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QUARTERLY NEWSLETTER FROM THE MEDICAL STAFF PRACTICE GROUP

Do the Right Thing — Reporting Voluntary Actions Taken While "Under Investigation" to the NPDB

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Many health care entities struggle with the dilemma of whether and when to make reports to the National Practitioner Data Bank ("NPDB"), particularly when the situations involve a physician or dentist who has voluntarily limited or otherwise ceased practicing at the hospital after quality of care or professionalism issues have arisen. In such instances, hospitals and their medical staffs must determine whether a practitioner had been "under investigation" at the time they voluntarily took a leave of absence, resigned, or otherwise restricted their clinical privileges. While the decision to report will always be fact dependent, hospitals must take into account statutory and regulatory requirements, the NPDB Guidebook, and relevant case law when deciding whether a there is a duty to report to the NPDB.

Overview of NPDB Relevant Reporting Requirements

The Health Care Quality Improvement Act ("HCQIA") of 1986[1] established the NPDB in an effort to improve quality of care, encourage peer review, and to restrict physicians moving from state to state "without disclosure or discovery of the physician's previous damaging or incompetent performance."[2] HCQIA created mandatory reporting requirements for health care entities, sets standards governing professional review actions, and provides liability protection to health care entities that conform with the standards.

To comply with federal law, hospitals and other health care entities with formal peer review processes must report certain adverse actions related to a physician or dentist's[3] professional competence or conduct to the NPDB. An adverse action is reportable if it adversely affects a practitioner's clinical privileges or medical staff membership for more than 30 days.[4] Actions that must be reported include reducing, restricting, suspending, revoking, or denying clinical privileges, or a decision not to renew a practitioner's clinical privileges if that decision was based on the practitioner's professional competence or professional conduct.[5] Health care entities must also report to the NPDB if a physician or dentist surrenders or otherwise voluntarily restricts their clinical privileges while under investigation or in return for the health care entity not conducting or proceeding with such an investigation.[6]

1 Title IV of Public Law 99-660 (42 U.S.C. § 11101 et seq.).
2 42 U.S.C. § 11101.
3 Reporting of other health care practitioners is optional but encouraged. 45 C.F.R. § 60.12(a)(2).
4 45 C.F.R. § 60.12(a).
5 National Practitioner Data Bank Guidebook ("NPDB Guidebook") at E-32. Generally, the entity taking the action will determine whether the physician's or dentist's professional competence or professional conduct adversely affects, or could adversely affect, the health or welfare of a patient.
6 45 C.F.R. § 60.12(a)(1)(ii).

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Surrender or Restriction of Clinical Privileges While Under Investigation

Investigations, in and of themselves, are not reportable. Rather, it is the decision by the physician or dentist to surrender, restrict, or resign their clinical privileges while under or to avoid an investigation that must be reported. What is considered a "surrender" or "restriction" can be much broader than a clear statement from a physician that they are resigning their clinical privileges and medical staff membership. For example, the NPDB considers the failure to renew an application for reappointment while under investigation to constitute a surrender of clinical privileges.[7] The same applies to a voluntary decision to not exercise certain clinical privileges or to take a leave of absence after a summary suspension has been imposed that prompted an investigation.[8]

Regardless of the reason for surrender or restriction, a report must be filed if an investigation was open or ongoing at the time.[9] For example, if a physician resigns from Hospital A because they decided to focus their practice at Hospital B, but an investigation by the Hospital A medical staff pertaining to unprofessional conduct remained ongoing at the time of the resignation, Hospital A must file a report with the NPDB.[10] Similarly, if a physician voluntarily restricts their own privileges amidst an investigation about their clinical competency, a report must also be filed, even if the physician was not notified about the investigation.[11] Further, a leave of absence that restricts clinical privileges also must be reported as a surrender of clinical privileges if the physician was under investigation at the time they took the leave of absence.[12]

"Investigation" Is Broadly Construed

While the NPDB statutes and implementing regulations do not define "investigation," the NPDB Guidebook broadly describes what constitutes an "investigation." The NPDB Guidebook states that an investigation runs "from the start of an inquiry [into a physician's practice] until a final decision on a clinical privileges action" has been reached.[13] Routine reviews applicable to all practitioners are not considered investigations; however, a formal, targeted process related to a specific practitioner's professional competence or conduct is considered an investigation for the purposes of reporting to the NPDB.[14] For example, the initial focused professional practice evaluation ("FPPE") applicable to all practitioners granted new privileges does not equate to a "investigation," whereas a "for cause FPPE" initiated by an ongoing professional practice evaluation does. Notably, an investigation is not limited to how a medical staff defines investigation in its bylaws or policies.[15] Even if a medical staff indicates in its bylaws that an investigation has not been commenced unless the medical executive committee has commissioned an investigation and/or appointed an ad hoc investigating committee, if the physician resigns or take a leave of absence while subject to a targeted review by another committee (such as a credentials committee), the NPDB may still consider the resignation or leave to be reportable.

Despite the broad expanse of what the NPDB considers an investigation, only investigations related to professional competence or conduct will lead to reporting obligations. In Long v. United States Dep't of Health & Hum. Servs.,[16] a physician challenged an NPDB report, alleging the underlying investigation did not pertain to his

7 NPDB Guidebook at E-36.
8 *Id.* at E-39.
9 *Id.* at E-49.
10 *See id.*
11 *Id.* at E-36.
12 *Id.* at E-50.
13 *Id.* at E-36
14 *Id.* at E-37.
15 *See id.* at E-36-E-37.
16 422 F. Supp. 3d 143 (2019), aff'd, No. 19-5358, 2021 WL 6102198 (D.C. Cir. Dec. 3, 2021).

