractice and 76 state licensure reports submitted to NPDB in September 1999.

the shorter delays by noting that, at times, organizations do not submit reports on the dates indicated. However, we could not determine how frequently reports had the wrong submission date and could not adjust our analysis to take this into consideration. Nonetheless, late and delayed reports can weaken NPDB's reliability as a mechanism for alerting others of potential problems with a practitioner's past performance.

HRSA officials told us that NPDB's new Internet-based reporting and querying system would alleviate processing delays by instantaneously incorporating submitted information into the data bank. As of October 1, 2000, the new Internet-based system became the primary means of reporting information to NPDB. However, instantaneous processing, without other improvements in the data bank's software controls, may exacerbate the problems of incomplete and inaccurate reporting that we found.

Malpractice Payment Reports Were Incomplete and Included Inappropriate Information

We found that the usefulness of NPDB's medical malpractice data was further compromised by the data bank's acceptance of incomplete report submissions. We selected 250 of the 1,300 malpractice reports submitted in September 1999 for a more detailed review and found that only 1 met NPDB requirements for disclosing the circumstances associated with payments. The *NPDB Guidebook* recommends that narrative descriptions include at least seven items of information describing the events leading up to the medical malpractice claim. Such information can help users identify potential weaknesses or problems in a practitioner's past

performance. Some items are descriptive, such as patient age, gender, and inpatient or outpatient status. However, others, such as the initial event or diagnosis and standard of patient care, relate more to the quality of practitioner performance. As table 1 shows, more than 95 percent of the malpractice reports in our sample did not mention whether the standard of patient care had been considered when the claim was settled or adjudicated. Moreover, of those reports whose narrative mentioned that the standard of patient care had been considered, only one noted the actual determination.[15]

Table 1: Malpractice Reports Submitted to NPDB, by Items of Information Missing

Items of information	Number of reports missing information	Percentage of GAO sample
Patient age	134	53.6
Patient gender	108	43.2
Patient type	199	79.6
Initial event (procedure/diagnosis)	68	27.2
Subsequent event	37	14.8
Damages (medical or legal)	61	24.4
Standard of patient care determination	239	95.6

Source: GAO analysis of 250 reports.

HRSA officials acknowledged that medical malpractice reports are often incomplete and explained that reports are submitted electronically and are not manually screened before acceptance into the data bank. They explained that NPDB's software only checks for the presence of text in the narrative section of malpractice reports. It does not verify that all seven items of information are present. They also

[15] Our analysis did not reveal any substantive difference in the completeness of reports involving settlements compared with those involving court judgments.

told us that NPDB contract staff do not routinely review the narratives and thus would not request additional narrative information, even if the narrative was incomplete or uninformative. NPDB contract staff only examine reports when there is a need to verify that a query has resulted in identifying the correct practitioner.[16] If staff note obvious errors or questionable information, the reporting institution is contacted and, if necessary, asked to submit a corrected report. Contract staff are not authorized to change any of the information reported to NPDB.

In addition to the problems of untimely and incomplete submissions, we also found that 71 of the 250 medical malpractice reports included patient and practitioner names in the narrative sections of the reports, in violation of NPDB reporting instructions. HRSA officials said that they were aware of the problem but had not found a cost-effective method for removing names. At one point, the NPDB contractor tested a "name-filtering" program that could be added to NPDB's software to detect and remove names inappropriately included in the narrative sections. However, the test was not successful because the program could not distinguish between individuals' names that should be removed and other names that could be included, such as those of institutions or street names. HRSA officials said they do not ask entities reporting information to NPDB to revise their submissions when names are included in the narrative.

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[16] NPDB uses a matching algorithm that compares queries with information in the data bank. Before NPDB determines that it has matched a query with the correct practitioner, a certain level of information must be identical. If NPDB identifies a potential but not definite match, an NPDB contract staff member compares information to verify the match.

Licensure Reports Were Inaccurate, Inconsistent, and Submitted in Duplicate

Our analysis of 266 licensure action reports, which includes 14 actions reported by the U.S. Drug Enforcement Administration (DEA) and professional societies, indicated additional weaknesses in NPDB's reliability.[17] As table 2 shows, 24 of the 252 reports submitted by state licensing boards contained errors that could confuse or mislead querying organizations about the severity of sanctions imposed. These errors were related to the way sanctions were coded in the reports submitted by state licensing boards. For example, several reports indicated that practitioners' licenses had been restored or reinstated when, in fact, they had been placed on probation. Other reports indicated that practitioners had been reprimanded when, instead, restrictions had been placed on their licenses. Other reports did not contain sufficient detail in the narrative section for us to determine whether they had been coded accurately.

HRSA has not established criteria for the information that should be included in the narrative sections of state licensure reports. Our analysis of the reports submitted in September 1999 revealed considerable variation in the amount and quality of narrative information. Some reports included sufficient detail to indicate why practitioners were disciplined. Others, however, contained insufficient explanations of disciplinary actions. For example, 26 of the state licensure reports we reviewed were based on actions taken by another state. The narrative sections of more than one-half of these reports did not note which

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[17] NPDB classifies reports submitted by DEA and professional societies as licensure actions.

Table 2: Disciplinary Action Reports Submitted to NPDB

Source of reports submitted to NPDB	Miscoded	Detail insufficient to verify coding	Number in sample
State licensing boards	24	57	252
Health care providers (clinical privilege restrictions)	23	3	79
Professional societies	0	4	7
DEA	0	7	7
Total	**47**	**71**	**345**

Source: GAO analysis.

state initially took action or why. In theory, organizations querying NPDB should receive information from all the states that have sanctioned practitioners. However, if the initial action was reported late—as 30 percent of the state reports we

reviewed were—or not at all, organizations querying NPDB might not be able to identify the appropriate state to contact to obtain additional information on the initial licensure action.

We also found reports that may have been inadvertently submitted twice to NPDB, making it appear as though practitioners had been disciplined more than once for the same offense in a relatively short time. We queried NPDB for information on four practitioners who were reported at least twice during September 1999 and found that the narrative sections of state licensure reports, in particular, lacked sufficient detail to determine whether they were duplicates or reports of separate actions taken against practitioners. For example, a state reported that a practitioner's license was surrendered twice within 1 week. The response we obtained to our query indicated that the second report had been erroneously submitted.

In another instance, a state reported issuing a public letter of reprimand because of the poor condition of a practitioner's medical records. Approximately 1 week later, the state submitted an identical report to NPDB. The information we received in response to our query did not provide sufficient detail to determine if the practitioner had been reprimanded once or twice for poor recordkeeping. Although NPDB software routinely generates notices to practitioners who have been reported to NPDB, practitioners may not realize that a second report notification may indicate that a duplicate report had been submitted. HRSA officials informed us that they have directed the NPDB contractor to begin identifying and removing duplicate reports from the data bank during the next contract year.

Clinical Privilege Restriction Reports Were Miscoded and Included Inappropriate Information

As with state licensure action reports, the reports that hospitals and other health care providers submitted on clinical privilege restrictions also contained errors affecting the accuracy of NPDB information. We found coding errors in about one-third of the 79 clinical privilege restriction reports we reviewed. Several health care providers used codes that indicated licensure actions had been taken when, in fact, the practitioners' clinical privileges had been restricted. In another instance, a provider coded a report as though the practitioner's privileges had been restricted, while the narrative section stated that the application for privileges had been denied. While the narrative sections of clinical privilege reports generally contained sufficient information to discern which actions were taken, those purchasing copies of NPDB's public use file do not receive the narratives and thus might be misled about the severity of disciplinary actions taken against practitioners.

HRSA has not set criteria for the narrative sections of clinical privilege restriction reports but has been working with consultants to identify ways to improve the level of detail and consistency of reported information. A recently completed study recommended that HRSA revise NPDB's new Internet-based reporting format so that guidance specific to each type of disciplinary action is displayed as the reporter keys in the narrative information. For example, health care providers submitting reports on clinical privilege restrictions imposed due to alcohol or substance abuse would be instructed to include

information in the narrative about the specific circumstances under which the practitioner displayed a substance abuse problem. Similarly, providers reporting practitioners whose privileges were restricted because of incompetence would be instructed to state specifically what the practitioner did or did not do.

HRSA officials told us that some of the study's recommended changes might be too detailed to implement. They said that, in the past, reporters have tended to select the top few choices for coding actions and might not review an even longer list before selecting the most appropriate code. Furthermore, HRSA officials' analysis of the extensive use of the "not otherwise classified" category has led them to believe that some reporters prefer to be less specific when reporting practitioners to the data bank. As of December 31, 1998, 49 percent of the reports concerning disciplinary actions were coded as not otherwise classified, while 34 percent of the malpractice reports were so coded. HRSA officials said that they are reviewing the study's recommendations to determine which ones are feasible for implementation.

Controls Do Not Ensure Reporting Accuracy

HRSA officials cited practitioner notifications and the dispute resolution process as two control mechanisms that ensure the accuracy of information reported to NPDB. However, our analysis of reports submitted to the data bank and the results of our queries for information on particular practitioners suggest that these controls have not prevented erroneous information from remaining in the data bank once it is reported. As previously noted, there are

instances—such as duplicate reports—when practitioners are notified but may not realize that the same information has been erroneously reported twice.

One NPDB Executive Committee member we spoke with told us that it is very difficult to get information in the data bank corrected—and costly, if practitioners get legal assistance. We found several examples of this. For instance, on September 1, 1999, a hospital reported restricting a practitioner's privileges because of poor recordkeeping. The practitioner disputed the report, noting that the hospital planned to monitor his medical records and not restrict clinical privileges. About 1 week later, the hospital attempted to correct the information, requesting that NPDB cancel the initial report. However, in doing so, the hospital incorrectly coded the action as a state license revocation. As of July 2000, when we queried NPDB, the incorrect information on the initial restriction and the erroneously reported licensure revocation were still in the data bank.

Our July 2000 query also yielded information on a practitioner that, based on our analysis, should no longer be available to organizations querying the data bank. In this instance, a state reported revoking a license because the practitioner did not meet its continuing medical education requirements. The practitioner disputed the report and supplied evidence to the state of its error. Although the state reported the mistake to NPDB in February 2000, we received both reports in response to our query, indicating that the information had not been expunged. These reports would likely be of particular concern to the practitioner because this was the only information that NPDB had on this individual. HRSA

officials said that while there may be instances when practitioners have difficulty getting reported information corrected, the practitioner notification and dispute resolution processes are generally adequate to address most problems.

User Fee Structure Not Validated and Controls Over Collections and Disbursements are Inadequate

As stated earlier, NPDB operations are funded by the fees that users pay to query the data bank for information on practitioners.[18] HRSA does not receive a separate appropriation for these purposes. In fiscal year 1999, HRSA collected $14 million in user fees, disbursed about $12 million, and had a $6.8 million cash balance at the end of fiscal year 1999. In recent years, HRSA has not adequately examined whether the level of the user fees to finance NPDB operations is appropriate. In reviewing the collection and disbursement activities, we also found that controls over NPDB transactions did not ensure that all collections were received and that disbursements were for authorized purposes.

At the end of fiscal year 1994, NPDB had a cash balance of $3.3 million. As table 3 shows, this balance

[18] Section 427(b) of the Health Care Quality Improvement Act of 1986, as amended in 1987, states that user fees may not exceed the costs of "processing the requests for disclosure and providing such information." However, beginning with the HHS appropriation act for fiscal year 1993 and each year through fiscal year 2000, an additional provision has been included regarding user fees. The provision states that, in addition to user fees authorized by section 427(b) of the 1986 act, fees shall be collected for the full disclosure of information and be "sufficient to recover the full costs of operating" the data bank.

has fluctuated over the last 5 years. Officials told us these fluctuations occurred because some of these funds were used for software and hardware enhancements to NPDB.

Table 3: 5-Year Trend in Accumulated NPDB Fees (in Millions of Dollars)

	FY 95	FY 96	FY 97	FY 98	FY 99
Beginning user fee balance	$3.3	$4.6	$2.6	$2.4	$3.1
Collections	10.8	7.6	9.3	12.0	14.0
Recoveries[a]	0	0.2	0.3	0	1.6
Total available	14.1	12.4	12.2	14.4	18.7
Disbursements	(9.5)	(9.8)	(9.8)	(11.3)	(11.9)
Ending user fee balance	$4.6	$2.6	$2.4	$3.1	$6.8

[a]At the beginning of the year an estimated amount of NPDB funds are set aside for NPDB's portion of HRSA's overhead. At the end of the year, funds that are not used are reported as recoveries.

HRSA officials told us that the agency does not have a plan for its financial operations that would project cash flows such as revenue, disbursements, and capital investments. Neither has it reassessed the amount it needs to cover NPDB operating expenses.

While the accumulated fee balance in fiscal year 1999 is consistent with HRSA's long-standing policy of retaining about 4 to 6 months of operating expenses, HRSA has not confirmed that this is an appropriate time frame. Performing an analysis could also help HRSA determine whether the balance could be used to adjust the rates charged for NPDB queries.

HRSA's management is responsible for establishing internal controls to account for and manage user fees properly. The Comptroller General's *Standards for Internal Control in the Federal Government* contain the criteria that federal agencies should follow in establishing and maintaining internal controls.[19] As such, HRSA management is responsible for developing the detailed policies, procedures, and practices that fit its agency's operations. Specifically, this includes implementing procedures to (1) assess user fees properly, (2) collect and record user fees, and (3) reconcile user fees assessed with those collected and recorded.

HRSA and the Division of Financial Operations (DFO) did not have controls to ensure that all assessed user fees were collected and properly recorded in the general ledger. For example, unique identifying numbers that NPDB assigns to each batch of queries for credit card transactions do not remain with the transactions once they are entered into the commercial bank for processing. When the batch is electronically submitted to the commercial bank for collection, the bank assigns a new identifying number, deposits the funds in HRSA's Department of Treasury account, and sends a daily deposit ticket to

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[19] The Comptroller General's *Standards*, as updated in November 1999, were issued pursuant to the Federal Managers' Financial Integrity Act of 1982.

DFO, which records the funds in HRSA's general ledger.

However, because the commercial bank assigned the batch of queries a different identifier than the one originally assigned by NPDB, HRSA cannot track the amounts of assessed user fees for credit card transactions to the related collection amounts in the general ledger. Officials at the commercial bank told us that they did not know that HRSA needed a unique identifier for credit card transactions and that HRSA officials had not contacted them about this issue. Without a common identifier, HRSA cannot be assured that all assessed fees have been collected and may be foregoing income that it is due. DFO and bank officials told us that, as a result of our review, they have begun discussions about ways to correct this problem.

DFO officials realized that there were discrepancies between the amount of user fees assessed and the amount collected and had conveyed this information to the division within HRSA that oversees NPDB operations. However, the discrepancies between amounts assessed and actual collections were not reconciled because HRSA and DFO officials have not agreed on which organization is responsible for performing these reconciliations. HRSA officials acknowledged that reconciliations should be performed but stated that DFO maintains the necessary documents and that HRSA does not have access to them.

DFO reported that about $8.3 million in user fees were collected during the first 8 months of fiscal year 2000, while HRSA's contractor reported $8.7 million in fees assessed in the same period. At the time of our review, an analysis had not been performed to

determine the reasons for this difference. However, DFO officials speculated that the difference could be due to denied credit card transactions, electronic funds transfer (EFT) charges, or differences in when the commercial bank and HRSA post transactions.

HRSA officials told us that DFO compares the collections recorded in the general ledger to Treasury's records; however, this procedure is not sufficient because the collections that are recorded in the general ledger may not be accurate. As noted above, HRSA does not reconcile assessments with actual collections. Reconciliation procedures are a control necessary to ensure accurate reporting of user fee receipts. Until a reconciliation is performed between the user fees assessed in NPDB and the user fees collected and recorded in HRSA's general ledger, HRSA cannot be assured that the general ledger is accurate. The Comptroller General's *Standards for Internal Control in the Federal Government* states that internal control activities help ensure that management directives are carried out. These activities include reconciliations and maintenance of related records that provide evidence that these activities were executed and appropriately documented.

HRSA and DFO also cannot ensure that the user fees collected electronically—about 30 percent of NPDB's receipts—are properly allocated between NPDB and HIPDB. HRSA's contractor operates NPDB and HIPDB and assigns unique identifying numbers to each query processed by the data banks. However, the bank commingles EFT transactions for the two data banks and sends deposit information to DFO without differentiating between NPDB and HIPDB transactions. Because DFO cannot independently determine how much should be allocated to each data

bank, it subtracts total HIPDB assessments—as shown in the contractor's report—from the total deposits to arrive at the amount credited to NPDB. This allocation process assumes that all assessed user fees are collected.

Given the current allocation process, neither HRSA nor DFO can ensure that the amounts that either data bank allocates in EFT-related collections are accurate and that the collections posted to the general ledger for each data bank are accurate. Without this knowledge, HRSA cannot be assured that it is receiving all fees it is due nor can it ascertain whether these collections stem from NPDB or HIPDB queries. Although EFT transactions accounted for only about 30 percent of HRSA's total user fee receipts for fiscal years 1998 and 1999, these transactions are expected to increase. According to HRSA officials, the agency plans to request that all users of NPDB pay for queries electronically to reduce processing costs. When this procedure is fully implemented, EFT transactions will become an even larger part of NPDB's transactions. HRSA and DFO officials also told us that as a result of our review, they are revising the allocation process so that it more accurately reflects collections for each data bank.

Based on our review of NPDB disbursements, we determined that controls were not effective. After reviewing and testing 118 statistically selected disbursements from a population of 102,393, we estimate that HRSA and DFO could not provide adequate documentation for 7,810 transactions.[20]

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[20] We are 95 percent confident that the actual total lies between 3,973 and 13,563 disbursement transactions.

We also estimate that HRSA and DFO could not provide any documentation for 6,942 disbursement transactions.[21] The Comptroller General's *Standards for Internal Control in the Federal Government* states that all transactions and significant events need to be clearly documented and that documentation should be readily available for examination.

Conclusions

Quantifying and reducing underreporting to NPDB are admittedly difficult, but without a coherent strategy for systematically addressing the areas of greatest significance, agency efforts may continue to be ineffective. While NPDB is presently the nation's only central source of medical malpractice payment information, it is not clear that all such data are being properly reported. Underreporting of clinical privilege restrictions is another area of particular concern because these reports are seen as better indicators of professional competence and involve events far more recent than medical malpractice settlements and judgments. However, HRSA only recently requested that HHS seek the additional legislative authority that the HHS/OIG recommended as necessary for addressing noncompliance by hospitals and other health care providers. Even more troubling is HRSA's failure to implement the law regarding nurses and other practitioners, despite their increasing importance in the delivery of health care services.

While we only sampled 1 month's submissions, our review suggests that NPDB information may not be

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[21] We are 95 percent confident that the actual total lies between 3,325 and 12,533 disbursement transactions.

as accurate, complete, or timely as it should be. Nearly one-third of the reports involving disciplinary actions were either miscoded or did not have sufficient detail to determine what action was taken and why. Inaccuracies in the way reported information was coded could confuse or mislead querying organizations about the severity of actions taken against practitioners. Additionally, duplicate reports overstate the amount of information that NPDB has on a particular practitioner. Some reporters may have purposely submitted vaguely coded and uninformative reports; however, HRSA bears part of that responsibility. The agency has not established criteria for the descriptive information that must be reported by states and other entities when notifying the data bank of the disciplinary actions taken. Moreover, the agency does not have procedures for ensuring that reporters adhere to the criteria it has established for medical malpractice reports, including inappropriate references to patients' names. Furthermore, the practitioner notification and dispute resolution processes have not ensured that inaccurate and erroneously reported information is removed from the data bank and not released to entities seeking information on specific practitioners.

Finally, without an examination of its financial operations, HRSA has little assurance that its NPDB user fees are appropriate. An analysis of its cash balances and cash flows—user fee collections and disbursements—would be the best way for HRSA to determine the appropriateness of fees. Moreover, HRSA needs to improve controls over its collection and disbursement activities. For example, HRSA and DFO did not have adequate controls to ensure that all assessed user fees were collected and properly

recorded in its general ledger. As a result, HRSA could be foregoing income that it is due. Until monthly reconciliations of user fee information are performed, HRSA cannot be assured that its assessments and collections are accurate and complete. In addition, neither HRSA nor DFO have procedures to ensure proper allocation of EFT user fee receipts between NPDB and HIPDB. Without these procedures, HRSA cannot ascertain whether its collections stem from NPDB or HIPDB. Also, controls over NPDB disbursements were not effective because supporting documentation that would provide confidence that disbursements were for authorized purposes was too often missing or inadequate.

Recommendations for Executive Action

To address underreporting, we recommend that the Secretary of Health and Human Services determine what resources and authorities are required to monitor and enforce compliance with NPDB's reporting requirements efficiently and effectively, and then seek the necessary legislative remedies to carry out these responsibilities. Additionally, the Secretary should require the Administrator of HRSA and the Director of DFO to work together to accomplish the following:

- Develop an annual financial plan for projecting cash flows—including revenue, operating expenses, and capital investments—as a basis for assessing operating cash needs. This includes assessing the adequacy of the human capital and technical resources needed for NPDB operations. Further, taking into consideration existing cash balances and projected cash flows, they should

evaluate whether current user fees are appropriate.

- Develop procedures to ensure that all assessed user fees are collected, including (1) establishing an audit trail of user fees from the NPDB system to the general ledger and (2) periodically reconciling user fees.
- Develop procedures to ensure that user fees are properly allocated between NPDB and HIPDB.
- Ensure that NPDB disbursements are adequately documented. This could be done by establishing internal controls that require original support and a clear audit trail for all disbursements.

We also recommend that the Administrator of HRSA

- Take immediate action to incorporate information on the disciplinary actions taken against nurses and other health care practitioners into NPDB.
- Incorporate NPDB into the agency's strategic plan, including the measures needed to improve the reliability of reported information.
- Develop criteria for the information that should be included in the narrative sections of reports concerning disciplinary actions taken against practitioners.
- Develop procedures for routinely checking the accuracy and completeness of information reported to NPDB and for obtaining corrections from reporters, when necessary.
- Revise NPDB user and practitioner notifications to include disclosures on the limitations of the data and warnings regarding duplicate submissions as an interim measure until

procedures to monitor data quality are implemented.

Agency Comments and Our Evaluation

In written comments (reprinted in app. II) on a draft of this report, HHS said that it generally agreed with the report's findings. HHS concurred with three of our recommendations and described actions it is taking. It disagreed with the rest of our recommendations.

HHS concurred with our recommendation concerning compliance monitoring and enforcement. The Department agreed that it needs to assess the additional resources and authorities needed to address noncompliance proactively. However, HHS noted that, to improve compliance with reporting requirements, HRSA needs to coordinate its efforts with OIG and the health care community. HHS also concurred with our recommendation to properly allocate user fees between NPDB and HIPDB. The Department noted that HRSA has directed its commercial bank to implement procedures separating collections between NPDB and HIPDB. Finally, HHS concurred with our recommendation to develop criteria for the narrative section of disciplinary action reports and indicated that HRSA has begun taking steps to do so.

HHS did not concur with our recommendation to develop an annual financial plan. HHS indicated that this is unnecessary because HRSA projects its revenue, disbursements, and capital investments annually, and monitors income and expenditures on a monthly basis. We acknowledge that, although HRSA may make projections to adjust user fees, it could not provide us with a written plan during our study indicating how, and how often, these projections are made.

Similarly, HHS did not agree with our recommendation that it develop procedures over the collection process, including establishing an audit trail of user fees from NPDB to the general ledger and periodically reconciling these fees. It indicated that NPBD user fees are collected promptly and properly. Despite its disagreement with our recommendation, HHS stated that HRSA's contractor and bank will implement procedures to create an audit trail and DFO will routinely reconcile amounts processed with amounts deposited and recorded in HRSA's general ledger.

HHS also did not concur with our recommendation regarding disbursements. It acknowledged that it could not provide documentation for some transactions, but explained that these disbursements occurred before HHS adopted its new accounting system. HHS said that its new system ensures effective internal controls over disbursements and a clear audit trail. Further, HHS noted that the organization managing the NPDB accounting system for HRSA—HHS' Program Support Center—had received clean opinions from its independent auditor on its internal controls for fiscal years 1998 and 1999. However, our test results showed that HRSA's controls over disbursements are not effective. Several of the disbursements for which HRSA could not provide documentation occurred after the new system was implemented. In addition, we believe that HHS' statement that the Program Support Center has received clean opinions on its internal controls is misleading. Our review of these internal control reports showed that the audits involved computer system controls and not the detailed testing of disbursements that was covered by our audit.

HHS disagreed with our recommendation to immediately incorporate into NPDB disciplinary

action information against nurses and other health care practitioners. Instead, it indicated that it needs to review the Medicare and Medicaid Patient and Program Protection Act of 1987—in light of more recent legislation that established HIPDB—before it can take any action. We believe that HHS has had ample time to study this issue because the original Act became effective more than 13 years ago and HIPDB was established in legislation that was passed more than 4 years ago.

HHS did not concur with our recommendations to improve the reliability of information contained in NPDB. In regard to our recommendation to include NPDB operations into HRSA's strategic plan, HHS stated that it does not include individual programs in a plan that covers broad programmatic areas. Instead, it indicated that HRSA's 2001 Annual Performance Plan contains information about NPDB operations. While HRSA believes that its Performance Plan may be an appropriate place to address NPDB operations, there is no mention in this plan of NPDB or measures associated with improving the reliability of its information. We continue to believe that this information should be incorporated into the agency's strategic plan.

Finally, HHS also disagreed that it should develop procedures to ensure the accuracy and completeness of NPDB information and that it should revise its notification to users regarding limitations in the data. HHS responded that HRSA already has adequate procedures in place to ensure the integrity of NPDB information. It also said that users are properly informed about the contents and limitations of NPDB data. However, we believe that the results of our detailed tests raise serious concerns about the integrity of NPDB information. For example, over 95

percent of the medical malpractice reports we reviewed were missing information on standard of patient care determinations. Accordingly, we continue to believe that our warnings about the data's limitations are warranted.

HHS also suggested several technical comments, which we incorporated where appropriate.

As agreed with your offices, unless you announce its contents earlier, we plan no further distribution of this report until 30 days after its issuance date. At that time, we will send copies to the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Claude E. Fox, Administrator of HRSA; and interested congressional committees. Copies of this report will also be made available to others upon request.

If you have any questions about HRSA's operation of NPDB as described in this report, please contact Leslie G. Aronovitz at (312) 220-7600. If you have questions about HRSA's financial operations relative to NPDB, please call Gloria Jarmon at (202) 512-4476. Other GAO contacts and staff acknowledgments are listed in appendix III.

