IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF KIERAN SLEVIN, M.D. LICENSE NO. 25MA8620600 TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION, Docket No. A-000168-24 Civil Action On Appeal From: State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, State Board of Medical Examiners OAL Docket No. 05046-21 Sat Below: Hon. Dean Buono, A.L.J.

BRIEF OF APPELLANT

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PRELIMINARY STATEMENT

Appellant, Kieran A. Slevin, M.D. ("Dr. Slevin"), is an interventional pain management specialist who has been practicing for eighteen years. As part of his pain management practice, he prescribed Subsys, a TIRF REMS (Transmucosal Immediate-Release Fentanyl Risk Evaluation and Mitigation Strategies) product, which is used to treat cancer, to an extremely small number of patients - T.O., J.W., N.P. and B.C. ("Complaint Patients").

Notwithstanding Dr. Slevin's years of experience, expertise, and exceptional care, the Attorney General (the "AG") sought to suspend or revoke Dr. Slevin's license, alleging that Dr. Slevin prescribed Subsys to his patients in exchange for lavish dinners, all-expenses-paid trips for trainings, and alleged cash payments by Insys for speaking fees and for encouraging non-cancer patients to take this drug for off-label use. Moreover, the AG alleged that Dr. Slevin allowed his treatment and prescription decisions to be influenced by the benefits he received as a prescriber participating in the Insys Speaker Program. Lastly, the AG alleged that Dr. Slevin violated the appropriate standard of care, and Dr. Slevin had poor patient recordkeeping.

Dr. Slevin disputed the allegations, and the matter was heard at the Office of Administrative Law. Dr. Slevin prevailed on all allegations except one—the record keeping violation.

Although the only allegation substantiated by Administrative Law Judge Dean Buono (the "ALJ") was the record keeping violation, the ALJ recommended that Dr. Slevin's license be suspended for six months, and the ALJ assessed Dr. Slevin twenty percent of investigatory costs, expert fees, and/or attorneys' fees, totaling $39,534. The State Board of Medical Examiners (the "Board") modified both the ALJ's decision and penalty recommendation. In addition to the ALJ's findings, the Board arbitrarily found that Dr. Slevin violated N.J.S.A. 45:1-21(e) due to his alleged poor record keeping, and it implemented a monetary fine in an aggregate of $150,000 and increased the twenty percent monetary penalty to fifty percent for a total assessment of $98,835.

The record does not support any findings for record keeping violations, and the penalty imposed for these violations shocks one's sense of fairness. First, there was no expert testimony offered at the hearings to support the contention that Dr. Slevin's record keeping practices were deficient or in violation of the applicable standards. Second, contrary to the ALJ's findings and the Board's subsequent adoption of those findings, Dr. Slevin's patient records are replete with his rationale for treatment ordered and with relevant negative findings, when necessary. Third, there is no evidence to support the Board's finding that Dr. Slevin intentionally or materially altered patient records, nor is there any evidence that Dr. Slevin failed to

keep contemporaneous records. And finally, the Board disregarded the amount of monetary fines the ALJ suggested, and inflated it without cause or rationale.

Both the findings and punishments are unsupported by the record. Dr. Slevin, therefore, respectfully asks this Court to reverse the decision of the Board. In the alternative, Dr. Slevin asks that the matter be remanded to the ALJ for consideration of the materials that were overlooked at the time the ALJ issued his order.

PROCEDURAL HISTORY[1]

The AG filed a complaint against Dr. Slevin on November 23, 2020 (the "Complaint"), alleging that Dr. Slevin violated standards of care when prescribing Subsys to four of his patients. Among other claims, the AG alleged that Dr. Slevin's prescribing of Subsys was indiscriminate and constituted gross negligence and/or repeated acts of negligence; that there was no medical documentation to support the prescription of Subsys to the affected patients; that Dr. Slevin's medical decision-making and his elections to prescribe Subsys were improperly influenced by his participation as a speaker in Insys' "speak program," and that Dr. Slevin altered patient records and failed to maintain

[1] 1T refers to the transcript dated May 22, 2023
2T refers to the transcript dated May 23, 2023
3T refers to the transcript dated May 25, 2023
4T refers to the transcript dated May 31, 2023
5T refers to the transcript dated June 1, 2023
6T refers to the transcript dated July 31, 2023
7T refers to the transcript dated August 1, 2023
8T refers to the transcript dated September 11, 2024

records that were consistent with the requirements of the Board's recordkeeping regulations under N.J.A.C. 13:35-6.5; specifically, that the progress notes were not original to each visit and were "largely copy and paste forwards." (JA81-112). Dr. Slevin filed an answer denying the allegations on December 18, 2020. (JA00113-125).

The ALJ held hearings between May 22, 2023, and August 1, 2023. (JA32). The ALJ's Initial Decision recommended dismissal of all charges against Dr. Slevin, with the exception of a medical recordkeeping violation. (JA31-69). The ALJ found that Dr. Slevin "violated N.J.S.A 45:1-21(h) because he failed to comply with the record keeping obligations imposed by N.J.A.C. 13:35-6.5, and that the charges proven regarding [Dr. Slevin's] preparation of treatment record and lack thereof, constitutes negligence but not of a gross nature." (Ibid.). The ALJ found that Dr. Slevin did not alter any medical records or engage in professional misconduct. (Ibid.) Nevertheless, the ALJ recommended that Dr. Slevin be suspended for six months and assessed Dr. Slevin twenty percent of investigatory costs, expert fees, and/or attorneys' fees. (Ibid.).