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professional conduct or competence.[17] The court disagreed, citing to evidence that the CEO discussed "serious concerns raised by [the medical staff] related to the significant disruption of hospital services," and a letter from an ad hoc committee stating that the physician had conducted himself in a "confrontational manner" that caused disruptions and undermined the appropriate team approach to patient care.[18] Further, the court found a communication that ordered the physician to undergo a psychological evaluation and the ad hoc committee's recommendations for an external chart review as adequate evidence that the investigation had been related to the physician's professional competence or conduct.[19]

The NPDB reporting requirements apply regardless of whether the practitioner knew of the initiation of an investigation or had mistakenly thought that an investigation had been completed.[20] In addition, the NPDB Guidebook provides that an investigation remains ongoing until the entity's decision-making authority takes a final action or formally closes the investigation.[21] Therefore, documentation of an investigation, including any final action or closure, can be a key factor in determining whether to report a resignation or restriction.

In *Doe v. Leavitt,*[22] a nurse filed a written complaint against a physician alleging the physician had threatened the nurse.[23] The following day, the medical staff executive committee temporarily suspended Dr. Doe's privileges and appointed an ad hoc committee to inquire into the nurse's allegations, which determined the report had been credible.[24] The executive committee proposed that Dr. Doe be allowed to return to work if they agreed to regular proctoring and psychological evaluations.[25] The physician rejected the proposal and voluntarily relinquished their clinical privileges and the hospital accepted the physician's resignation.[26] The physician challenged the NPDB report subsequently filed by the hospital, arguing that the investigation had ended when the ad hoc committee presented its report to the executive committee and, therefore, the physician did not resign while under investigation.[27] The Court of Appeal disagreed with the physician, finding that the investigation remained ongoing at the time the physician resigned, finding that an "investigation" ends only when a health care entity's "decision-making authority either takes a final action or formally closes the investigation."[28]

Courts Give Deference to the NPDB Guidebook

Courts give great deference to the NPDB Guidebook when determining the meaning of the term "investigation" even though the NPDB Guidebook is not the product of formal rulemaking. Therefore, health care entities should be diligent in reviewing the NPDB Guidebook, including the multiple Q&As that address reporting actions while under investigation, when determining whether to report.

In *Doe v. Rogers,*[29] when a hospital's representatives met with a physician to discuss a clinical incident, the physician agreed to refrain from exercising their surgical privileges pending investigation.[30] Later that day, the physician executed a letter voluntarily suspending their surgical privileges for two weeks.[31] Two days later, the physician voluntarily resigned from the medical staff, prompting the hospital to submit an NPDB report.[32]

When the physician challenged the NPDB report, the *Rogers* court gave deference to the NPDB Guidebook's definition of investigation in determining that the physician had resigned while under investigation.[33] The court stated 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."[34] Further, the court presumed that Congress intended to give the term "investigation" its "ordinary meaning" and the term is ordinarily understood to mean a "systematic examination." The court concluded that the hospital embarked on a "systematic examination"[35] 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,

17 *Id.* at 146, 156.
18 *Id.* at 150-151.
19 *Id.* at 151.
20 NPDB Guidebook at E-36-E37.
21 *Id.*
22 552 F.3d 75 (2009).
23 *Id.* at 77.
24 *Id.* at 78.
25 *Id.* at 77.
26 *Id.*
27 *Id.*
28 *Id.* at 86.
29 139 F.Supp.3d 120 (2015).
30 *Id.* at 130.
31 *Id.* at 130-131.
32 *Id.* at 131.
33 *Id.* at 135.
34 *Id.*
35 *Id.* at 137 (citing to Merriam–Webster, http://www.merriam-webster.com/dictionary/investigation).

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and organizing a team to conduct a Root Cause Analysis."[36] The court found these activities to be fundamental characteristics and demonstrative evidence of the beginning of an investigation.[37] Additionally, the court rejected the physician's argument that there was no evidence of a formal investigation as defined under the medical staff bylaws. The court instead held that the term investigation is defined as contemplated by HCQIA and not by the hospital's internal governing documents.[38]

In another more recent case, *Wisner v. Dignity Health,*[39] a medical staff had asked for information from the physician in connection with a pending criminal indictment in response to the physician's request to be on the call panel.[40] The physician resigned his privileges and an NPDB report was filed regarding the "resignation while under investigation."[41] The physician challenged the appropriateness of the report, arguing that he was not "under investigation" at the time he resigned.[42] Although neither the statute nor the implementing regulations related to the NPDB define "investigation," the California Court of Appeal determined that the NPDB Guidebook is entitled to a high level of deference due to the agency's expertise and knowledge and found "expansive interpretation of what constitutes an investigation is necessary."[43] Upon concluding that an investigation commences as soon as there is a focused "inquiry" into potential misconduct, the court affirmed that the physician was under investigation and that the defendants were immune from liability under HCQIA.[44]

Practical Considerations

To the extent it does not compromise an investigation, medical staffs should consider putting physicians and dentists on notice as soon as they are under investigation as it could impact the subject physician's or dentist's own decisions about their clinical privileges and membership.

In deciding whether to report a surrender or voluntary restriction of clinical privileges while under or to avoid an investigation, health care entities should carefully review the facts and not focus only on how their bylaws define investigation. Nevertheless, medical staffs should still include language in their bylaws defining investigation, including guidance on when notice should be provided to practitioners.

If a health care entity determines a report should be filed, it should assure that it has written documentation of an investigation. Examples of acceptable evidence may include committee meeting minutes, correspondence from officers directing an investigation, or notices to practitioners of an investigation (although as noted above practitioners' knowledge of an ongoing investigation is not required).[45] The same holds true for an entity that decides a resignation or investigation should not be reported because the practitioner was not – or was no longer – under investigation. Closures of investigation, whether due to an action taken or a determination that no action is warranted, should be documented in meeting minutes and a letter to the practitioner under review.