/s/ Leslie G Aronowitz
Leslie G. Aronovitz
Director, Health Care
Program Administration
and Integrity Issues

/s/ Gloria L. Jarmon
Gloria L. Jarmon
Managing Director
External Liaison

Appendix I

Scope and Methodology

To address issues related to underreporting, we reviewed NPDB's authorizing legislation and regulations and the *NPDB Guidebook* to identify the reporting requirements and instructions given to those accessing the data bank. We interviewed HRSA officials and reviewed the agency's fiscal year 2000 and 2001 performance plans and the fiscal year 1999 performance report to determine how NPDB fits into HRSA's overall strategic plan.[1] Additionally, we reviewed NPDB's annual reports for calendar years 1993[2] through 1999 and internal research proposals prepared by HRSA's Division of Quality Assurance, the unit overseeing NPDB operations. We interviewed HHS/OIG officials and reviewed their reports on the data bank to obtain information on NPDB's weaknesses and open recommendations. We also reviewed HRSA-sponsored studies on issues related to underreporting, including *Hospital Peer Review and the National Practitioner Data Bank* (July 1999), *The Roundtable on Hospital Reporting to the NPDB* (1996*), HRSA's Report to the Congress on Small Malpractice Payment Issues* (1996), and the data bank's user satisfaction surveys.

We reviewed HRSA's December 24, 1998, notice of proposed rulemaking, comments the agency received on the proposal, and the *Federal Register* notice that

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[1] The Government Performance and Results Act of 1993 (P.L.103–62) specifically requires that federal agencies develop multiyear strategic plans, annual performance plans, and annual performance reports.

[2] The 1993 annual report covered the period Sept. 1, 1992, to Aug. 31, 1993.

subsequently withdrew the proposal. We reviewed the minutes of meetings held since late 1998 and interviewed 17 of the 24 health care industry representatives and advocacy groups on NPDB's Executive Committee. This included interviewing officials from medical and dental professional societies such as the American Medical Association, the American Dental Association, American Association of Dental Examiners, the Federation of State Medical Boards, and the National Council of State Boards of Nursing. In addition, we interviewed officials of the Physicians Insurers Association of America and Harvard Risk Management Foundation, which represent the medical malpractice industry. We also interviewed representatives of the American Hospital Association, the National Committee for Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, and representatives of advocacy groups such as Public Citizen and the American Association of Retired Persons. Finally, we reviewed the federal Memorandums of Understanding that HRSA negotiated with the Departments of Defense, Transportation, and Veterans Affairs; the Drug Enforcement Administration; the Indian Health Service; and the Public Health Service.

To evaluate the accuracy, completeness, and timeliness of NPDB data, we obtained electronic copies of the 1,645 reports submitted to NPDB during September 1999 and electronic copies of the 447 reports that were submitted as corrections, changes, or in dispute of the September reports, as of June 2000.[3] We categorized these reports by type of

[3] We omitted reports concerning 298 practitioners that HHS/OIG submitted to NPDB as being excluded from participation in the

information reported—medical malpractice payment, state licensure action, and clinical privilege restrictions.[4] Because these three types of reports have different requirements for coding and descriptive information, we analyzed each type separately.

We used NPDB's reporting time frames to gauge the timeliness of reports. We compared the dates malpractice payments were made or disciplinary actions were taken (date of action) with the dates that the reports were submitted (the certification date) to NPDB. In total, we analyzed 1,552 reports for timeliness, including 1,300 medical malpractice payment reports and 252 state licensure actions. We did not analyze the timeliness of clinical privilege restrictions because their submission deadlines vary by the method used to transmit the information to NPDB, and we could not determine which method had been used. Reports submitted electronically have a 15-day deadline, while those submitted on paper pass through state licensing boards and are allowed up to 30 days to reach NPDB.

We also analyzed the currency of information included in the 1,300 medical malpractice reports submitted to NPDB during September 1999. We compared the dates of the events initiating the claims (date of act or omission) with the dates that the payments were reported to NPDB. We could not analyze the currency

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Medicare and Medicaid health care programs. This present study was focused on the accuracy, completeness, and timeliness of reports involving malpractice payments and disciplinary actions taken against practitioners.

[4] We grouped the Drug Enforcement Administration and professional society reports together with state licensure actions because NPDB classified all three as licensure actions.

of state and health care provider reports because they do not contain comparable information.

We assessed only medical malpractice payment reports for completeness because this was the one type of report that had NPDB-prescribed criteria on the data that should be included in narrative descriptions. We selected 250 of the 1,300 medical malpractice payment reports to determine the frequency with which seven of the items of information were present.[5] We randomly selected 125 reports, then added to that number 101 reports involving practitioners who had been reported more than once during September 1999 and 24 reports that were disputed.

We assessed the accuracy of state licensure actions and clinical privilege restriction reports by determining the internal consistency of the narrative and coded information contained in individual reports. As part of this analysis, we also identified the frequency with which reporters identified why a particular action was taken against a practitioner. In total, we analyzed 345 reports for accuracy, including those involving 252 state licensure actions, 79 clinical privilege restrictions, 7 actions limiting professional society memberships, and 7 DEA actions curtailing practitioners' authorization to prescribe controlled substances.

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[5] As specified in the *NPDB Guidebook*, medical malpractice reports should include information on the patients' age, gender, inpatient or outpatient status, the events (initial and subsequent) precipitating the claim, and the medical or legal damages incurred. The reports are also to include information on whether a standard of patient care determination had been made in connection with the settlement or judgment.

We also queried NPDB for information on 34 practitioners reported during September 1999. We selected these 34 practitioners due to the nature of the reported information, such as apparently erroneous or duplicate report submissions. We did this to determine what information NPDB would provide on these practitioners and to gauge the impact of potentially erroneous reports.

Two limitations affect our analysis of information reported to NPDB. First, we had to rely on NPDB's own criteria and the internal consistency of reports to gauge timeliness, accuracy, and completeness. There was no independent, single source for much of the information contained in NPDB. Second, we only had a snapshot of the information in the data bank. Working with HRSA officials, we selected 1 month's submissions to NPDB for our analysis. We did not find any evidence that would lead us to believe that September 1999 was an atypical month for NPDB. Besides the 34 practitioners for which we obtained query results, we do not know what other information has been reported on the practitioners included in our September 1999 sample.

To review the adequacy of HRSA's internal controls to ensure proper accountability and management of user fees, we interviewed officials from DFO and HRSA to understand how user fees are determined, assessed, collected, recorded, and disbursed. We also interviewed and reviewed the workpapers of independent public accountants who in fiscal year 1999 performed work technically known as "agreed-upon procedures" for user-fee-related issues.[6] The

[6] The term "agreed-upon procedures" means that the client and accountant have agreed that specific work will be performed in areas involving certain items of the financial statement. The

accountants told us they could not develop an audit trail for user fee transactions. To independently verify the accountants' work, we selected one credit card and one electronic funds transfer (EFT) to trace pertinent data from the point at which a user fee was assessed to its posting to HRSA's general ledger.

In addition, we selected and tested a statistical sample of the disbursement transactions from HRSA's general ledger that occurred between October 1, 1994, and May 31, 2000.[7] We traced the sampled disbursements from the general ledger to supporting documentation. We also reviewed the supporting documentation to determine whether the disbursements had been properly approved and reviewed pertinent laws, regulations, and guidance related to NPDB user fees to determine whether the disbursements were used for authorized purposes. Finally, we discussed with HRSA officials their reasons for maintaining excess user fees and reviewed documentation supporting management's decision to maintain these additional funds.

We performed our work between January 2000 and September 2000 in accordance with generally accepted government auditing standards.

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final report is limited to the results (findings) of the work performed.

[7] We statistically selected a probability sample of 118 disbursements from HRSA's population of 102,392. With this statistically valid probability sample, each disbursement had a nonzero chance of being included in the sample. Each sample element was subsequently weighted in the analysis to account statistically for all disbursements in the population, including those that were not selected.

Appendix II

Comments From the Department of Health and Human Services

[Logo]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

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NOV 9 2000

Ms. Leslie G. Aronovitz
Director, Health Care-Program Administration and Integrity Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Ms. Aronovitz:

Enclosed are the Department's comments on your draft report entitled, "National Practitioner Data Bank: Improvements Are Needed to Enhance the Data Bank's Reliability." The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department also provided some technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

/s/ June Gibbs Brown
June Gibbs Brown
Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. The OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE U.S. GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "NATIONAL PRACTITIONER DATA BANK: IMPROVEMENTS ARE NEEDED TO ENHANCE THE DATA BANK'S RELIABILITY"

General Comments

The Department of Health and Human Services (Department) thanks the General Accounting Office (GAO) for the opportunity to review and comment on GAO's draft report, "National Practitioner Data Bank: Improvements Are Needed to Enhance the Data Bank's Reliability." The Department believes that GAO's draft report accurately describes the regulatory evolution of the Department's National Practitioner Data Bank (NPDB). In general, we agree with the report's findings, though with some qualifications. The report describes the efforts of the NPDB to identify and improve the accuracy of data

collected and the underlying significant factor that the Department does not have meaningful cost-effective authority to penalize nonreporters.

GAO Recommendation

To address underreporting, we recommend that the Secretary of HHS determine what resources and authorities are required to efficiently and effectively monitor and enforce compliance with NPDB's reporting requirements, then seek the necessary legislative remedies to effectively carry out these responsibilities.

Department Comment

We concur with GAO's recommendation, though we believe the Department's Office of Inspector General (OIG) would have to be involved in any enforcement activity. The GAO report states that, "Most of HRSA's efforts to address underreporting have focused on medical malpractice insurers, while HHS/OIG and HRSA-sponsored studies have concluded that underreporting of clinical privilege restrictions by hospitals and other healthcare providers is a larger and more pressing issue. Moreover, experts widely agree that disciplinary actions, taken by state licensing boards and healthcare providers, are better indicators of professional competence than malpractice settlements."

The Department does not entirely concur with GAO's assessment. We must address underreporting on malpractice because it is required by statute; we will continue to broaden our view of underreporting to include privilege restrictions and other disciplinary actions.

The issue of nonreporting or underreporting is complicated and contentious because proactively addressing the issue may require increased legislative authority to allow access to internal medical facility records, peer review findings, and possibly an investigative capability that exceeds the current capacity and capability of NPDB staff. Such changes would require careful consideration and coordination with the health care community in order to have any chance of success.

The NPDB staff currently and actively investigate and pursue all specific allegations of violations of the Health Care Quality Improvement Act of 1986, including failure to report clinical privilege actions, medical malpractice payments and violations of confidentiality; and, where appropriate, refer allegations to the Department's OIG for further action.

GAO Recommendation

Additionally the Secretary should require the Administrator of HRSA and the Director of DFO work together to develop an annual financial plan for projecting cash flows – including revenue, operating expenses, and capital investments–as a basis for assessing operating cash needs. This includes assessing the adequacy of human capital and technical resources needed for NPDB operations. Further, taking into consideration the existing cash balances and projected cash flows, evaluate whether current user fees are appropriate.

Department Comment

We do not concur with GAO's recommendation. The Health Resources and Services Administration (HRSA) appropriately examines the level of user fees

and conducts appropriate planning. HRSA annually projects budgets that take into account revenue, disbursements, and capital investments. The fee charged to users of the system reflects the projections and historic trends of the financial health of the NPDB. The income and expenditures are monitored on a monthly basis and adjustments are made periodically. This has allowed the NPDB to adjust the user fees several times to achieve a balance of income versus expenditures while minimizing the financial planning and internal budget impact to users within the medical community.

The monitoring and planning done by HRSA has also allowed the NPDB to be periodically upgraded and enhanced in a timely and cost-effective manner with minimal impact to the medical community. Planning is also necessary to replace the contract to operate and maintain the NPDB. This is a costly process that may double the operating cost of the NPDB during the transition to a new contractor. The reserve that GAO questions resulted from this planning process and will be used to replace the expiring contract in the coming fiscal year. The HRSA would be remiss in its fiduciary responsibility ifno planning were done to forecast the additional financial burden imposed by these necessary actions.

GAO Recommendation

develop procedures to ensure that all assessed user fees are collected, including (1) establishing an audit trail of user fees from the NPDB system to the general ledger and (2) periodically reconciling user fees.

Department Comment

We do not concur. Overall, user fees are collected promptly and properly, and HRSA will make continued efforts to improve their efficiency and documentation.

The Division of Financial Operations (DFO) in the Department's Program Support Center (PSC) has taken the lead in this endeavor. Currently, the DFO reconciles amounts deposited by Mellon Bank and transferred to Treasury. The amount is then deposited and recorded in the core accounting system. Therefore, the amount reflected in the general ledger is accurate. The HRSA contractor has revised their weekly reports to more accurately reflect amounts successfully processed. Also, the contractor and Mellon Bank will commence capturing sequence identifying numbers from each other's systems which will create an audit trail from credit card and electronic funds transfer transactions. The DFO will routinely reconcile amounts successfully processed with amounts deposited and recorded in the general ledger.

The $400,000 difference reflected in paragraph 2 on page 30 of GAO's draft report is primarily due to inaccurate reporting by the contractor. Revised reports reflect a $16,845 difference over a 12-month period from what DFO ($13.4 million in user fees collected) and the contractor reported. This minimal difference primarily relates to the timing ofrecording transactions.

GAO Recommendation

develop procedures to ensure that user fees are properly allocated between NPDB and HIPDB.

Department Comment

We concur with GAO's recommendation. We have requested Mellon Bank to separate collections for each program based on the two header records being transmitted by the contractor for electronic funds transfer transactions. Mellon Bank is currently reviewing the feasibility of meeting this request and separating the amounts collected on their weekly reports to DFO.

GAO Recommendation

ensure that NPDB disbursements are adequately documented. This could be done through establishing internal controls that require original support, and a clear audit trail, for all disbursements.

Department Comment

We do not concur with GAO's recommendation, as there are already effective internal controls in place. It is our opinion that GAO's estimates reflected on pages 31 and 32 of the report relating to inadequate documentation are overstated. Documentation was provided for the majority of the transactions; items not provided for were primarily from transactions incurred in Fiscal Year (FY) 1996 when PSC utilized the Legacy Health Accounting System and the items were not available or identifiable at program offices. The PSC has since implemented internal controls to ensure obligations are authorized and disbursements are supported. The core accounting system does create a clear audit trail. In addition, PSC has received clean opinions from an independent audit firm for their FY 1998 and FY 1999 Statement on Auditing Standards 70 reviews relating to internal controls.

GAO Recommendation

We also recommend that the Administrator of HRSA take immediate action to incorporate information on the disciplinary actions taken against nurses and other healthcare practitioners into NPDB.

Department Comment

We do not concur with the recommendation to take immediate action. We will first review the issues associated with the implementation of the *Medicare and Medicaid Patient and Program Protection Act of 1987 (Act),* including its duplicative information with the Healthcare Integrity and Protection Data Bank and the necessity of providing hospitals' access to this information as required by the Act.

GAO Recommendation

incorporate NPDB into the agency's strategic plan, including the measures needed to improve the reliability of reported information.

Department Comment

We do not concur that the NPDB should be incorporated into the HRSA strategic plan, but we believe that the NPDB should be included in the overall HRSA performance plan. The HRSA stategic plan covers broad programmatic areas, and it would not be consistent to include specifics concerning individual programs such as the NPDB. The HRSA 2001 Annual Performance Plan does address the NPDB. While the reliability of data requires continued effort, we do not agree with the recommendation's implication that the data are essentially flawed.

GAO Recommendation

develop criteria for the information that should be included in the narrative sections of reports concerning disciplinary actions taken against practitioners.

Department Comment

We concur with GAO's recommendation. Criteria have been developed for information that should be included in the narrative sections of reports concerning medical malpractice payments. Efforts presently are underway to develop criteria for reports concerning disciplinary actions taken against practitioners.

GAO Recommendation

develop procedures for routinely checking the accuracy and completeness of information reported to NPDB and for obtaining corrections from reporters, when necessary.

Department Comment

We do not concur with GAO's recommendation because HRSA already has procedures for verifying and correcting the information contained in a report. A copy of each report submitted to the NPDB is sent to the reporter and the subject of the report. Each report can and often does identify corrections, omissions and discrepancies which the reporter is obliged to revise when appropriate. In addition, HRSA often identifies potentially erroneous information and asks the reporter to review and revise the information as necessary. Therefore, we believe this procedure of checks and balances is appropriate, has worked well, and therefore no additional corrective action is necessary.

GAO Recommendation

revise NPDB user and practitioner notifications to include disclosures on the limitations of the data, as well as warnings regarding duplicate submissions, as an interim measure until procedures to monitor data quality are implemented.

Department Comment

We do not concur with GAO's recommendation. The expectations of users are important, and currently the public perception of the NPDBdatabase is that ofa "flagging system." We do not include user and practitioner notifications because the literature describing the database already carries a full description of the database and its limitations.

Appendix III

GAO Contacts and Staff Acknowledgments

GAO Contacts

Geraldine Redican-Bigott, (312) 220-7678
Rosa Ricks Harris, (202) 512-9492

Staff Acknowledgments

Enchelle Bolden, Marian Cebula, Tiffani Clark, Lynn Filla-Clark, Tarunkant Mithani, and Barbara Mulliken also made key contributions to this report.

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Appendix H

[Logo]
DEPARTMENT OF HEALTH
& HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

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PRIVILEGED AND CONFIDENTIAL

Adam M. Brook, M.D.
66 Harbor Common
Memphis, TN 38103

RE: National Practitioner Data Bank
SECRETARIAL REVIEW DECISION

Practitioner:	**Adam M. Brook, M.D.**
Type of Report:	**Adverse Action Report**
Date of Report:	**December 03, 2009**
DCN:	**5500000059633157**

Dear Dr. Brook:

This letter is regarding your request that the Secretary of the Department of Health and Human Services (the Secretary) review the above-referenced Adverse Action Report (the Report) submitted to the National Practitioner Data Bank (the NPDB) by the Peconic Bay Medical Center (the PBMC) on December 03, 2009.

After review of the information available and the record presented to this office, the Secretary finds as follows:

> There 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. Your request that the Report be voided from the NPDB is hereby denied. The Report will remain in the NPDB.

According to the Report, the PBMC reported you for "voluntary surrender of clinical privileges(s), while under, or to avoid, investigation relating to professional competence or conduct (1635)." **The Basis for Action** specifies "other – not classified, specify (99)," with the **Other, as Specified being** "(AD) surrendered privileges." **The Description of Subject's Act(s) or Omission(s)** field in Section C of the Report states:

> "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 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."

You dispute the report claiming:

1. There was no investigation at the time of your resignation, which you confirmed with the PBMC. No specific review of your professional conduct or competence was open when you tendered your resignation, but rather a routine and general review of a very complicated case.
2. The 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. There was no deviation from the standard of care which has been confirmed by numerous medical experts and the New York State Department of Health.
3. You were not provided reasonable procedure or due process entitled to you by the New York State law, The investigation by PBMC was significantly flawed.
4. Your resignation was planned in advance with intention to complete a senior residency in a different hospital beginning November l, 2009. Therefore, you did not resign or surrender your

clinical privileges while under or to avoid investigation.

5. The description in the report is inaccurate as it describes your removal of a part of the patient's fallopian tube as "inadvertent."
6. PBMC failed to report the action within the required time frame (within 15 days of the event) and therefore the Report should have been rejected by the NPDB.
7. The report is inaccurate because it indicates that you agreed to exercise your privileges "pending the Hospital's investigation."

As you aware, we wrote to the PBMC on November 18, 2010 to request pertinent documentation concerning the case. We received a response from the PBMC on March 25, 2011 in which they shared a chronology and documentation surrounding the Adverse Action Report submitted on December 3, 2009. The submitted documentation (including exhibits) provided the following facts related to your professional conduct:

1. On October 5, 2009, your clinical privileges were summarily suspended (Exhibit 7) as a result of a laparoscopic appendectomy you performed on a fourteen year old female on October 2, 2009 in which you inadvertently removed a part of one of the patient's fallopian tube. Also, on October 5, 2009, the surgical error was reported by the anesthesiologist to the PBMC's Vice President of Medical Affairs (VPMA) and an incident report was filed by the operating room nurse to the PBMC's Director of Quality and Case Management (Exhibit 4).
2. Between October 6, 2009 and May 27, 2010, the PBMC conducted an investigation of the case including the following actions:

2.1. The minutes from the PBMC's Medical Staff Performance Improvement Committee Meetings held on October, 2009 and November, 2009 verify suspension of your clinical privileges due to an ongoing investigation of your case (Exhibits 13-15).

2.2. On October 5, 2009, the PBMC electronically filed with the New York State Department of Health a NYPORTS Short Form Report which also indicates a suspension pending completion of the investigation (Exhibit 8).

2.3. On November 2, 2009, the PBMC's Medical Staff Credentials Committee met and agreed that had you remained on the Medical Staff, your general surgical privileges would have been restricted pending additional education/proctoring (Exhibit 16).

2.4. On or about November 3, 2009, the Root Cause Analysis (RCA) Committee issued its NYPORTS Root Cause Report (Exhibit 15) and the PBMC filed its Summary Report For Sentinel Event with the Joint Commission in accordance with the Public Health Law, New York State Regulations/ Section 4 of the New York Patient Occurrence Reporting and Tracking System Manual.

3. On October 7, 2009, you submitted a letter of resignation effective October 16, 2009 (Exhibit 12).
4. On December 3, 2009, the PBMC submitted an Adverse Action Report to the NPBB (Exhibit 1).

As stated in 45 CFR §60.1l(a)(1) hospitals must report:

> "(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist –
> (A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct. . ."

Regarding your first claim, the PBMC'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 VPM Corporate Compliance Officer, Director of QM, and Medical Staff Coordinator. The notes state that "Dr. Brook 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.

Regarding your second and third claims, 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. You officially

resigned before the final closing of the PBMC's review(s) and that is a reportable event. The fact that you had to work in an unethical environment has no bearing on PBMC's legal responsibility to report your voluntary surrender of clinical privileges. The Secretary is explicitly making no finding concerning whether PBMC's investigation was warranted, whether you met the standard of care or whether due process was afforded to you according to PBMC's Bylaws or NY state laws. It is clear from the record that PBMC determined that you departed from the standard of care; the Secretary is poorly positioned to question a health care entity's conclusion is these types of matters. Due process issues must be resolved between you and the reporting entity and do not affect the reportability of your voluntary surrender of clinical privileges. Under the dispute resolution process, the Secretary can only review (1) whether the action is reportable under applicable law and regulations and (2) whether the Report accurately describes the reporter's action and reasons for action as stated in the reporter's decision documents.

Regarding your fourth claim, the NPDB regulations do not have any exceptions to reporting resignations on the basis of the reason for the resignation. As indicated on page F-8 of the NPDB Guidebook, "the reason the practitioner gives for leaving an entity while under investigation is irrelevant to reportability of the resignation." Therefore, even if you had planned your resignation in advance, it would have no bearing on the reportability of the action.

Regarding your fifth claim, the record indicates that PBMC concluded that your removal of a part of the patient's fallopian tube was "inadvertent." The minutes from the November, 2009 meeting of PBMC's Medical State Performance Improvement Committee

conclude that "removal of fallopian tube was inadvertent" (Exhibit 14). In addition, the Root Cause Report submitted by PBMC indicates that "inadvertent removal of the fallopian tube was due to misidentification of the anatomic structure" (Exhibit 15). Questioning PBMC's findings in this regard is beyond the scope of Secretarial Review.

Regarding your sixth claim, even if the NPDB determined that PBMC's report was late, it would not be a basis for voiding the report.

Regarding your seventh claim, in multiple places the record indicates that PBMC determined that the reason for the agreement to not exercise your privileges was caused by the PBMC's investigation. For instance, the minutes from the October [September], 2009 PBMC's Medical Staff Performance Improvement Committee indicate that you voluntarily removed yourself "pending completion of the investigation" (Exhibit 13 and the PBMC's March 24, 2011 letter, Page 5, Footnote 3).

Since the Secretary is denying your dispute, the Report will remain in the NPDB. The Secretary will order the Report removed from "Elevated for Decision by the Secretary" status and placed in "Reviewed by the Secretary" status. The Secretary will also insert the following statement into the Report:

> The practitioner requested Secretarial Review of this report. The Secretary can only review (1) whether the action is reportable under applicable law and regulations and (2) whether the report accurately describes the action. In this case, the Secretary can only determine whether the practitioner surrendered clinical privileges while under investigation or to avoid an investigation in a matter which could have led to a reportable

> professional review action had the investigation been completed and whether the report accurately describes the allegations relevant to the investigation and the related events. The Secretary cannot conduct an independent review of the surrender or resignation, inquire whether an investigation was warranted, whether a professional review action would have been taken if the investigation had been completed, whether the "due process" provided or to be provided by the reporting entity was adequate, or substitute his judgment for that of the entity. After review of the available information, the Secretary determined that some of the issues raised by the practitioner are beyond the scope of the Secretary's review authority. After review of the remaining issues, the Secretary determined that there is no basis to conclude that the report should not have been filed or that for agency purposes it is not accurate, complete, timely or relevant. Accordingly, the report shall be maintained as submitted by the reporting entity.

You may submit a brief statement for inclusion in the Report. Since you already have a statement in the Report, any new statement you submit will replace it. Your statement must not exceed 4,000 total characters, including punctuation and spaces. Please do not include, in the statement, names, addresses, or telephone numbers other than your own or your attorney's. If you include such information, it will be removed from your statement before it is entered into the NPDB.

For information on how to submit a new statement, please visit the NPDB-HIPDB Web site at www.npdb-hipdb.hrsa.gov or call the NPDB-HIPDB Customer Service Center at 1-800-767-6732. The

Customer Service Center is open Monday through Friday from 8:30 a.m. to 6:00 p.m. (5:30 p.m. Fridays) Eastern Time. The Customer Service Center is closed on all Federal holidays.

Should you wish to submit a request for reconsideration of this decision, please do so in writing. You should be specific about any **new information that was unavailable to you** at the time of review and which issue(s) you feel was inappropriately considered during the Report Review. You may submit your request to the following address:

The Data Bank
ATTN: Dispute Resolution
4094 Majestic Lane, PMB-332
Fairfax, VA 22033

The NPDB will send a copy of the Report with the Secretary's decision and statement along with your statement (if applicable) to you, the reporting entity, and any entity which has queried and received a copy of the Report within the past three years as well as future entities which query you.

