UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

CHRISTEN HOEDT, M.D.,)
Plaintiff,)
v.) No. 3:24-cv-00310
VANDERBILT UNIVERSITY, et al.,)
Defendants.)

MEMORANDUM OPINION

Everyone—physicians included—makes mistakes. Acknowledging this, Dr. Robert Caplan wisely stated more than twenty years ago that "[t]he only way to improve patient safety . . . is to be open and honest about [medical] errors. You can't understand something you hide."¹ This critique rings true here, where Christen Hoedt, M.D. ("Dr. Hoedt") brought this suit against Vanderbilt University ("VU"), Vanderbilt University Medical Center ("VUMC"), Rick W. Wright, M.D. ("Dr. Wright"), Gregory G. Polkowski, M.D. ("Dr. Polkowski"), and the United States Department of Health and Human Services ("HHS") after disputes arose between the parties about the quality of Dr. Hoedt's medical care. Dr. Hoedt seeks judicial review under the

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¹ Dr. Caplan, as the then-head of quality and safety at Virginia Mason Medical Center, made this remark to <u>The Seattle Times</u> in 2004 after a patient at the facility, Mary McClinton, died following a medical error. <u>See You Can't Understand Something You Hide: Transparency As A Path To Improve Patient Safety</u>, Health Affairs Blog, https://www.healthaffairs.org/content/forefront/you-can-t-understand-something-you-hide-transparency-path-improve-patient-safety (last visited Sept. 8, 2025). Serving as a quintessential example of the power of public transparency, McClinton's clinical team sought to learn from her unfortunate passing by investigating the error, disclosing it to her family and other hospital staff, and sharing their findings with other health professionals to ensure other patients would not be put at risk from similar mistakes. <u>See id.</u> Because McClinton's team was so forthright and thorough in addressing the harm caused, her family received answers on her passing, and other professionals changed their procedures to protect their patients and ensure best practices moving forward.

Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–06 et seq. of HHS's determination that all of the reports filed by Vanderbilt Wilson County Hospital ("Hospital") about Dr. Hoedt's clinical performance were compliant with the Health Care Quality Improvement Act ("HCQIA" or "Act"). Before the Court are Dr. Hoedt's and HHS's cross-motions for summary judgment on that issue, which are fully briefed and ripe for review. (Doc. Nos. 71–73, 78–80, 84–86). For the following reasons, the Court will grant HHS's Motion (Doc. No. 78) and deny Dr. Hoedt's Motion (Doc. No. 71).

I. REVIEW OF THE RECORD²

A. Applicable Statutes and Regulations

The HCQIA "was passed in 1986 to provide for effective peer review and interstate monitoring of incompetent physicians, and to grant qualified immunity from damages for those who participate in peer review activities." Meyers v. Columbia/HCA Healthcare Corp., 341 F.3d 461, 467 (6th Cir. 2003) (citing Austin v. McNamara, 979 F.2d 728, 733 (9th Cir. 1992) and 42 U.S.C. § 11101). The Act also aims to "provide incentive and protection for physicians engaging in effective professional peer review." 42 U.S.C. § 11101(5).

In furtherance of the Act's objectives, Congress established the National Practitioner Data Bank ("NPDB" or "Data Bank") to manage the collection and dissemination of professional information on physician conduct.³ 42 U.S.C. § 11134; 45 C.F.R. § 60.1. The HCQIA imposes

² These factual findings come from the findings in the administrative record (Doc. No. 64), which are conclusive because they are supported by substantial evidence in the record. Wokojance v. Weinberger, 513 F.2d 210, 212 (6th Cir. 1975).

³ The Data Bank is used primarily as an alert system. U.S. Dep't of Health & Human Servs., <u>National Practitioner Data Bank Guidebook</u>, at A-7 (2018), https://www.npdb.hrsa.gov/resources/NPDBGuidebook.pdf ("<u>Guidebook</u>") ("The NPDB is primarily a flagging system that may serve to alert users that a more comprehensive review of the qualifications and background of a health care practitioner, entity, provider, or supplier may be

reporting requirements on, among others, hospitals. 42 U.S.C. §§ 11131–34. The reporting requirement central to this case requires a health care entity to file a report with the Data Bank if it "takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days." 42 U.S.C. § 11133(a)(1)(A). The Act defines a professional review action as:

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 . . . of the physician.