Physicians should also be mindful of the NPDB reporting requirements. If considering a resignation after receiving notice of an investigation, the practitioner should consider whether resigning after the investigation has been closed would be more favorable to their professional interests. If the practitioner knows or suspects they may have been the subject of a past investigation, they may want to confirm with the health care entity that the investigation has been closed prior to taking an action that impacts their clinical privileges.

36 *Id.* at 138.
37 *Id.*
38 *Id.* at 142.
39 85 Cal. App. 5th 35 (2022).
40 *Id.* at 39.
41 *Id.* at 40.
42 *Id.*
43 *Id.* at 47.
44 *Id.* at 49.
45 NPDB Guidebook at E-37.

Texas House Bill 1998 Adds 1,998 Tasks to the Texas Medical Board's To-Do List

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Introduction

In June 2023, Texas Governor Greg Abbott signed House Bill 1998 ("HB 1998") into law, which became effective September 1, 2023. HB 1998 equips the Texas Medical Board ("TMB") with additional tools to protect patients from potentially dangerous physicians while maintaining transparency about physician disciplinary records. HB 1998 clarifies statutory language and closes loopholes in current statutes that govern the TMB and its disciplinary authority, physician license and renewal requirements, and the complaint investigation and resolution process.[1] Although the TMB has more tools in its toolbox since September 1, 2023, the success of HB 1998 will depend on the TMB's ability to implement and enforce these new requirements.

HB 1998's Direct Lineage to Dr. Christopher Duntsch

As many readers know, Dr. Christopher Duntsch — nicknamed "Dr. Death" — killed or injured more than 30 patients in botched spinal surgeries in Dallas, Texas before finally losing his Texas medical license in 2013.[2] He was sentenced to life in prison six years ago in a case that made national headlines and spawned a hugely successful podcast and subsequent Peacock miniseries.[3]

In response to Dr. Death, an Austin, Texas new station, KXAN, spent three months retrieving thousands of physician disciplinary records from medical boards across the country dating back to 2017.[4] KXAN then cross-referenced those records with the TMB's public physician profiles one name at a time. At least 49 doctors who had disciplinary actions in other states — including having their medical licenses suspended, revoked, or surrendered — were still able to practice in Texas.[5] Some of these physicians were found to have disciplinary actions in multiple states.[6] KXAN found some physicians were disciplined following criminal charges including drunk driving, domestic violence, possession of a controlled substance, and operating a firearm while intoxicated.[7] Certain examples included a neurosurgeon who operated on the wrong part of the spine, a surgeon who operated while intoxicated, and a doctor who prescribed excessive quantities of Oxycodone leading to a patient's death.[8] In these cases, and dozens more, the TMB's website listed "NONE" for out-of-state disciplinary actions.[9] In total, the KXAN team discovered disciplinary actions taken against physicians licensed in over 30 different states with no record on the TMB website even though the physicians were licensed in Texas.[10]

State Rep. Julie Johnson, D-Farmers Branch, reacted to KXAN's investigations with plans to draft a bill and change Texas law. In an interview with KXAN, Johnson stated "[my] immediate reaction was, well, if the Texas Medical Board isn't going to do it on its own, as a member of the legislature, I'm going to file a bill. I'm going to do something about it."[11] And she did. In February 2023, Rep. Johnson introduced HB 1998. According to the committee Bill Analysis,[12] HB 1998 sought to address the TMB overlooking prior physician disciplinary actions in other states by clarifying language and closing a number of loopholes in the statutes that govern the TMB and its disciplinary authority, physician license and renewal requirements, and the complaint investigation and resolution process.

HB 1998's Changes to Texas Law

On May 29, 2023, HB 1998 was signed by the Texas House and Senate. On June 13, 2023, Governor Greg Abbott signed HB 1998 into law. The changes in HB 1998, summarized below, became effective September 1, 2023.

A summary of HB 1998's changes include:

1. The TMB must now administer a continuous query on the National Practitioner Data Bank, and within 10 working days after discovering new information, update a physician's public profile to include any new information regarding disciplinary action against the physician. The TMB will assess physicians a surcharge to pay for the costs of the continuous query, due at the time of license issuance and registration permit renewal. The National Practitioner Data Bank continuous query, the 10-day deadline to update physician profiles, and surcharge are all new requirements.

2. An applicant for a Texas medical license is not eligible for a license if the applicant holds a medical license in another state that is currently restricted, canceled, or suspended for cause. An applicant

1 Bill Analysis, Statement of Intent SRC-EPB C.S.H.B. 1998 88(R).
2 https://www.kxan.com/investigations/5-years-after-dr-death-doctors-still-come-to-texas-to-leave-pasts-behind/.
3 *Id.*
4 *Id.*
5 *Id.*
6 *Id.*
7 *Id.*
8 https://www.kxan.com/investigations/texas-medical-board-lawmakers-push-for-change-after-kxan-medical-transparency-investigations/.
9 *Id.*
10 https://www.kxan.com/investigations/5-years-after-dr-death-doctors-still-come-to-texas-to-leave-pasts-behind/.
11 https://www.kxan.com/investigations/texas-medical-board-lawmakers-push-for-change-after-kxan-medical-transparency-investigations/.
12 88R 23775-D (Substitute Document Number 88R 20547).

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is also not eligible for a Texas license if the applicant held a license to practice medicine in another state that has been revoked by a licensing authority for a reason that would be grounds for the TMB to revoke a license to practice medicine in Texas.

3. The TMB must submit a complete set of fingerprints to the Department of Public Safety ("Department") for each license applicant and the Department must classify and check the fingerprints against those in the Department's fingerprint records. A license holder must submit a complete set of fingerprints with their registration permit renewal application for the purpose of completing the criminal record check. Previously, the TMB was permitted to submit fingerprints to the Department but was not mandated to do so.

4. A medical peer review committee or health care entity shall report, in writing, to the TMB the results and circumstances of a medical peer review that adversely affects the clinical privileges of a physician for a period of more than 14 days. Previously, this reporting was required only after the physician's privileges were adversely affected for more than 30 days.