Yours truly,

/s/ Judy Rodgers
Judy Rodgers, M.H.A.
Senior Advisor
Division of Practitioner Data Banks

cc: Richard Kubiak, Vice President, Peconic Bay Medical Center
Leonard M. Rosenberg, Esq, Garfunkel Wild, P.C.
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Appendix I

CARDOZO LAW REVIEW
Vol. 33:5

BLACKLISTED:

THE CONSTITUTIONALITY OF THE FEDERAL SYSTEM FOR PUBLISHING REPORTS OF "BAD" DOCTORS IN THE NATIONAL PRACTITIONER DATA BANK

*Katharine A. Van Tassel**

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INTRODUCTION

The United States has a growing number of government-created blacklists,[1] including those for convicted sexual predators, suspected gang members, and suspected terrorists. The latest surprise entry in this trend is the federally created data bank of "bad" physicians called the National Practitioner Data Bank (NPDB).[2] The NPDB is the first time the federal government has engaged in blacklisting since the McCarthy era. Physicians are blacklisted after being "found" to have provided poor quality of care through a highly subjective, and oft-times summary, peer review process conducted by private hospitals.

Physician blacklisting by the NPDB has become a pressing national issue as it has serious legal and social consequences. First, the physician blacklisting

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[1] The term blacklist means "a list of persons who are disapproved of or are to be punished or boycotted." *Definition of "Blacklist,"* MERRIAM-WEBSTER'S ONLINE DICTIONARY, http://www.merriam-webster.com/dictionary/blacklist (last visited Aug. 14, 2011).

[2] 42 U.S.C. § 11101 (2006); 45 C.F.R. § 60.1 (2010).

process has a high risk of error as it is both over inclusive, unfairly destroying the careers of many competent physicians, and under inclusive, as it ignores many incompetent physicians. Second, the NPDB reporting system encourages the perpetuation of custom-based practices undermining efforts to improve the quality and cost of healthcare through the practice of evidence-based treatment choices. Third, the NPDB system is being used to silence physician whistleblowers which also negatively impacts quality of care. Finally, last year the NPDB expanded its scope to take on blacklisting of *all* licensed healthcare practitioners in the United States, including dentists, nurses, physicians' assistants, and social workers, extending its reach to over six million people.[3] This expansion magnifies the NPDB's negative effects exponentially as it begins to affect the practice habits of all healthcare professionals.

In order to highlight the problems with the NPDB, this Article compares physician blacklisting with other forms of blacklisting. For example, both physician and sexual predator blacklisting programs have the same goals: allowing the public to engage in self-protection by preventing "predators" from traveling to new locations to prey on a new group of unsuspecting victims. And both sexual predators and physicians suffer similar stigmatization as the result of the "badge of infamy" that comes with being blacklisted. But this is where the similarities end.

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[3] BUREAU OF LABOR STATISTICS, U.S. DEP'T OF LABOR, CAREER GUIDE TO INDUSTRIES, 2010-11 EDITION (2010), *available at* http://www.bls.gov/oco/cg/cgs035.htm (indicating that the number of healthcare professionals in the United States is 6,283,900)

Accused sex offenders get all of the trappings of due process to avoid being wrongfully convicted and incorrectly placed on sexual predator blacklists. In contrast, most physicians, who are serving the community, get very few due process protections before being blacklisted. And some physicians are provided no due process rights at all. On the whole, the NPDB fails to fairly protect the liberty and property rights of targeted physicians.

The problems with the NPDB can be resolved by providing physicians, and other healthcare providers, with the same kind of due process protections that are provided to alleged sexual offenders before they are blacklisted. Adding these procedural protections will protect competent physicians from the erroneous destruction of their careers while also increasing the accuracy of the NPDB, which will protect patients from incompetent providers. Overall, the very specific due process protections suggested by this Article will improve healthcare quality, cost, and access.

This Article first provides a brief summary of the history of blacklisting in the United States. Then a comparison is made between physician blacklisting and other forms of blacklisting. This comparison reveals that physicians receive far fewer procedural safeguards than other targeted populations that pose a much greater risk of harm. The next Section explains the NPDB reporting and publishing system in order to then explore its constitutionality by applying the three-part test of *Mathews v. Eldridge*. The *Mathews* test suggests that the NPDB unconstitutionally impacts both the property and liberty rights of the targeted physicians. This exercise also raises startling questions regarding the overall negative impact of the NPDB reporting system on the quality and cost of healthcare, issues of current and

pressing national importance. The NPDB reporting system appears to encourage the perpetuation of custom-based practices undermining efforts to improve the quality and cost of healthcare through the practice of evidence-based treatment choices. The NPDB system is also being used to silence physician whistleblowers, negatively impacting quality of care. The last Part of the Article suggests that the problems with the NPDB can be resolved by providing physicians, and other healthcare providers, with the same kind of due process protections that are provided to alleged sexual offenders before they are blacklisted. Adding the specific procedural protections suggested by this Article will protect physicians from the erroneous destruction of their careers while also increasing the accuracy of the NPDB and improving healthcare quality, cost, and access.

I. HISTORY OF BLACKLISTING IN THE UNITED STATES

A. *History of Blacklisting: General Criminal Registries, McCarthyism, Suspected Gang Members, Suspected Terrorists, and No-Fly Lists*

The principal goal of the justice systems of most early civilizations was the achievement of vengeance.[4] Deterrence was usually a secondary benefit.[5] In colonial America, the settlers took matters up a notch by making use of shame and shaming in order to both further these goals and to

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[4] James A. Cox, *Bilboes, Brands, and Branks: Colonial Crimes and Punishments*, COLONIAL WILLIAMSBURG J., Spring 2003, available at http://www.history.org/foundation/journal/spring03/branks.cfm.

[5] *Id.*

encourage repentance.[6] The settlers regularly used the simple, but cruel, expedient of physical branding to achieve these goals while also ensuring that members of the community could engage in self-protection.[7] Branding also meant that potential recidivists could not travel to new communities in order to prey on a new group of unwary victims[8]:

> Burglary was punished in all the colonies by branding with a capital B in the right hand for the first offense, in the left hand for the second, "and if either be committed on the Lord's Daye his Brand shall bee sett on his Forehead as a *mark of infamy.*"[9] In Maryland, every county was ordered to have branding irons, with the lettering specifically prescribed: SL stood for seditious libel and could be burned on either cheek. M stood for manslaughter, T for thief, R for rogue or vagabond, F for forgery.[10]

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[6] LAWRENCE M. FRIEDMAN, A HISTORY OF AMERICAN LAW 69 (2d ed. 1985).

[7] *Id.* at 69–70.

[8] Pieter Spierenburg, *The Body and the State: Early Modern Europe, in* THE OXFORD HISTORY OF THE PRISON: THE PRACTICE OF PUNISHMENT IN WESTERN SOCIETY 49, 53 (Norval Morris & David J. Rothman eds., 1995) ("[B]randing was a preindustrial method for identifying recidivists.")

[9] Cox, *supra* note 4 (emphasis added)

[10] *Id.; see also* CYNDI BANKS, PUNISHMENT IN AMERICA 11 (2005) ("For example, the laws of colonial New Jersey stipulated that a first offense of burglary would be punished by branding the letter 'T' on the hand of the accused, and a second offense by branding an 'R' on the accused's forehead.").

By the early 1800s, branding was seen as socially unacceptable torture.[11] Consequently, American society needed a new method for identifying those who posed the risk of criminal harm to others. Establishing this means fell to the police, which, by the mid-1800s, had become more organized, professional, and proactive in the realm of public safety.[12] As described by Professor Peter Becker, "[s]tigma was no longer directly inscribed on the body of the perpetrator, but was rather administered in collections of data by the police."[13] This data was initially used by the police to identify repeat offenders for purposes of sentencing and rehabilitation efforts and later to prevent and detect crimes in the community.[14] To further these efforts, the police embraced new technologies as they were developed to create criminal registries with various

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[11] WAYNE A. LOGAN, KNOWLEDGE AS POWER: CRIMINAL REGISTRATION AND COMMUNITY NOTIFICATION LAWS IN AMERICA 4 (2009); *see also* Spierenburg, *supra* note 8, at 52 (noting that punishment in Europe moved from bodily disfigurement to confinement in prisons). In *Wilkerson v. Utah,* 99 U.S. 130 (1878), the Supreme Court commented that punishments involving torture—for example, drawing and quartering, public dissecting, burning alive, or disembowelling and "others in the same line of unnecessary cruelty"—would constitute cruel and unusual punishment violating the Constitution regardless of the crime. *Id.* at 135–36.

[12] LAWRENCE M. FREIDMAN, CRIME AND PUNISHMENT IN AMERICAN HISTORY 27–30, 66–71 (1993); KERMIT HALL, THE MAGIC MIRROR: LAW IN AMERICAN HISTORY 176–78, 184–85 (1989).

[13] Peter Becker, *The Standardized Gaze: The Standardization of the Search Warrant in Nineteenth-Century Germany, in* DOCUMENTING INDIVIDUAL IDENTITY 139, 155 (Jane Caplan & John Torpey eds., 2001) (describing a parallel phenomenon in Germany); *see also* LOGAN, *supra* note 11, at 20.

[14] LOGAN, *supra* note 11, at 20.

degrees of success, from photographic technologies,[15] to anthropometry,[16] and finally to dactyloscopy,[17] known now as fingerprinting.

According to Professor Wayne Logan, "[i]n the United States, registration was only haltingly embraced—targeting particular non-criminal sub-populations: emancipated African Americans in antebellum times, German Americans during World War I, and other select subgroups."[18] However, the 1920s and 1930s brought public anxiety over a perceived crime wave perpetrated by underworld gangsters and hoodlums. With an increased interest in crime prevention came a renewed interest in criminal registration and a small wave of local registration laws were passed.[19] Then, the 1940s changed the public's focus to wartime issues and the brief interest in registration receded until the 1950s with the appearance of a new breed of criminal, the Mafia.[20] The public's fear of the Mafia translated into the passage of another, and somewhat larger, wave of

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[15] *Id.* at 4.

[16] *Id.* at 9–10. Anthropometric, or bodily, identification was created by Alphonse Bertillon—and so was called "Bertillonism"—and involved measuring three data points including the dimensions of the head, finger, and ear, descriptions of facial features, and peculiar marks. *Id.* at 10.

[17] *Id.* at 13.

[18] *Id.* at 20.

[19] *Id.* at 22–28.

[20] *Id.* at 28; *see also* REPORT BY THE PRESIDENT'S COMM'N ON LAW ENFORCEMENT & ADMIN. OF JUSTICE, THE CHALLENGE OF CRIME IN A FREE SOCIETY 192-98 (1967) (noting that Senate hearings led by Tennessee Senator Ernest Kefauver received national media attention and generated public concern over the Mafia).

mostly local, criminal registration laws.[21] These early criminal registration laws were controversial, with journalists condemning the stigmatizing effects of registration:

> It was the old idea of the brand all over again, though it took the form of this blacklist file instead of the old scarlet letter of New England. There was little thought of doing anything to rehabilitate these people- or even to protect society from them. The emphasis was merely on having them branded and filed, Gestapo style, so that they could be hounded and cracked down upon when the public mood so demanded . . . .[22]

Justice officials of the times warned that criminal registration laws created alarming precedent, and cautioned that "'[b]efore embarking upon this new practice with a particularly offensive group of individuals, we should not overlook the fact that we may be opening the door to similar practices for other groups as time goes on.'"[23] History proved these predictions to be correct when the public fear of the Mafia morphed into the fear of communists and this

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[21] LOGAN, *supra* note 11, at 28. By 1969, fifty-two localities had passed criminal registration laws and eight states had criminal registration laws. By 1989, twelve states had criminal registration laws. *Id.*

[22] *Id.* at 38 (quoting HOWARD JAY WHITMAN, TERROR IN THE STREETS 383–84 (1951)).

[23] *Id.* at 38–39 (quoting Memorandum from Richard McGhee, Cal. Dir. of Corr., to Earl Warren, Governor of Cal. (July 2, 1947)).

same time period saw the birth of McCarthyism and blacklisting at the federal level for the first time.[24]

However, by the end of the 1950s the United States Supreme Court brought an end to blacklisting of alleged communists,[25] and by the end of the 1980s, public interest in the creation of criminal registries had almost completely waned.[26] Instead, in response to the social pressures to act to deal with the two crises of the times, legislative efforts were redirected to two different types of blacklisting. First, police databases of alleged gang members sprang up across the country in the mid-1980s at the state level in response to the very real problems with rising crime

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[24] The McCarran Internal Security Act, also known as the Subversive Activities Control Act of 1950 seq.), was part of a legislative package that was designated as the Internal Security Act of 1950. See 50 U.S.C. §§ 788–795 (2006)(repealed 1993). This Act created a blacklist of Communist organizations maintained by the U.S. Attorney General. The Act also established the Subversive Activities Control Board to investigate alleged Communist action and suspected Communist front organizations in order to populate the blacklist. *Id.*

[25] In *Yates v. United States*, 354 U.S. 298 (1957), the Court focused on the difference between "advocacy of abstract docrine and advocacy directed at promoting unlawful action." *Id*. at 316. According to the Court, "the advocacy and teaching of forcible overthrow as an abstract principle" was not punishable as long as it was "divorced from any effort to instigate action to that end." *Id*. In *Albertson v. SACB*, 382 U.S. 70 (1965), the Court held that the registration portion of the McCarran Act infringed upon the members' Fifth Amendment right against self-incrimination, essentially marking the end to attempts to register members of the Communist Party.

[26] LOGAN, *supra* note 11, at 48. Reservations over fairness and the impact on civil liberties, along with serious doubts about both the completeness and the accuracy of the registries, appeared to relegate criminal blacklists to the archives. *Id.*

rates associated with the growth of gangs.[27] In the same timeframe, public attention was captured by the perceived medical malpractice insurance crisis and a series of sensationalized cases of known negligent practitioners who were allowed to continue harming patients.[28] Public fear lead to the second time that a blacklist was created on the federal level—one of "bad" doctors. As more fully described in the next sections, from 1986 to 1992, federal legislative blacklisting efforts yielded laws and regulations that created the NPDB with a focus on cleansing the healthcare system of these "bad" doctors.

Coming hard on the heels of physician blacklisting, in the early 1990s, a series of highly publicized kidnapping, rape and murder of child victims by repeat offenders dramatically reanimated public interest in the use of criminal blacklists for sex offenders and the legislative blacklisting focus switched yet again:

> In July [of 1993], 10 year old Zachary Snider of Indiana was molested and murdered by a neighbor who, unbeknownst to community members, was a convicted sex offender. In September, 7-year-old Asheley Estell was abducted from a Texas playground and killed, resulting in the arrest of a previously convicted child molester. A month later, 12-

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[27] Gang databases began being used by law enforcement in the mid-1980s. OFFICE OF JUVENILE JUSTICE AND DELINQUENCY PREVENTION, OJJDP COMPREHENSIVE GANG MODEL: A GUIDE TO ASSESSING YOUR COMMUNITY'S YOUTH GANG PROBLEM, 38 (May, 2009), *available at* http://www.nationalgangcenter.gov/Content/Documents/Assessment-Guide/Assessment-Guide.pdf.

[28] See *infra* Part II.A.

> year-old Polly Klass was kidnapped at knife point from a slumber party in her California home, while her mother slept in an adjacent room. Her body was found two months later and Richard Allen Davis, who had a history of kidnapping and other offenses, was arrested, convicted, and eventually executed for the crime.[29]

By 1995, every state had registration laws and the new phrase "sexual predator" became part of the nation's vocabulary.[30] This second generation of laws greatly expanded the scope of the registration requirement to include community notification.[31] As Professor Wayne Logan explains, this expansion was driven by a desire by communities to engage in self-protection and was premised on the public's "right to know."[32]

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[29] LOGAN, *supra* note 11, at 54.

[30] *Id.* at 95 (noting that prior to the 1990s, victimizers were portrayed in clinical terms, such as "sexual psychopath" or "sexually dangerous person").

[31] *Id.* at 49.

[32] *Id.* at 101–103. The remarkable increase in sexual offender registration laws was the result of the Federal Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act, Pub. L. No., 103–322, 108 Stat. 2038 (1994)(codified as amended at 42 U.S.C. §14071 (2006)(repealed 2006)). The Wetterling Act relied upon Congress's spending power to 'encourage' states to pass registration and permissive community notification laws to avoid losing ten percent of their federal Byrne Formula Grant Program funds. 42 U.S.C. §14071 (g)(2)(2006)(repealed 206). The reliance by state criminal justice programs on the funds afforded them by the Byrne Program meant that every state quickly adopted registration laws. LOGAN, *supra* note 11, at 65. The Wetterling Act subjected sexually violent predators to lifetime registration. *Id*. at 59. However, as the implementation of community- notification

Frustrated with the continued lack of uniformity in the strength of state programs, Congress passed the Adam Walsh Child Protection and Safety Act of 2006 (AWA) which substantially overhauled federal registration and community notification by establishing a uniform national system.[33] Under the AWA, all sexual offenders, including juveniles, must register and information on each registrant must be provided to the community by state-created and -maintained websites.[34] Registrants are also placed in the federal Dru Sjodin National Sex Offender Public Website.[35] To ensure state compliance, the Sex

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programs was not mandatory, only some states created community-notification programs. *Id.* at 60. In 1996, Congress reacted to the states' reluctance to engage in community notification by making it mandatory with the passage of Megan's Law. *See* Megan's Law, Pub. L. 104-45, 110 Stat. 1345 (1996) (amending 42 U.S.C. §1407(d)(1994)). Once again, all of the states quickly fell into line with the federal mandate in order to avoid losing federal funding. *See* LOGAN, *supra* note 11, at 65. The registration and community-notification programs required by the Wetterling Act and Megan's Law included the requirement that "[i]nformation must be released to members of the public as necessary to protect the public from registered offenders." Final Guidelines for Megan's Law and Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act, 69 Fed. Reg. 39009, 39019 (July 21, 1997). States retained discretion with regard to which registrants would be part of community notification and what information would be provided leading to a wide variation in the range and quality of state programs. LOGAN, *supra* note 11, at 60–62. A series of federal laws that added on additional layers or requirements ensued in order to improve the quality of state programs. *Id.* at 62.

[33] Pub. L. 109-248, 120 Stat. 587 (2006) (codified at 42 U.S.C. § 16901 (2006)).

[34] LOGAN, *supra* note 14, at 62.

[35] *Id.* at 64.

Offender Sentencing, Monitoring, Apprehending, Registering and Tracking (SMART) Office within the Department of Justice was created.[36]

Of course, since September 11, 2001, the U.S. government's Terrorist Screening Center maintains a No-Fly List of people who are not allowed to fly on commercial flights for travel into, within, or out of the United States.[37] On September 11, 2001, the FBI had a list of sixteen people who were on a list they kept of people they deemed to present a risk to aviation.[38] By November 2001, the FBI list grew to 400 names.[39] At that point, responsibility for the list was transferred to the Federal Aviation Administration.[40] In mid-December, the list was split to create a list of those not allowed to fly and a list of those who were to be more carefully searched at airports.[41]

The news program *60 Minutes* obtained a copy of the list and reported that the no-fly list contained 44,000 names, and that the list of those who must be more carefully searched at airports contained 75,000

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[36] *Id.* at 65.

[37] *Frequently Asked Questions,* FED. BUREAU OF INVESTIGATION TERRORIST SCREENING CENTER, http://www.fbi.gov/about-us/nsb/tsc/tsc_faqs (last visited Aug. 6, 2011).

[38] *See* Attachment A, Part 1 of Public Record at 2, Gordon v. FBI, 390 F. Supp. 2d 897 (N.D. Cal. 2004) (No. C 03-01779), *available at* http://www.aclunc.org/cases/landmark_cases/asset_upload_file371_3549.pdf (including a PowerPoint presentation created by the U.S. Department of Transportation's Transportation Security Intelligence Service in December of 2002 regarding the TSA Watch List, which was introduced into the public record during the case of *Gordon v. FBI* in 2003).

[39] *Id.*

[40] *Id.*

[41] *Id.* at 3.

names.[42] With regard to the Terrorist Watch List, the Transportation Security Center's website entitled "Myth Busters" states that "[a]ccording to the Terrorist Screening Center, there are less than 400,000 individuals on the consolidated terrorist watch list."[43] The only way for someone to find out if they are on the No-Fly List or the Terrorist Watch list is to be stopped at the airport when they are trying to fly—information that thousands of harmless citizens are learning in this highly disruptive and emotionally upsetting way.[44]

What should stand out in this very general overview of the history of blacklisting in the United States is that most blacklisting efforts are focused on individuals who are targeted because of some characteristic that makes them much more likely to engage in very dangerous criminal activity that carries with it a serious risk of physical harm. The blacklisting of physicians, whose mission is to serve the community, does not seem to fit this pattern. As such, it is easier to understand a decision to neglect due process protections for suspected terrorists in light of the nature and degree of the threat of harm, than this same decision when applied to physicians.

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[42] *Unlikely Terrorists on No Fly List,* CBSNEWS.COM (Oct. 8, 2009, 1:00 PM), http://www.cbsnews.com/stories/2006/10/05/60minutes/main2066624.shtml. According to this *60 Minutes* report, the government will not release the criteria it relies upon to create the list. *Id.*

[43] *Myth Buster: TSA's Watch List is More Than One Million People Strong,* TRANSP. SECURITY ADMIN., http://www.tsa.gov/approach/mythbusters/tsa_watch_list.shtm (last visited Aug. 6, 2011).

[44] *See Unlikely Terrorists on No Fly List, supra* note 42.

B. Procedural Protections: Comparing Blacklisting of Sexual Predators, Suspected Gang Members, Suspected Terrorists and No-Fly Lists with the Blacklisting of Physicians

In *Connecticut Department of Public Safety v. Doe* (*CDPS*),[45] the United States Supreme Court found that a prior conviction is both *a necessary* and sufficient condition for registration and community notification of sexual offenders to be constitutional. In *CDPS*, the Court held that "the law's requirements turn on an offender's conviction alone—a fact that a convicted offender has already had a procedurally safeguarded opportunity to contest."[46] The Court explained:

> In cases such as *Wisconsin* v. *Constantineau* and *Goss* v. *Lopez* we held that due process required the government to accord the plaintiff a hearing to prove or disprove a particular fact or set of facts. But in each of these cases, the fact in question was concededly relevant to the inquiry at hand. Here, however, the fact that respondent seeks to prove—that he is not currently dangerous—is of no consequence under Connecticut's Megan's Law. As the DPS Website explains, the law's requirements turn on an offender's conviction alone—a fact that a convicted offender has already had a procedurally safeguarded opportunity to contest. … No

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[45] 538 U.S. 1 (2003).

[46] *Id.* at 7.

> other fact is relevant to the disclosure of registrants' information.[47]

In contrast to blacklisting sexual predators, when physicians are blacklisted by the federal government, they have not been provided with a procedurally safeguarded opportunity to contest the accuracy of the facts included in the reports that are filed with, and then disseminated by, the NPDB.[48] Moreover, alleged sexual predators are provided with the additional safeguard of having the highest burden of proof placed on the government to prove the allegations against them. Hospitals in peer review only have to establish the allegations against physicians by a preponderance of the evidence.[49] Finally, there is no requirement that anyone check the blacklists of sexual predators. In juxtaposition, hospitals face stiff sanctions for failing to query the NPDB blacklist for negative reports on every physician who applies for staff privileges and for negative reports every two years for all physicians who already have staff privileges.[50]

The same comparison can be made with regard to suspected gang members and terrorists as well as no-fly lists. While these types of blacklists contain a high risk of error that makes them constitutionally suspect,[51] at least if a person is arrested and a

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[47] *Id.* (citations omitted).

[48] *See infra* notes 146–76, 268–343 and accompanying text.

[49] *See* CREDENTIALING AND PEER REVIEW PRACTICE GRP. OF THE AM. HEALTH LAW ASS'N, PEER REVIEW GUIDEBOOK 75 (3d ed. 2003) [hereinafter PEER REVIEW GUIDEBOOK].

[50] *See infra* note 141 and accompanying text.

[51] *See generally* Joshua D. Wright, *The Constitutional Failure of Gang Databases,* 2 STAN. J. C.R. & C.L. 115 (2005) (explaining

prosecutor attempts to use gang membership to either obtain a conviction or enhance a sentence, that person is provided with a procedurally safeguarded opportunity to contest the accuracy of the alleged membership.[52] And if a person discovers that they are falsely placed on one of these lists, that person has a right to access to the courts to obtain injunctive relief to get their name removed.[53] As discussed *infra*, physicians who are blacklisted, in the vast majority of cases, do not have access to the judicial system at all.[54]

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the high risk of error associated with gang databases and persuasively arguing that they are unconstitutional).

[52] CHARLES M. KATZ & VINCENT J. WEBB, POLICING GANGS IN AMERICA 241 (2006).

[53] Wright, *supra* note 51, at 124. Wright points to two illustrative cases:

> [T]wo teenage Vietnamese-American girls in California were fortunate enough to have their names removed and photographs purged as a result of a settlement after the ACLU filed a class action lawsuit on their behalf. A more recent case involved a Union City Police Department sweep of James Logan High School in Union City, California. School administrators detained approximately sixty Hispanic and Asian students who were taken from the school cafeteria to vacant classrooms for questioning. Photos of the students were taken and put in the Union City Police gang database and have not been removed to this date. The ACLU has filed a class action lawsuit on behalf of three of the students.

Id. (citations omitted).

[54] *See infra* notes 172, 343–52 and accompanying text.

II. THE NATIONAL PRACTITIONER DATA BANK

A. *History*

The history and motivation behind the creation of the NPDB is similar in some interesting ways to that of Megan's Laws and other blacklisting efforts. Each of these blacklists resulted from a legislative response to public fears caused by an exaggerated perception of the risk of harm. Professor Wayne Logan, in his excellent book *Knowledge as Power: Criminal Registration and Community Notification Laws in America,* writes:

> Much as the nation's first registration laws were prompted by an "emergency" over the perceived threat of an influx of "gangsters," modern laws have been motivated by a sustained sense of exigency concerning sex offenders. Alarming statistics adduced by political leaders have, in turn, been absorbed by the media and the public, leading to a self-perpetuating legislative process resulting in today's nationwide network of registration and notification laws. And, much as in the early 1930s, when the nation was convinced that it was in the grip of a "crime wave," compelling immediate action, the statistical record belied this perception: child and adult sexual abuse has actually declined since the 1990s.[55]

Much of the same can be said of the social and political catalysts for physician blacklisting. In the mid-1980s, at the time of the passage of the Health Care Quality Improvement Act of 1986 (HCQIA) and

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[55] LOGAN, *supra* note 11, at 97.

the creation of the NPDB, the United States was in the middle of a perceived medical malpractice insurance crisis. Insurance companies were pulling out of markets and insurance costs were increasing at rates that were causing some physicians to leave the practice. As pointed out by Professor David Nye:

> When the President of the American College of Obstetricians and Gynecologists reported in February 1986 on the state of his profession, he chose Charles Dickens' opening words in *A Tale of Two Cities*. "It was the best of times, it was the worst of times," recited Dr. William Mixson. On one hand, Mixson noted the significant advances in medical care for obstetrical patients and the reduced risks of infant mortality. On the other hand, reported Mixson, the professional liability of members of his profession had reached "crisis proportions."[56]

Stories from the press about this perceived crisis flooded the American consciousness.[57] Lawyers and the tort system were routinely blamed, with then-President Ronald Regan and Attorney General Edwin Meese joining in the fingerpointing. For this group, tort reform was touted as the solution to the problem.[58] Others blamed "bad" doctors for the malpractice insurance crisis and advocated getting

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[56] David J. Nye et al., *The Causes of the Medical Malpractice Crisis: An Analysis of Claims Data and Insurance Company Finances,* 76 GEO. L.J. 1495, 1495 (1988).