<u>Id.</u> § 11151(9); <u>see also Guidebook</u>, at E-38 ("A summary suspension is reportable if it is: (1) In effect or imposed for more than 30 days[;] (2) Based on the professional competence or professional conduct of the physician . . . that adversely affects, or could adversely affect, the health or welfare of a patient[; and] (3) The result of a professional review action taken by a hospital or other health care entity.") (numbering added). "Adversely affecting," as written in § 11151(9), is defined expansively to include "reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity." 42 U.S.C. § 11151(1).

To ensure the reliability of reported information, "Congress directed the Secretary of the Department of Health & Human Services [("Secretary")] to promulgate regulations establishing 'procedures in the case of disputed accuracy of the information'" filed with the Data Bank. <u>Leal v. Sec'y, U.S. Dep't of Health & Hum. Servs.</u>, 620 F.3d 1280, 1282 (11th Cir. 2010) (citing 42 U.S.C. § 11136(2)). "Under those regulations, a physician who disputes the accuracy of a report

prudent"). The information in it "serve[s] as only an indicator of professional quality and not as conclusive or complete evidence of it." 53 Fed. Reg. 9264, 9265 (Mar. 21, 1988); see also Guidebook, at A-7 ("NPDB information should *not* be used as the sole source of verification of professional credentials").

can seek Secretarial review[.]" <u>Id.</u>; <u>see</u> 45 C.F.R. § 60.16(c)(2). The Secretary's review is "limited to having the report reviewed for accuracy of factual information and to ensure that the information was required to be reported." <u>Id.</u> (citation and quotations omitted). Due to the limited scope of review, the Secretary will not review the merits of the hospital's professional review action, nor will it assess the due process the physician received related to the review action. 45 C.F.R. § 60.21(c)(1).

B. Dr. Hoedt's Suspension and Reinstatement

Dr. Hoedt is an orthopedic surgeon who began practicing at the Hospital in June 2021. (Doc. No. 64 at 45). According to the Hospital, concerns about Dr. Hoedt's quality of care arose soon after he started his work there. (<u>Id.</u> at 45, 47–53, 63–64). Those worries continued over the following months. (<u>Id.</u>). Specifically, the Hospital was concerned that Dr. Hoedt had a higher infection rate compared to his peers and the national average. (<u>Id.</u>). This led to questions about his surgical technique. (<u>Id.</u>). These issues came to a head when, on March 16, 2022, one of Dr. Hoedt's patients died unexpectedly following a surgical procedure. (<u>Id.</u> at 45, 65, 70).

The next day, the Hospital summarily suspended Dr. Hoedt's clinical privileges. (<u>Id.</u> at 32, 45, 59, 70, 121). In a March 21, 2022 letter confirming Dr. Hoedt's suspension, the Hospital informed him that the decision to suspend his privileges "was reached by the [Hospital] Medical Executive Committee [("MEC")] following concerns expressed regarding the number of surgical revisions you perform, your surgical infection rate, and aspects of your surgical technique." (<u>Id.</u> at 32).

On March 31, 2022, the MEC met to discuss Dr. Hoedt's suspension. (<u>Id.</u> at 59–60). During the meeting, an investigating committee presented the MEC with a PowerPoint presentation documenting concerns and issues related to Dr. Hoedt's care. (<u>Id.</u> at 47–58, 60). After discussing "Dr. Hoedt's clinical performance including an increased volume of surgical site

infections as well as patient safety, selection and management[,]" the MEC recommended permanently revoking Dr. Hoedt's clinical privileges at the Hospital. (<u>Id.</u> at 60). In response, Dr. Hoedt requested a hearing to determine the justification for his summary suspension and the MEC's recommendation for the permanent revocation of his clinical privileges. (<u>Id.</u> at 45 ("[Dr.] Hoedt was informed of the recommendations and he requested a Fair Hearing.")).

On July 8, 2022, the Hospital filed a report with the NPDB about Dr. Hoedt's suspension of clinical privileges at the Hospital ("Report #1"), stating:

Dr. Hoedt's clinical privileges and medical staff membership with Vanderbilt Wilson County Hospital were suspended for concerns regarding his clinical performance including an increased volume of surgical site infections and patient safety, selection, and management. The MEC continued the suspension and made a recommendation for the revocation of Dr. Hoedt's clinical privileges. Dr. Hoedt timely requested a fair hearing to challenge the bases of the suspension and recommendation for revocation. The fair hearing proceedings are pending scheduling.

(<u>Id.</u> at 7-8).