In its Final Decision, while stating that it adopted "in their entirety, the findings of fact and conclusions of law made by ALJ Buono," (JA3) the Board added to the ALJ's decision by finding, on its own and without any proof, "that

Dr. Slevin altered his patient records . . . (specifically, the records for each of the four patients who were identified by initial . . .) when responding to the two legal demands made of him that he produces his patient records." (JA3-4). The Board found that the alleged alterations were made in violation of N.J.A.C. 13:35-6.5(b)(2) and were "intentional and material." (JA4). The Board supplemented the ALJ's conclusion and found that Dr. Slevin "(1) failed to comply with provisions of Board regulations, in violation of N.J.S.A. 45:1-21(h), and (2) engaged in acts of professional misconduct in violations of N.J.S.A. 45:1-21(e)." (JA4). The Board went further than the ALJ and implemented a monetary fine in of $150,000 and increased the twenty percent award of fees and costs to fifty percent for a total assessment of $98,835 without explanation. (JA5).

On August 20, 2024, Dr. Slevin filed a motion for reconsideration and for a stay of the suspension with the Board. By order dated August 23, 2024, the Board denied the application for a stay. (JA5542). The Board heard the motion for reconsideration on September 11, 2024, and denied the motion for reconsideration on September 17, 2024. (JA5539-41).

On September 18, 2024, Dr. Slevin filed a notice of appeal of the Board's Order. (JA77-80).

STATEMENT OF FACTS

Dr. Slevin is an anesthesiologist and interventional pain medicine physician licensed to practice medicine in New Jersey, New York, Pennsylvania, and Delaware. (5T26:5-7; 6T34:5-6).

Dr. Slevin began treating the Complaint Patients while he was the Chief of Pain Medicine at Virtua Health System for the southern campuses ("Virtua"). (4T34:7-12, 38:10-15). Dr. Slevin eventually left Virtua to open his own private practice, North American Spine & Pain Consultants ("North American"). (4T17:25). As a result of a contractual dispute with Virtua, upon his departure, Virtua prevented Dr. Slevin from accessing his previous treatment records for the patients he had cared for at Virtua, including the Complaint Patients. (4T42:3-16; 5T72:25 to 73:3; 7T66:19 to 21:2)

The Complaint Patients remained under Dr. Slevin's care at North American. Early on, North American faced several administrative challenges, particularly with its electronic medical records system, Omni MD (the "EMR System"). (4T43:24 to 44:18). The system lacked seamless integration features, requiring documents, such as medication prescriptions, imaging, physical therapy orders, laboratory reports, and other records, to be manually scanned. (4T45:11–27). This lack of seamless integration is a challenge that the entire profession encounters. (4T44:20-25, 45:11-27).

Additionally, the EMR System often omitted pages when printing. (4T45:2-5). There were times, throughout business hours, when the EMR System was offline and unavailable due to a lack of bandwidth, which meant that patient records could not be accessed and updated. (4T44:24-25). Also, Dr. Slevin faced issues with the EMR System's billing modules and encountered problems while running financial reports, as did many other professionals. (4T45:6-8).

Following visits with Dr. Slevin, due to the shortcomings with the EMR System, patients would take documents to the front desk to be scanned for inclusion in their file. Dr. Slevin's office staff would then manually scan the documents. (5T69:14-20). During this manual scanning and inclusion process, some documents were inadvertently omitted. The limitations of the non-integrated system contributed to the oversight in Dr. Slevin's record keeping. (5T84:14 to 85:7). While Dr. Slevin accepts full responsibility for the omitted records, this was not a deliberate oversight. Rather, it reflects the unfortunate reality of using the EMR System. (Ibid.)

Jeffrey Gudin, M.D. ("Dr. Gudin"), an anesthesiologist, pain-management specialist expert, who testified on behalf of Dr. Slevin, stated that he had similar issues with the EMR System and posited that "it is completely within reason that a voluminous system, . . . where each and every piece of paper needs to be scanned

by an entry level employee, that there can be easily deficient medical records outside of the control of the practicing clinician." (7T52:8-16).

Chirstopher Gharibo, M.D. ("Dr. Gharibo"), an anesthesiologist and pain-management specialist, testified on behalf of the AG, but failed to provide any testimony regarding the standard of detail that must be provided for patient records. Dr. Gharibo also did not testify about the integration of the EMR System into the medical practice.

A. Practice Philosophy and Compliance

Despite the challenges created by the faulty EMR System, Dr. Slevin demonstrated exceptional dedication and provided outstanding care to his patients. Patients were screened on their first visit before the prescription of any medications. (4T66:16-17). Risk profile and level determined the frequency at which a patient is drug screened. (4T66:21 to 67:24). Some patients provided urine specimens on a weekly, monthly, or quarterly basis. (4T66:24 to 67:4). Any patient prescribed opioids was drug screened at least once quarterly. (4T68:20-22).

Prior to the requirement to query the Prescription Drug Monitoring Programs, Dr. Slevin's office called pharmacies to verify patient compliance and to prevent medication from being obtained from multiple sources and pharmacies. (4T68:7-19). Dr. Slevin required patients to sign and comply with a

Controlled Dangerous Substances ("CDS") Agreement, which outlined the requirements and responsibility to provide urine drug screens upon request and notify the practice of CDS prescribing by another provider. (4T 70:2-11:6).

B. Prescribing of Subsys

Between 2014 and 2017, Dr. Slevin's practice treated approximately 500 to 600 patients per month. (4T74:5-8). Dr. Slevin limited his off-label prescribing of Subsys to the Complaint Patients. (4T74:9-25). He also prescribed Subsys to two or three cancer patients. (4T73:14 to 74:4). Overall, patients prescribed Subsys represented approximately 1% of Dr. Slevin's practice. (4T74:9 16).