[57] *See id.* at 1496–98.

[58] *Id.*

rid of incompetent physicians.[59] Acting on this second viewpoint, in the early to mid-1980s:

> [S]tates and health care accrediting bodies stepped up their promotion of peer review—the process by which physicians judge the competence of their fellow professionals and recommend disciplinary action for those found dangerously incompetent. As this process gathered force, physicians aggrieved by the results of peer review increasingly appeared in federal court claiming that the actions of their peers were anti-competitive and violated federal antitrust laws. Although hospitals and peer review participants generally prevailed in these lawsuits, the victories entailed costly and time-consuming litigation.[60]

Stepping into this volatile scene was the U.S. Supreme Court case of *Patrick v. Burget*.[61] In *Patrick,* the plaintiff, Dr. Timothy Patrick, worked at the Astoria Medical Clinic (the Astoria Clinic) for one year in a small Oregon town of 10,000.[62] Two of the defendants in the case were partners in the Astoria Clinic, Dr. Gary Boelling and Dr. Franklin Russell.[63]

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[59] H.R. REP. NO. 99–903, at 1 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6384, 6384 ("This bill is needed to deal with one important aspect of the medical malpractice problem in this country–incompetent and unprofessional physicians.").

[60] Manion v. Evans, 986 F.2d 1036, 1037 (6th Cir. 1993).

[61] 486 U.S. 94 (1988).

[62] *Id.* at 95–96.

[63] *Id.* at 96–97.

Another defendant was a surgeon working at the Astoria Clinic, Dr. Richard Harris.[64]

After his one year at the Astoria Clinic, Dr. Patrick decided not to join the Astoria Clinic as a partner, instead leaving to start his own practice.[65] Dr. Patrick's new practice reflected both his specialty as a vascular surgeon and his practice as a general surgeon.[66] Dr. Patrick's new general surgery practice was in competition with the Astoria Clinic.[67] In light of this competition, the partner's in the Astoria Clinic refused to enter into cross-coverage agreements with Dr. Patrick.[68] In addition, instead of referring their patients who needed vascular surgery to the local office of Dr. Patrick, they sent these patients fifty miles away to other doctors.[69]

In the meantime, the doctors who worked at the competing Astoria Clinic began to criticize Dr. Patrick for failing to obtain adequate backup coverage and outside consultations.[70] Then, in 1979, Dr. Boelling, a partner in the Astoria Clinic, made a complaint against Dr. Patrick to the executive committee of the Columbia Memorial Hospital's (CMH) medical staff. Dr. Boelling claimed that Dr. Patrick left a patient in the care of a recently hired associate, who then left the patient unattended.[71] CMH was the only hospital in Astoria, Oregon at that

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[64] *Id.* at 97.

[65] *Id.* at 96.

[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *Id.*

[71] *Id.* at 96–97.

time.[72] And during the relevant time period, a majority of the physicians at the CMH were either employees or partners of the Astoria Clinic.[73]

The person who chaired the investigation of this complaint was none other than Dr. Russell, a partner in the Astoria Clinic and a competitor of Dr. Patrick's.[74] Based on this investigation, the executive committee referred this complaint, along with information about other cases handled by Dr. Patrick, to the State Board of Medical Examiners (BOME).[75] The members of the BOME committee criticized Dr. Patrick's medical practices to the full BOME, which then issued a letter of reprimand that had been drafted by the same Dr. Russell who performed the hospital investigation and who was a competitor of Dr. Patrick.[76] Once Dr. Patrick began to pursue judicial review of the BOME, the BOME completely retracted the reprimand letter.[77]

Then, only two years later, defendant Richard Harris, an Astoria Clinic surgeon, requested that CMH review Dr. Patrick's clinical privileges at the CMH.[78] The executive committee of the CMH's medical staff performed this review and decided to terminate Dr. Patrick's privileges on the ground that his care of his patients was below the extraordinarily

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[72] *Id.* at 96.

[73] *Id.*

[74] *Id.* at 97.

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.*

vague "standards of the hospital."[79] Dr. Patrick demanded a hearing, as provided by hospital bylaws.[80] And, not much of a surprise, the same Dr. Boelling appears in the story again as the chair of the five member ad hoc committee that heard the charges and the defense.[81]

After the members of the committee refused to testify about their personal bias against him, Dr. Patrick resigned his staff privileges before the committee reached its decision rather than risk termination.[82] He then filed an antitrust lawsuit alleging that the clinic's physicians violated antitrust laws by bringing a sham hospital peer review proceeding in order to eliminate him as a competitor by destroying his practice.[83] Dr. Patrick won $650,000 in antitrust damages in the jury trial. The court trebled the damages to $2.2 million under the antitrust laws and awarded $228,600 in attorney's fees.[84] On appeal, the Ninth Circuit Court of Appeals specifically found that "there was substantial

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[79] *Id.* The validity of this type of vague standard and the perils that are associated with its use are explained *infra* notes 276–99 and accompanying text.

[80] *Patrick,* 486 U.S. at 97.

[81] *Id.*

[82] *Id.*

[83] *Id.* at 97–98.

[84] *Id.* at 98. The Ninth Circuit later reversed, finding that the trial court did not properly instruct the jury on the state action of antitrust immunity to peer review activities. Ultimately, the U.S. Court reversed the Ninth Circuit, holding that Oregon's peer review statute did not provide for active supervision as necessary to establish antitrust immunity under the state-action doctrine. *Id.* at 98–99.

evidence that respondents had acted in bad faith in the peer-review process."[85]

Rather than focus on the sham peer review aspects of the case,[86] the press spin on the case that caught national attention was that an incompetent physician terminated a peer review proceeding in order to avoid a verdict on his competence.[87] Then, that same incompetent physician turned around and sued the members of the peer review committee and won millions.[88] This mischaracterization of the case allegedly caused alarm among those in the medical profession as it raised the specter of possible retaliatory litigation for good faith participation in peer review.[89] Members of Congress speculated that this undocumented fear discouraged physicians from participating in peer review to avoid the risk of being

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[85] *Id.* at 98.

[86] The Court of Appeals specifically found:

> [T]here was substantial evidence that respondents had acted in bad faith in the peer-review process. The [Court of Appeals] held, however, that even if respondents had used the peer-review process to disadvantage a competitor rather than to improve patient care, their conduct in the peer-review proceedings was immune from antitrust scrutiny. The court reasoned that the peer-review activities of physicians in Oregon fall within the state-action exemption from antitrust liability because Oregon has articulated a policy in favor of peer review and actively supervises the peer-review process.

Id. at 98.

[87] *See* Nicholas Kadar, *How Courts Are Protecting Unjustified Peer Review Actions Against Physicians by Hospitals,* 16 J. AM. PHYSICIANS & SURGEONS 17, 20 (2011).

[88] *Id.*

[89] *Id.; see also* H.R. REP. NO. 99–903, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6384, 6385–86.

sued for millions.[90] To alleviate these speculative fears, a bill was introduced by Congressman Ron Wyden of Oregon to provide immunity from retaliatory lawsuits for those engaging in "good faith" peer review.[91]

While the *Patrick* case was playing out in the press, another series of well-publicized cases[92] caught the attention of the nation through the effective use of the same narrative technique or storytelling that was used later to trigger Megan's Laws. For example, the *Boston Globe's* 1986 story on the infamous Dr. Frederick Huffnagle was akin to reading a spine-tingling horror story.[93] Within two years of obtaining staff privileges at Beverly Hospital in Danvers, Connecticut, Dr. Huffnagle was placed on probation in 1970 for performing experimental hip replacement surgery without conducting a prior consultation or obtaining the proper equipment.[94] Dr. Huffnagle had

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[90] Kadar, *supra* note 87, at 20; H.R. REP. NO. 99–903, at 2–3.

[91] Kadar, *supra* note 87, at 20; H.R. REP. NO. 99–903.

[92] Charlotte L. Rosenberg, *How Bad Doctors Dodge Discipline,* 62 MED. ECON. 241 (1985) (reporting on thirty-three physicians who engaged in state hopping after negative state licensure proceedings); U.S. GEN. ACCOUNTING OFFICE, GAO-84-53, EXPANDED FEDERAL AUTHORITY NEEDED TO PROTECT MEDICARE AND MEDICAID PATIENTS FROM HEALTH PRACTITIONERS WHO LOSE THEIR LICENSES, at iii, 7–8 (1984), *available at* http://www.gao.gov/assets/150/141458.pdf (identifying thirty-nine doctors who relocated to new states after losing their license in another state and pointing out that far less than one percent of physicians have problems that lead to licensure sanctions which translates into less than one per 1000 physicians).

[93] *Small Percentage of Doctors Responsible for Surge in Malpractice Suits, Rates,* BOS. GLOBE, June 15, 1986, at 1.

[94] *Id.*

never performed the surgery before, nor had anyone else at the hospital where the surgery was performed. Due to this incident, among "other serious continuing difficulties," Beverly Hospital declined to renew his staff privileges.[95]

No problem for Dr. Huffnagle, who also had staff privileges at nearby Hunt Memorial.[96] In spite of the problems at Beverly Hospital, Dr. Huffnagle continued to perform surgeries at Hunt Memorial, including several surgeries on Beatrice Higgins.[97] Although she had osteoarthritis, Beatrice could still walk to the grocery store to get her groceries when she first met Dr. Huffnagle.[98] The good doctor implanted an artificial knee in Beatrice that was the wrong size.[99] When he removed it, he fractured a bone and ruptured a tendon. Five year later, Beatrice was still confined to a nursing home and could only leave in a wheelchair.[100]

In 1981, Dr. Huffnagle moved to California, leaving behind five malpractice suits in which patients were compensated for injuries.[101] Dr. Huffnagle obtained staff privileges at Westminster Hospital in California by claiming that his staff privileges had never failed to be renewed and that no settlements had been paid pursuant to any malpractice claims against him.[102] Dr. Huffnagle only lasted one year at Westminster;

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[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *Id.*

[102] *Id.*

however, in that one year, he had four more malpractice lawsuits filed against him.[103] Twenty-nine-year-old Roger Lucas was a bindery supervisor who pulled a muscle in his back when stacking crates.[104] Four years after a botched surgery by Dr. Huffnagle, Roger Lucas was left seriously disabled and in constant pain. He was unable to ever work again.[105] After his year in California, Dr. Huffnagle moved to Massachusetts and was easily hired by Massachusetts Osteopathic.[106]

Stories like those of Dr. Huffnagle and Dr. Patrick enflamed public passions and legislators were pressured to act. As described in HCQIA's legislative history:

> [G]roups such as state licensing boards, hospitals and medical societies that should be weeding out incompetent or unprofessional doctors often do not do so. Even when such bodies do act against bad physicians, these physicians find it all to [sic] easy to move to different hospitals or states and continue their practices in these new locations.
>
> The result has been a series of highly visible situations in which physicians with a long history of incompetence or unprofessional conduct have continued to

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[103] *Id.*

[104] *Id.*

[105] *Id.*

[106] *Id.*

> cause needless deaths and injury for years after their damaging behavior was noticed.[107]

As is apparent from this passage, the public perception was that physicians and hospitals were reluctant to report their peers and were thereby increasing the overall legal liability for their profession. This reluctance to report was seen as contributing to the overall medical malpractice insurance crisis. After the *Patrick* case, this reluctance to report incompetent physicians was blamed on the alleged fear of retaliatory lawsuits.[108]

Together, the perceived medical malpractice insurance crisis, the *Patrick* case and the series of cases in which known incompetent physicians, like Dr. Huffnagle, were allowed to continue to injure patients, came together in 1986 through the all-pervasive media to incite the same kind of public fear that triggered other forms of blacklisting, such as lists of criminals, alleged communists and gang members, and, later, Megan's Laws for sexual predators.

Thus, in 1986, Congress diagnosed an "increasing occurrence of medical malpractice" throughout the nation that warranted the intervention of the federal government and the bill that Congressman Ron Wyden of Oregon introduced was adopted as the

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[107] H.R. REP. No. 99–903, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6384, 6385.

[108] A more likely cause was a culture prevalent in most hospitals characterized by a reluctance on the part of physicians to report their colleagues to the hospital administration. *See* U.S. GEN. ACCOUNTING OFFICE, GAO-01-130, NATIONAL PRACTITIONER DATA BANK: MAJOR IMPROVEMENTS ARE NEEDED TO ENHANCE DATA BANK'S RELIABILITY 10–11 (2000), *available at* http://www.gao.gov/new.items/d01130.pdf.

HCQIA.[109] In the Act itself, Congress explained the purposes behind the legislation:

> (1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.
>
> (2) There is a national 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.
>
> (3) This nationwide problem can be remedied through effective professional peer review.
>
> (4) The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review.
>
> (5) There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.[110]

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[109] 42 U.S.C. §§ 11101–11152 (2006).

[110] *Id.* § 11101. For a more complete discussion of HCQIA, see Katharine A. Van Tassel, *Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines,* 36 SETON HALL L. REV. 1179, 1194–97 (2006).

In order to prevent physicians from challenging the results of peer review in court and winning damages, like the case of Dr. Patrick, HCQIA created a form of protection from liability in damages for hospitals and peer review participants.[111] The point was not to make it impossible for physicians to challenge a sham peer review and thereby to obtain injunctive relief from sanctions unrelated to quality of care, but to insulate the participants from having to pay out money damages if the challenging physician prevailed. For this reason, the Act does not actually use the term "immunity." Instead, it provides that if a "professional review action" meets the Act's standards, the peer reviewers "shall not be liable in damages under any law of the United States or of any State . . . with respect to the [professional review] action."[112] HCQIA also established the NPDB in order to prevent physicians like Dr. Huffnagle from "mov[ing] from State to State without disclosure or discovery of the physician's previous damaging or incompetent performance."[113]

As Professor Tom Baker points out in his popular and highly regarded book *The Medical Malpractice Myth,*[114] the reality is that there was not a crisis in medical malpractice insurance during the 1980s; however, there is no doubt that there was, and still

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[111] This immunity does not extend to civil rights claims or government antitrust prosecutions. *See* 42 U.S.C. § 11111 (2006); Robert J. Enders, *Federal Antitrust Issues Involved in the Denial of Medical Staff Privileges,* 17 LOY. U. CHI. L.J. 331 (1986).

[112] 42 U.S.C. § 11111(a)(1).

[113] 42 U.S.C. § 11101(2).

[114] *See generally* TOM BAKER, THE MEDICAL MALPRACTICE MYTH (2005).

is,[115] a crisis in the amount of medical malpractice committed. Professor Baker does a masterful job of deconstructing and debunking "the beliefs that undergird the call for tort 'reform' and impede the ability of the polity to focus on, and respond constructively to, the real problems of healthcare in twenty-first century America."[116] So, just as was the case with the disconnect between the reality of the level of the threat from sexual predators that triggered Megan's Law, Professor Baker persuasively argues that the real cause of the rise in insurance rates in the 1980s was the insurance cycle and that there was no real relationship between "bad" doctors and the perceived insurance crisis.[117] Similarly, it is more likely that the reluctance of physicians to report a colleague is related to a long-standing cultural aversion to turning in a peer for poor performance than to a fear of retaliatory lawsuits like that of Dr. Patrick.[118]

Importantly, Professor Baker points out what many, until recently, have ignored—there is an

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[115] Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care,* 363 NEW ENG. J. MED. 2124, 2130 (2010) ("In a statewide study of 10 North Carolina hospitals, we found that harm resulting from medical care was common, with little evidence that rate of harm had decreased substantially over a 6-year period ending in December 2007.").

[116] Mary Coombs, *The Medical Malpractice Myth,* 27 J. LEGAL MED. 243, 243 (2006) (reviewing BAKER, *supra* note 114).

[117] *Id.* at 243–45; *see also* Thomas Baker, *Medical Malpractice and the Insurance Underwriting Cycle,* 54 DEPAUL L. REV. 393, 396–422 (2005) (providing a "primer on the liability insurance underwriting cycle that draws on the research prompted by the mid-1980s insurance hard market").

[118] *See infra* notes 258–59 and accompanying text.

astonishing amount of malpractice that occurs in the United States:

> [T]here really is not any question about the epidemic of medical malpractice. Report after report stretching back into the 1970s makes that fact very clear. The reports also make clear that there really are very few medical malpractice lawsuits, especially compared to the amount of medical malpractice. Depending on how we count, there are between seven and twenty-five serious medical malpractice injuries for every one medical malpractice lawsuit. By comparison, almost everyone who gets injured by a negligent driver files an auto lawsuit or claim.[119]

The California Medical Insurance Feasibility Study[120] was the first major study of medical errors that came out in the mid-1970s. This study discovered that one out of every twenty patients was injured by physicians and one out of every ten of these patients died as a result. Of these injuries, one out of every six was the result of malpractice. This translated into physicians injuring 140,000 patients and killing 14,000 patients in California in 1974.[121] Interestingly, this data suggests that a conversion to a no-fault system would be far more expensive than the current tort system as every one of these patients would

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[119] BAKER, *supra* note 114, at 23.

[120] Don Harper Mills, *Medical Insurance Feasibility Study: A Technical Summary,* 128 W. J. MED. 360 (1978).

[121] BAKER, *supra* note 114, at 25–26.

merit compensation that would be far more than what the tort system was paying out.[122]

The Harvard Medical Practice Study (HMPS)[123] came out in the mid-1980s, during the second medical malpractice insurance "crisis."[124] This study was commissioned and paid for by the State of New York and was performed by researchers from Harvard.[125] The results were basically the same as the California study.[126] Doctors injured one out of twenty-five patients and one out of every four of these cases was caused by negligence.[127] There were 27,000 injuries from medical malpractice in New York in 1984.[128] This study suggests that there are 150,000 patient deaths every year inadvertently caused by physicians, half of which are the result of medical malpractice.[129]

The seminal report on medical errors in hospitals came from the Institute of Medicine (IOM) in 1999 and is entitled *To Err Is Human.* This report documented the fact that between 44,000 and 98,000 patients die each year in hospitals due to preventable medical mistakes.[130] And in 2010, a follow-up study of

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[122] *Id.* at 26–27.

[123] T.A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I,* 13 B.M.J. QUALITY & SAFETY HEALTH CARE 145 (2004).

[124] BAKER, *supra* note 114, at 27.

[125] *Id.*

[126] *Id.* at 29.

[127] *Id.*

[128] *Id.*

[129] *Id.* at 30.

[130] INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26 (Linda T. Kohn et al. eds., 2000).

ten hospitals in North Carolina found that "harms remain common, with little evidence of widespread improvement."[131]

While the rationales that motivated the creation of the NPDB in the first instance are suspect, the fact that there is a real and continuing medical malpractice crisis means that the NPDB is actually a good idea. The problem is that it is currently constructed in a way that does not fairly balance the interests of the stakeholders, including the patients, the doctors, and the hospitals. It also has very questionable efficacy as the data that it contains is likely to be misleading or incorrect. In addition, because of the reporting sources that it relies on to create this data, it is also likely to actually be negatively impacting healthcare quality, cost, and access. This Article does not suggest that the NPDB be discontinued; instead, this Article suggests a revision of the processes that the data bank relies upon to greatly improve the NPDB's impact on quality, cost, and access to healthcare.

B. *The National Practitioner Data Bank Reporting and Query Mandates*

In addition to creating "immunity" from suit, HCQIA also set up the NPDB.[132] The Health Resources and Services Administration (HRSA) has

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[131] Landrigan et al., *supra* note 115, at 2130.

[132] 42 U.S.C. § 11134 (2006); 45 C.F.R. § 60.1 (2010) ("The Health Care Quality Improvement Act of 1986 . . . authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists and other health care practitioners.").

federal responsibility for oversight of the NPDB.[133] HRSA completed the regulations that established the operation of the NPDB in October of 1989.[134] While HRSA is responsible for ensuring compliance with these regulations, the actual day-to-day operation of the NPDB is performed by a private operator.[135]

The Act and its regulations established mandatory reporting requirements.[136] Insurance companies must report malpractice payments and settlements on behalf of physicians.[137] State licensing boards must report disciplinary actions.[138] Healthcare providers, for example, hospitals and health plans, must report disciplinary actions that restrict a physician's clinical privileges for more than thirty days.[139] Even private professional societies such as the American Medical Association (AMA) and the American Dental Association must report sanctions that negatively impact membership.[140] HRSA also negotiated a private agreement with some federal agencies, such as the Department of Veterans Affairs, to report on physicians who they insure, employ, or regulate.[141] Since 1997, practitioners who are excluded from participating in the Medicare and Medicaid Programs who either default on federal loan agreements or who

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[133] U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 7.

[134] *See* 45 C.F.R. § 60.3 (2010); National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, 54 Fed. Reg. 42,722, 42,730 (Oct. 17, 1989).

[135] U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 7.

[136] *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Id.* at 7–8.

engage in fraud or abuse must also be reported to the NPDB.[142]

Hospitals also have an obligation to query the NPDB every two years on each physician who already has staff privileges and for every physician applying for staff privileges.[143] Others, such as professional societies and state licensure boards, are allowed to query but are not obligated to do so.[144] Individual physicians are allowed to query, but only for information about themselves.[145]

C. Recent Expansion to Include Blacklisting of All Healthcare Practitioners

On March 1, 2010, new regulations significantly expanded the list of healthcare professionals that the NPDB reports on from just physicians and dentists to *all* healthcare practitioners.[146] The new regulations also expanded the kind of events that must be reported to include *any* negative action or finding, not just those related to competence or professionalism.[147]

In addition, the list of entities that can query the NPDB has expanded to include "private sector hospitals, nursing homes, and other organizations so that [disciplinary records] may be used when making employment, affiliation, certification, or licensure decisions."[148] Thus:

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[142] *Id.* at 8–9.

[143] *Id.* at 9.

[144] *Id.*

[145] *Id.*

[146] *See supra* note 3 and accompanying text.

[147] 45 C.F.R. § 60.10 (2011).

[148] U.S. Dep't of Health and Human Servs., *Why Is Section 1921 So Important?,* THE NATIONAL PRACTITIONER DATA BANK,

> Hospitals and their human resource departments and nurse recruitment offices now have access to licensure actions on all types of health care professionals. They may query the Data Bank on all types of health care professionals including nurses, nurse aides, and other allied health care professionals when making their hiring decisions. The ability to perform pre-employment screenings of potential health care employees is an invaluable resource that can enhance the hiring process and increase an organization's efforts towards patient safety.[149]

III. THE HOSPITAL PEER REVIEW HEARING PROCESS

There are three major systems in place that act to monitor the quality of patient care: the state medical malpractice system, the state licensure system, and the private hospital peer review system. The first two systems are public and therefore afford due process to physician defendants prior to providing negative reports to the NPDB. Unless it is a government-run hospital, like those run by the Veterans Administration (VA), hospital peer review is private and there is no obligation to provide physicians with due process protections during the hearing process. Private peer review is a self-policing system where physicians informally evaluate each other and turn in

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http://www.npdb-hipdb.hrsa.gov/resources/section1921.jsp (last visited Aug. 11, 2011).

[149] *Id.*

those physicians who are allegedly failing to provide quality patient care.[150]

If, after an investigation and hearing conducted by the hospital, a physician is found to have provided poor quality of care, that physician may be penalized in a variety of ways, including the termination of the physician's hospital staff privileges.[151] Hospitals must send reports of all actions "that adversely affect[] the clinical privileges of a physician for a period of longer than 30 days"[152] to the state licensure board, which, in turn, is required to report this information to the NPDB.[153] Hospitals must check the NPDB for negative reports before granting staff privileges to a physician.[154] The NPDB reporting and publication system has the intended impact on the targeted physician as, once the NPDB has published a negative report on a physician, the physician's reputation is irreparably damaged. Physicians report that a negative report is a "career ender" because it is difficult, if not impossible, to find a new position after

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[150] Van Tassel, *supra* note 110, at 1190. There are several general categories of conduct that could trigger the imposition of formal sanctions. Examples include inadequate clinical competence, physical and mental impairment, disruptive behavior, loss of license or malpractice insurance, or repeated violations of medical staff bylaws. This Article focuses on the standards that are used to evaluate clinical competence. This evaluation can occur in situations in which a physician is either denied staff privileges in the first instance based on clinical competence concerns, or when staff privileges are curtailed, terminated, or not renewed as a result of allegations of clinical incompetence. *Id.* at 1190–91.

[151] *Id.* at 1191–94.

[152] 42 U.S.C. § 11133(a)(1)(A) (2006).

[153] 45 C.F.R. § 60.5(d) (2011).

[154] 42 U.S.C. § 11135(a)(1) (2006).

a negative NPDB report.[155] As explained *infra,*[156] the inability to obtain hospital staff privileges seriously curtails the scope of the license to practice medicine granted by the state.

A. *The Hospital Process*

In the context of the delivery of healthcare, the term "peer review" refers to the evaluation of the performance of a physician by other physicians[157] pursuant to the obligations of the hospital medical staff to ensure "the quality of care, treatment, and services delivered by practitioners who are credentialed and privileged through the medical staff process."[158] A hospital medical staff committee charged with performing peer review to maintain or improve the quality of patient care has multiple responsibilities, including completing the credentialing of physicians. The credentialing process involves the assembly and assessment of information dealing with the competence and professional conduct of physicians who apply for hospital staff privileges, either for the first time or when applying for the renewal of those privileges.[159]

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[155] *See infra* Part IV; *see also* Sheree Lynn McCall, *A Hospital's Liability for Denying, Suspending and Granting Staff Privileges,* 32 BAYLOR L. REV. 175, 175 (1980) ("A physician's livelihood is dependent on acquiring and maintaining hospital staff privileges.").

[156] *See infra* Part IV.

[157] SLEE'S HEALTHCARE TERMS 474 (4th ed. 2001).

[158] JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK, P MS.1, at MS-2 (2005) [hereinafter CAMH].