The hearing requested by Dr. Hoedt on the rationale for his suspension and the MEC's recommendation of revocation of his clinical privileges was scheduled for September 13, 14, and 15, 2022. (<u>Id.</u> at 67). Instead of having the hearing, however, the Hospital and Dr. Hoedt engaged in a successful mediation of the issue. (<u>Id.</u> at 45–46). This resulted in a Settlement Agreement between the parties (<u>id.</u> at 138–41), requiring Dr. Hoedt to participate in a proctoring program that would commence "no later than September 26, 2022" and "end March 16, 2023." (<u>Id.</u> at 138 ¶¶ 4–5). The parties further agreed that:

Upon successful completion of the proctoring program as determined by VUMC, [the Hospital] will conclude the investigation, Dr. Hoedt's full staff privileges at [the Hospital] shall be reinstated, and Dr. Hoedt will resign his medical staff privileges and membership at [the Hospital], and not later reapply. The resignation of Dr. Hoedt from the staff of [the Hospital] after completion of the proctoring and conclusion of the investigation shall not be a reportable event of the NPDB.

(<u>Id.</u> at $138 \, \P \, 9$).

In the Settlement Agreement, the parties agreed that the Hospital would "submit a Revision-to-Action Report to the [NPDB] (Modification of Previous Action) that shall modify the adverse action previously reported to the NPDB by the Hospital" in Report #1. (Id. at 138 ¶ 6). The parties also agreed that the Hospital would submit the following language to the NPDB:

Dr. Hoedt perfected his right to a fair hearing to challenge the bases for the prior adverse action and recommendations of the Vanderbilt Wilson County Medical Executive Committee: facts remain in dispute as to those bases. Dr. Hoedt exercised his due process rights by participating in mediation which resulted in the hospital requiring an agreed upon proctoring program at Vanderbilt University Medical Center to take place between September 26, 2022 and March 16, 2023.

(<u>Id.</u>). Consistent with this, on September 12, 2022, the Hospital submitted a Revision-to-Action report to the NPDB as a "modification of [the] previous action" on Dr. Hoedt's suspension ("Report #2"). (<u>Id.</u> at 11). Report #2 contained the language the parties agreed to under the Settlement Agreement. (<u>Id.</u>).

On October 2, 2022, the Hospital informed Dr. Hoedt that he completed his proctoring arrangement. (Id. at 33). At that time, the Hospital told Dr. Hoedt that his "privileges at [the] Hospital are reinstated." (Id.). After reinstatement of Dr. Hoedt's clinical privileges, he inquired through the NPDB website on whether the Hospital was "required to update a NPDB report after reporting a physician's summary suspension when the suspension is lifted and his privileges are restored?" (Id. at 15). The NPDB responded that the action taken to summarily suspend privileges takes affect "when it is first imposed by the hospital official" and "[i]f the authorized committee or body vacates the summary suspension, the entity must void the previous report submitted to the NPDB." (Id. at 16). Based on this, Dr. Hoedt, through mediation, tried to get the Hospital to void its prior NPDB reports indicating that Dr. Hoedt had been summarily suspended. (Id. at 34–36). The Hospital did not engage with Dr. Hoedt's request. (Id.).

The Hospital filed another Revision-to-Action report on December 9, 2022 about Dr. Hoedt ("Report #3"). (Id. at 18). In that Report, the Hospital noted that "Dr. Hoedt completed the agreed upon proctoring program." (Id.).

C. Dr. Hoedt's Appeals

Dr. Hoedt sought review of the accuracy and reportability of the Reports, per the NPDB's administrative process described in 45 C.F.R. § 60.21. (Id. at 8, 11–12, 15–16, 18, 29–31). The NPDB elevated Dr. Hoedt's challenge to the Reports to dispute resolution status on February 17, 2023. (Id. at 24). Dr. Hoedt argued that the Reports should be voided because: (1) Report #1 was inaccurate on the reason for Dr. Hoedt's summary suspension; (2) Report #1 erroneously included the MEC's vote to recommend revocation of Dr. Hoedt's privileges and the reasons for that vote, because his privileges were not revoked; (3) Report #1 was required to be voided after Dr. Hoedt's summary suspension was "vacated" upon the reinstatement of his clinical privileges on October 2, 2022; (4) the proctoring arrangement outlined in Report #2 lasted only two weeks, making it not reportable and rendering Report #2 void; and (5) because Reports #1 and #2 are void, Report #3 should be as well, given that it only reports a modification to the prior Reports. (Id. at 11–12, 18, 29–34).