Dr. Gudin opined that, between 2014 and 2016, prescribing Subsys off label to non-cancer patients was not contraindicated by the federal Food and Drug Administration. (6T31:19-22). In fact, Dr. Gudin testified that 60% to 90% of TIRF REMS products, including Subsys, were commonly prescribed off label for non-cancer pain. (6T19:18 to 20:16; 7T61:18-21). Subsys had a 90% patient satisfaction rate. (7T175:23 to 176:4).

Dr. Slevin took tremendous care in deciding which opioids to prescribe. For example, Complaint Patients B.C. and J. W. had been prescribed Actiq prior to treating with him. (2T139:2-6; 5T30:13-14). Dr. Slevin chose to not continue prescribing Actiq because it was found to cause dental issues, including tooth decay, and had an unsafe disposal mechanism posing harm to children. (5T 30:14-33).

Initially, when considering whether to prescribe Subsys, Dr. Slevin initiated a medication trial lasting around five to seven days to assess its suitability for the patient. (4T78:4-8). Approval was not necessary for the initial Subsys trial. (4T 78:15-17). Nevertheless, prescribing beyond this initial trial phase mandated approval and was accompanied by a robust and thorough procedure for both prescribers and patients. Dr. Slevin had to register with the TIRF REMS program, sign a TIRF REMS provider agreement, and pass a post-education knowledge assessment. (4T75:20 to 76:22; 5T31:24 to 32:2).

Furthermore, patients were required to receive education and counseling of the medication's high-risk characteristics, and they had to sign a TIRF REMS Patient-Provider Agreement before Subsys could be dispensed. (4T77:9-17). Subsys was unequivocally withheld unless a fully executed TIRF REMS Patient-Provider Agreement ("Agreement") was executed and on record. Dr. Slevin testified that "the medication would never have been prescribed without this documentation being completed." (5T45:20 to 46:2). Moreover, it is undisputed that Subsys could not be dispensed by the pharmacy without an Agreement in place. Dr. Gudin testified that, "per the TIRF REMS guidance document, prescriptions would not be issued by a certified pharmacy if those documents had not been signed by both the patient and the provider." (7T71:15-19).

C. Subpoena Responses

Dr. Slevin received the AG's first subpoena on or around January 2016. (4T50:22-25). His office manager compiled the medical records, and Dr. Slevin compiled bank documents and emails; these documents were provided to his former counsel, who submitted the subpoena response. (4T52:15-23).

Dr. Slevin received a second subpoena approximately two years later requesting patient records. (4T51:24 to 52:9). Again, his office manager compiled the medical records and transmitted the records to his new counsel. (4T52:10-19). Dr. Slevin's first attorney also shared the records with his subsequent attorney. (4T53:1-2).

Dr. Slevin relied on his office staff to print the patient record for inclusion in the subpoena response. Dr. Slevin acknowledged that prescription records had not been included in response to the first subpoena but were included in response to the second subpoena and accepted full responsibility for that oversight. (5T84:14 to 85:7). He clarified that each element of the patient record needed to be printed individually, and some pages were unintentionally missed. (5T86:8-17). Dr. Slevin explained that, while preparing the subpoena responses, some prescriptions were either not printed or sent to counsel, but never reached the AG's office. (5T85:8-22). Dr. Slevin further explained that these records were voluminous and difficult to organize due to the EMR Systems limitations.

(5T91:21-25). Thus, Dr. Slevin's counsel tried to put them in order before submitting the subpoena response, but perhaps some documents were omitted or lost in the process of organizing them. (5T91:21-25).

D. Patient Records Amendments

Dr. Slevin testified about his current understanding of the proper method for making changes to a patient's medical record. (4T53:18 to 54:5). He was forthcoming about a time when he made changes to the patient records produced in response to the second subpoena. (4T54:6-8). He took this action with the full awareness that the AG would review the modifications to the patient's record, and he had no intent to conceal them. (4T54:9-17). His intent was to clearly specify the dates of service, simplify the record for better clarity, include physical findings and rephrase information that was previously located elsewhere in the note, arrange his notes in a more organized manner, enhance the documents comprehensibility, and document patient encounters that had taken place but had not been previously recorded in the note. (4T54:20 to 55:11).

Dr. Slevin testified that "[he] never added anything that wasn't true or [he] never deleted anything that . . . was substantive and should have remained in the record." (4T54:20 to 55:11). The modifications made to patient records were not intentional or material amendments and the modifications were not carried out in bad faith.

E. Comprehensiveness of the Patient Records

Dr. Gudin opined that not every part of each patient encounter is documented in the patient record. (7T155:10-14). Dr. Gudin explained why some portions of a patient encounter are omitted. He testified: "there are phone calls in between visits, there are patients showing up at the front desk with prescription issues, there are lab reports that come back when the chart is not open or available. So, yes, we do our best, but oftentimes there are things that don't make it into the medical record." (7T193:24 to 194:5).

The AG did not present any expert testimony concerning the standard of proof for recordkeeping.

STANDARD OF REVIEW

Appellate review of a professional board's disciplinary action is limited. In re License Issued to Zahl, 186 N.J. 341, 353 (2006). An administrative agency's decision will be upheld "unless there is a clear showing that it is arbitrary, capricious, or unreasonable, or that it lacks fair support in the record." In re Herrmann, 192 N.J. 19, 27-28 (2007). A reviewing court will decide only whether there is "sufficient credible evidence" in the record by considering the "proofs as a whole." Close v. Kordulak Bros., 44 N.J. 589, 599 (1965). Additionally, an appellate court exhibits "due regard" to the agency's expertise where that is a factor. Ibid. Thus, courts will "afford substantial deference to the actions of administrative agencies such as the

Board." Zahl, 186 N.J. at 353. In other words, an appellate court will not substitute its own judgment for that of the administrative agency. Id. at 354 (citing In re Polk, 90 N.J. 550, 578 (1982)).