[159] PEER REVIEW GUIDEBOOK, *supra* note 49, at 60; CAMH, *supra* note 158, at MS-1. The credentialing committee gathers and

analyzes the qualifications of the applicants. CAMH, *supra* note 158, at MS-17 to MS-24. It then provides a summary of this information to the medical staff executive committee. The medical staff executive committee then makes a recommendation to the governing body, usually a board of directors. *Id.* at MS-17. The board of directors is commonly comprised of lay persons who generally accept the medical judgments of the medical executive committee. John H. Colteaux, Note, *Hospital Staff Privileges: The Need for Legislation,* 17 STAN. L. REV. 900,907 (1965). The competence and professionalism of each physician who is a current member of the hospital staff must also be evaluated by the credentialing committee. CAMH, *supra* note 158, at MS–17 to MS-24. According to CAMH, the continued accreditation of the hospital is dependent upon the medical staff of hospitals ongoing participation in "performance improvement activities," including the implementation of a properly designed peer review process. *Id.* at MS-16 to MS-17, MS-17 to MS-26. Another source for the requirement that hospitals engage in peer review is Medicare's Conditions of Participation for Hospitals. These conditions for participation mandate that hospitals conduct ongoing periodic evaluations of their physicians as part of "an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. . . . [The program must] involve[] all hospital departments and services," and "track medical errors and adverse patient events, analyze their causes, and implement preventative actions and mechanisms." 42 C.F.R. § 482.21 (2011). If a physician is identified through these processes who does not appear to be providing quality patient care, either informal or formal punitive or restrictive sanctions may be imposed to attempt to improve the targeted physician's performance. Informal measures can include assistance by colleagues, self-correction, guidance with later reassessment, or supervisory oversight. PEER REVIEW GUIDEBOOK, *supra* note 49, at 2–3. The targeted physician usually completes the informal measures under the supervision of the department chair and the chief of staff. If informal measures do not work or are inappropriate from the start, what this Article will refer to as the formal peer review process will be initiated. The formal peer review process could result in restrictions on the scope of practice the physician may engage in within the hospital, a

When a physician already has staff privileges, the formal peer review process can be used to investigate the report of an incident involving poor patient care.[160] The institution's medical staff bylaws describe the process that is to be followed. While the processes can vary in their details from hospital to hospital, there are several features common to most hospital peer review hearing processes. First, medical

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suspension of staff privileges until corrective measures are taken by the physician or further education is received by the physician, or staff privileges could be terminated altogether. *Id.*

[160] *Id.* at 22. It is possible that a physician could have a negative report made to the NPDB at the very start of his or her career. Usually, a brand new physician is placed on a one-to-two-year probationary period with probationary staff privileges. At the end of the probationary period, the medical executive committee reviews the physician's records and then decides if that new physician should have an extension of the probationary period, be promoted to full medical staff status, or be terminated. *See, e.g.,* Chessick v. Sherman Hosp. Ass'n, 546 N.E.2d 1153, 1155–56 (Ill. App. Ct. 1989) (restrictions placed on advancement from probationary status to full staff based on "substandard" care). Termination can also take the form of a nonrenewal of privileges. A physician's medical staff appointment is generally only for one to two years. This creates a continuous need to reapply. This renewal period commonly coincides with an investigation into the level of a physician's quality of care. *See, e.g.,* Dayan v. Wood River Twp. Hosp., 152 N.E.2d 205, 206 (Ill. App. Ct. 1958); Duby v. Jordan Hosp., 341 N.E.2d 876, 878–79 (Mass. 1976) (noting that an attempted termination of physician's privileges failed as the necessary two-thirds vote under the bylaw for termination was not obtained; physician's privileges were not renewed as a result of the same charges based on a less rigorous provision of the bylaws dealing with renewal that only required a simple majority). If a renewal is denied, the appeal of the denial of renewal is generally made directly to the board of directors. Consequently, the board of directors will act as the investigator, prosecutor, jury, and appellate body.

staff bylaws are considered to be enforceable contracts between the members of the medical staff and the hospital.[161] These bylaws dictate who, or the bodies which, can file a complaint or a request for corrective action, which can trigger an investigation. The person, or body, that decides whether to initiate the investigation is also listed in the bylaws.[162] Unless there is an emergency,[163] this decision is normally made by the medical staff executive committee.[164]

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[161] *See* MICHAEL A. CASSIDY, IMMUNITY FOR CREDENTIALING DECISIONS UNDER FEDERAL AND STATE LAW 38 (2003). If the act of adopting medical staff bylaws is not considered to be the creation of a contract, courts have found consideration to support finding a contract in subsequent acts. *See, e.g.,* Virmani v. Presbyterian Health Servs., 488 S.E.2d 284, 287–88 (N.C. Ct. App. 1997) (holding that enactment of bylaws pursuant to preexisting duty does not create a contract but that offering staff privileges is sufficient consideration to create same); *see also* Sadler v. Dimensions Health Corp., 787 A.2d 807 (Md. Ct. Spec. App. 2001), *rev'd and remanded,* 836 A.2d 655 (Md. 2003); *cf.* Monroe v. AMI Hosps. of Tex., Inc., 877 F. Supp. 1022, 1029 n.5 (S.D. Tex. 1994) (noting that bylaws do not constitute contract under Texas law).

[162] PEER REVIEW GUIDEBOOK, *supra* note 49, at 23.

[163] *Id.* When the situation poses "immediate danger" to patients warranting immediate summary suspension of the physician's staff privileges, one individual can be designated as the decision-maker, commonly the chief of staff, or the decision can be made by the executive committee. *Id.*

[164] In *Pulido v. St. Joseph Memorial Hospital,* 547 N.E.2d 1383 (Ill. App. Ct. 1989), summary judgment was granted against a physician who pointed out that the same four-member executive committee conducted the investigation, found that summary suspension of staff privileges was warranted, and then also heard the appeal of their own decision, which they affirmed. *Id.* at 1387–90. The hospital board of trustees then affirmed. *Id.*

If a decision is made to investigate a complaint, as a general rule, the physician will be notified.[165] Either the executive committee will conduct the investigation itself, or it will appoint an ad hoc committee made up of members of the general medical staff to do so. Beyond the possibility of being interviewed, which may or may not happen, the physician has no role in the investigation phase.

Once the investigation is complete, the next step depends on whether the medical executive committee or an ad hoc committee of the medical staff has conducted the investigation. If the medical staff executive committee has conducted the investigation, it will draw up the list of charges and its recommended corrective action. This judgment can then be appealed by the physician to the governing body of the hospital.[166] The appeal is not reviewed de

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[165] The *Peer Review Guidebook* advocates giving the physician the full details of the complaint. PEER REVIEW GUIDEBOOK, *supra* note 49, at 23; *see also, e.g.,* Campbell v. St. Mary's Hosp., 252 N.W.2d 581,584 (Minn. 1977) (noting that the physician was notified of the investigation). It is not always the case that physicians are given notice that an investigation is being undertaken. *See, e.g.,* Islami v. Covenant Med. Ctr., Inc., 822 F. Supp. 1361, 1365 (N.D. Iowa 1992) (noting that physician was not informed of investigation).

[166] *See* Van Tassel, *supra* note 110, at 1189–94; CAMH, *supra* note 158, at MS–24. After a highly informal "hearing" on the matter, the decision of the board of directors then constitutes a final action of the hospital that the physician can appeal to a trial court. PEER REVIEW GUIDEBOOK, *supra* note 49, at 28. This hearing is likely to be pro forma and informal as

> hospital governing boards are normally composed of medical laymen who are unable to question the judgment of the staff on the evidence presented. Moreover, the board is dependent on the loyalty and goodwill of the medical staff and will be inclined to follow its recommendations for the sake of harmony in

novo but is based on the record created by the hearing in front of the executive committee.[167] The board of directors is commonly comprised of lay persons who are likely to concur with the medical judgments of the medical executive committee.[168] If the investigation has been undertaken by an ad hoc committee, it will draft the set of charges and make recommendations for corrective actions. The recommended corrective action of the ad hoc committee will be sent to the targeted physician who can file an appeal with the executive committee. The executive committee will have a summary, highly informal "hearing" in order to reach a decision. This decision can then be appealed to the board of directors.

> the hospital. Under these conditions, a board level hearing will often involve no more than the *pro forma* approval of the medial board's decision.

Colteaux, *supra* note 159, at 907–08.

[167] PEER REVIEW GUIDEBOOK, *supra* note 49, at 28. In *Carson v. Northwest Community Hospital,* 548 N.E.2d 579 (Ill. App. Ct. 1989), the executive committee both conducted the investigation and recommended that the physician be summarily suspended. *Id.* at 580. The physician requested a hearing before the executive committee. After the hearing, the executive committee issued a decision sustaining the suspension based on its finding that the physician provided "inadequate post-operative care." *Id.* The physician appealed and an ad hoc panel of five physicians convened nine times over six months to hear the case. *Id.* The panel found that the summary suspension should be lifted, conditioned on completion of training and one-year probationary status. *Id.* The hospital board of directors rejected the panel's recommendation and reinstated the summary suspension. *Id.*

[168] Colteaux, *supra* note 159, at 907.

Importantly, the HCQIA[169] grants immunity from suit for those who participate in the formal peer review hearing process if this hearing process was "fair."[170] While this process sounds good on paper, in operation it creates a high risk that physicians will be sanctioned for a whole list of reasons that are unrelated to the quality of patient care.[171] And the fairness precondition is currently being given no teeth by the reviewing courts and access to the court system to review peer review hearing decisions is almost nonexistent.[172] Importantly, as a result of the interpretation by the courts that the bad faith of the decision-makers does not render the proceeding unfair, peer review can be used to silence whistleblowers who attempt to improve quality of care.[173]

IV. BLACKLISTED: THE END OF A PHYSICIAN'S CAREER

A physician clearly has a property interest in his or her license to practice medicine.[174] Many states[175]

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[169] 42 U.S.C. §§ 11101–11152 (2006); *see also supra* notes 109–13 and accompanying text (describing the HCQIA).

[170] Van Tassel, *supra* note 110, at 1194–97.

[171] *See infra* Part V.B.2.

[172] *See* Kadar, *supra* note 87, at 18–20 (explaining how this lack of access to the judicial system is insulating bad faith peer review as courts engage in circular reasoning by, first, refusing to find bad faith relevant as long as the there was a reasonable belief that the sanction was justified and, second, deferring to the judgment of the decision-makers on whether the judgment was reasonably justified).

[173] *See infra* Part V.B.2.b.

[174] That a professional license is property and is protected by the Constitution is recognized by both state courts, *see, e.g.*, State *ex rel.* Kassabian v. State Bd. of Med. Exam'rs, 235 P.2d 327, 331

also acknowledge staff privileges as a property right standing alone because the loss of staff privileges has major implications for a physician's ability to practice medicine and negatively impacts the scope of the license to practice granted by the state.[176] A good example is that of a surgeon. For a surgeon, the

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(Nev. 1951), and by federal law, *see* Schware v. Bd. of Bar Exam'rs, 353 U.S. 232, 238–39 (1957).

[175] In many states, the general rule is that a physician's staff privileges constitute a property interest protected by the Due Process Clause of the Fourteenth Amendment. *See, e.g.,* Darlak v. Bobear, 814 F.2d 1055, 1061 (5th Cir. 1987) ("Where medical staff privileges have been held to constitute an interest protected by the fourteenth amendment, it has been because there was an explicit or implicit agreement providing for no termination of the privileges without cause and a hearing, or because denial of staff privileges 'might effectively foreclose . . . practicing in the area because of harm to [a] professional reputation and because of the lack of other [comparable] facilities.'" (quoting Daly v. Sprague, 675 F.2d 716, 727 (5th Cir. 1982))); Lew v. Kona Hosp., 754 F.2d 1420, 1424 (9th Cir. 1985) ("The state of Hawaii has recognized a licensed doctor's property right in employment as a probationary hospital staff member."); Anton v. San Antonio Cmty. Hosp., 567 P.2d 1162, 1174 (Cal. 1977) ("'[T]he essential nature ofa qualified physician's right to use the facilities of a hospital is a property interest which directly relates to the pursuit of his livelihood.' This interest is clearly fundamental . . . .").

[176] *See* BARRY R. FURROW ET AL., HEALTH LAW § 7–1, at 374 (5th ed. 2004) (explaining that a precondition to the practice of medicine is access to hospitals); McCall, *supra* note 155, at 175 ("A physician's livelihood is dependent on acquiring and maintaining hospital staff privileges. This access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career."); Note, *The Physician's Right to Hospital Staff Membership: The Public-Private Dichotomy,* 1966 WASH. U. L.Q. 485, 510–11 (noting that a successful doctor must have access to hospitals).

inability to use hospital facilities to treat patients so greatly curtails the physician's ability to practice his or her profession that it is, in effect, the end of that physician's career and his or her license to practice medicine is worthless.[177] The clearest example of this impact is when there is only one hospital facility in the community.[178] Termination of clinical privileges

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[177] McCall, *supra* note 155, at 175; FURROW, *supra* note 176, at 374 (explaining that precondition to the practice of medicine is access to hospitals).

[178] Kiracofe v. Reid Memorial Hosp., 461 N.E.2d 1134, 1142 (Ind. Ct. App. 1984) (Ratliff, J., concurring) (noting that when a hospital is the only one in a community, "its economic impact is great, and the denial of hospital privileges, in many cases, is tantamount to denying a physician the opportunity to practice his or her chosen profession"). In *Greisman v. Newcomb Hospital,* 192 A.2d 817 (N.J. 1963), the court described the situation as follows:

> The Newcomb Hospital is the only hospital in the Vineland metropolitan area and it is publicly dedicated, primarily to the care of the sick and injured of Vineland and its vicinity. . . . Doctors need hospital facilities and a physician practicing in the metropolitan Vineland area will understandably seek them at the Newcomb Hospital. Furthermore, every patient of his will want the Newcomb Hospital facilities to be readily available. It hardly suffices to say that the patient could enter the hospital under the care of a member of the existing staff, for his personal physician would have no opportunity of participating in his treatment; nor does it suffice to say that there are other hospitals outside the metropolitan Vineland area, for they may be too distant or unsuitable to his needs and desires. All this indicates very pointedly that, while the managing officials may have discretionary powers in the selection of the medical staff, those powers are deeply imbedded in public aspects, and are rightly viewed, for policy reasons . . . as fiduciary powers to be exercised reasonably and for the public good.

Id. at 824.

at that one hospital means that the physician will be barred from the practice of medicine in that community.[179]

Even for a physician who practices in a very large community with multiple hospitals, an adverse peer review outcome can have the same disastrous result. All hospitals must check the NPDB for negative reports as part of the background check done as part of the credentialing process before the physician will be allowed to admit and treat patients in that hospital.[180] Once a physician has had his hospital staff privileges terminated or curtailed at one hospital, a second hospital is highly unlikely to allow the physician staff privileges as, in so doing, the second hospital places itself at risk of being sued for negligent credentialing.[181]

In addition, if a physician has staff privileges at several hospitals, as many do, the termination or limitation of staff privileges at one hospital is highly likely to result in the same limitation (or greater limitations or termination) at the other hospitals.[182] This is because all hospitals are obligated to check

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[179] *Kiracofe,* 461 N.E.2d at 1142; *Greisman,* 192 A.2d at 824.

[180] *See supra* note 143 and accompanying text.

[181] In a U.S. General Accounting Office (GAO) report on the problems with the accuracy of the data contained in the NPDB, the agency acknowledged that the information contained in the data bank "can affect a practitioner's reputation and livelihood." U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 3. A HRSA survey revealed that NPDB users, including credentialing committees, chiefs of the medical staff, department chairs, and the chief executive officers, found the reports to be an important part of the credentialing process. *See* Teresa Waters et al., *The Role of the National Practitioner Data Bank in the Credentialing Process,* 21 AM. J. MED. QUALITY 30, 34 (2006).

[182] *See infra* note 185.

the NPDB on all physicians who have staff privileges every two years.[183]

As explained by Dr. Edward Dench, Jr., former president of the Pennsylvania Medical Society, a data bank report "can essentially make you unemployable, and it can be the difference between getting insurance and not getting insurance."[184] This opinion is confirmed by an extensive study commissioned by the State of California into the reasons for the low and declining level of reporting of negative peer review actions to the NPDB:

> [P]hysicians who have been the subject of a[] [negative peer review] state that it is difficult or impossible to find a new position, their professional lives are ruined, other entities will not grant privileges even if they have fulfilled the terms of the discipline, and they spend years and hundreds of thousands of dollars in court trying to clear their professional names and reputations. . . . Physicians who had experienced [having a negative peer review report state that it] . . . was a "career ender."[185]

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[183] *See supra* note 143 and accompanying text.

[184] Steve Twedt, *A Negative Data Bank Listing Isn't Easy To Erase,* PITT. POST-GAZETTE, Oct. 27, 2003, at A7.

[185] JEAN ANN SEAGO ET AL., LUMETRA, COMPREHENSIVE STUDY OF PEER REVIEW IN CALIFORNIA: FINAL REPORT 65, 94 (2008), *available at* http://www.mbc.ca.gov/publications/peer_review.pdf ("[Physicians with negative peer review reports] described not being able to find any position or job after having a[] [negative] report filed and spending three to five years in [peer review] hearings and other procedures to fight for their reputations, even after the [licensure board] found no wrongdoing on their part. They reported spending thousands of dollars to fight the charges so they could again practice as physicians").

Take the case of Dr. John Ulrich, Jr. Dr. Ulrich protested the layoffs of the people who filled two staff positions at the county-owned Laguna Honda Hospital and then joined several others in sending a letter of protest as the layoffs would harm patient care.[186] In less than two weeks, Dr. Ulrich was informed that he was being investigated for clinical incompetence,[187] charges that were later determined by the state board of medial licensure to be unfounded.[188] When Dr. Ulrich heard of the charges, he resigned his staff privileges, not realizing that the charges and his resignation would be reported to the NPDB.[189] The report the hospital sent to the California Medical Board and the NPDB stated:

> Dr. Ulrich resigned from the Medical Staff, and relinquished his privileges, following receipt of a letter announcing the commencement of a formal investigation into his practice and professional conduct as a member of the Medical Staff and while caring for patients at the Hospital. That investigation was prompted as a result of concerns regarding apparent deficiencies in his practice and conduct spanning the full range of Hospital care, including incomplete diagnoses, inappropriate diagnostic and therapeutic orders, failures to accept appropriate responsibility for the course of patient treatment, and an overall absence of clear, effective management of hospitalizations. Dr. Ulrich submitted his resignation before

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[186] Ulrich v. San Francisco, 308 F.3d 968, 972 (9th Cir. 2002).

[187] *See id.*

[188] *Id* at 973–74.

[189] *Id.* at 973.

> this investigation had progressed to any findings or recommendations.[190]

When he learned of the NPDB report, Dr. Ulrich tried to rescind his resignation.[191] The hospital refused, so Dr. Ulrich sued. The NPDB refused to remove the report in spite of the California Medical Board's findings that the charges were unfounded.[192] At the trial, the presidents of two California medical associations told the court that "it will be virtually impossible" for Dr. Ulrich to find work at any U.S. hospital with that report in the data bank.[193]

The federal district court held that, once the hospital accepted Dr. Ulrich's resignation, the hospital had no obligation to rescind the report that it made to the NPDB.[194] Thus, the fact that there was a report by the hospital that detailed the charges against Dr. Ulrich, and the fact that he resigned his privileges in the face of those charges, was an accurate reflection of the facts. This meant that the report contained in the NPDB was an accurate reflection of what had occurred at the hospital level.[195] Ultimately, the Ninth Circuit Court of Appeals held that Dr. Ulrich could pursue his argument that he had been retaliated against for exercising his free speech rights.[196] As of 2003, five years after the report was made to the NPDB, Dr.

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[190] *Id.*

[191] *Id.*

[192] *Id.* at 974.

[193] *Id.*

[194] *Id.*

[195] *Id.*

[196] *Id.* at 981.

Ulrich was still fighting to have the report removed.[197]

An analysis of the NPDB Public Use File for 1990 to 2009 found that, of 10,672 physicians who had been sanctioned by either a restriction or termination of their clinical privileges, 3218 lost their privileges permanently and 389 lost their privileges for more than a year.[198] The bottom line for these 3218 physicians is that their ability to practice medicine by admitting their patients into hospitals for treatment has either been seriously curtailed or completely eliminated. This inability to treat their patients results in severe contraction of the scope of their license to practice medicine granted by the state. For some, this limitation on the scope of the ability to practice medicine, or the effective extinguishment of the license to practice, will further the public's interest in protecting patients from harm. But others will have suffered from a grave injustice as fully explained *infra* in Part VI.B.2.

Over and above the almost immediate impact of a negative NPDB report on employment on the scope of the license to practice medicine and on the ability to properly treat patients, the more long-term problem the physician will face is whether the negative peer review report will trigger an investigation by the state licensure board. One study has revealed that there is a state-to-state disparity between licensure

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[197] Tweet, *supra* note 184.

[198] ALAN LEVINE ET AL., STATE MEDICAL BOARDS FAIL TO DISCIPLINE DOCTORS WITH HOSPITAL ACTIONS AGAINST THEM 1 (2011), *available at* http://www.citizen.org/documents/1937.pdf. Hospitals are required to forward their NPDB reports to each of the state licensure boards where the targeted physician is licensed. 45 C.F.R. § 60.5 (2011).

boards on whether to pursue licensure actions based on information received from hospital peer review.[199] Importantly, forty-five percent of the physicians who were reported to the NPDB faced follow-up state licensure board actions against them.[200]

With regard to the broad impact that the NPDB reports have on physicians and their employment prospects generally, as well as physicians' access to hospital facilities in order to practice medicine, a national survey conducted by HRSA revealed that in 2007 alone, 48,075 licensure, credentialing, or membership decisions were affected by information contained in the NPDB.[201]

Adding to the cascade of negative effects a physician faces from a negative peer review report is the loss of both medical insurance and the termination of managed care contracts. In most states, a physician cannot practice without liability insurance. The inability to obtain insurance then turns the license to practice medicine into a useless

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[199] ALAN LEVINE & SIDNEY WOLFE, HOSPITALS DROP THE BALL ON PHYSICIAN OVERSIGHT: FAILURE OF HOSPITALS TO DISCIPLINE AND REPORT DOCTORS ENDANGERS PATIENTS 13 (2009), *available at* http://www.citizen.org/documents/18731.pdf. The acting director of the Office of Professional and Medical Conduct in New York state said that thirty-one percent of the facility reports her board receives have led to charges of misconduct or surrender of license. This means that nearly one in three mandatory reports results in the board opening a disciplinary action. In many states, fewer than ten percent of consumer complaints lead to disciplinary complaints. *Id.*

[200] LEVINE ET AL., *supra* note 198, at 1; LEVINE & WOLFE, *supra* note 199, at 13.

[201] *Id.* at 6 & n.7. The question that the HRSA survey asked was, "Would your decision regarding the practitioner have been different if you had not received the NPBD response?" *Id.* at n.7.

piece of paper. And the loss of managed care contracts alone can destroy a physician's practice, even without all of the other negative consequences of being blacklisted.[202] The amazing growth of managed care compels the participation of almost all healthcare providers in managed care contracts. Physicians who are not part of a practice group with managed care contracts, or who are not preferred providers with multiple managed care organizations, have a difficult time maintaining a practice. In order to be considered for, or maintain, these contracts, healthcare providers must work to stay in good standing with these managed care organizations. Physicians who lose hospital staff privileges for quality of care reasons are highly likely to face the immediate termination of managed care contracts.

V. THE CONSTITUTIONALITY OF NPDB PHYSICIAN BLACKLISTING

Unfortunately, in light of the serious consequences to the physician, it appears that the NPDB is based on private hospital peer review processes that fail to fairly protect the property and liberty rights of those

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[202] Potvin v. Metro. Life Ins. Co., 997 P.2d 1153, 1160 (Cal. 2000) ("[T]he American Medical Association and the California Medical Association, assert in their joint brief that . . . 'the control exercised by managed care organizations makes access to provider panels a practical prerequisite to any effective practice as a health care provider.' Various legal commentators agree. . . . [R]emoving individual physicians from preferred provider networks . . . could significantly impair those physicians' practice of medicine."); *see also* John P. Little, Note, *Managed Care Contracts of Adhesion: Terminating the Doctor-Patient Relationship and Endangering Patient Health,* 49 RUTGERS L. REV. 1397, 1448 (1997) ("Many physicians rely on [managed care] participation to maintain their practices.").

targeted physicians. The private hospital peer review processes employed by many hospitals not only fail to offer any quality of care benefits to off-set these fairness and constitutional concerns, many of these processes may actually act to negatively impact the quality of patient care, increase the cost of healthcare, and decrease access to healthcare.

It is important to note that the state action necessary for the constitutional violations discussed in the next Section arises when the federally run NPDB sends negative peer review reports to the private hospitals, other healthcare providers, insurance companies, or managed care entities. This act of blacklisting by the federal government is the state action that is the predicate for the due process claims discussed in the next Section.

A. *Infringement on Protected Liberty and Property Interests*

The Fifth and Fourteenth Amendments state that the government may not deprive a person of life, liberty, or property without due process of law.[203] Physician blacklisting negatively impacts both the physician's liberty interest in his or her name, reputation, and integrity, as well as the physician's property interest in the state-issued license to practice medicine. Both of these deprivations occur without due process of law.

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[203] U.S. CONST. amend. V ("No person shall . . . be deprived of life, liberty, or property, without due process of law . . . ."); U.S. CONST. amend. XIV, § 1 ("No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.").

1. A Physician's Property Interest in the License to Practice Medicine

As discussed *supra,*[204] a physician clearly has a property interest in his or her license to practice medicine.[205] Many states[206] also acknowledge staff privileges as a property right in and of itself because loss of staff privileges has major implications for a physician's ability to practice medicine and negatively impacts the scope of the license to practice granted by the state.[207] Once again, a good example of how the scope of a physician's license to practice medicine is curtailed is when a surgeon is barred from obtaining privileges at a hospital so that the physician cannot treat his or her patients. This is the functional equivalent of a state licensure board placing restrictions on a physician's license to practice, which, obviously, cannot be done without providing a full due process hearing.

2. A Physician's Liberty Interest in Reputation

A series of three U.S. Supreme Court cases, *Wisconsin v. Constantineau,*[208] *Goss v. Lopez,*[209] and

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[204] *See supra* notes 174–76 and accompanying text.

[205] *See supra* notes 174–76 and accompanying text.

[206] *See supra* note 175 and the authorities cited therein.

[207] FURROW, *supra* note 176, at 374 (explaining that a precondition to the practice of medicine is access to hospitals); McCall, *supra* note 155, at 175 ("A physician's livelihood is dependent on acquiring and maintaining hospital staff privileges. This access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career."); Note, *supra* note 176, at 510–11 (noting that a successful doctor must have access to hospitals).

[208] 400 U.S. 433 (1971).

[209] 419 U.S. 565 (1975).