The NPDB disagreed. On June 26, 2023, the NPDB issued three separate dispute resolution decisions, one for each Report. (<u>Id.</u> at 84–96). The first decision corresponds with the NPDB's decision on Dr. Hoedt's objections to Report #1. (<u>Id.</u> at 84). In Report #1, the NPDB characterized Dr. Hoedt's suspension as relating to his surgical infection rate and aspects of his surgical technique. (<u>Id.</u> at 85). The NPDB rejected Dr. Hoedt's other arguments on voiding Report #1, finding that Dr. Hoedt's summary suspension was not vacated, but rather was *lifted*, such that

⁴ The Court will refer to Reports #1, #2, and #3 collectively as "Reports."

the Hospital was not required to void Report #1. (<u>Id.</u> at 86). Based on this decision, the NPDB rejected Dr. Hoedt's challenges to Reports #2 and #3, finding that the Hospital was required to update Report #1 as modifications to that action came about. (<u>Id.</u> at 89–91, 93–95). The NPDB further advised Dr. Hoedt that Report #2 was reportable as a modification of the initial summary suspension, making that his proctoring lasted under 30 days irrelevant. (<u>Id.</u> at 90–91). The NPDB informed Dr. Hoedt in its decisions that he could seek reconsideration of each. (<u>Id.</u> at 107–11).

Dr. Hoedt sought reconsideration with HHS on July 6, 2023. (Id.). HHS rejected each of Dr. Hoedt's appeals on January 10, 2024. (Id.). In doing so, HHS maintained that the Hospital's articulation of why Dr. Hoedt's privileges were revoked was accurate. (Id. at 160). HHS also affirmed the determination that the difference between Dr. Hoedt's suspension being lifted, rather than vacated, negated any right he had to voiding Report #1. (Id. at 161). Ultimately, HHS affirmed the decisions to maintain the Reports in full. (Id. at 158–73). Based on HHS's final decisions, the Hospital did not void the Reports, and Dr. Hoedt initiated the instant action seeking judicial review of HHS's reconsideration determination. (Id.; Doc. Nos. 1, 29).

II. LEGAL STANDARD

The parties each move for summary judgment. (Doc. Nos. 72, 79). However, as HHS correctly points out, because the cross-motions seek judicial review of an agency action under 5 U.S.C. §§ 701–06, the parties' motions are more appropriately categorized as motions for judgment on the administrative record. See Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89 (D.D.C. 2006) (summary judgment standard "does not apply because of the limited role of a court in reviewing the administrative record"). Given this, the APA provides the standard of review, stating in relevant part:

[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 . . . In making the foregoing determinations,

the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

5 U.S.C. § 706(2)(A). Because the facts have already been determined by the reviewing agency, "the entire case on review is a question of law." Am. Bioscience, Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001).

The ultimate question the Court must decide here is whether HHS's agency action was arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence in the case, without observance of procedure required by law, or not in accordance with the law. 5 U.S.C. §§ 706(2) et seq. Under this standard, "the party challenging the agency's action must 'show that the action had no rational basis or that it involved a clear and prejudicial violation of applicable statutes or regulations." Kroger Co. v. Reg'l Airport Auth. of Louisville & Jefferson Cnty., 286 F.3d 382, 389 (6th Cir. 2002) (quoting McDonald Welding v. Webb, 829 F.2d 593, 595 (6th Cir. 1987)).

An agency action is arbitrary and capricious if:

the agency has relied on factors which Congress has not intended it to consider, 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 or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). The Court's review in this regard is "extremely narrow[,]" Oakbrook Land Holdings, LLC v. Comm'r, 28 F.4th 700, 720 (6th Cir. 2022), because the Court "may not substitute [its] own policy judgment for that of the agency." Fed. Commc'ns Comm'n v. Prometheus Radio Project, 592 U.S. 414, 423 (2021). Instead, the Court must "simply ensure[] that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained [its] decision[s]." Id.

Still, the Court "must ensure that the agency considered each 'important aspect of the problem' and issued a decision rooted in the law and facts." Kentucky v. U.S. Env't Prot. Agency, 123 F.4th 447, 468 (6th Cir. 2024) (quoting Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 436 U.S. 29, 43 (1983)). Indeed, "[a]gency action is 'not in accordance with the law' when it is in conflict with the language of the statute [or regulation] relied upon by the agency." City of Cleveland v. Ohio, 508 F.3d 827, 838 (6th Cir. 2007); see Marbury v. Madison, 5 U.S. 137, 177 (1803) ("It is emphatically the province and duty of the [court] to say what the law is."); see also 5 U.S.C. § 706 ("To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action."); Loper Bright Enters. v. Raimondo, 603 U.S. 369, 398, 412 (2024) (the APA requires courts, not agencies, to "decide 'all relevant questions of law' arising on review of agency action" and "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority") (quoting 5 U.S.C. § 706).