5. Reportedly, this change was to "close a loophole" that allowed hospitals to suspend doctors for less than 30 days to avoid reporting them to the National Practitioner Data Bank.[13]

6. The TMB may refuse to admit a person to its examination or refuse to issue a license and may take disciplinary action if the person holds a license subject to disciplinary action in another state based on acts that are prohibited under Texas law.[14] Acts prohibited under Texas law include fraud, unprofessional or dishonorable conduct, and impersonating a physician, etc. The TMB, however, must (a) refuse to issue a license to an applicant who held a license in another state that has been revoked for a reason that would be grounds for the TMB to revoke a license in Texas and (b) revoke a license if the license holder, while holding their license in Texas, held a license in another state that has been revoked for a reason that would be grounds for the TMB to revoke a license in Texas.

7. The TMB may suspend or restrict the license of a person arrested for an offence related to (a) criminal homicide; (b) trafficking of persons; or (c) sexual or assaultive offences, when the offence meets certain criteria.[15] Previously, the TMB had the authority to suspend or restrict the license of a person arrested for an offence related to (a) sexual assault of a child; (b) aggravated sexual assault of a child; (c) continuous sexual abuse of young child or disabled individual; or (d) indecency with a child.[16]

8. It is now a Class A Misdemeanor for a person to knowingly make a false statement on their application for a Texas medical license. It is a state jail felony for a person to knowingly make a false statement on their application for a license with the intent to defraud or harm another. Previously, a person making a false statement on their application for a license constituted tampering with a governmental record or perjury as provided by the Texas Penal Code.

9. Expert physician panels appointed by the TMB to assist with complaints and investigations related to medical competency may now include physicians licensed to practice medicine in a member state pursuant to the Interstate Medical Licensure Compact. Previously, only physicians licensed to practice medicine in Texas were eligible to serve on the expert physician panels.

10. The TMB will now charge physicians a maximum $15 surcharge to pay for the administration of the Texas Physician Health Program, due at the time of license issuance and registration permit renewal. Previously, participants in the Texas Physician Health Program paid a maximum $1,200 annual fee for their participation.

Conclusion

More than a decade after Dr. Duntsch shocked the world, Texas and the medical community continue to navigate options designed to prevent a patient from encountering another Dr. Death. HB 1998 places an incredible amount of pressure on the TMB to protect the public from dangerous physicians. The TMB has already stated it would be "staff and time intensive" to post all out-of-state disciplinary records online.[17] In response, state Sen. Borris Miles, D-Houston, replied "[t]he Texas Medical Board must prioritize patient safety and ensure the public can easily find out the disciplinary history of any doctor. The Board needs to get into compliance with the law immediately by making these disciplinary records available to patients."[18] The success of HB 1998 appears to lie with the TMB's ability to comply with the new more onerous requirements of the law. At this time, the TMB has not promulgated and published rules to assist with the implementation of HB 1998.

13 https://www.kxan.com/investigations/texas-medical-board-lawmakers-push-for-change-after-kxan-medical-transparency-investigations/.
14 Section 164.052 of the Texas Occupations Code provides a list of prohibited practices by a physician or Texas license applicant.
15 These offenses are associated with the following chapters of the Texas Penal Code: (1) Chapter 19 (criminal homicide); (2) Chapter 20A (trafficking of persons); or (3) Chapters 21 or 22 (sexual or assaultive offences).
16 These offenses are associated with the following chapters of the Texas Penal Code: Section 22.011(a)(2) (sexual assault of a child); (2) Section 22.021(a)(1)(b) (aggravated sexual assault of a child); (3) Section 21.02 (continuous sexual abuse of young child or disabled individual); or (4) Section 21.11 (indecency with a child).
17 https://www.kxan.com/investigations/texas-medical-board-lawmakers-push-for-change-after-kxan-medical-transparency-investigations/.
18 https://www.kxan.com/investigations/texas-medical-board-lawmakers-push-for-change-after-kxan-medical-transparency-investigations/.

You Can Handle the Truth: Court Rejects Privacy Challenge to NPDB Report Outlining the Reasons for a Surrender of Clinical Privileges While Under Investigation

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In a recent challenge to an Adverse Action Report filed with the National Practitioner Data Bank ("NPDB"), the United States District Court, District of Columbia agreed with the Secretary of the Department of Health and Human Services ("HHS"), the NPDB, and officials administering the NPDB ("Defendants") and upheld the filed NPDB Report. A physician filed suit challenging the reportability of an Adverse Action Report to the NPDB filed by Peconic Bay Medical Center (the "Hospital") after the physician resigned while under investigation. The physician, Dr. Adam Brook, alleged that the information included in the NPDB report was factually inaccurate. The court held: (i) the action was reportable under the Health Care Quality Improvement Act ("HCQIA")[1] ; and (ii) the Privacy Act[2] did not require HHS to amend or remove the statement from the NPDB.[3]

The Surgery, Resignation, and Report

Dr. Brook began working at the Hospital in June 2009 as a thoracic and general surgeon. Shortly thereafter, he performed an appendectomy on a 14-year-old, removing what he believed to me considered an "inflamed band," which later was discovered to be part the patient's fallopian tubes. Three days later, Dr. Brook agreed to refrain from exercising his surgical privileges during the Hospital's investigation. A little more than a week later, while the investigation was ongoing, Dr. Brook provided the Hospital a letter stating he resigned his privileges and membership from the Hospital. The Hospital's quality assurance review later determined the physician's performance of the appendectomy did not meet the expected standard of care.