Paul v. Davis,[210] setup the legal framework for evaluating a physician's liberty interest to determine if it rises to the level of importance necessary to invoke due process protections. The first case, *Wisconsin v. Constantineau,*[211] involved a statute that created a police-maintained blacklist of people who were labeled "excessive" drinkers.[212] The statute allowed the police to distribute these lists to local liquor stores to prevent those who were blacklisted from being allowed to purchase liquor.[213] The Supreme Court agreed that this blacklisting infringed on Constantineau's liberty interest in her reputation without due process.[214] The Court found that being blacklisted was "degrading" and that "a person's good name, reputation, honor or integrity" was at stake and that the blacklisted individual was entitled to notice and an opportunity to be heard.[215]

Four year later, the Court in *Goss* held that a high school that suspended a group of students for ten days without a hearing violated the Fourteenth Amendment as "[t]he fourteenth amendment forbids the State to deprive any person of life, liberty, or property without due process of law."[216] The Court explained that "[p]rotected interests in property are normally 'not created by the Constitution. Rather, they are created and their dimensions are defined' by an independent source such as state statutes or rules

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[210] 424 U.S. 693 (1976).

[211] 400 U.S. 433.

[212] *Id.* at 435–36.

[213] *Id.* at 435.

[214] *Id.* at 436.

[215] *Id.* at 437.

[216] Goss v. Lopez, 419 U.S. 565,572 (1975).

entitling the citizen to certain benefits."[217] The Court found that the students had a property interest in education by virtue of the State of Ohio's recognition of a right to an education.[218] The Court went on to hold that this interest in education was negatively impacted without due process of law:

> The authority possessed by the State to prescribe and enforce standards of conduct in its schools although concededly very broad, must be exercised consistently with constitutional safeguards. Among other things, the State is constrained to recognize a student's legitimate entitlement to a public education as a property interest which is protected by the Due Process Clause and which may not be taken away for misconduct without adherence to the minimum procedures required by that Clause.[219]

Importantly, the Court also found that the student's liberty interests were also negatively impacted without due process of law:

> The Due Process Clause . . . *forbids arbitrary deprivations of liberty*. "Where a person's *good name, reputation, honor, or integrity* is at stake because of what the government is doing to him," the minimal requirements of the Clause must be satisfied. School authorities here suspended [the high school students] from school for periods of up to 10 days based on charges of misconduct. If

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[217] *Id.* at 572–73 (citing Bd. of Regents v. Roth, 408 U.S. 564, 577 (1972)).

[218] *Id.* at 573–74.

[219] *Id.* at 574.

> sustained and recorded, those charges *could seriously damage the students' standing with their fellow pupils and their teachers as well as interfere with later opportunities for higher education and employment.*[220]

The Court in *Goss* was unimpressed with the high school's argument that

> even if there is a right to a public education protected by the Due Process Clause generally, the Clause comes into play only when the State subjects a student to a "severe detriment or grievous loss." The loss of 10 days . . . is neither severe nor grievous and the Due Process Clause is therefore of no relevance.[221]

The Court stated that it does not decide whether there is a protected interest at stake by looking at the weight of the interest at stake, but does so by looking at the *nature* of that interest[222]:

> [The students] were excluded from school only temporarily, it is true, but the length and consequent severity of a deprivation, while another factor to weigh in determining the form of the hearing, 'is not decisive of the basic right' to a hearing of some kind.' The Court's view has been that, as long as a property deprivation is not *de minimis*, its gravity is irrelevant to the question whether account must be taken of the Due Process Clause. A 10-day suspension from school is

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[220] *Id.* at 574–75 (emphasis added) (citations omitted) (quoting *Constantineau,* 400 U.S. at 437).

[221] *Id.* at 575.

[222] *Id.* at 575–76.

> not *de minimis*, in our view, and may not be imposed in complete disregard of the Due Process Clause. . . . Neither the property interest in educational benefits temporarily denied nor the liberty interest in reputation . . . is so insubstantial that suspensions may constitutionally be imposed by any procedure the school chooses, no matter how arbitrary.[223]

One year later, in the last of the trio, the Court in *Paul v. Davis*[224] narrowed the due process protection afforded a person's liberty interest in his or her reputation by finding that the publication of the name of an individual on a blacklist of shoplifters prior to any actual conviction did not rise to the level of a constitutional violation.[225] In *Paul*, Edward Davis was arrested for alleged shoplifting. Davis's name and photo were then placed on a blacklist of "active" shoplifters that was posted in local shops before the shoplifting charges were proven in court.[226] Davis sued under § 1983 claiming that he had been deprived of his "liberty" without due process of law.[227] As in *Constantineau,* Davis was blacklisted without any notice or hearing opportunity.[228]

The *Paul* Court found that the publication of the shoplifter's list did not violate the Due Process

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[223] *Id.* at 576 (citations omitted) (quoting Fuentes v. Shevin, 407 U.S. 67, 86 (1972)).

[224] 424 U.S. 693 (1976).

[225] *Id.* at 712.

[226] *Id.* at 694–96.

[227] *Id.* at 696–97.

[228] *Id.* at 696.

Clause.[229] The Court distinguished *Constantineau* and *Goss* by stating that an interest in reputation alone is not enough to create a protected interest. In addition to damage to reputation by virtue of state action, the complainant must have had "a right or status previously recognized by state law" that was "distinctly altered or extinguished."[230] The narrowing of the scope of the liberty interest in reputation by the Court in *Paul* has come to be known as the "stigma-plus" test.[231]

The publication of the negative peer review reports by the NPDB is more analogous to *Constantineau* and *Goss* than to *Paul.* As in all three of the cases, the reports published by the NPDB officials caused damage to the physicians' reputations. However, unlike Davis in *Paul,* the targeted physicians have a right recognized by state law—the license to practice medicine that has been "distinctly altered" and, in some cases, effectively "extinguished" similar to the situations in *Constantineau* and *Goss.* And compared to the interests at stake in *Constantineau* and *Goss*—namely, the right to purchase liquor and the right not to be excluded from school for ten days—physician blacklisting implicates far more pressing state-recognized rights: the right to practice medicine and the right to provide the full range of medical services to the patients in a physician's practice as granted by

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[229] *Id.* at 712.

[230] *Id.* at 711.

[231] DAVID W. LEE, HANDBOOK OF SECTION 1983 LITIGATION § 5.05[A], at 605 (2010 ed.) ("The stigma-plus refers to a claim brought for injury to one's reputation (the stigma), coupled with the deprivation of some tangible interest, such as the loss of government employment or property right (the plus), without adequate process.").

the state. As described earlier,[232] when the NPDB publishes the negative results of peer review hearings, it is clear that it damages the good name, reputation, honor, and integrity of the targeted physician, seriously damaging the physician's standing with their fellow physicians and patients. In addition, the targeted physician's ability to practice medicine pursuant to the state-granted license is irreparably damaged. Once again, a cardiovascular surgeon or a neurosurgeon who is unable to obtain hospital admitting privileges because they have been blacklisted will be unable to perform surgeries, severely circumscribing the scope of their license to practice medicine. In many cases, a physician's ability to treat his or her patients will be effectively barred.[233]

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[232] *See supra* Part IV.

[233] In contrast to the situation that occurs when a physician is blacklisted by the NPDB is the case of *Siegert v. Gilley,* 500 U.S. 226 (1991). In *Seigert,* a physician voluntarily resigned his position at a federal hospital to avoid being terminated. *Id.* at 227–28. He obtained a new position at an Army hospital conditioned upon a background check that included obtaining references from his prior position. *Id.* at 228. The supervisor at the physician's former job sent a negative reference letter and the physician was terminated from the Army hospital. *Id.* The physician sued for money damages claiming a violation of his liberty interest in reputation without due process. *Id.* at 229. The Court held that the physician's claim was an attempt to constitutionalize the tort of defamation similar to the claim of the plaintiff in *Paul. Id.* at 232–34. As in *Paul,* the physician in *Siegert* failed to claim that, in addition to damage to reputation by virtue of state action, he had "a right or status previously recognized by state law" that was "distinctly altered or extinguished." *Paul,* 424 U.S. at 711. Unlike the situations in *Paul* and *Siegert,* which both dealt solely with claims of damage to reputation, blacklisting by the federally run NPDB negatively impacts the scope of the state-granted license to practice

It is important to note that the impact of physician blacklisting reaches far beyond the physician. When a licensed physician can no longer practice medicine, that physician's patients are deprived of access to their choice of healthcare provider and many of those same patients who are on Medicare and Medicaid may lose access to healthcare entirely.[234]

As the physician blacklisting by the NPDB negatively impacts a physician's constitutionally protected liberty and property interests, the next step is to determine what procedures are necessary to avoid erroneous deprivation of these interests.

B. *Applying* Mathews v. Eldridge

In *Mathews v. Eldridge,*[235] the U.S. Supreme Court established a three-part rubric for determining whether state and federal procedures meet due process requirements. As recently explained in *Hamdi v. Rumsfeld,* the *Mathews* test is "[t]he ordinary mechanism that we use for balancing such

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medicine. Additional differences include the fact that the physician in *Seigert* voluntarily left his first position, waiving his due process rights, and the fact that the case dealt with one reference letter. *Id.* at 228. In juxtaposition, the NPDB is a national system for the mandated dissemination of negative peer review reports created without due process that incorporates all hospitals and a significant number of other healthcare providers, state licensure departments, insurance companies, and managed care entities in the entire country.

[234] *See* Katharine A. Van Tassel, *Does the Hospital Peer Review Process Negatively Impact Healthcare Quality, Cost and Access?,* STETSON L. REV. (forthcoming 2012) (describing how the hospital peer review hearing process, coupled with the NPDB reporting system, could be negatively impacting healthcare quality, cost, and access with a particularly negative potential impact on minority physicians and minority and low-income patients).

[235] 424 U.S. 319 (1976).

serious competing interests, and for determining the procedures that are necessary to ensure that a citizen is not 'deprived of life, liberty, or property, without due process of law.'"[236] The *Mathews* test involves the balancing of three factors:

> [T]he private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional and substitute procedural requirement would entail.[237]

Application of this balancing test indicates that the practice of the NPDB of relying on incorrect and misleading data and relying on the reports of private hospital peer review hearings to create its blacklist violates due process. As such, additional protections are required to avoid the erroneous blacklisting of physicians.

1. The Private Interest Affected by the Official Action

As discussed, the liberty and property interests at stake for blacklisted physicians are significant. Importantly, the physician's inability to practice medicine continues for as long as the physician remains on the blacklist, which will be the rest of the physician's lifetime. While violent sexual predators

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[236] 542 U.S. 507, 528–29 (2004) (quoting U.S. CONST. amend. V).

[237] *Mathews,* 424 U.S. at 335; *see also* Wright, *supra* note 51, at 137.

are also blacklisted for life, nonviolent sexual predators are subject to far shorter blacklisting—ten years for some—and some sexual predators are not blacklisted at all. Once again, unlike physicians, all sexual predators are provided with full due process hearings before being blacklisted. It is unclear why physicians, who are serving the community, are not afforded the same protection as sexual predators prior to being blacklisted.

2. The Risk of Erroneous Deprivation Through the Procedures Used

There is a very high risk that a physician will be erroneously blacklisted by the NPDB and will be subject to loss of liberty and property without recourse. The blacklisting database contains misleading and inaccurate data.[238] In addition, it appears to suffer from serious underreporting of data.[239] Finally, and maybe most importantly from a policy standpoint, the NPDB relies on reports from private hospital peer review processes that are flawed both in theory and in practice.[240] These processes, at best, rely on the application of inherently vague and subjective criteria. But in practice, they are much worse. These vague standards can be applied to create a negative peer review report based on reasons that are unrelated to quality of patient care. These

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[238] *See infra* Part V.B.2.a.

[239] *See infra* Part V.B.2.a.

[240] In order to resolve questions regarding underreporting, the California legislature commissioned an independent review of peer review in the state. The resulting report confirmed the concerns of many: "This report cites inconsistencies in the way [healthcare] entities conduct peer review, select and apply criteria . . . and interpret [state] law . . . ." JEAN ANN SEAGO ET AL., *supra* note 185, at 1.

reasons could be to silence whistleblowers who report poor quality of care, to remove economic competition, to give vent to personal animus, or to discriminate.[241] In addition, many of these standards allow for decision-making that relies upon highly unreliable evidence of what constitutes quality of care.[242] These processes are both over broad in that they allow negative reports to be created for physicians who use best practices[243] and are under inclusive in that they allow physicians who ignore best practices to escape criticism.[244] Adding to all of these other problems is that the likelihood that a choice of treatment will lead to a negative peer review report is more closely linked to the particular hospital and state where the care is provided than to the quality of that treatment.[245]

In comparison, the standards that are contained in the statutes that criminalize sex offenses are clearly articulated, providing both notice of the conduct that will be penalized and placing strict limitations on arbitrary and capricious decision-making. And the likelihood of prosecution is linked to the nature of the criminal conduct and not to the location where the conduct occurred.

The first of the following Subsections describes the misleading and inaccurate data contained in the database. Then, the next two Subsections explain the different risks of error inherent in the two main standards that hospital peer review processes rely

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[241] *See infra* Part V.B.2.b.ii.

[242] *See infra* Part V.B.2.b.ii.

[243] *See infra* Part V.B.2.b.ii.

[244] *See infra* Part V.B.2.b.ii.

[245] *See infra* Part V.B.2.b.iii.(A).

upon to evaluate physician competence. The two main categories of standards[246] are: (1) those that allow complete discretion of the hospital administrators; and (2) those that rely on customary care standards.

a. The NPDB Contains Misleading and Inaccurate Data

The NPDB contains misleading data as there is significant underreporting of clinical privilege restrictions by hospitals and other healthcare providers[247] as well as underreporting of medical malpractice payments.[248] In the context of hospital peer review, underreporting has been a significant and ongoing problem. Early estimates by the AMA were that there would be about 10,000 reports annually.[249] This estimate appears extremely conservative in light of the IOM report that 98,000 people are killed each year in hospitals as a result of preventable medical mistakes.[250] However, for the entire period from 1990 to 1999, fewer than 9000 reports were made.[251] From 2000 until 2007, the range of reporting has been from the low in 2006 of 532 to the high of 687 in 2003.[252]

Even more troubling is the wide variation in reporting from hospital to hospital. By December of

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[246] For a full discussion of all of the standards used to measure clinical competence in hospital peer review, see Van Tassel, *supra* note 110, at 1207–41.

[247] *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 10.

[248] *Id.* at 10–12.

[249] *Id.* at 13.

[250] *See* INST. OF MED., *supra* note 130, at 26.

[251] U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 13.

[252] LEVINE & WOLFE, *supra* note 199, at 37.

2007, approximately fifty percent of hospitals in the United States had never reported a single negative peer review action to the NPDB.[253] And reporting varies from state to state, with seventy-five percent of hospitals in Connecticut participating by filing reports but only thirty percent of hospitals in Louisiana participating in the program by reporting.[254] In fact, relying on hospital-specific studies, a HRSA analysis concluded that "clinical privilege reporting seemed to be concentrated in a few facilities even in States with comparatively high overall hospital clinical privileging reporting levels."[255] This data suggests that the likelihood of being reported to the NPDB is more related to the location where the physician is practicing than the quality of the care that is provided.[256]

While some claim that the low and declining level of reporting[257] is related to a continued fear of

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[253] *Id.* at 2.

[254] *Id.*

[255] *Id.* at 9–10 (citing HEALTH RES. & SERVS. ADMIN., 2005 HRSA ANNUAL REPORT 8 (2005)).

[256] Reporting avoidance is not hard to do. Hospitals can engage in workarounds by leveling sanctions that impact clinical privileges by less than thirty days, by placing physicians on a leave of absence, or using other types of nonreportable interventions. "[E]ntities try numerous remedial interventions (peer counseling, education, training, mentoring, observation, behavioral counseling, UCSD Physician] Assessment and Clinical Education (PACE) Program) before informing the physician that a 'final proposed action' is being taken." JEAN ANN SEAGO ET AL., *supra* note 185, at 64.

[257] Laura-Mae Baldwin et al., *Hospital Peer Review and the National Practitioner Data Bank: Clinical Privileges Action Reports,* 281 J. AM. MED. ASS'N 349 (1999) (finding that NPDB reporting is low and declining). In the January 1995 issue of the California Medical Board's newsletter, the president stated that

retaliatory litigation, it is likely that other factors are at play in light of how well-known it is that lawsuits by targeted physicians will be summarily dismissed.[258] With regard to the consistently low level of reporting, studies suggest that physicians as a group have traditionally had a "cultural aversion" to turning in a peer for poor performance.[259] With regard to the decline in reporting, it is possible that the NPDB itself may be serving as a disincentive to effective hospital peer review practices as there is a growing concern among physicians regarding the fairness of the NPDB reporting process.[260]

"[o]ver the past year we have noted a deterioration in the cooperation required between hospitals and the Board in protecting consumer/patient safety. We have experienced incomplete reports . . . and, on some occasions, excuses for not reporting at all." LEVINE & WOLFE, *supra* note 199, at 17 (quoting Rebecca Cohen & David Swankin, *Hospital Reporting to State Regulators and to the National Practitioner Data Bank,* CITIZEN ADVOC. CENTER, March 1997, at 2, 3).

[258] For example, concerned about underreporting, the California legislature requested an independent review of peer review in the state. This study surveyed physicians across the state. The study revealed that more than one-half of the respondents had no reluctance in reporting poor physician performance of colleagues to hospital administrators, one-third were reluctant to report a friend or colleague, and only one-fifth were "fearful of being sued for restricting trade or some other potential retribution. JEAN ANN SEAGO ET AL., *supra* note 185, at 1.

[259] LEVINE & WOLF, *supra* note 199, at 17–18.

[260] Baldwin et al., *supra* note 257, at 354 (reporting "the high degree of dissatisfaction with the concept of the NPDB and its operation"); Nicholas Kadar, *How Courts Are Protecting Unjustified Peer Review Actions Against Physicians by Hospitals,* 16 J. AM. PHYSICIANS & SURGEONS 17, 21 (2011) (noting that courts are twisting HCQIA by finding that the bad faith of peer review decision-makers is not relevant); Lawrence R. Huntoon, *Sham Peer Review: Disaster Preparedness and*

This underreporting is very misleading as it is likely to result in significant errors in hiring choices and the allocation of staff privileges. When choosing between two physicians who are both applying for hospital staff privileges, the hospital is likely to choose the physician who has no or fewer negative reports in the NPDB. In fact, because of the significant problem with underreporting, there is a very real possibility that the chosen physician actually has far more actual problems with the quality of patient care than the physician who is not chosen. As mentioned previously, in 2007 alone, 48,075 licensure, credentialing, or membership

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Defense, 16 J. AM. PHYSICIANS & SURGEONS 2 (2011) (detailing how doctors can be targeted based on politics and suggesting proactive defensive measures); John Dale Dunn, *The Art of War Adapted to U.S. Medicine 2011,* 16 J. AM. PHYSICIANS & SURGEONS 25 (2011) (using analogy to Sun Tzu's *The Art of War* to deal with misconduct on the part of the hospital in pursuing peer review); *Hospitals Make War on Doctors,* ASS'N FOR AM. PHYSICIANS & SURGEONS (Mar. 31, 2011), http://www.aapsonline.org/index.php/site/article/hospitals_make_war_on_doctors (detailing how hospitals can abuse the peer review process); Yann H.H. van Geertruyden, Comment, *The Fox Guarding the Henhouse: How the Health Care Quality Improvement Act of 1986 and State Peer Review Protection Statutes Have Helped Protect Bad Faith Peer Review in the Medical Community,* 18). CONTEMP. HEALTH L. & POL'Y 239 (2001). An excellent and well-researched series on the number of physicians who have been targeted by abusive uses of peer review is detailed in an extensive series of articles written by Steve Twedt and John Beale of the *Pittsburgh Post-Gazette. See, e.g.,* Steve Twedt, *The Cost of Courage: How the Tables Turn on Doctors,* PITT. POST-GAZETTE, Oct. 26, 2003, at A1 (first of the series). Additionally, there are a growing number of organizations that support physicians in their allegations against "sham peer review," such as The Center for Peer Review Justice, Inc., the Semmelweis Society, the Association of American Physicians and Surgeons, Inc., and the Alliance for Patient Safety.

decisions were affected by information contained in the NPDB.[261]

In the context of medical malpractice, many practitioners have been protected from being reported to the NPDB in situations involving the use of the "corporate shield."[262] This is when the parties remove the physician's name from claims and pleadings, leaving only the name of the hospital or other corporate entity. As the malpractice payment is made on behalf of the corporate entity, there is no obligation to report.[263] Some opine that as many as "50% of other-wise required NPDB reports were thought to be diverted via the corporate shield."[264] Adding to the underreporting are the multiple legal ways that NPDB reporting can be avoided including paying out-of-pocket, waiving a patient's debt or reimbursing a prior payment, payment of a claim via verbal demand, payments pursuant to mediation where there has been no written demand for payment, high-low agreements, and statutory presuit notification periods.[265]

In addition, when insurance companies do actually make a report, it can be misleading as many cases are settled for business reasons unrelated to problems with the care provided to the patients. For example, insurance companies may settle a case merely because the settlement demand is less than

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[261] LEVINE & WOLFE, *supra* note 199, at 6 & n.7.

[262] Haavi Morreim, *Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank,* 27 OHIO ST. J. ON DISP. RESOL. 109, 137–41 (2012).

[263] *Id.*

[264] *Id.* at 138.

[265] *Id.* at 132–41.

the cost of litigation, even if it is likely that the physician will ultimately prevail. This is especially the case in the large number of states that allow insurance companies to settle malpractice claims in spite of the protests of the physician that she or he met the standard of care and the case is frivolous.

Finally, with regard to the over probative value that decisionmakers place on reports of medical malpractice payments generally, the HMPS, mentioned previously, concluded that there was a very weak correlation between malpractice claims or payments and negligence.[266] The study demonstrated that medical malpractice claims are actually rarely made after a patient has been injured from a negligent act and that claims are frequently made when the injury was not caused by negligence.[267] The Armed Forces Institute of Pathology reached a similar conclusion in its study of the relationship between malpractice payments and substandard care.[268] The study found that malpractice-claim payments and amounts correlate poorly with standard of care determinations.[269] Compounding this situation, a large number of the malpractice reports made to the NPDB do not make any mention

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[266] A. Russell Localio et al., *Relation Between Malpractice Claims and Adverse Events Due to Negligence: Results of the Harvard Medical Practice Study III,* 325 NEW ENG. J. MED. 245 (1991).

[267] *Id.*

[268] Richard L. Granville & Stephen V. Mawn, *A Threshold Question: How Do Payment Amounts in Medical Malpractice Claims Relate to the Medical Care Rendered?,* 94–1 LEGAL MED. OPEN FILE 6 (1994).

[269] *Id.* at 6–9.

of the role that the standard of care made in the decision to settle the claim.[270]

Thus, when choosing between two physicians who are both applying for hospital staff privileges, the hospital is likely to choose the physician who has fewer malpractice reports in the NPDB. In fact, just like the situation with negative peer review reports, because of the significant problem with underreporting, there is a very real possibility that the chosen physician actually has far more medical malpractice claims and settlements than the physician who is not chosen.

There are also serious weaknesses in the compilation of the data that raises questions about their reliability.[271] In a U.S. General Accounting Office (GAO) report of an investigation of the NPDB, it was noted that there are duplicate reports that overstate, and may in fact double, the amount of negative reports that the data bank has on any particular physician.[272] According to this study, one-third of the hospital peer review reports are inaccurate and a large number of the state licensure actions contained misleading or inaccurate information on the level of discipline given or the actual number of times a practitioner was subjected to discipline.[273] Unfortunately for these physicians, the mechanisms for correcting these problems were also found by the GAO to be defective.[274]

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[270] *Id.* at 5.

[271] U.S. GEN. ACCOUNTING OFFICE, *supra* note 108, at 16.

[272] *Id.* at 14.

[273] *Id.* at 22–24.

[274] *Id.* at 16. It is important to note that this study was conducted in 2000 and that HRSA claims that the processes

Finally, there does not appear to be any mechanism to remove negative peer review reports in light of a subsequent finding by medical licensure boards that there is no merit to hospital charges of incompetence,[275] even though medical licensure board proceedings are far more rigorous than private peer review and are conducted by disinterested third parties in keeping with due process requirements.

b. The Reliance on Vague Standards Used to Identify "Bad" Doctors Creates a High Risk of Error

After explaining the basic principles that animate the vagueness doctrine, the next two Subsections explain the different nature of the risks of error inherent in the two most common standards that hospital peer review processes rely upon to evaluate physician competence. The two main categories of standards[276] are: (1) those that allow complete discretion of the hospital administrators; and (2) those that rely on customary care standards.[277]

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used by the NPDB to collect and record data have improved since that time. However, there has been no follow-up study or outside evaluation that documents whether these improvements have actually worked to improve the reliability of the data. An independent evaluation is particularly important before reaching any conclusions that these problems have been corrected as HRSA previously disagreed with many of the GAO's findings that the NPDB processes were inadequate causing inadequate data. *Id.* at 16.

[275] *See supra* notes 186–97 and accompanying text.

[276] For a full discussion of all of the standards used to measure clinical competence in hospital peer review, see Van Tassel, *supra* note 110, at 1214–32.

[277] *See infra* Part V.B.2.b.ii, iii.

i. The Vagueness Doctrine

Vagueness principles call for clearly articulated standards that limit the discretion of the decision-makers and that provide notice of the conduct that will trigger penalties. As Justice Brennan explained, the absence of clearly articulated standards that are capable of objective application creates an unacceptable risk of arbitrary and capricious decision-making leading to a high risk of error[278]:

> By demanding that government articulate its aims with a reasonable degree of clarity, the Due Process Clause ensures that state power will be exercised only on behalf of policies reflecting a conscious choice among competing social values; reduces the danger of caprice and discrimination in the administration of the laws; and permits meaningful judicial review of state actions.[279]

Clearly articulated rules are essential to avoiding the risk of error as "known standards . . . limit the

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[278] These questions parallel the vagueness analysis most courts follow in the context of vagueness challenges to criminal statutes. *See generally* Robert Batey, *Vagueness and the Construction of Criminal Statutes—Balancing Acts,* 5 VA. J. SOC. POL'Y & L. 1, 25–26 (1997) ("In resolving questions under the vagueness doctrine, courts must first evaluate whether the allegedly deficient language raises problems of fair notice of the requirements of criminal law or of arbitrary and discriminatory enforcement by police or prosecutors. If there is sufficient concern on either of these fronts, a judge should balance the necessity for the ambiguous language to achieve the legislative goal against the chilling effect of the ambiguity on protected or desirable conduct.").