The Court, however, can review disciplinary action. In doing so, the Court must analyze whether the agency's action violates express or implied legislative policies. The Court must consider whether the agency followed the law; whether the record contains substantial evidence to support the findings on which the agency based its action; and whether, in applying the legislative policies to the facts, the agency clearly erred in reaching a conclusion that could not reasonably have been made on a showing of the relevant factors. In Re Carter, 191 N.J. 474, 482-83 (2007).

When reviewing administrative sanctions, the Court should consider whether the punishment is so disproportionate to the offense, in light of all of the circumstances, as to shock one's sense of fairness. Id. at 484; see also In re Hendrickson, 235 N.J. 145, 159 (2018); In re Markoff License Revocation, 299 N.J. Super. 607, 613 (App. Div. 1997) (affirming Board's decision not to reinstate physician's license because sanction did not "shock one's sense of fairness"). While a court "has no power to act independently as an administrative tribunal or to substitute its judgment for that of the agency. It can interpose its views [ ] where it is satisfied that the agency has mistakenly exercised its discretion or misperceived

its own statutory authority." Zahl, 186 N.J. at 354 (quoting In re Polk License Revocation, 90 N.J. 550, 578 (1982)).

LEGAL ARGUMENT

I. The Board's Decision Is Arbitrary, Capricious, and Unreasonable and Not Supported by the Record (JA4).

The record on appeal does not demonstrate that Dr. Slevin neglected his record-keeping responsibilities under N.J.S.A. 45:1-21(e) and N.J.S.A. 45:1-21(h). The expert testimony presented during the hearings, including that of the AG's witnesses, supports the conclusion that Dr. Slevin's record-keeping practices adhered to common practices. In fact, the AG's witness did not even attempt to set forth a standard for the amount of detail required under to be considered a contemporaneous record. In this case, there is no evidence backing the Board's conclusion that Dr. Slevin failed to maintain contemporaneous records.

A. The Board's Adoption of the ALJ's Finding of Facts and Conclusions of Law was Arbitrary, Capricious and Unreasonable and Unsupported by the Record.

The ALJ concluded, and the Board adopted, that Dr. Slevin failed to keep contemporaneous records in violations of N.J.A.C. 13:35-6.5(b)(2). N.J.A.C. 13:35-6.5(b) requires a physician to prepare "contemporaneous" records and states that "to the extent applicable" those records should include the date of treatment, the patient complaint, the history, findings on examination, progress notes, orders for tests and a diagnosis or medical impression.

The Board's Final Decision states that Dr. Slevin's "patient records failed to adequately detail 'why' he chose to prescribe Subsys to each of the [Complaint Patients], and similarly failed to document 'how' patient reacted to taking Subsys." That finding is not supported by the record. (JA19).

Moreover, as referenced above, N.J.A.C. 13:35-6.5(b) does not expressly state the patient records need to include the "why" and "how" to be considered a contemporaneous record. Furthermore, N.J.A.C. 13:35-6.5(b) does not define what level of detail is needed for the records to be considered contemporaneous, and the AG presented no evidence as to the standard of proof as to the detail that must be provided. Indeed, that standard is not contained in the regulations, and Dr. Gharibo, the AG's expert, made no attempt to articulate that standard.

The only expert testimony on the subject was offered by Dr. Slevin's expert, Dr. Gudin. He explained that not every encounter finds its way into the medical record. (7T155:10-14). He cited examples of those encounters, such as phone calls between visits, patients raising issues related to prescriptions, and lab reports which sometimes arrive when the record is not available. (7T193:24 to 194:5).

To the extent the AG wanted to prove a case based on insufficient detail, it was obligated to present a standard through documentary evidence or expert testimony. The AG has done neither. Thus, the Board's conclusion that Dr. Slevin failed to "adequately detail" the "why and "how" is arbitrary and capricious because

no standard to make that determination was set forth by statue or by expert testimony. The AG cannot discipline a physician based on unexpressed rules.

Furthermore, even if the standard for adequate detail was set forth, any conclusion that Dr. Slevin's records are not adequately detailed is also unsupported by the record. Dr. Slevin maintained contemporaneous permanent professional treatment records.

For example, in the case of Complaint Patient T.O., in Dr. Slevin's note of February 4, 2015, Dr. Slevin explained exactly why he was considering the prescribing of Subsys:

> The patient has had severe and chronic neuropathic pain since a syringe was left in her abdomen following a surgical procedure. She is now reporting insufficient pain relief and end of dose failure from Dilaudid and I will add Subsys to her regimen 200 mg for breakthrough pain.
>
> [(JA2757).].

Similarly, in the case of Complaint Patient J.W., in his note of July 15, 2024, Dr. Slevin indicated: J.W. "states today she is having very frequent flare ups. Subsys trialed is helpful for flare ups, but her insurance has denied." (JA2224). Then, in a subsequent note on September 10, 2014, Dr. Slevin wrote:

> I will trial her with SL fentanyl spray to treat breakthrough pain of #30 trial. She has failed to respond to multiple other SAO in the past and has had good pain relief with Actiq in the past.
>
> [(JA4909).]

In the case of Complaint Patient N.P., Dr. Slevin stated directly why he decided to prescribe Subsys. In his note of May 24, 2014, he recorded:

> Refilled Subsys, some today — he has gabapentin. He continues to take Subsys 400 mcg as needed up to 4 per day as this is helping to control his severe failed back surgery and neuropathic pain. He has failed to respond to other short acting opioids for management of his breakthrough pain and has responded well to fentanyl sublingual spray prn for severe breakthrough pain.
>
> [(JA1305).].