On December 3, 2009, the Hospital submitted an Adverse Action Report to the NPDB concerning Dr. Brook's surgery and subsequent resignation (the "Report"). It stated, in part:

> 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.[4]

Dr. Brook disputed the Report with the NPDB, challenged the characterization of the incident and requested the Hospital retract the report as he alleged it was "factually inaccurate."[5] When the Hospital refused to retract the report, Dr. Brook requested the Secretary of HHS review and retract the report. The Secretary ultimately denied Dr. Brook's request and determined "[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."[6] Following the Secretary's decision, Dr. Brook filed suit.

Dr. Brook's Lawsuit

Dr. Brook filed suit against the Secretary of HHS, the NPDB, and three named officials who assisted with NPDB maintenance of the Adverse Action Report ("Defendants").[7] Dr. Brook alleged the defendants violated the Administrative Procedures Act ("APA"), Privacy Act sections 522a(g)(1)(A) and (C), and his constitutional rights.[8] Previously, the court granted Defendants' motion for summary judgment as to the APA claim except as to the narrow question of whether the following statement was reportable to the NPDB: "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").[9] The Court dismissed Dr. Brook's constitutional allegations and Privacy Act § 522a(g)(1)(C) claim, and remanded the Privacy Act § 522a(g)(1)(A) claim to the Agency.[10]

1 42 U.S.C.A. § 11101 et seq.
2 5 USCA § 552a.
3 Brook v. Rogers, No. 12-01229 (TFH), 2023 WL 1778792 (D.D.C. Feb. 2, 2023).
4 *Id.* at *2.
5 *Id.* at *2.
6 *Id.* at *2.
7 *Id.* at *2.
8 *Id.* at *2.
9 *Id.* at *2.
10 *Id.* at *2.

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The Agency ultimately determined the Statement was reportable to the NPDB under HCQIA.

Subsequently, Defendants' filed a renewed motion to dismiss, or alternatively a motion for summary judgment, and Dr. Brook filed a cross motion for summary judgment.

The Hospital's Statement in the Adverse Action Report was Reportable

Under HCQIA,[11] a hospital must report certain professional review actions,[12] including when the hospital "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."[13] The report should include "a description of the acts or omissions or other reasons for the action or, if known, for the surrender."[14]

Dr. Brook sought the court's review under the APA of the Secretary's determination that the Statement was reportable as it "provides a more complete history of the events relevant to [Dr. Brook's] resignation while under investigation."[15] Furthermore, the Secretary found reporting "of the reasons for surrender" is required when known, as "the results of an investigation could be useful information for future queriers in determining the reasons for surrenders."[16] Ultimately, reviewing courts may only set aside agency action as unlawful if it determines such action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[17] Here, the court declined to set aside the Secretary's decision.

First, the court addressed Dr. Brook's argument that the Statement was not reportable under the APA because Dr. Brook was not suspended as a result of the Hospital's investigation. The Court found that HCQIA "unambiguously" allows for reporting the results of the Hospital's investigation.[18]

Second, Dr. Brook challenged the Secretary's conclusion that "results of an investigation could be useful information for future queriers," asserting this was logically incorrect because it relies on the premise that a practitioner would have knowledge of a hospital investigation results prior to the investigation's conclusion. The court disagreed with this argument explaining that the Secretary's example provided that a physician would have knowledge of "whether he departed from the standard of care in a given procedure, which could prompt him to resign before the investigation is complete."[19] The court concluded that this information could provide relevant information regarding the surrender of privileges.

Finally, the court rejected Plaintiff's arguments challenging the Hospital's investigation procedures. The court explained that "discontent with the Hospital procedures" does not amount to the Secretary's findings being arbitrary and capricious.[20]

The Department's Requirement to Amend the Adverse Action Report if it contains "Errors of Fact, Not Judgment"

Dr. Brook claimed HHS violated Section 522a(g)(1)(A) of the Privacy Act by failing to amend the Adverse Action Report that he alleged contained "errors of fact, not judgment" that should be corrected, including that the Hospital fabricated documents and administrators committed fraud to have him resign.[21] The Defendants moved to dismiss the claim alleging the Statement was an opinion or judgment, not fact, and thus, did not require amendment.[22] The court dismissed the doctor's claim, finding that the Statement contained the Hospital's judgment regarding Dr. Brook's actions during the procedure. The court further explained that the Privacy Act compels an agency to rectify the record for a "subjective judgment. . . 'based on a demonstrably' false premise," which was not demonstrated here.[23]

Takeaways

The court in this matter made it clear that hospitals are entitled to protection for reporting (i) a physician's surrender of privileges while under or to avoid investigation, (ii) the reasons for the surrender of privileges while under or to avoid investigation, if known; and (iii) the results of investigation when they are pertinent to the surrender of privileges. The court agreed with the HHS Secretary's assertion that there are situations where the reporting of a hospital's investigation may be beneficial for entities querying the NPDB in the future. As such, hospitals subject to this case law may choose to include such information in appropriate reports regarding a surrender of privileges.

11 42 U.S.C. § 11101 *et seq.*
12 42 U.S.C. § 11133.
13 42 U.S.C. § 11133(a)(1)(B).
14 42 U.S.C. § 11133(a)(1)(B).
15 *Id.* at *3.
16 *Id.* at *4.
17 *Id.* at *4 (citing 5 U.S.C. § 706(2)(A)).
18 *Id.* at *4.
19 *Id.* at *6.
20 *Id.* at *6.
21 *Id.* at *7.
22 *Id.* at *7.
23 *Id.* at *8.

Battle of the Regulations: VA Proposes Rule To Improve NPDB Reporting Compliance

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On April 3, 2023, the Department of Veteran Affairs (the "VA") introduced a proposed rule that would remove its regulations at 38 CFR Part 46 ("Part 46") governing the National Practitioner Data Bank ("NPDB").[1] Once removed, the VA will rely on the Department of Health and Human Services' ("HHS") regulations for NPDB reporting that are codified at 45 CFR Part 60 ("Part 60"). The proposed change will allow the VA to comply with NPDB reporting requirements more easily and effectively.