[279] Whisenhunt v. Spradlin, 464 U.S. 965,969 (1983) (Brennan, J., dissenting).

allocation choices of . . . officials. They require that choices be made according to principle rather than the preference of the official."[280] As such,[281] courts reject claims that "a discretion to proceed by ad hoc orders rather than by rules is necessary to permit an

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[280] ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW 170–71 (2d ed. 2001). And, of equal importance, "[k]nown standards allow a person to better understand what . . . [is expected] of her, so that she can plan her life in some forehanded way." *Id.* at 170. As Professor Lon Fuller observed, "[t]he first desideratum of a system for subjecting human conduct to the governance of rules is an obvious one: there must be rules." LON L. FULLER, THE MORALITY OF LAW 46 (rev. ed. 1969); *see also* Mayer v. Wing, 922 F. Supp. 902, 911–12 (S.D.N.Y. 1996) (holding that a regulation that allowed for termination of in-home healthcare benefits when it was "inappropriate" allowed for arbitrary decision-making in violation of procedural due process as "[d]ue process demands that decisions regarding entitlements to government benefits be made according to 'ascertainable standards'").

[281] Professors Aman and Mayton, in their administrative law hornbook, explain that:

> Using a due-process based prescription of standing rules, the courts, along with trying to assure evenhandedness, have also tried to assure a measure of stability in agency action. They have required agencies to develop, codify, and publish rules so that the private sector is informed of what it can expect from government and manage its affairs accordingly. In this context, a requirement of rules has been described and applied as an aspect of a vagueness doctrine.
>
> But unlike the usual vagueness doctrine case, the claim is not against the statute itself. Rather, the claim is against an agency, for its failure to render a vague statute more specific by implementing it through rules.

AMAN & MAYTON, *supra* note 280, at 72.

agency to make decisions finely tuned to the facts and circumstances of an individual case."[282]

In the context of a medical administrative proceeding like peer review,[283] the vagueness doctrine is being used to challenge the hospital's process for its neglect in failing to clarify vague standards through specific rules. Thus, fairness in this civil context refers to actions taken "according to known standards that are impartially applied through revealed procedures."[284] A good example that arose in a

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[282] *Id.* at 73. In *Dixon v. Love,* 431 U.S. 105, 115 (1977), the Supreme Court maintained that the ability of an agency to suspend a driver's license by using a subjective case-by-case decisionmaking process that turned upon an "ordinary and reasonable care" standard, rather than objective rules, would reduce the fairness of the system. The Court also stated that "[t]he decision to use objective rules in this case provides drivers with more precise notice of what conduct will be sanctioned and promotes equality of treatment among similarly situated drivers." *Id.*

[283] In the context of private hospitals, courts have treated peer review as an administrative proceeding. In *Balkissoon v. Capitol Hill Hospital,* 558 A.2d 304 (D.C. 1989), the court explained that

> [t]he actions of hospitals in regard to staff privileges can be analogized to administrative agencies. "Both the administrative agency and the hospital board of trustees do exercise discretion and bring expertise to their respective tasks. Both must also pay due respect to procedural safeguards whether because of constitutional due process or fundamental fairness."

Id. at 308 n.8 (quoting Garrow v. Elizabeth Gen. Hosp., 401 A.2d 533, 537–38 (N.J. 1979)); *see also* Storrs v. Lutheran Hosps. & Homes Soc'y of Am., Inc., 609 P.2d 24, 29 n.14 (Alaska 1980) (holding that via stipulation of the parties, the decision made pursuant to the peer review process "should be treated as an administrative decision and that the review of that decision should be treated as a review of an administrative decision").

[284] *Id.* at 170.

different context, but that is equally applicable here, is the case of *Soglin v. Kauffman.*[285] In *Soglin,* several students were expelled by the administration of the University of Wisconsin which applied a "misconduct" standard. In finding that this standard was unconstitutionally vague, the court stated:

> No one disputes the power of the University to protect itself by means of disciplinary action against disruptive students. Power to punish and the rules defining the exercise of that power are not, however, identical. Power alone does not supply the standards needed to determine its application to types of behavior or specific instances of "misconduct."[286]

Clearly, "[p]rocedures and hearings offer little protection without such rules and standards as might give content to the hearings."[287] Or, as the Fifth Circuit has so succinctly stated, "[t]he idea of a hearing is fine. But what is to be heard?"[288]

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[285] 418 F.2d 163 (7th Cir. 1969).

[286] *Id.* at 167.

[287] AMAN & MAYTON, *supra* note 280, at 73.

[288] Block v. Thompson, 472 F.2d 587, 588 (5th Cir. 1973) (per curiam) (noting that in the absence of specific objective criteria, after a hearing on the pros and cons of granting or denying a privilege, the decision-makers could "take a show of hands and then adapt its decision to this momentary plebiscite"). This query was echoed by the Seventh Circuit when it stated that "[t]he requirements of due process include a determination of the issues according to articulated standards. The lack of such standards in this case deprives any hearing, whether before an agency or a court, of its meaning and value as an opportunity for the plaintiffs to prove their qualifications for assistance." White v. Roughton, 530 F.2d 750, 754 (7th Cir. 1976); *see also* Raper v. Lucey, 488 F.2d 748 (1st Cir. 1973).

ii. Standards that Rely on the Unfettered Discretion of Hospital Administrators

Applying the vagueness doctrine to evaluate the standards used in hospital peer review leads to the conclusion that these standards afford few limitations on the discretion of the decision-makers leading to a high risk of arbitrary and capricious decision-making and error. In addition, these standards fail to provide notice to the physicians of the kind of conduct to avoid in order to avoid sanctions.

The most obvious example of a vague standard that is commonly used in peer review is one that expressly vests complete and unfettered discretion in decision-makers is one that gives a hospital's governing body "the right to remove any member of the medical staff or to deprive any physician or surgeon of the privileges of the hospital whenever in their sole judgment the good of the hospital or the patients therein may demand it."[289] Also included in this category are those bylaws that are less blatant but, in application, still call for a purely subjective determination. These standards define the required level of competence as that which the decision-makers determine is the "best possible care,"[290] or

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[289] N. Broward Hosp. Dist. v. Mizell, 148 So. 2d 1, 2–5 (Fla. 1962); *see also* Tasher v. St. Tammany Parish Hosp., No. 87-1139, 1988 U.S. Dist. LEXIS 1018, at *5 (E.D. La. Feb. 9, 1988) (holding that the executive committee had complete discretion to summarily suspend privileges "whenever action must be taken immediately in the best interest of patient care in the hospital").

[290] Wyatt v. Tahoe Forest Hosp. Dist., 345 P.2d 93, 95 (Cal. Ct. App. 1959) (noting that only physicians and surgeons who, in the judgment of the board, would provide the "best possible care and professional skill" were granted staff privileges); *see also* Duby v. Jordan Hosp., 341 N.E.2d 876, 880 (Mass. 1976)

"adequate medical care,"[291] or "high quality medical care."[292]

None of the standards in this category contain any limits on the discretion of decision-makers which creates an extraordinary risk that decisions to exclude certain physicians could be made based on reasons having nothing to do with the interests of patient safety.[293] These reasons could be economic,[294]

(judging the level of a physician's competence by determining if it met the "best possible care").

[291] Koellingv. Bd. of Trs. of Mary Francis Skiff Mem'l Hosp., 146 N.W.2d 284, 296–97 (Iowa 1966) (noting the board of trustees conclusion that the physician had failed to provide "adequate" medical care); *see also* Bock v. John C. Lincoln Hosp., 702 P.2d 253, 255 (Ariz. Ct. App. 1985) (noting that physician's staff privileges were terminated because the executive committee determined that the physician "failed to demonstrate to the Medical Committee that [he was] qualified to practice as an Internal Medicine specialist").

[292] Gaenslen v. Bd. of Dirs. of St. Mary's Hosp. & Med. Ctr., 232 Cal. Rptr. 239, 242 (Cal. Ct. App. 1985) (applying the standard in bylaws that excluded physicians from staff privileges who did not provide "high quality" care); *Huffaker,* 540 P.2d at 1399–1401 (applying requirement that physicians provide a "high quality of medical care").

[293] The immunity protections put into place by both HCQIA and state immunity legislation result in a loss of access to the judicial system by these aggrieved physicians. If peer review is being used for purposes unrelated to quality of care, then this loss of legal recourse is unjustified.

As HCQIA immunity was put into place to encourage peer review that enhanced the quality of patient care while at the same time protecting physicians' interests, it is questionable whether peer review proceedings that act merely to protect hospital autonomy in decision-making should enjoy HCQIA protections. This type of standard coupled with HCQIA immunity unjustifiably cuts off a physician's ability to challenge staffing decisions unrelated to quality of care concerns through a judicial appeal.

based upon personal dislike,[295] or discriminatory in nature.[296] Another growing concern is that peer review is being used to silence whistleblowers who are trying to call attention to poor quality of care or risky practices that could cause patient harm.[297]

This broad category of standards also fails to provide notice to physicians of what conduct will place them at risk of being investigated and reported to the NPDB.[298] Thus, what constitutes "incompetence" can be defined by administrative decision-makers in a "we know it when we see it" fashion, making the standard a moving target that varies with the make-up of the deciding body. The list of process protections that most hospitals now provide (and are required under HCQIA as a condition for judicial immunity), such as a hearing and the right to counsel, are all empty formalities if, after the hearing is completed, the decision-makers can take the course of action their personal inclinations dictate. This is especially the case as

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[294] *See generally* John D. Blum, *Economic Credentialing: A New Twist in Hospital Appraisal Processes,* 12 J. LEGAL MED. 427 (1991); John D. Blum, *Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies: A Legal Analysis,* 14 U. PUGET SOUND L. REV. 561 (1991); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment,* 137 U. PA. L. REV. 431 (1988); Judith E. Orie, *Economic Credentialing: Bottom-Line Medical Care,* 36 DUQ. L. REV. 437 (1998).

[295] *See generally* PEER REVIEW GUIDEBOOK, *supra* note 49, at app. B.

[296] *See, e.g., id.* at app. A.

[297] *See infra* Part V.B.3.b.

[298] *See, e.g.,* Moore v. Bd. of Trs. of Carson-Tahoe Hosp., 495 P.2d 605, 607–09 (Nev. 1972) (noting a bylaw that allowed for termination for "unprofessional conduct").

many courts have seen fit to conclude that the absence of good faith is irrelevant to the question of whether the proceeding was fair.[299] Physicians' interests in the ability to practice their profession and to avoid being blacklisted, as well as patients' interests in choosing their own physicians, find little to no protection in these standards. This variety of vague standard create a high risk that physicians who provide high-quality patient care will be erroneously reported to the NPDB.

Tying into this consideration is the fact that these vague standards raise questions about the meaningfulness of judicial review. As one court described, absent clearly articulated criteria, "it is impossible for any reviewing body to objectively and independently determine if an applicant has established 'competence.'"[300] Thus, courts will be unable to determine if the peer review result was driven by considerations unrelated to the quality of patient care.

iii. Customary Care Standards

Examples of the second category of standards include those that hold physicians to a standard of care as measured by the "[hospital's] standard of competence,"[301] or the "standard of the hospital or the medical staff,"[302] or "the general standards of the

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[299] *See* Kadar, *supra* note 87, at 21.

[300] Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1226 (Alaska 1992).

[301] Adkins v. Sarah Bush Lincoln Health Ctr., 544 N.E.2d 733, 736 (Ill. 1989) (noting disciplinary proceedings begun as a result of a physician's treatment of patients allegedly failing to conform to "the Center's standard of competence").

[302] Campbell v. St. Mary's Hosp., 252 N.W.2d 581, 588 (Minn. 1977) (noting hospital bylaw that held corrective action

surgical committee."[303] This Article labels these standards as "customary care" standards. As a general matter, "customary care" is that care which would customarily be given by other physicians under the same or similar circumstances. This practice of providing customary care is also referred to by many as "eminence-based medicine."

Arguably, the standards that fall into this category could be said to provide greater clarity which should provide a greater limitation on the decision-makers' ability to terminate staff privileges based on personal predilections unrelated to the quality of patient care. In addition, this clarity should provide greater notice to physicians of what conduct falls below a hospital's expectations. Unfortunately, a growing body of evidence demonstrates that there is a wide variation in customs across the country and that the choice of customary treatment is more linked to geography than to quality.[304] In addition, many customary treatment choices have a negative impact on quality of care.[305]

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appropriate when "professional conduct of any member of the staff shall be considered to be lower than the standard of the hospital or the medical staff"); *see also* DAN B. DOBBS, THE LAW OF TORTS § 242, at 633 (1st ed. 2000).

[303] Rhee v. El Camino Hosp. Dist., 247 Cal. Rptr. 244, 246, 248–49, (Cal. Ct. App. 1988) (discussing how a newly minted surgeon who had excellent credentials and training evaluations during his residency ran afoul of a group of surgeons in the hospital where he started his practice and how members of this group of physicians, who served on the peer review panels charged with judging whether the new surgeon met the in-house standard, testified that the new surgeon "did not 'meet the general standards of the surgical community at El Camino Hospital'").

[304] *See infra* Part V.B.2.b.iii.(A).

[305] *See infra* Part V.B.2.b.iii.(B).

These problems with the "customary care," or eminence-based, model of medical practice have led to the new push to move the United States to a modern, evidence-based model of medical practice.[306] Customary care is based on physician preference and not on objective, scientific evidence.[307] The evidence-based model for medical practice is based on empirical data generated by clinical outcomes and effectiveness research that suggests the optimum treatment for a rapidly growing number of clinical conditions.[308] This use of empirical data generated through scientific methodology to make medical

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[306] *See, e.g.,* SHANNON BROWNLEE ET AL., IMPROVING PATIENT DECISION-MAKING IN HEALTH CARE: A 2011 DARTMOUTH ATLAS REPORT HIGHLIGHTING MINNESOTA (2011); Elliot S. Fisher et al., *The Implications of Regional Variations in Medicare Spending Part 1: The Content, Quality and Accessibility of Care,* 138 ANNALS INTERNAL MED. 273 (2003).

[307] James N. Weinstein et al., *Trends and Geographic Variations in Major Surgery for Degenerative Diseases of the Hip, Knee, and Spine,* HEALTH AFF., Oct. 2004, at 81, 82 ("[I]n the absence of professional consensus based on outcomes, individual or small groups of physicians can hold onto idiosyncratic clinical rules of thumb defining who needs surgery. In a given region, local physicians tend to apply their rules of practice consistently, which results in the 'surgical signature' phenomenon: rates for specific surgical procedures that are idiosyncratic to a region, sometimes deferring dramatically among neighboring regions.").

[308] Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines,* 77 CALIF. L. REV. 1483, 1506 (1989). As clinical practice guidelines are created using empirical data generated through scientific methodology, physicians who incorporate clinical practice guidelines into medical decision-making are said to be practicing evidence-based medicine.

decisions shows great promise for enhancing quality of care while decreasing the cost of care.[309]

For example, empirical studies recently demonstrated that the long-held belief that hormone replacement therapy would help prevent heart disease in women was not true.[310] Another example is the long-time, customary practice by physicians of giving antiarrhythmia drugs to all patients who experienced irregular heartbeats after a heart attack.[311] A recent randomized clinical trial demonstrated that patients with mild arrhythmias are actually *more* likely to die if they are given antiarrhythmia drugs.[312] Based on this empirical evidence, many, but not all, physicians have modified their practice and adopted the evidence-based choice and only give the medication to those with severe

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[309] Van Tassel, *supra* note 110, at 1241–55 (explaining how Clinical Practice Guidelines (CGPs) will enhance quality of care); *see also* Ronen Avraham, *Private Regulation,* 34 HARV. J.L. & PUB. POL'Y 543, 550–52 (2011) (advocating this same use of CPGs by hospitals but adding a proposal of providing immunity from suit for those who apply CPGs).

[310] Mark A. Hlatky et al., *Quality-of-Life and Depressive Symptoms in Postmenopausal Women After Receiving Hormone Therapy: Results from the Heart and Estrogen/Progestin Replacement Study (HERS) Trial,* 287 J. AM. MED. ASS'N 591 (2002) (noting results of study where 2763 postmenopausal women with preexisting coronary artery disease who were randomly assigned to take either estrogen/progestin HRT or a placebo, researchers found no overall reduction in the rate of coronary heart disease events among the women receiving HRT compared to those receiving the placebo).

[311] Christine Gorman, *Are Doctors Just Playing Hunches?,* TIME (Feb. 15, 2007), http://www.time.com/time/magazine/article/0,9171,1590448,00.html.

[312] *Id.*

cardiac arrhythmias post-heart attack.[313] Time and again, the switch by physicians from customary care choices to evidence-based choices has avoided errors in patient care and saved lives.[314]

On the other hand, some physicians adhere to customary practice even in the face of empirical evidence to the contrary, placing their patients at risk of death. While it might be hard to imagine that physicians would ignore empirical evidence that one of their customs is actually hurting their patients, unfortunately, this occurs all too frequently. In 2004, a major study revealed that doctors and hospitals "fail with alarming frequency to deliver essential lifesaving treatments for some of the most common causes of death—heart attack, pneumonia and heart failure."[315] For example, patients who are given aspirin within the first twenty-four hours after a heart attack can have up to a thirty percent increase

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[313] *Id.*

[314] *Id.*

[315] Ford Fessenden, *It's the Simple Things, but Some Hospitals Don't Do Them,* N.Y. TIMES, Aug. 21, 2005, § 4 (The Nation), at 3; Ashish K. Jha, et al., *Care in the U.S. Hospitals–The Hospital Quality Alliance Program,* 353 NEW ENG. J. MED. 265, 266 (2005) ("A consortium of organizations, including the Centers for Medicare and Medicaid Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Hospital Association, and consumer groups such as the American Association of Retired Persons, initiated an effort now called the Hospital Quality Alliance (HQA) to [convince] hospitals nationwide [to] report data to the CMS on indicators of the quality of care for acute myocardial infarction, congestive heart failure, and pneumonia."); U.S. Dep't of Health & Human Servs., *Hospital Compare,* MEDICARE.GOV, http://www.hospitalcompare.hhs.gov/ last visited Apr. 16, 2012). This project is called the Hospital Quality Alliance Project. *Id.*

in the rate of survival.[316] However, of 3500 hospitals studied, physicians in those hospitals failed to give aspirin to one out of every sixteen patients.[317] In the first half of 2004, a total of 12,000 patients in these hospitals alone did not receive this simple lifesaving treatment.[318] The report shows there is a wide variation, from state to state and region to region, in whether this simple lifesaving treatment is provided to patients.[319] For example, the data showed that the hospitals studied in Massachusetts provided this treatment ninety-seven percent of the time,[320] whereas the hospitals in Arkansas provided the treatment only eighty-five percent of the time.[321]

A 2010 *New England Journal of Medicine* study of ten hospital systems demonstrated that the rate of injuries in hospitals from physician errors remains unchanged in the ten years since the IOM report.[322] Unfortunately, 98,000 people still die each year from avoidable medical errors in hospitals.[323] Importantly, the study found that "the penetration of evidence-based safety practices has been quite modest. For example, . . . [c]ompliance with even simple interventions such as hand washing is poor in many centers."[324]

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[316] Fessenden, *supra* note 315.

[317] *Id.*

[318] *Id.*

[319] *Id.*

[320] *Id.*

[321] *Id.*

[322] *See supra* note 130 and accompanying text.

[323] *See supra* note 131 and accompanying text.

[324] Landrigan et al., *supra* note 115, at 2130.

As discussed below, a similar change in hospital peer review from the customary care model to an evidence-based care model in order to evaluate physician competence will also reduce the risk of error in physician blacklisting. The bottom line is that customary care is a highly unreliable gauge of the quality of patient care that leads to a high risk of error in physician blacklisting.

(A) "Customary" Medical Care Is More Closely Related to Location than to Quality

In the 1980s, a group of startling empirical studies suggested that customary care was more closely linked to geography than quality. These studies revealed that the choices that physicians made in the diagnosis and treatment of the same clinical condition were based on the location that the physician happened to be practicing[325] and that there was a wide variation in customary care for the same condition that existed from region to region.[326] For example:

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[325] Mark A. Hall & Michael D. Green, *Introduction,* 37 WAKE FOREST L. REV. 663, 670–71 & n.11 (2002) (citing Bruce E. Landon et al., *Personal, Organizational, and Market Level Influences on Physicians' Practice Patterns: Results of a National Survey of Primary Care Physicians,* 39 MED. CARE 889, 889 (2001) (failing to find, through the use of clinical vignettes, any evidence of "a consistent practice style" for certain common discretionary medical decisions)).

[326] *See generally* John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery,* 182 SCIENCE. 1102 (1973); John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand,* 16 SOC. SCI. MED. 811, 812–17 (1982) (detailing differences in surgical practices); John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action,* HEALTH AFF., May 1984, at 6, 7 [hereinafter Wennberg, *Dealing with Medical Practice Variations*]

> [I]n Maine, by the time women reach seventy years of age in one hospital market the likelihood they have undergone a hysterectomy is 20 percent while in another market [it] is 70 percent. In Iowa, the chances that male residents who reach age eighty five have undergone prostatectomy range from a low of 15 percent to a high of more than 60 percent in different hospital markets. In Vermont, the probability that resident children will undergo a tonsillectomy has ranged from a low of 8 percent in one hospital market to a high of nearly 70 percent in another.[327]

The studies that gave us this data on practice variations prompted the creation of The Dartmouth Atlas of Health Care.[328] The Dartmouth Atlas uses

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(documenting variations in surgical procedures and medical treatments); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty,* HEALTH AFF., May 1984, at 74, 77–80 (detailing physician variations in choice of diagnosis and procedure); MARK R. CHASSIN ET AL., VARIATIONS IN THE USE OF MEDICAL AND SURGICAL SERVICES BY THE MEDICARE POPULATION 2–3 (1986), *available at* http://www.rand.org/pubs/notes/2009/N2678.pdf (measuring variation in rates of use by Medicare beneficiaries).

[327] Wennberg, *Dealing with Medical Practice Variations, supra* note 326, at 9; *see also* James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace?,* 11 ANNALS HEALTH L. 125, 137 (2002) (stating that "to ask an expert . . . what the 'customary practice' is [for a particular condition] on a national basis . . . is to ask a question to which there cannot be, for many diagnosis and treatment decisions, a coherent answer").

[328] THE DARTMOUTH ATLAS OF HEALTH CARE, http://www.dartmouthatlas.org (last visited Feb. 19, 2012).

very large healthcare-claims databases, including Medicare and Blue Cross organizations, to provide data on the wide variation of treatments for the same condition from region to region across the entire United States.[329] For example, a patient is twenty times more likely to have surgery if that patient lives in Idaho Falls, Missoula, or Mason City than if that patient lives in Newark, Bangor, or Terre Haute.[330] Other examples include: the rate of spinal surgery in Bradenton, Florida is seventy-five percent greater than in its neighbor to the north, Tampa, Florida,[331] and a patient is fifty percent more likely to have hip surgery if that patient lives in Ft. Lauderdale than in neighboring Miami.[332] And this surgical signature repeats itself all over the country.[333]

These studies demonstrate that what is customary care is based on physician preferences unlinked from best practices and that these preferences can be highly dependent on the region in which the physician practices. Importantly, a treatment choice that is a customary choice for a region does not mean that this is a quality choice; it simply means that it is the treatment of choice for that particular region.

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[329] *Research Methods,* THE DARTMOUTH ATLAS OF HEALTH CARE, http://www.dartmouthatlas.org/tools/faq/researchmethods.aspx (last visited Aug. 10, 2011).

[330] CTR. FOR THE EVALUATIVE CLINICAL SCIS., DARTMOUTH ATLAS OF HEALTH CARE: STUDIES OF SURGICAL VARIATION (SPINE SURGERY) 7 (2006), *available at* http://www.dartmouthatlas.org/downloads/reports/Spine_Surgery_2006.pdf.

[331] *Id.* at 19.

[332] ELLIOTT S. FISHER ET AL., TRENDS AND REGIONAL VARIATION IN HIP, KNEE, AND SHOULDER REPLACEMENT 17 (2010), *available at* http://www.dartmouthatlas.org/downloads/reports/Joint_Replacement_0410.pdf.

[333] *Id.*

Consequently, there is a high risk that physicians who are practicing high-quality, evidence-based patient care will be erroneously reported to the NPDB merely because they did not choose the treatment that is customary in that region.

(B) Customary Care Can Be "Bad" Patient Care

Not only can customary care be unrelated to quality of care, it may actually be "bad" patient care. The 1980s brought another group of studies that revealed "serious weaknesses in the scientific underpinnings of many customary practices."[334] These studies also disclosed the "substantial overuse of many medical and surgical procedures."[335]

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[334] Clark C. Havighurst, *Practice Guidelines As Legal Standards Governing Physician Liability,* 54 L. & CONTEMP. PROBS. 87, 89 (1991). For example, the use of certain respiratory techniques and gastric freezing of ulcers, which were quickly adopted as "standard practice," were ultimately discredited by scientific studies. *Id.* at 88–89 & n.6 (citing David Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care,* HEALTH AFF., Spring 1988, at 19, 20 ("[F]or at least some important practices, the existing evidence is of such poor quality that it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes that would have occurred with other options."); David Eddy, *Clinical Policies and the Quality of Clinical Practice,* 307 NEW ENG. J. MED. 343, 343 (1982) ("There is reason to believe that there are flaws in the process by which the profession generates clinical policies.")); *see also* FURROW, *supra* note 176, at 33.

[335] Havighurst, *supra* note 334, at 88–89 & n.7. There are wide variations in the use of "laboratory tests, prescription drugs, X-rays, return appointments, and telephone consultations among similarly trained doctors in a wide variety of practice settings. Research on appropriateness indicates that from one quarter to one third of medical services may be of no value to patients." FURROW, *supra* note 176, at 34 (citing Robert Brook & Kathleen

In a recent article in *The New Yorker,* Harvard Professor Atul Gawande examined the reasons that McAllen, Texas is one of the most expensive markets in the country, second only to Miami, Florida.[336] Medicare spends twice the national average on Medicare enrollees in McAllen—$15,000 per enrollee per year.[337] Compared to neighboring El Paso, a similar community, McAllen's hospitals performed worse than El Paso's on the twenty-five metrics that Medicare uses to rate quality.[338] And yet:

Lohr, *Will We Need to Ration Effective Medical Care?,* ISSUES IN SCI. & TECH., Fall 1986, at 68). Another study found a "seventeen-fold variation in lab use among internists dealing with clinical patients." *Id.* at 34 (citing Steven A. Schroeder et al., *Use of Laboratory Tests and Pharmaceutical Variation Among Physicians and Effect of Cost Audit on Subsequent Use,* 225 J. AM. MED. ASS'N 969 (1973)). For example, one study on the insertion of pacemakers in a large group of individuals indicated that "44% of the implants were definitely indicated, 36% possibly indicated, and 20% were not indicated." *Id.* (citing Lee Goldman et al., *Costs and Effectiveness of Routine Therapy with Long-Term Beta-Adrenergic Antagonists After Acute Myocardial Infarction,* 319 NEW ENG. J. MED. 52 (1988)). Another example is a study that demonstrated that carotid endarterectomies, which remove blood clots in the arteries leading to the brain, were only indicated in thirty-two percent of the cases reviewed. *See* Havighurst, *supra* note 334, at 88–89 & n.7 (citing Robert Brook et al., *Predicting the Appropriate Use of Carotid Endarterectomy, Upper Gastrointestinal Endoscopy, and Coronary Angiography,* 323 NEW ENG. J. MED. 1173, 1173 (1990) ("We concluded that 17 percent of coronary angiographies, 17 percent of endoscopies, and 32 percent of endarterectomies represented inappropriate overuse [using a liberal standard].")).