Copies of explanations of why Dr. Slevin prescribed Subsys and documentation of how the patients reacted to taking the medication—all contained in his medical records. See (JA126-2857) Admittedly, there are thousands of pages of medical records in this case, and it would take many, many hours to pore through each entry. But the truth of the matter is that, for whatever reason, whoever was responsible for reviewing the medical records missed pertinent records, like those cited above, that show Dr. Slevin kept sufficient records.

These were extremely difficult and complex patients whom Dr. Slevin saw on a monthly basis over the course of many years. To fully appreciate what is in those records requires an extraordinary amount of time and study. Both the ALJ and the Board failed to adequately review what was present in the record and, because of this failure, the Board wrongfully adopted the ALJ's decision.

Thus, Dr. Slevin respectfully requests that, in the event that this appellate panel does not reverse the Board's decision, it remand the matter to allow the Board to adequately review the record below and conclude that Dr. Slevin did in fact keep adequately detailed contemporaneous records.

B. The Board's Additional Finding That Dr. Slevin Intentionally and Materially Altered Patient Records Is Not Supported by the Record.

Despite the ALJ's clear finding that Dr. Slevin did not alter any medical records, and the Board's unanimous adoption of the ALJ's factual findings and legal conclusions regarding the first four counts of the Complaint, the Board introduced an additional and unfounded allegation. Specifically, the Board claimed that Dr. Slevin "altered his patient records (specifically, the records for the [Complaint Patients]) in response to the two legal demands for his patient records. (JA81-112). This contradictory assertion undermines the established evidence and raises serious concerns about the integrity of the Board's decision-making process. It is imperative that this appellate panel evaluate this additional finding, as it lacks substantiation and does not align with the record or the ALJ's initial decision.

The Final Decision acknowledged that the ALJ made no findings of fact or conclusions of law directly addressing the charges of altering patient records. (JA1-30). Yet the Board, without any proof, concluded that the alleged alterations were "intentional and material" and in violation of N.J.A.C. 13:35-6.5(b)(2),

which states corrections/additions to an existing record can be made, provided that each change is clearly identified as such, dated and initiated by the licensee. (JA4). Based upon this additional finding, the Board concluded that Dr. Slevin violated of N.J.S.A. 45:1-21(e) in addition to N.J.S.A. 45:1-21(h).

While an agency is not bound by an ALJ's legal conclusions, its decision must still be supported by the record. See A.M.S. ex rel. A.D.S. v. Margate City Bd. of Ed., 409 N.J. Super. 149, 159 (App. Div. 2009). Here, the Board's additional finding that Dr. Slevin altered records is unsupported by the record.

In response to the AG's subpoenas, Dr. Slevin delegated the task of compiling medical records to his then legal counsel and office staff. Discrepancies in the completeness of the records provided the extensiveness of said records. Clarifications from Dr. Slevin regarding the exclusion and subsequent inclusion of prescriptions in the subpoena responses shed light on inadvertent errors.

In preparing the subpoena response, Dr. Slevin explained that prescriptions were either not printed due to the EMR System's ineffectiveness or were sent to counsel but did not reach the AG's office. (5T85:8 -22). He further clarified that the transmitted records were disorganized, and counsel attempted to arrange them before submitting the subpoena response. However, Dr. Slevin acknowledged the possibility that some documents might have been omitted or lost during the organization process. (5T91:21-25). Dr. Slevin took responsibility for these

omissions but wanted to clarify that these errors were not done to intentionally mislead the AG.

Dr. Slevin explained that the EMR System lacked seamless integration capabilities, necessitating a manual scanning process for documents, including prescriptions for medications, imaging, and physical therapy, laboratory reports, and other records. (4T45:11-23). Electronic prescribing was not supported by the EMR System. (4T45:16-27). Additionally, the EMR System often omitted pages when printing. (4T45:2-5).

There were times, throughout business hours, when the EMR System was offline and unavailable due to a lack of bandwidth which meant that patient records could not be accessed and updated. (4T44:24-25). Also, there were issues with the billing module and with running financial reports. (4T45:6-8). These challenges are not uncommon in the medical field. Many practitioners grapple with the limitations in these systems, experiencing occasional errors and omissions in documentation, inadvertently leading to perceptions of incomplete records. It is crucial to recognize these systemic challenges as a common concern rather than an isolated issue unique to Dr. Slevin. (7T193:24 to 194:5); Michelle Kang Kim, et al., Challenges in and Opportunities for Electronic Health Record-Based Data Analysis and Interpretation, GutandLiver.Org (2023).

Moreover, when examining the alterations made to patient records in response to the second subpoena, Dr. Slevin transparently and forthrightly testified to his intentions. His adjustments were to improve clarity and organization within the records for better comprehensibility, focusing on accurately documenting patient encounters, not concealing information. (4T54:20 to 55:11). He did this with the full awareness that the AG would review the modifications, which demonstrates that Dr. Slevin was not concealing the adjustments. (4T54:9-17).

Dr. Slevin testified that "[he] never added anything that wasn't true, or [he] never deleted anything that . . . was substantive and should have remained in the record." (5T87:17-20). In sum, the alterations were not intended to strengthen his case.

Furthermore, redactions were made by some unknown person within the AG's office. The Virtua records were not turned over to Dr. Slevin's counsel until the eve of the hearing. Thus, Dr. Slevin's counsel had no opportunity to review the redactions the AG made.