The VA's Participation in the NPDB Reporting System

The Health Care Quality Improvement Act of 1986 ("HCQIA") (Public Law (Pub. L.) 99-660) established the NPDB. However, HCQIA's reporting and querying requirements did not include federal hospitals, such as those that operate under the VA. Additionally, the VA is restricted from complying with certain provisions of HCQIA related to reporting procedures and requirements for reporting medical malpractice payments and clinical privileges because the VA, as a federal agency, is bound by its own policies and other federal laws such as the Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680). As a result, the VA and HHS entered into a Memorandum of Understanding ("MOU"), as required by 42 U.S.C. 11152(b), which governs the VA's reporting obligations to the NPDB.

The MOU dictates, among other things, the following records of actions that must be reported to the NPDB: (i) payments related to medical malpractice claims, including settlements, made on behalf of VA practitioners; (ii) adverse clinical privileging actions, and (iii) adverse actions against health care providers, suppliers, or practitioners as required under Section 1128E of the Social Security Act. The VA formalized the provisions of the MOU and published the regulations in Part 46. The VA-specific regulations set forth policy regarding VA participation in the NPDB reporting system that applies to all physicians, dentists, and other licensed health care practitioners involved in patient care who are employed, appointed, or contracted with the VA.[2]

Prior to the recent proposed rule, the VA was the only federal agency that published its own regulations on NPDB compliance. Other federal agencies such as the Department of Defense, U.S. Public Health Service, and Indian Health Service rely on Part 60 as authority, or they implemented agency policies on reporting requirements.[3]

The VA's Proposed Adoption of HHS Regulations Under Part 60 and Removal of Part 46

NPDB reporting requirements under Part 46 are not as comprehensive as the HHS NPDB regulations under Part 60, which contributes to the VA's noncompliance with reporting requirements.[4] The following examples highlight the current inconsistencies and challenges with the VA maintaining separate NPDB rulemaking, which places self-imposed limitations on the agency:

- The VA's Part 46 does not encompass all required and permissive NPDB reporting requirements like Part 60. For example, Part 60 has been amended on several occasions to include additional reporting requirements that are applicable to the VA, such as the reporting of exclusions from participation in Federal and State health care programs and other adjudicated actions or decisions. Even though these amendments are applicable to the VA, Part 46 does not explicitly address these reporting requirements, which results in noncompliance and uncertainty.

- Definitions in Parts 46 and 60 are wholly inconsistent. A significant example of this inconsistency is the definition of professional review action. Under Part 46, the term means, in part "a recommendation by a professional review panel (with at least a majority vote) to affect adversely the clinical privileges of a physician or dentist."[5] Yet, under Part 60, the same term means in part, "an action or recommendation of a health care entity taken in the course of a professional review activity . . . which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner."[6] Additionally, under Part 60, a professional review action is not considered to be based on the competence or professional conduct of a practitioner if the action is primarily based on the five (5) following scenarios:

  1. the practitioner's association, or lack thereof, with a professional society;

  2. the practitioner's fees, advertising, or engaging in other competitive acts intended to solicit or retain business;

  3. the practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services;

1 Reporting to the National Practitioner Data Bank, 88 Fed. Reg. 19,581 (proposed Apr. 3, 2023) (part 46 to be removed and reserved).
2 38 C.F.R. Pt. 46 (2022)
3 U.S. Dep't of Health & Human Servs., NPDB National Practitioner Data Bank, https://www.npdb.hrsa.gov/orgs/federalAgencies.jsp (last visited Aug. 21, 2023).
4 Department of Veterans Affairs, Office of Inspector General, *April 2022 Highlights,* https://www.va.gov/oig/pubs/highlights/VAOIG-Highlights-202204.pdf
5 38 C.F.R. § 46.1 (2022).
6 45 C.F.R. § 60.3 (2022).

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4. the practitioner's participation in private practice; or

5. any other matter that does not relate to the competence or professional conduct of the practitioner.

However, the VA's Part 46 only lists two (2) scenarios, which are (i) a practitioner's association with, administrative supervision of, delegation of authority to, support for, or training of, a member or members of a particular class of health care practitioner or professional; or (ii) any other matter that does not relate to the competence or professional conduct of a practitioner in his or her practice at a Department of Veterans Affairs health care facility.

- Part 60 allows for voluntary reporting on other health care practitioners, but the VA is precluded from reporting on other health care practitioners because Part 46 is silent on voluntary reporting.

- Whenever Part 60 is amended, the VA must wait until HHS publishes a final rule. During the waiting period, the VA is adhering to outdated regulations codified in Part 46, which leads to noncompliance.

Based on these examples, among other rationale, the VA has determined, in consultation with HHS, that Part 46 should be removed. Instead, the VA has proposed to rely on Part 60 for NPDB reporting, supplemented with a MOU between the VA and HHS, as well as VA policy to address NPDB compliance on issues involving the delivery of health care by a federal agency.

Conclusion

The VA contends the proposed rule will improve compliance, create clearer guidance, allow the VA to adhere to all mandatory and permissive reporting requirements, and better assist the VA with promoting quality health care and deterring fraud and abuse within the VA's health care delivery system. Comments to the proposed rule were due by June 2, 2023, and we will continue to watch for updates.

Federal Court Finds Corrected NPDB Reports Filed Prior to Peer Review Hearing Did Not Violate Due Process or Warrant Injunctive Relief

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A federal district court in North Carolina denied a motion for temporary restraining order and preliminary injunction by two pathologists who filed suit after a hospital's Medical Executive Committee ("MEC") suspended and recommended the revocation of their privileges and also granted the individual and hospital Defendants' motion to dismiss the pathologists' complaint. The hospital submitted a report to the National Practitioner Data Bank ("NPDB"), which mistakenly stated that the suspensions were "permanent," but later corrected the reports to state that the suspensions were "indefinite" pending resolution of the hearing and appeal process. The court rejected the physicians' argument that the hospital deprived the physicians of due process by filing NPDB reports, suspending their privileges, reducing their salaries, and removing their administrative titles without first being provided hearings to challenge the accuracy of the reports.