Considering this, where the statutory language at issue is ambiguous, agencies are entitled to deference over their rulings and informal interpretations of that language. Chao v. Occupational Safety & Health Rev. Comm'n, 540 F.3d 519, 526 (6th Cir. 2008). That deference is "not controlling upon the courts[,]" but instead is evaluated based "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." Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944); see Loper Bright, 603 U.S. at 394 (affirming that Skidmore deference remains a tool that courts can use in evaluating ambiguous statutes).

III. ANALYSIS

Dr. Hoedt contends that he is entitled to judgment in his favor because HHS erred in three material ways in rejecting his appeals of the NPDB's orders. First, the <u>Guidebook</u> instruction dictates Report #1 should be voided because his suspension ended; second, by not finding the factual inaccuracies in the Reports; and third, by failing to properly determine that the MEC's recommendation that Dr. Hoedt's clinical privileges be permanently revoked is not a reportable event. HHS disagrees, reasoning that Dr. Hoedt bases his arguments on a flawed understanding of the scope of the Secretary's review and incorrect interpretations of relevant statutory and regulatory language. Instead, HHS asserts it is entitled to judgment on the record because the Secretary's decisions to uphold the NPDB's rulings were well-reasoned, in accordance with the HCQIA statutory framework, and supported by the record. The Court will consider the parties' various arguments in turn.

A. The Secretary Correctly Determined That the Hospital Lifting Dr. Hoedt's Suspension Did Not Void the Reports.

The Court starts with the parties' first, and most critical, dispute: whether the <u>Guidebook</u> mandates that Report #1 (and, by extension, Reports #2 and #3) must be voided because the Hospital ended Dr. Hoedt's suspension after he completed his proctoring program. In evaluating that question, the Court starts by interpreting relevant portions of the Act and its implementing regulations. <u>United States v. Coss</u>, 677 F.3d 278, 283 (6th Cir. 2012) ("The starting point for any question of statutory interpretation is the language of the statute itself.") (citation and quotations omitted); <u>Roberto v. Dep't of the Navy</u>, 440 F.3d 1341, 1350 (Fed. Cir. 2006) ("The rules of statutory construction apply when interpreting an agency regulation."); <u>see Yates v. United States</u>, 574 U.S. 528, 537 (2015) ("The plainness or ambiguity of statutory language is determined [not

only] by reference to the language itself, [but as well by] the specific context in which that language is used, and the broader context of the statute as a whole.") (citation and quotations omitted).

As HHS emphasizes, the Act delegated to it and the Secretary the responsibility to implement "procedures in the case of disputed accuracy of" information in NPDB reports. 42 U.S.C. § 11136(2). To that end, under 45 C.F.R. § 60.21(c)(2)(iv), if the Secretary:

Determines that the adverse action was not reportable and therefore should be removed from the NPDB, the Secretary will inform the subject and direct the NPDB to void the report. The NPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

A plain reading of the regulations states that physicians may dispute information in reports with the Secretary, and if appropriate, a reporting entity must void a report if the Secretary determines that the adverse action was not reportable. Per 42 U.S.C. § 11133(a)(1)(A), the parties agree the Hospital was required to report Dr. Hoedt's summary suspension. There is nothing in the administrative record suggesting that the Secretary told the Hospital to void Report #1 after Dr. Hoedt's summary suspension ended because the suspension was no longer reportable. The Act and supporting regulations conclusively indicate that the Hospital ending Dr. Hoedt's suspension has no bearing on the validity of Report #1. <u>Id.</u> Given that there is nothing in the Act or regulations providing for voiding reports under the circumstances presented, "the judicial inquiry is complete" and Dr. Hoedt's argument fails. <u>5 Desert Palace, Inc. v. Costa</u>, 539 U.S. 90, 98 (2003) (citation and quotations omitted).

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⁵ While the Court does not rely on the legislative history of the Act to reach this conclusion, it is worth noting that the purpose of the Act—which is, in part, to facilitate the "interstate monitoring of incompetent physicians"—supports a finding that reports are not void merely because a physician subject to an adverse action completed further medical training post-report. See Meyers, 341 F.3d at 467.