It is fair to say that the chain of custody of these records is highly questionable. It is thus impossible to say that any particular discrepancy in the two sets of records was caused by Dr. Slevin. However, none of the discrepancies were a product of intentional misconduct by Dr. Slevin as Dr. Slevin

supplemented his responses with additional records once he was aware documents were missing.

Lastly, Dr. Slevin acknowledged the oversight, he took full responsibility for the exclusion of prescriptions in responding to the first subpoena and included the prescriptions in responding to the second subpoena. (5T84:14 to 85:7). Dr. Slevin elaborated that each element of the patient record required individual printing, and some pages were unintentionally missed by the office staff. The oversight occurred possibly because not every component was verified during the printing process. (5T86:8-17).

For all of these reasons, the additional finding set forth by the Board is unsupported by the record and any such finding should be vacated.

II. Dr. Slevin's Punishment Is Disproportionate to the Offenses Found (JA4).

If the Court is not inclined to find that the Board's decision is arbitrary and capricious and unreasonable or unsupported by the record, Dr. Slevin argues in the alternative that his punishment is disproportionate the offenses found.

Moreover, as the ALJ noted in the initial decision, "the licensing board (and, on appeal, the court) determines how far beyond such deviation the conduct must be to constitute 'gross neglect' or 'gross malpractice' such that the board may suspend or revoke a license. And, in the absence of evidence that the licensee personally

participated in such conduct, the board should not suspend or revoke his license." (JA31) (emphasis added) (citing Kerlin, 151 N.J. Super. 179, 186–87 (1977)).

Additionally, in the ALJ's findings, which the Board adopted "in their entirety," it concluded that "the charges proven regarding [Dr. Slevin's] preparation of treatment records and lack thereof constitute negligence but not of a gross nature." Therefore, based upon the precedent cited by the ALJ, it was improper for Dr. Slevin's license to be suspended because 1) Dr. Slevin did not personally participate in the record keeping violations and 2) the ALJ found that his lack of record keeping was negligence "but not gross in nature."

Furthermore, in In re Polk, the Court remanded the matter to the Board because "as a matter of simple fairness . . . . [t]he record strongly suggests that the Board may have reached a fixed determination as to punishment without giving sufficient consideration to the mitigating circumstances." 90 N.J. at 579. Therefore, the Court concluded that "[a] remand [was] appropriate so that the Board can reconsider the sanction to be imposed upon Polk after giving Polk's attorney further opportunity to present information and argument material to the issue of punishment." Ibid.

Neither the ALJ nor the Board took mitigating factors into account when assessing whether Dr. Slevin's license should be suspended. Specifically, they failed to consider Dr. Slevin's previously unblemished record, as he has never been fined

or otherwise disciplined by the Board; that the alleged record-keeping violation stemmed from a clerical error rather than deliberate misconduct; and Dr. Slevin's proactive response upon discovering the error, including accepting full responsibility and promptly providing all requested documentation. These considerations should have been weighed to ensure a fair and balanced evaluation of the circumstances.

Moreover, Dr. Slevin's violation did not put patient's health, safety, or welfare at risk. In fact, Dr. Slevin was originally charged with violating N.J.S.A. 45:1-21(b), (c), (d), and (e), and N.J.S.A. 45:9-6 and the ALJ and the Board agreed that "the [AG] failed in its burden of proof to establish that [Dr. Slevin] violated professional medical standards by employing fraud and deception, gross negligence, or professional misconduct as outlined here. [Moreover, the ALJ] further conclude[d] that the Board [did] not prove that [Dr. Slevin] deviated from the standard of care and did not meet its burden of proving neglect and malpractice that would constitute gross neglect and/or gross malpractice." (JA31-76).

Thus, the Board's disciplinary sanctions are disproportionate to the offenses found because Dr. Slevin's conduct was not gross in nature, the Board failed to consider mitigating circumstances, and there was no harm to the patient's health, safety, or welfare. Kerlin, 151 N.J. Super. at 186–87; In re Polk, 90 N.J. at 579. Therefore, Dr. Slevin's license should not have been suspended.

Lastly, the Board decided to implement stiffer monetary fines without any explanation. It implemented an arbitrary monetary fine of $150,000, and increased the investigatory costs, expert fees, and/or attorneys' fees from twenty percent to fifty percent for a total assessment of $98,835. The twenty percent figure was calculated because eighty percent of the original charges brought by the AG were dismissed by the ALJ. However, the Board provided no justification for increasing the fine to fifty percent, since that figure does not correlate to any findings against Dr. Slevin. Thus, this substantial increase in not supported by the record.

Dr. Slevin therefore respectfully requests that the Court vacate the suspension of his medical license and rescind the imposed monetary penalties. In the alternative, if the Court does not vacate the suspension, it is respectfully requested that the Court remand this matter to the ALJ for further examination of the medical records that were previously overlooked.

CONCLUSION

The record on appeal does not establish that Dr. Slevin failed to comply with his record keeping obligations under N.J.S.A. 45:1-21(e) and N.J.S.A. 45:1-21(h). The only expert testimony offered at the hearings, including the testimony of the AG's own witnesses, supports the conclusion that Dr. Slevin's recording keeping practices were within the appropriate standards. Although a Board's Final Decision

is entitled to deference, appellate courts are tasked with canvassing the record to ensure the decision is supported by facts and, when a decision is not, appellate courts do not hesitate to reverse.

Here, there is no evidence to support the Board's Decision finding that Dr. Slevin altered patient records or failed to keep contemporaneous records. Moreover, when the Board ordered monetary fines and the suspension of Dr. Slevin's license, it did not take any mitigating factors into consideration, nor did it recognize that Dr. Slevin actions were not found to be grossly negligent. Therefore, Dr. Slevin's license should not have been suspended.