Hospital Disciplines Physicians Following Investigation

Plaintiffs Harsharan Kaur Singh, M.D. and Volker Reinhold August Nickeleit, M.D. (the doctors) are tenured professors of pathology at the University of North Carolina Chapel Hill School of Medicine ("UNC"), a public university in North Carolina. Defendant UNC-Health is an integrated health care system owned by the State of North Carolina and administered as an affiliate enterprise of UNC.[1] In the Fall of 2020, UNC's Human Resources Office received complaints about Plaintiffs and engaged in a lengthy investigation into the allegations, which was ultimately completed on January 21, 2022. The court filings do not detail the nature of complaints.[2] Based on the HR investigation, UNC's Professional Executive Committee requested that the MEC take corrective action against the Plaintiffs and the MEC formed an Ad Hoc Committee to conduct a peer review investigation.[3]

The doctors met with the Ad Hoc Committee, the Ad Hoc Committee submitted its report and recommendation to the MEC three weeks later, and the MEC held a special meeting to discuss the matter.[4] The doctors were given notice of the meeting and the opportunity to attend and speak or provide written statements. They each submitted written statements to the MEC.[5] At its meeting, the MEC voted to recommend the revocation of the doctors' privileges to the Board of Directors, and to immediately revoke their privileges pending final decision by the Board of Directors upon conclusion of the hearing and appeals process due to concerns of harm to other individuals.[6] In effect, the MEC voted to immediately suspend the doctors' privileges and recommend revocation. The MEC notified the doctors that their appointments to the UNC Medical Staff had been rescinded and their clinical privileges at UNC Health had been revoked and advised the doctors of their right to request hearings under the Medical Staff Bylaws, which they did.[7] Defendants also reported the revocation of the doctors' clinical privileges to the NPDB approximately one week after notifying them of the action and prior to any hearing.[8] The doctors filed their suit alleging that their procedural due process rights were violated when Defendants reported to the NPDB that the doctors' clinical privileges had been permanently revoked.[9]

Liability as to Defendants

Before analyzing the doctors' due process claims, the court first determined whether any of the Defendants were immune from liability under the sovereign immunity doctrine and otherwise warranted dismissal from this action. Specifically the doctors argued that UNC Health was not immune from suit under sovereign immunity because it was not "an arm or alter ego of the State of North Carolina."[10] Applying a four-factor test utilized by the Fourth Circuit,[11] the court determined

1 *Singh v. Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *2 (M.D.N.C. May 12, 2022). The full list of Defendants includes the University of North Carolina at Chapel Hill ("UNC-CH"), the University of North Carolina Health Care System d/b/a UNC Health Care ("UNC-Health"), and the University of North Carolina School of Medicine ("UNC-SOM") (collectively, the "University Defendants"), and Janet Hadar, MSN, Thomas S. Ivester, M.D., Russell Broaddus, M.D., Lisa Voss Derek V. Hoar, and Harvey L. Lineberry, Ph.D.
2 *Id.*
3 *Id.*
4 *Id.*
5 *Id.*
6 *Id.*
7 *Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *2.
8 *Id.* at *3. Although the report mistakenly indicated the revocation was permanent, UNC Hospitals submitted a correction report to the NPDB changing the entry from "Permanent" to "Indefinite."
9 *Id.* at *3, 8.
10 *Id.* at *4. Plaintiffs conceded that UNC-CH and UNC-SOM were immune from suit under sovereign immunity.
11 *See Ristow v. S.C. Ports Auth.*, 58 F.3d 1051, 1052 n.3 (4th Cir. 1995) (quoting Ram Ditta v. Md. Nat. Cap. Park & Plan. Comm'n, 822 F.2d 456, 457-48 (4th Cir. 1987)).

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that UNC Health and the other University Defendants were immune from suit under sovereign liability and denied the preliminary injunction as to those Defendants, leaving only the individually named defendants in their official capacities.[12]

Based on this determination, the Court issued a separate order granting Defendants' Motion to Dismiss for the University Defendants.[13] The Court also granted the Motion to Dismiss as to the individually named Defendants in that same order finding that (1) the doctors lack a legally cognizable interest in their salaries, (2) the doctors' claim regarding the temporary suspension of their clinical privileges is not ripe, (3) the doctors failed to state a claim for prospective relief regarding the temporary suspension of their clinical privileges, and (4) Defendants are entitled to qualified immunity for the suspension of the doctors' clinical privileges and the reporting to the NPDB.[14]

Due Process Argument

The court denied the doctors' request for preliminary injunctive relief under their due process claim. First, the court held that the doctors' claim was not ripe as to the suspension of clinical privileges, reduction in salary, and loss of title because the due process required by the Medical Staff Bylaws of UNC Health was still ongoing, a hearing would be held as required by those Medical Staff Bylaws, and such a hearing was being scheduled by the parties.[15] While the court stated that doctors' procedural due process liberty interest claims as to the NPDB reports were initially ripe for review, UNC Health's voluntary actions in amending the notice to correct "permanent" to "indefinite" in the NPDB reports rendered the doctors' liberty interest claim moot.[16] Moreover, the Court held that a disclosure to the NPDB does not deprive an employee of a constitutionally protected liberty interest where that report harms their reputation.[17] The Court concluded Defendants were entitled to qualified immunity on the doctors' property interest claim in their clinical privileges and their liberty interest claim in the report to the NPDB because such reports do not implicate constitutionally protected rights.[18]