Seeking to overcome this, Dr. Hoedt relies on the <u>Guidebook</u>'s commentary on proper circumstances for reporting entities to void reports to demonstrate such action is appropriate here. This is in error. The unambiguous statutory and regulatory language leaves little room for HHS's interpretation of this legal landscape. <u>See supra</u>, Section II. Nonetheless, for the sake of thoroughness, the Court will briefly address Dr. Hoedt's argument on the merits.

The <u>Guidebook</u> instructs that reports should be voided or modified under three circumstances. Under the first, "[i]f the summary suspension ultimately does not last more than 30 days," the suspension is not reportable under the Act and "the report must be voided." <u>Guidebook</u>, at E-38; <u>see</u> 42 U.S.C. § 11133(a)(1)(A). This situation does not apply to Report #1, as Dr. Hoedt's clinical privileges were not reinstated for more than six months after the Hospital initially suspended them. In the second circumstance, "[i]f the authorized hospital committee or body vacates the summary suspension, the entity must void the previous report submitted to the NPDB." <u>Guidebook</u>, at E-39. Dr. Hoedt asserts that when his summary suspension ended, the Hospital effectively "vacated" it, entitling him to a voided Report #1. HHS disagrees, reasoning that the third <u>Guidebook</u> circumstance—stating that if a summary suspension is "subsequently [] modified or revised as part of a final decision by the governing board or similar body," the reporting entity must submit a Revision-to-Action Report supplementing the initial report—is what happened here. <u>Id.</u>

The Court agrees with HHS and the Secretary that the third circumstance is most appropriate for addressing Dr. Hoedt's summary suspension with the Data Bank. The Secretary's finding that the Hospital "lifting" Dr. Hoedt's suspension was not the same as vacating it is supported by a plain reading of the <u>Guidebook</u> and its surrounding guidance. Indeed, "vacate" is defined as "[t]o nullify or cancel; make void; invalidate." <u>Vacate</u>, Black's Law Dictionary (12th

ed. 2024). The Hospital did not take any action to "nullify" or "invalidate" Dr. Hoedt's suspension by, for example, making a finding that it was unwarranted or inappropriate. See, e.g., Jenkins v. Methodist Hosps, of Dallas, Inc., 478 F.3d 255, 260 (5th Cir. 2007) (addressing scenario where NPDB report was voided because a fair hearing "unanimously disagreed with [the physician's] summary suspension"). Instead, it elected to end Dr. Hoedt's suspension, given his successful completion of the proctoring agreement. See supra, Section I.B. As the Secretary stated, this is consistent with a "lift" of his suspension, defined as "[t]o stop or put an end to[.]" Lift, Black's Law Dictionary (12th ed. 2024). This outcome is also consistent with other provisions of the Guidebook that provide for the limited circumstances where voiding reports is appropriate. For instance, the Guidebook instructs that reports should be voided only when "the report was submitted in error," the action "was not reportable because it did not meet NPDB reporting requirements," or "the action was overturned on appeal." Guidebook, at E-8 (emphasis added).

Because there is nothing in the record suggesting that Dr. Hoedt's suspension was vacated, or "overturned," by the Hospital, the Secretary properly determined that the Hospital was correct to file Revision-to-Action reports after Dr. Hoedt's summary suspension ended, rather than voiding Report #1 entirely. Accordingly, the Court rejects Dr. Hoedt's argument on this issue, and finds the Secretary's determination that Report #1 need not be voided because Dr. Hoedt's suspension ended to be compliant with the APA.

B. The Secretary Did Not Err in Determining the Accuracy of the Reports.

The Court turns to the parties' second dispute, whether the Secretary erred in finding that the Hospital's stated reason for Dr. Hoedt's summary suspension was accurate.⁶ Dr. Hoedt

⁶ Dr. Hoedt does not contest on reply that he waived his arguments that the "Date of Action" and "Date Action Became Effective" on Report #1 are inaccurate because he did not raise those issues with HHS directly. Coalition for Gov't Procurement v. Fed. Prison Indus., Inc., 365 F.3d 435,

contends that, contrary to what HHS asserts here, it was not his high infection and complication rates, but rather his patient's unexpected death on March 16, 2022, that led to his suspension. HHS disagrees, reasoning that Dr. Hoedt fails to appreciate that his patient's death and his poor clinical performance are not mutually exclusive, and that the Secretary's review of the accuracy of Report #1 was supported by substantial evidence in the record.