Dr. Slevin, therefore, respectfully submits that the decision of the Board should be reversed, and the suspension of Dr. Slevin's license should be vacated, and the monetary fines should be rescinded. In the alternative, Dr. Slevin submits that the matter be remanded to the ALJ for consideration of the materials that were overlooked at the time the ALJ issued his order.

Respectfully submitted,
MANDELBAUM BARRETT PC

Dated: January 16, 2025

By: *<u>/s/ Andrew Gimigliano</u>*
Andrew Gimigliano

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO.: A-000168-24 T4

IN THE MATTER OF

KIERAN SLEVIN, M.D.
LICENSE NO. 25MA8620600

TO PRACTICE MEDICINE
IN THE STATE OF NEW JERSEY

Administrative Action

On Appeal From a Final Order of the New Jersey State Board of Medical Examiners

Sat Below:
The New Jersey State Board of Medical Examiners

BRIEF ON BEHALF OF COMPLAINANT-RESPONDENT THE NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS

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PROCEDURAL HISTORY AND COUNTERSTATEMENT OF FACTS[1]

October 13, 2016, the State Board of Medical Examiners (the "Board") issued a document subpoena for medical records maintained by its licensee Appellant Kieran Slevin, M.D. (Ja4702).[2] The subpoena was part of an investigation into Slevin regarding his prescribing of controlled dangerous substances ("CDS").

The subpoena requested the medical records of five patients. Ibid. Four of those patients, B.C., J.W., N.P., and T.O., became the focus of the Board's investigation.[3] "Medical records" were defined in the subpoena as "each and every document that relates or refers in any way to treatment, diagnoses, prognosis, evaluations, consultations, billing or testing with regard to the test finding, medical history, including history of past substance abuse, prescriptions, imaging films and interpretations, and documents relating to TIRF REMS." Ibid.

On July 17, 2017, Respondent responded to the subpoena, certifying that the records produced were true, accurate and complete. (Ja4710). These records

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[1]Because they are closely related, the procedural history and counterstatement of facts are combined for efficiency and the court's convenience.

[2]"Ja" refers to the joint appendix submitted by the parties; "Ab" refers to Slevin's brief.

[3]Patient names are redacted pursuant to Board policy.

are referred to as set 1. (See Ja2732 to 3178).

Despite his certification, Slevin later claimed that set 1 was not in fact a complete set of records. (5T84:15 to 18).[4] Following the Board's request for any additional patient records, Slevin, on February 10, 2018, submitted a second set of records identified as set 2 (Ja126 to Ja2731). He certified that this second set of records was true, accurate and complete. (Ja4708).

A review of these sets of records, placed in evidence during the OAL hearing, shows that set 1 was incomplete despite Slevin's certification. For example, the first set of records were missing all prescriptions for Subsys. Dr. Slevin called this "an oversight". (5T85:5). A comparison of the two sets of records showed that dozens of dates of service were omitted from the first set. That included nine dates of service for T.O. that are missing from set 1 but appear in set 2; for example, a visit on 11/11/2016 appears in set 2 (Ja0275) but is absent from Set 1 (Ja2732 to Ja2858). Patient B.C.'s records are missing twenty-one dates of service from set 1 that appear in set 2; for example, a visit

[4]1T refers to the transcript dated May 22, 2023.
2T refers to the transcript dated May 23, 2023.
3T refers to the transcript dated May 25, 2023.
4T refers to the transcript dated May 31, 2023.
5T refers to the transcript dated June 1, 2023.
6T refers to the transcript dated July 31, 2023.
7T refers to the transcript dated August 1, 2023.
8T refers to the transcript dated September 11, 2024.

on 11/1/2016 appears in set 2 (Ja0747) but is absent from Set 1 (Ja3686 to Ja3837). Patient N.P.'s records are missing twelve dates of service from set 1 that appear in set 2; for example, a visit on 11/1/2016 appears in set 2 (Ja1460) but is missing from Set 1 (Ja2858 to Ja3031).

On November 23, 2020, the Attorney General filed an Administrative Complaint ("Complaint") with the New Jersey Board of Medical Examiners (the "Board") against Slevin. (Ja1). The Complaint alleged that Slevin's practice of medicine violated the standard of care through the reckless prescribing of Subsys, a unique fentanyl product known to be up to 100 times more powerful than morphine. This rapid onset fentanyl is sprayed under the tongue and rapidly absorbed into the membranes. The possible side effects of Subsys, a powerful Transmucosal Immediate Release Fentanyl ("TIRF") medication, include sedation, nausea, vomiting, respiratory and/or circulatory depression, and physical or psychological dependence. The medication also carries the risk of overdose and death. The Complaint alleged that Slevin prescribed the drug in violation of N.J.S.A. 45:1-21(c), (d), (e), and (m) when he prescribed it to the exemplar patients with no medically indicated reason, which was exacerbated by the intensive titration which occurred.

The Complaint also alleged that Slevin's records failed to meet the basic requirements of the Board as set forth in N.J.A.C. 13:35-6.5, in that he

committed a multitude of recordkeeping deficiencies.

Following discovery, Administrative Law Judge Dean Buono presided over a seven-day hearing in the OAL, spanning dates from May 22, 2023 through July 31, 2023. (Ja1).

During the OAL hearing, the Attorney General offered into evidence the two sets of records for each patient produced by Slevin. These records and other evidence including expert testimony demonstrated that Slevin's record keeping, and production to the Board during its investigation, were rife with errors, omissions and alterations.

Even in the records that were produced, Slevin admitted that pertinent information, such as assigning patients to a risk category, was not included. For example, when testifying about information he considered pertinent to his treatment of N.P., he admitted it should have been included in the patient record. (5T91:5-10).