The court noted the following facts in its holding: (1) UNC's Medical Staff Bylaws specify procedures for corrective action, hearing, and appellate review as to all physicians who are members of the Active, Courtesy, Affiliate, or Honorary Staff; (2) the Medical Staff Bylaws "describe the fundamental principles of Medical Staff self-governance and accountability to the Governing Body"; (3) the Medical Staff Bylaws specify the procedures for corrective action; and (4) the Medical Staff Bylaws provide that a Medical Staff member is entitled to a hearing when a committee recommends actions including restriction, denial, reduction, suspension, or revocation of clinical privileges.[19] Significantly, the court found it was not disputed that these processes were followed by the UNC's staff, nor that the doctors had requested a hearing in accordance with the Medical Staff Bylaws.[20]

Based on this finding, the court held that it lacked subject matter jurisdiction over the individually named Defendants because the doctors' interim suspension of clinical privileges pending a final decision was not sufficient to invoke due process rights, particularly given that a due process hearing was proceeding and almost certain to occur.[21] Notwithstanding, the court further held that doctors' request for a preliminary injunction for both the revocation of their clinical privileges, stripping of administrative titles, and reduction of salaries as well as the report to the NPDB failed substantively because they could not establish each factor required to obtain a preliminary injunction, including (1) a likelihood of success on the merits, (2) risk of irreparable harm, (3) the balance of equities tips in their favor, and (4) the injunction is in the public interest.[22]

Key Take-Away

This case highlights the importance of instituting clear procedures for corrective action, notice, hearing, and review in a hospital's medical staff bylaws and following such provisions when recommending corrective action against providers. Additionally, while it is best practice to review all NPDB reports prior to final submission to ensure the accuracy of those reports and the statements contained therein, it is just as important to promptly remedy any inaccuracies to protect a hospital against potential liability resulting from an inaccurate report.

12 *See Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *7.
13 *See Singh v. Univ. of North Carolina at Chapel Hill,* 2023 WL 2329857, at *3 (M.D.N.C. Mar. 2, 2023)
14 *Id.* at *16.
15 *See Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *7. The Court further held that the doctors lacked a constitutionally protected interest in their administrative titles or full salaries. Singh v. Univ. of North Carolina at Chapel Hill, 2023 WL 2329857, at *7.
16 *Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *9.
17 *Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *16.
18 *Id.*
19 *Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *10.
20 *Id.*
21 *Id.* (citing Braswell v. Haywood Reg'l Med. Ctr., 234 F. App'x 47, 49, 54–55 (4th Cir. 2007); Darlak v. Bobear, 814 F.2d 1055, 1062-64 (5th Cir. 1987); and Caine v. Hardy, 943 F.2d 1406, 1411– 12 (5th Cir. 1991)).
22 *See Univ. of North Carolina at Chapel Hill,* 2022 WL 1500545, at *11-16 (citing Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)).

Changes Come, But It Stays the Same: The Joint Commission Changes National Practitioner Data Bank Query Requirements

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In this year of change in accreditation requirements, one change may have gone unnoticed. On March 20, 2023, The Joint Commission ("TJC") issued notice and prepublication of its approval to change the language of MS.06.01.05, EP 7, setting out the timeframes for querying the National Practitioner Data Bank ("NPDB"). The standard requires an objective evidence-based process for the granting and renewal of privileges. Element of Performance 7 previously required a query of the NPDB on three separate occasions: (1) when privileges are initially granted; (2) when privileges are renewed; and (3) when a new privilege is requested. Effective August 27, 2023, the language no longer defines the occasions for query but instead requires a query of the NPDB "in accordance with applicable law and regulation."

While this change may appear to lighten the workload and decrease the frequency for NPDB queries, that is not the case. The federal regulations governing both reporting and querying of the NPDB require a hospital to query the NPDB at the time of appointment and at least every two years thereafter. Additionally, there must be a query if a practitioner requests new or seeks to expand existing privileges. This is especially vital to remember as some organizations move from two to three-year appointments. The federal law has not changed, and the organization is still required to query the NPDB at least every two years. If the organization is on the NPDB continuous query, this requirement will be satisfied. However, for those organizations not on continuous query, it is necessary to have a system in place to be sure the required queries occur. It is particularly important to be sure to query the NPDB when an existing medical staff member requests new privileges at your institution.

During this time of change, it is essential to remember that the purpose of the Health Care Quality Improvement Act is to promote professional review activities and reporting by providing protection under both federal and state laws for members of a professional review body and its members who take an action in the furtherance of quality health care. Through receiving notice of actions through NPDB querying, it is expected that organizations and medical staffs will put in place appropriate protections to guard against a poor-quality practitioner or one who is not competent to perform certain privileges. With the recent changes in TJC requirements, this is an opportune time to remind medical staff members of the protections afforded to them when they recommend such appropriate protections.

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Part 3 | February 23, 2024

Part 4 | March 1, 2024

Part 5 (CA/TX) | March 8, 2024

About Polsinelli's Medical Staff Practice

Polsinelli's Health Care attorneys guide hospitals and health systems through the medical staff governance process including credentialing, peer review, bylaws and medical staff and governing body relationships. From practitioner credentialing to hearings and appeals, and defense of litigation, our attorneys are versed in the intricacies involved in the life cycle of hospital-medical staff relationships.

Polsinelli has handled almost every type of matter involving medical staff and mid-level practitioners and has advised client on compliance with accreditation standards, hospital licensing laws, peer review laws, and federal laws governing the conduct of medical staff fair hearings. Specifically, we have extensive experience counseling hospitals on medical staff bylaws and related rules, regulations, policies and procedures, and codes of conduct. We have been active helping clients in implementing processes for effectively managing disruptive and inappropriate behaviors and in developing processes for empowering the well-being committee and managing impaired and aging providers.

Our team has experience advising through the credentialing process, advising peer review committees, representing medical executive committees in hearings and appeals, and interfacing with government entities. We also have defended hospitals and surgical centers in lawsuits filed by affected practitioners, during and after peer review.

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