[336] Atul Gawande, *The Cost Conundrum,* NEW YORKER, June 1, 2009, at 36.

[337] *Id.*

[338] *Id.*

> Between 2001 and 2005, critically ill Medicare patients received almost fifty percent more specialist visits in McAllen than in El Paso, and were two-thirds more likely to see ten or more specialists in a six month period. In 2005 and 2006, patients in McAllen received twenty percent more abdominal ultrasounds, thirty percent more bonedensity studies, sixty percent more stress tests with echocardiography, two hundred per cent more nerve-conduction studies to diagnose carpal-tunnel syndrome, and five hundred and fifty percent more urine-flow studies to diagnose prostate troubles. They received one-fifth to two-thirds more gall bladder operations, knee replacements, breast biopsies, and bladder scopes. They also received two to three times as many pacemakers, implantable defibrillators, cardiac-bypass operations, carotid endarterectomies, and coronary artery stents. And Medicare paid for five times as many home-nurse visits.[339]

Based on extensive research, Professor Gawande concluded that "[t]he cause of McAllen's extreme costs was, very simply, the across-the-board overuse of medicine."[340] And each time a patient is subjected to unnecessary invasive tests and surgery, that patient is subjected unnecssarily to the risks associated with the procedure. In some cases, these

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[339] *Id.*

[340] *Id.*

risks can not only be physically disabling, they can be life-threatening.[341]

So, again, these series of studies strongly suggest that using customary care[342] as the measure for physician competence translates into a high risk of error in blacklisting physicians as, not only can customary care be unrelated to quality of care, it may actually be "bad" patient care. This not only impacts quality of care, it has major implications for cost of care. It is estimated that thirty percent of the cost of

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[341] A recent study of 1200 patients revealed that lumbar diskectomy, the most common surgery in the United States for people with back and leg pain, is largely unnecessary. James N. Weinstein et al., *Surgical vs. Nonoperative Treatment for Lumbar Disc Herniation,* 296 J. AM. MED. ASS'N 2441, 2447 (2006). The study demonstrated that patients who had surgery and those that had more conservative treatments, such as physical therapy, enjoyed the same level of recovery. *Id.* This means that surgery patients who receive the customary treatment of lumbar diskectomy are unnecessarily exposed to the serious risks and costs associated with the surgery.

[342] Compounding this problem are the conclusions drawn by a series of studies conducted in the 1990s that found that "physician agreement regarding quality of care is only slightly better than the level expected by chance." Ronald L. Goldman, *The Reliability of Peer Assessments of Quality of Care,* 267 J. AM. MED. ASS'N 958, 958 (1992); *see also* Rodney A. Hayward et al., *Evaluating the Care of General Medicine Inpatients: How Good Is Implicit Review?,* 118 ANNALS INTERNAL MED. 550, 550 (1993); Haya R. Rubin et al., *Watching the Doctor-Watchers: How Well Do Peer Review Organization Methods Detect Hospital Care Quality Problems?,* 267 J. AM. MED. ASS'N 2349, 2349 (1992). The conclusions drawn by these studies are not surprising in light of the remarkably wide variation in practices utilized by physicians evidenced by the studies described in the prior Sections.

Medicare could be saved if this overuse generated by regional customs was avoided.[343]

All together, these studies on the variation and effectiveness of customary treatment and the very low level of agreement among physicians regarding what care is quality care, raise serious questions regarding the appropriateness of the use of customary care as a proxy for measuring physician competence.

c. State-to-State Variation in the Amount of Judicial Review of Hospital Peer Review to Correct for Errors

Unlike the system of judicial review for sex offenders that uniformly provides full due process review, there is a wide range in the amount of review that the courts provide for physicians who have been sanctioned through the peer review process. Some state courts will only review hospital peer review decisions for compliance with the procedures required by the hospital's bylaws.[344] Consequently, many state courts defer completely to hospital decision-makers on findings of physician competence. These courts opine that, because such a decision is so subjective, it is effectively unreviewable.[345] On the other hand, one

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[343] Guwande, *supra* note 336.

[344] FURROW, *supra* note 176, § 4-6, at 104–05.

[345] Representative of those courts that take the position that it is not possible, or desirable, to create clearly articulated standards to evaluate physician competence is the case of *Jackson v. Fulton-DeKalb Hospital Authority,* 423 F. Supp. 1000 (N.D. Ga. 1976). In *Jackson,* a physician appealed the suspension of his surgical privileges, which were found by the hospital to be "detrimental to the maintenance of proper standards of medical practice." *Id.* at 1005. The U.S. District Court for the Northern District of Georgia upheld the suspension in the face of a challenge that the standard was "impermissibly vague and arbitrary." *Id.* at 1006. In doing so, the court threw up its hands

group of state courts found that specific criteria that can be objectively applied in measuring physician competence are achievable and felt competent to ensure that peer review fairly created and applied such criteria.[346] This disparity in judicial review means that some physicians will be protected from the publication by the NPDB of a negative report based on an erroneous finding of incompetence and some will not receive the same protection.[347]

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in defeat, thereby abdicating its obligation to ensure that the peer review process conforms to basic principles of fairness:

> In the area of personal fitness for medical staff privileges precise standards are difficult if not impossible to articulate. . . . The subjectives of selection simply cannot be minutely codified. The governing board of a hospital must therefore be given great latitude in prescribing the necessary qualifications for potential applicants.

Id. (quoting Sosa v. Bd. of Managers of the Val Verde Mem'l Hosp., 437 F.2d 173, 176 (5th Cir. 1971)).

[346] *See, e.g.,* Wyatt v. Tahoe Forest Hosp. Dist., 345 P.2d 93, 97 (Cal. Ct. App. 1959) (noting that the standard set up was so vague and uncertain "that admission to the staff can depend on the whim and caprice of the directors"); Kiester v. Humana Hosp. Alaska, Inc., 843 P.2d 1219, 1225–26 (Alaska 1992); *see also* Miller v. Eisenhower Med. Ctr., 614 P.2d 258, 265 (Cal. 1980) (finding that rules governing the admission of physicians cannot stand if the standard is "unreasonably susceptible of arbitrary or discriminatory application"); Williams v. Kleaveland, 534 F. Supp. 912, 917 (W.D. Mich. 1981) (holding that "rules established by hospitals to regulate the conduct of doctors must be capable of objective application"); Martino v. Concord Cmty. Hosp. Dist., 43 Cal. Rptr. 255, 258–60 (Cal. Ct. App. 1965) (stating a hospital must set up standards that are clear, and not vague, ambiguous, or uncertain).

[347] For a full discussion of this series of cases, see Van Tassel, *supra* note 110, at 1207–32.

These different levels of judicial review can determine whether a damaging report will be made to the federally supported NPDB. For example, if two physicians in two different states with different standards of review are targeted for the *very same conduct,* one could be reported to the NPDB because there was no judicial review while the other is not reported because judicial review is provided that exonerates the physician. If both apply for staff privileges in a third state, the physician who was reported to the NPDB will be barred from the appointment. These disparate levels of judicial review raise serious due process concerns.

It almost defies credibility that the process that the federal government relies upon to blacklist targeted physicians through the NPDB reporting system is more closely tied to the location of the physician's practice than quality.[348] As this Section establishes, the location of a physician's practice can dictate whether a physician's choice of a treatment for a particular patient comports with the customary choice.[349] The location of a physician's practice can dictate whether the hospital participates in peer review or not.[350] If the hospital does participate in peer review, it may be one that actively chooses to impose sanctions that will avoid the NPDB reporting requirements or one that simply does not report at all.[351] The location of a physician's practice can also dictate whether the state licensure board investigates physicians who are the subject of negative peer

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[348] *See supra* Part V.B.2.b.iii.(A).

[349] *See supra* Part V.B.2.b.iii.

[350] *See supra* notes 253–56 and accompanying text.

[351] *See supra* note 256 and accompanying text.

review reports.[352] Finally, the location of a physician's practice can dictate whether or not the state courts provide judicial review of peer review proceedings.[353]

Adding together all of the points in the process where reporting or not is simply a matter of geography leads to a disquieting conclusion: it appears that the chances that a physician's practice and life are destroyed are more closely related to geography than to the quality of care that the physician provides to patients. In contrast, the chances that an alleged sexual offender will be prosecuted are not dependant on the location where the conduct occurred, but on the nature of that conduct.

3. Probable Value of Additional Procedural Safeguards Including Impact on Healthcare Quality, Cost, and Access

The next step in the *Mathews* analysis requires an analysis of the "probable value, if any, of additional or substitute procedural safeguards."[354] It is clear that adding the same procedural safeguards to the hospital peer review process that are provided to alleged sexual predators will dramatically improve the accuracy of the information in the database. It will prevent physicians from being added to the database for reasons unrelated to the quality of patient care (the over breadth problem),[355] and will add physicians who are practicing poor quality patient care (the under inclusive problem).[356] It will

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[352] *See supra* notes 200–01 and accompanying text.

[353] *See supra* Part V.B.2.c.

[354] 424 U.S. 319, 335 (1976).

[355] *See supra* Part V.B.1–2.

[356] *See supra* Part V.B.1–2.

also deal with the problem of inaccurate and misleading information as clearly articulated standards based on the practice of evidence-based medicine will allow both for judicial review and for very clearly stating in the NPDB the circumstances under which a physician was disciplined and in what way he or she failed to provide quality of care.

a. Requiring Clearly Articulated Standards Encourages the Use of Evidence-Based Medicine

Moving away from the use of custom as a proxy for quality has additional benefits on the quality and cost of healthcare. For example, state tort systems are moving away from using customary care as the exclusive proxy for quality of care. In a medical malpractice case, in order to meet the "standard of care," a physician must "possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances."[357] States are slowly moving away from what is currently the majority rule that uses customary practice as conclusive evidence of the standard of care as they are recognizing the problems with using custom, as discussed above, as a proxy for quality.[358] For these reasons, among others, these states are allowing the introduction of risk-

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[357] Burns v. Metz, 513 N.W.2d 505, 508 (Neb. 1994); Vergara *ex rel.* Vergara v. Doan, 593 N.E.2d 185, 188 (Ind. 1992) (holding that jurors "may judge the doctor's conduct by [the] minimum standard of care for the particular practice"). For an excellent overview of medical malpractice law, see DOBBS, *supra* note 302, § 242, at 634–35.

[358] *See generally* Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law,* 87 IOWA L. REV. 909 (2002) (discussing the merits of the role of custom as conclusive evidence of the standard of care in malpractice litigation and the movement by many states to use custom as only some evidence of the standard of care).

benefit analysis grounded in empirical science as evidence of what is reasonable quality care. Thus, the tort system is operating instrumentally to encourage the transition away from custom-based medical practice to evidence-based medical practice.

The positive impact that an evidence-based standard of care has, in both the medical malpractice and the hospital peer review context, is borne out by a recent empirical study that used data on treatment utilization rates from the 1977 to 2005 compiled by the National Hospital Discharge Surveys. This study estimated that there was "a 30-50% reduction in the gap between the state and national utilization rates of various obstetric, cardiac and diagnostic procedures following the abandonment of a rule requiring physicians to meet the standards set by local physicians and the contemporaneous adoption of a national-standard rule."[359] The author of the study finds, in the context of medical malpractice, that "custom-based liability standards may indeed encourage the perpetuation of customary practices and likewise discourage deviations from custom."[360] He concludes that

> the results of this study more generally suggest that a malpractice rule that bases standards of care on customary physician practices may indeed incentivize the perpetuation of those customary practices

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[359] Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules,* 102 AM. ECON. REV. (forthcoming) (manuscript at 1), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1432559.

[360] *Id.*

> and, at the same time, discouraging deviations from custom. . . .
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> The employment of custom-based standards, moreover, carries a number of important policy implications, particularly with respect to the possible role that they may play in discouraging cost-reducing innovations in delivery practices. Legal scholars have long recognized that the effectiveness of managed care and related strategies may be blunted by a medical liability system that holds physicians to a standard of care determined according to customary physician practices, where those practices were developed in a predominantly fee-for-service environment that may have encouraged excessive practice styles.[361]

The author goes on to state that

> [b]y arguably establishing the empirical relevancy of the customary component to malpractice standards, this study validates these concerns and thereby lends support to proposals that call for a relaxation of customary-standard requirements, including those that argue for a stronger role for "reasonableness" in malpractice-standard determinations or, as above, a more definitive role for clinical practice guidelines in malpractice proceedings.[362]

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[361] *Id.* at 37–38.

[362] *Id.* at 38. And, as I argue in my first article on hospital peer review, a greater role for Clinical Practice Guidelines in the hospital peer review process. Van Tassel, *supra* note 110, at 1241–55.

As is the case with the use of customary care standards in medical malpractice litigation, the reliance in peer review on customary care acts to entrench custom-based decision-making at the cost of quality of care. This conclusion finds support in a 2010 *New England Journal of Medicine* study of ten hospital systems that demonstrated that the rate of injuries in hospitals from physician errors remains unchanged in the ten years since the IOM report in spite of multiple initiatives to improve quality.[363] The 2010 report concludes that 98,000 people still die each year from medical errors in hospitals.[364] Importantly, the study found that "the penetration of evidence-based safety practices has been quite modest. For example, . . . [c]ompliance with even simple interventions such as hand washing is poor in many centers."[365]

Finally, as discussed above by Professor Guwande, adherence to the custom-based approach acts to increase the cost of medical care as many treatments, surgeries, tests, and physician visits are unnecessary.[366]

b. Requiring Good Faith in Accord with Due Process Protects Against Blacklisting Whistleblowers

Another implication of maintaining the status quo is the impact that the current NPDB process is having on whistleblowers and what this means to quality of care. The story of Dr. Ulrich, discussed earlier, is a good example of how the current vague standards, coupled with the broad judicial

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[363] Landrigan et al., *supra* note 115, at 2130.

[364] *Id.* at 2125.

[365] *Id.* at 2130.

[366] *See supra* notes 331–40 and accompanying text.

interpretation of HCQIA immunity, can have a negative impact on quality of patient care. Recall that Dr. Ulrich raised red flags about the negative impact that staffing cuts would have on the quality of patient care. Within two weeks, he learned that he was being investigated for alleged clinical incompetence. After he resigned, he was reported to the state licensure board and the NPDB.

This story is being repeated across the country with whistleblowers who protest problems with quality of patient care being threatened with peer review investigation and NPDB reporting to silence their criticisms[367]:

> "It is clear that we are hearing more cases of these kind of really difficult conflicts occurring between hospitals, and, in some instances, hospital boards, and the medical staff," said Dr. Paul M. Schyve, senior vice president of the Joint Commission on Accreditation of Healthcare Organizations, which accredits most U.S. hospitals. Schyve said one factor driving these disputes is the economic pressure hospitals face to keep costs down and maintain a good imagine.[368]

However, when these conflicts arise, physician whistleblowers "face a unique vulnerability, one that can make disagreeing with their hospital administrators a career-ending move. Once they've been labeled disruptive, doctors may face sanctions

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[367] *See* Twendt, *supra* note 260 ("In medical centers as small as Centre Community Hospital in State College and as prestigious as Yale and Cornell, doctors who step forward to warn of unsafe conditions or a colleague's poor work say they have been targeted by hospital administrators or boards.").

[368] *Id.*

and effective banishment from the profession. That gives hospitals considerable leverage when conflicts occur."[369] In one extreme example of this situation, one physician faced exactly this situation for pushing for an investigation into a nurse who was allegedly murdering patients night after night.[370]

In one survey of 448 emergency room physicians across the United States, twenty-three percent reported that they had lost a job, or had been threatened with termination, when they had raised quality of care concerns.[371] These types of narratives raise the question of whether the courts' broad interpretation of HCQIA immunity for hospital peer review is having the unintended effect of silencing the very people who are in the best position to point out problems with the quality of patient care.[372]

Importantly, before the advent of blacklisting by the NPDB, physicians were the one group in the hospital who had the power to speak up without fear

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[369] *Id.* A University of Baltimore study ordered by the Maryland General Assembly on credentialing found that "whistleblower physicians who alienate hospital officials are vulnerable to having their admitting privileges taken away, with devastating effects on their practices." Steve Twedt, *The Cost of Courage: Doctor Says Whistleblowers Need More Protection,* PITT. POST-GAZETTE, Oct. 29, 2003, at A1.

[370] Steve Twedt, *Doctors Pay for Reporting Suspicions,* PITT. POST-GAZETTE, Oct. 28, 2003, at A6.

[371] Twedt, *supra* note 260.

[372] *See id.* ("'We're the only people who can stand up for patients,' said Dr. Scott Plantz, an emergency medicine specialist who headed the survey of emergency physicians. 'The nurses can't, because they're employees of the hospital. But doctors aren't, or at least they weren't in the past. With managed care and doctors working for hospitals, it gets worse and worse and worse.'").

of retribution if hospital practices were placing patients at risk of harm. It appears that the current system insulates the use of sham peer review to silence these voices.

Finally, requiring good faith in peer review recognizes that the power to select the medical staff "is deeply imbedded in public aspects, and [is] rightly viewed, for policy reasons . . . as [a] fiduciary power[] to be exercised reasonably and for the public good."[373]

4. Government's Interest and Administrative Burdens of Additional Safeguards

The final step in the *Mathews* analysis is to examine the weight of the governmental interest in keeping the status quo with regard to current procedures, adding in the administrative burden to the government of adding certain procedural safeguards.[374] The purpose of the NPDB is to improve the quality of patient care by preventing a physician who is a poor practitioner from traveling to a new location and providing the same level of poor care to a second, unsuspecting group of patients. So the governmental interest is in increasing the quality of patient care by identifying and labeling poor-quality physicians. First, it is important to point out that there have been no empirical studies that demonstrate that the NPDB has had any impact on the quality of patient care. Thus, any benefit that the current system may have is based on speculation grounded upon the highly suspect presumption that the system the NPDB relies upon for its data does, in fact, accurately identify poor-quality practitioners. As

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[373] Kiracofe v. Reid Mem'l Hosp., 461 N.E.2d 1134, 1143 (Ind. Ct. App. 1984).

[374] Mathews v. Eldridge, 424 U.S. 319,335 (1976).

demonstrated, the standards used in the hospital peer review hearing process lead to both under and over inclusive results. This lack of accuracy leads to the logical (though also nonempirically tested) conclusion that, as currently constructed, the NPDB is unlikely to be properly identifying poor-quality physicians and, thus, does not have the positive impact on the quality of patient care that it would have if its accuracy was improved.

Regardless, providing physicians with full due process during the hospital peer review hearing process will not negatively impact the government's mission; in fact, adding this procedural protection will have a dramatically positive impact on the accuracy of the database and, thus, on the quality of patient care which is consistent with government interests. Moreover, the procedural due process protections that this Article suggests will also have a positive impact on the cost of healthcare and on access to healthcare.[375] These due process protections should include the requirement that hospital peer review be based on clearly articulated standards that adopt best practices to encourage evidence-based patient care. In a prior article, I set forth a very detailed, step-by-step system for establishing best practices that is built upon the committee system already in use by hospitals.[376] This committee system would allow for physician choice among Clinical Practice Guidelines[377] which will suggest treatment

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[375] *See supra* Part V.B.3.a.

[376] Van Tassel, *supra* note 110, at 1241–55.

[377] Clinical Practice Guidelines are based on empirical data generated by clinical outcomes and effectiveness research that suggest the optimum treatment for a rapidly growing number of clinical conditions. Leahy, *supra* note 308, at 1506.

choices based on best outcomes derived from empirical studies.[378]

In order to make these changes, Congress could amend the HCQIA to limit participation in federal healthcare programs like Medicare and Medicaid to only those hospitals that agree to provide full due process protections during the hospital peer review hearing process.[379] This requirement is similar to the

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[378] *Id.* This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care while decreasing the cost of care. Van Tassel, *supra* note 110, at 1241–55; *see also* Avraham, *supra* note 309 (advocating this same use of CPGs by hospitals but adding a proposal for providing immunity from suit for those who apply CPGs).

[379] If congressional action is not forthcoming, then physicians who have been blacklisted should join together in a class-action suit against the federal government asserting that their due process rights have been violated resulting in damage to their property and liberty interests under *Goss v. Lopez.* The class-action suit could seek to enjoin the NPDB from publishing reports from hospitals that use peer review processes that do not provide due process protections. Another avenue is to bring § 1983 claims against state governments and state officials. As currently required by the new 2011 regulations, hospitals are required to report negative peer review sanctions to their state licensure boards and these state licensure boards are required to provide these private peer review reports to the NPDB. *See* 45 C.F.R. § 60.5 (2011). This participation in the NPDB reporting process provides the state action that is the predicate for this type of claim. Title 42, § 1983 of the U.S. Code provides:

> Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party

tool used by the federal government to "persuade" states to adopt Megan's Law, which required the blacklisting of sexual predators. Congress conditioned major federal funding for law enforcement programs provided by the Byrne Formula Grant Program on compliance with Megan's Law.[380]

Comparing this situation to that of the parties in the recent Supreme Court case in *Hamdi v. Rumsfeld* is instructional. In *Hamdi,* the government asserted that the war on terror would be adversely impacted by providing due process to defendants accused of

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> injured in an action at law, suit in equity, or other proper proceeding for redress . . . .

To be cognizable under § 1983, the claims of the targeted physicians must establish both a deprivation of a constitutional right and the effectuation of the deprivation of that right under color of state law. *See* Paul v. Davis, 424 U.S. 693, 696–97 (1976); Adickes v. S.H. Kress & Co., 398 U.S. 144, 150 (1970). The actions of NPDB officials, at issue in this Article, in reporting the peer review hearing results involving the targeted physicians typically are intentional and performed in their official capacities.

[380] The remarkable increase in sexual offender registration laws was the result of the Federal Jacob Wetterling Crimes Against Children and Sexually Violent Offender Registration Act, Pub. L. No. 103–322, 108 Stat. 2038, 2042 (1994) (codified as amended at 42 U.S.C. § 14071 (2000)), *repealed by* Adam Walsh Child Protection and Safety Act of 2006, Pub. L. No. 109–248, § 129, 120 Stat. 587, 600. The Wetterling Act relied upon Congress's spending power to "encourage" states to pass registration and permissive community-notification laws to avoid losing ten percent of their Federal Byrne Formula Grant Program funds. *See* 42 U.S.C. § 14071(f)(2) (1994), *repealed by* Adam Walsh Child Protection and Safety Act of 2006, Pub. L. No. 109–248, § 129, 120 Stat. 587, 600. The reliance by state criminal justice programs on the funds afforded them by the Byrne Program meant that every state quickly adopted registration laws. LOGAN, *supra* note 11, at 65.

being terrorists.[381] According to the government, this litigation would distract military officers from their day-to-day duties and would risk disclosure of military secrets.[382] In the matter at hand, there is no risk of any distraction from the government's mission. In fact, as described above, additional safeguards facilitate the government's pursuit of its "mission" to enhance the quality of patient care. The *Hamdi* Court concluded that:

> The "risk of erroneous deprivation" of a detainee's liberty interest is unacceptably high under the government's proposed rule . . . . [The court held] that a citizen-detainee seeking to challenge his classification as an enemy combatant must receive notice of the factual basis for his classification, and a fair opportunity to rebut the Government's factual assertions before a neutral decisionmaker.[383]

As in *Hamdi,* the risk of erroneous deprivation of a physician's liberty and property interests based on the processes used by the NPDB is extremely high. And one is hard pressed to harmonize a rule that guarantees enemy combatants due process while denying these same protections to physicians who are serving their communities.

Moving to the second governmental interest consideration—that of cost—adding these safeguards does not increase the administrative costs for the government. Government-run hospitals, like the VA, are already required to provide due process to

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[381] Hamdi v. Rumsfeld, 542 U.S. 507, 507 (2004).

[382] *Id.* at 531–32.

[383] *Id.* at 532–33.

physicians in peer review. This proposal brings private hospitals into line with government hospitals.

Consequently, applying the *Mathews* balancing test is outcome determinative. The risk of erroneous deprivation is high. The cost of the loss is extraordinary to physicians. And there is no cost to the government in the form of hampering its interests in pursuing its mission to enhance quality of care or adding to the costs of pursing that mission through the use of the NPDB. In fact, the accuracy of the NPDB is enhanced, making it more likely to improve the quality of patient care while also decreasing the cost of that care and increasing patient access to healthcare.

CONCLUSION

Addressing the systematic problems with the methods used to construct and maintain the NPDB has become an issue of pressing national importance for several reasons. First, it appears that the NPDB reporting system encourages the perpetuation of custom-based practices and discourages deviations from these customs undermining efforts to improve quality and cost of care through the practice of evidence-based treatment choices. Second, the NPDB system as currently constructed is being used to silence physician whistleblowers, once again negatively impacting quality of care. Third, the NPDB has very recently expanded its scope to take on blacklisting of *all* licensed healthcare practitioners in the United States, including dentists, nurses, physician's assistants, social workers, dental hygienists, physical therapists, and pharmacists,

extending its reach to over six million people.[384] This means that the negative impact that the NPDB may have on the quality and cost of care is being magnified exponentially as it begins to affect the practice habits of all healthcare professionals. Finally, the lives of physicians are being unfairly destroyed by a process that fails to properly safeguard their property and liberty interests.

The problems with the NPDB can be resolved by providing physicians, and other healthcare providers, with the same kind of due process protections that are provided to alleged sexual offenders before they are blacklisted. These due process protections should include the requirement that hospital peer review be based on clearly articulated standards that adopt best practices to encourage evidence-based patient care. In order to make these changes, Congress could amend HCQIA to limit participation in federal healthcare programs like Medicare and Medicaid to those hospitals that agree to provide full due process protections during the hospital peer review hearing process. Providing physicians with full due process protections before including them on the NPDB blacklist will better protect physicians from the erroneous destruction of their careers while increasing the accuracy of the NPDB. These solutions will improve the efficacy of the database in furthering quality of patient care while improving healthcare cost and access.

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[384] *See* BUREAU OF LABOR STATISTICS, *supra* note 3 (indicating that the number of healthcare professionals in the United States is 6,283,900).