The Court, again, agrees with HHS. Ultimately, Dr. Hoedt's position "misunderstands the purpose of the Data Bank and the scope of the Secretary's review." <u>Leal</u>, 620 F.3d at 1283. "Congress enacted the Health Care Quality Improvement Act, which led to the creation of the Data Bank, after finding that there was '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." <u>Id.</u> (quoting 42 U.S.C. § 11101). To this end, 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." <u>Id.</u> (citing 42 U.S.C. § 11135(a)(1) ((requiring a hospital to request information from the Data Bank about a physician when the physician applies to be on the medical staff or for clinical privileges)). This information is intended "only to alert eligible entities that there *may* be a problem with the performance of a particular health care practitioner" because the practitioner has been the subject of an adverse disciplinary action. <u>Guidebook</u>, at A-7.

Given that the 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,

^{461–62 (6}th Cir. 2004) ("[I]t is inappropriate for courts reviewing agency decisions to consider arguments not raised before the administrative agency involved."); (see Doc. No. 84 (not responding to HHS's waiver argument)). Accordingly, the Court will not substantively address those arguments.

the Secretary's review of information in the Data Bank is limited in scope." <u>Leal</u>, 620 F.3d at 1284. The review process does not allow the physician to challenge the reporting hospital's adverse action, or to challenge the allegations about the conduct that led to the reported action. <u>Id.</u>; <u>see supra</u>, Section I.A. Instead, "[t]he 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." <u>Leal</u>, 620 F.3d at 1284. Following those standards, to the extent Dr. Hoedt disputes the Hospital's version of his conduct that led to his suspension, that dispute is outside the scope of the Secretary's review. In turn, is not properly before this Court for consideration. <u>See id.</u> (finding the same); <u>see also Guidebook</u>, at F-5 (explaining that the "underlying reasons for the report" cannot be disputed by a physician).

Where Dr. Hoedt appropriately disputes whether Report #1 "accurately depicts the action taken as reflected in the written record [on Dr. Hoedt's summary suspension] provided by" the Hospital, see Leal, 620 F.3d at 1284, the evidence contained in the administrative record shows that it does. For instance, as HHS highlights, the record supports that on March 21, 2022, after Dr. Hoedt had been informed of his summary suspension, the Hospital sent Dr. Hoedt a letter confirming his suspension. (Doc. No. 64 at 32). The letter confirmed the reason for Dr. Hoedt's summary suspension was because the Hospital had "concerns [] regarding the number of surgical

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⁷ The same is true for Dr. Hoedt's issues with HHS's characterization on whether he got a fair hearing, as such due process matters are not properly before HHS for consideration. <u>See</u> 45 C.F.R. § 60.21(c)(1) (stating the Secretary "will not consider . . . the due process that the [physician] received").

⁸ While Dr. Hoedt understandably takes issue with having to defend himself against the characterization of his medical practices in Report #1, it is worth noting that Data Bank reporting procedures provide for a physician's response to any reported information. (See, e.g., Doc. No. 64 at 175 (containing Dr. Hoedt's response to the Hospital's gripes with him)).

revisions [he] perform[ed], [his] surgical infection rate, and aspects of [his] surgical technique." (Id.). The letter also explained why the Hospital felt suspension was necessary under these conditions, stating plainly that "[t]hese allegations warrant review and consideration of whether you have engaged in clinical performance which may have affected or resulted in danger to the health and/or safety of [Hospital] patients." (Id.). Ten days later, the Hospital affirmed this was the reason for Dr. Hoedt's suspension during the MEC meeting. The meeting minutes reflect that MEC discussed "Dr. Hoedt's clinical performance including an increased volume of surgical site infections as well as patient safety, selection and management." (Id. at 60).

Consistent with the Hospital's letter to Dr. Hoedt and the MEC's minutes, Report #1 stated that the Hospital had "suspen[ded] [Dr. Hoedt's] clinical privileges" due to "inadequate or improper infection control practices" and "substandard care or inadequate skill level." (Id. at 7). The parallels between the administrative record and Report #1 to the Data Bank establish the "report's factual accuracy in the only sense that matters under the Act." Leal, 620 F.3d at 1284. That some of the Hospital's submissions *also* reference Dr. Hoedt's deceased patient—an event logically connected to Dr. Hoedt's subpar medical practices—does not alter this conclusion. (See, e.g., Doc. No. 64 at 45 (Hospital letter stating that summary suspension occurred after a patient of Dr. Hoedt's died "after completion of a revision surgery," and also mentioning MEC meeting on Dr. Hoedt's inadequate care)).

At bottom, the similarities between the Hospital's rationale for suspending Dr. Hoedt in the administrative record and its description of that action in Report #1 shows that the Secretary's determination that Report #1 was factually accurate is supported by substantial evidence in the record.

C. The Secretary Did Not Err in Finding the MEC's Recommendation to be Appropriately Included in Report #1.

Lastly, the parties disagree on the Secretary's determination that the Hospital properly reported on the MEC's recommendation that Dr. Hoedt's privileges be permanently revoked was a reportable event. As discussed above, see supra, Section I.A, a professional review action "that adversely affects the clinical privileges of a physician" for longer than 30 days is reportable. 42 U.S.C. § 11133(a)(1)(A). A professional review action is defined as:

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 . . . of the physician.

<u>Id.</u> § 11151(9) (emphases added). Like the above analysis, <u>see supra</u>, Section III.A, in interpreting § 11151(9), the Court starts with its plain text. "Under § 11151(9), a disciplinary action taken against a physician qualifies as a professional review action if the physician is disciplined for conduct that either adversely affects patient health or welfare, or could do so." <u>Leal</u>, 620 F.3d at 1285.

The Court need not decide whether the MEC's recommendation alone constitutes "discipline" for reporting purposes, as other provisions of the Act describing what is reportable demonstrate why this information was properly included in Report #1. See supra, Section III.A. For instance, under 42 U.S.C. §§ 11133(a)(3)(B) and (C), "[t]he information to be reported under this subsection" includes both "a description of the acts or omissions or other reasons for the action" and "such other information respecting the circumstances of the action . . . as the Secretary deems appropriate." An "act," as used here, is defined as "[s]omething done or performed, esp[ecially] voluntarily; a deed." Act, 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." <u>Description</u>, Black's Law Dictionary (11th ed. 2019). "Putting these definitions together, the statute requires a 'delineation or explanation' or 'something done or performed'" or any other information respecting those circumstances—"which in this case means a delineation or explanation [or other information] of the Hospital's" decision to summarily suspend Dr. Hoedt's privileges. <u>Brook v. Rogers</u>, 656 F. Supp. 3d 78, 87 (D.D.C.), <u>aff'd sub nom.</u> <u>Doe v. Rodgers</u>, 2023 WL 1978697 (D.C. Cir. Feb. 14, 2023), <u>cert. denied</u>, 144 S. Ct. 328 (2023).

This all-encompassing language demonstrates 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" or a MEC's related recommendation. <u>Id.</u> While the Court need not reach the legislative history of the Act to come to this conclusion, it is noteworthy that it supports this broad reading of hospital reporting requirements. <u>See id.</u> (collecting cases); <u>see also H.R.</u> Rep. No. 99-903 (§ 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."). By providing the MEC's recommendation based on the results of its internal investigation into Dr. Hoedt's clinical practices, the Hospital enables those using the Data Bank information to fully understand the circumstances of Dr. Hoedt's suspension. This also protects patients by giving entities enough information to make informed hiring choices.

Indeed, the MEC made its recommendation to permanently revoke Dr. Hoedt's clinical privileges after discussing the "the investigation into allegations [of sub-standard care] which led to the summary suspension." (Doc. No. 64 at 59). This information not only speaks to the "acts... or other reasons for the action," § 11133(a)(3)(B), but also provides the Secretary with "information respecting the circumstances of the action[,]" §11133(a)(3)(C). Further, as HHS

notes, this is consistent with § 11151(9)'s mandate that a professional review action can include

recommendations from a professional review entity. Even if the MEC's recommendation is not,

standing alone, reportable, it undoubtedly provided the Secretary with necessary relevant

information pertaining to the undisputedly reportable event: Dr. Hoedt's summary suspension.

Given the broad set of information that is reportable under the Act, the Secretary's

determination that the MEC's recommendation was properly reported is supported by substantial

evidence in the administrative record, and is not contrary to law. Accordingly, Dr. Hoedt's final

argument for judgment in his favor is rejected. His motion will be denied. Because HHS has

demonstrated that the Secretary's decisions were proper under the APA, its motion will be granted.

IV. CONCLUSION

For the foregoing reasons, HHS's Motion for Summary Judgment (Doc. No. 78) will be

granted, and Dr. Hoedt's Motion for Summary Judgment (Doc. No. 71) will be denied.

An appropriate order will enter.

WAVERLY IL CRENSHAW, JR.

LINITED STATES DISTRICT HIDGE