In another example of omission, Slevin's records also failed to document communication with other doctors who were concurrently treating his patients. For example, Slevin admitted that during the entire time that she treated with Slevin, T.O. continued with her gastroenterologist Dr. Elizabeth Egan. Although he claims to have communicated with Dr. Egan, Slevin conceded that he omitted this from the patient record. (5T59:19-60:2).

In addition to producing incomplete records, and omitting critical information, a comparison of records in set 1 and set 2 *from the same date* reveal alterations. For example, Set 1 for J.W. on May 14, 2015 includes mention of Dr. Silverman. (Ja3067). Specifically,

> [J.W.] is taking Adderall 20 mg BID- Dr. Silverman prescribed in Long Island every 6-8 weeks. She is a neuropsych. She also prescribes Cymbalta & Lorazepam. [J.W.] also reports that Dr. Silverman 2 weeks ago DC's Lorazepam and prescribed Xanax 1 mg TID prn anxiety. She reports that she uses 2.5 mg per day. [J.W.] reports that she took oxycodone from 2008 prior to her last OV in March. I have a lengthy discussion with her and her husband regarding her risks of polypharmacy including the risk of respiratory arrest with self-escalation of her BDZ with opioids. I will not increase her medications today."
>
> [Ibid.]

In Set One, Dr. Slevin continued J.W. on Subsys at 600 mcg four to five times a day, #150 per month commenting, "This is controlling her pain. She will continue to take the methadone 10 mg TID for ATC coverage of her pain." Ibid. However, Set Two's records for this same visit deleted all of the Set 1 information and substituted the following:

> On 5.14 I prescribed Subsys 800 mcg 1 Sl Q4 PRN #150 – this is controlling her pain with greater success than the previous dose of 600 mcg used earlier in her treatment course. She was again instructed on the proper use of the Subsys unit and on proper disposal techniques for the unit. UDS was checked and noted to be appropriate.

[Ja2272].

Another example is found in patient N.P.'s records for March 16, 2015. (Set 1 - Ja2900, Set 2 Ja - 1356). In Set 1, Slevin maintained N.P. at 600 mcg of Subsys. In Set 2, however, the record is different and states that Slevin will change the Subsys dose from 600 mcg to 800 mcg to better control her break through pain. Ibid. This same inconsistency is found in the April 15, 2015 note. (Set 1 – Ja2905, Set 2 – Ja1361).

The reasons for the many discrepancies in what should have been the same record was revealed only during Slevin's testimony. Slevin admitted that he had altered these records, long after the treatment dates, making corrections to both sets:

> Q: Did you physically sit down at the computer and change the medical record to insert information?
>
> Dr. Slevin: I sat down and I moved things around in the medical record. I added dates. I corrected errors in the physical exam, things that I knew not to be accurate in the prior physical—I never added anything that wasn't true or I never deleted anything that, you know was substantive and should have remained in the record.
>
> . . .
>
> I accept responsibility for not having done it the correct way. I didn't know what I didn't know.
>
> [5T87:11-20; 5T89:8-10].

While the experts differed on many things, they did agree that Slevin's record keeping was inappropriate. Dr. Gharibo, the State's expert testified about a series of discrepancies between the two sets of records. (3T105:16 to 114:11). He stated that it was clear from his expert review that the two sets of records had been altered and that this occurred with multiple patients at issue in the complaint. Ibid. In his written report, which was admitted in evidence, he concluded that for each of the four patients reviewed, Slevin's record keeping was poor. (Ja4892 to Ja4920).

Even Respondent's own expert, Dr. Gudin, conceded that Slevin's records violated the Board's regulations "Medical records, are, of course, suppose to be contemporaneous. And I know there are rules and regulations about how you are suppose to edit medical records with date and timestamp and signature, for example, I cannot justify what Dr. Slevin did . . ." (7T37:23-38:3). He further admitted that Slevin's alterations do not meet the standard set out in Board regulations and "agreed to the deficiencies in the records." (Ibid.; See also 7T38:17-24; and 7T121:20-122:6).

On March 5, 2024, ALJ Buono issued an initial decision finding that the Attorney General had failed to meet its burden regarding Slevin's use of Subsys and the receipt of payments from its manufacturer and dismissed the portions of counts one to four that dealt with these issues. (Initial Decision ("ID") Ja31 to

Ja76).

But on counts one thru four, ALJ Buono found that Slevin engaged in negligence and professional misconduct with regard to his medical recordkeeping. Ibid. Based upon his review of the patient records and the expert testimony, ALJ Buono found, for each of the four patients, that "on both initial and subsequent examinations [Slevin] failed to document relevant negative findings appropriately, failed to document his rationale for the treatment he ordered, had inconsistencies in his notes, and included what appears to be cut-and pasted text from month to month without reflecting changes in dosages." (Ja60).

In reaching this conclusion, ALJ Buono noted that both experts found Slevin's records wanting. The Attorney General's expert, Dr. Gharibo, "criticized the nature of respondent's records at times, portraying them as at times cryptic, lacking in description, and inadequate to understand what had occurred in reaction to the drugs prescribed." (Ja65). The ALJ also found that Slevin's own expert, Dr. Gudin, "commented on the lack of information [in the patient records] at times. The respondent did not provide adequate representation as to why he chose to prescribe this particular medication to patients." (Ja65-Ja66).

As a penalty for the recordkeeping violation, ALJ Buono recommended suspension of Slevin's license for a period of 6 months, during which time he would take a remedial course in medical recordkeeping. (Ja68). The ALJ also recommended ordering Slevin to pay 20% of the investigatory costs, expert fees, and/or attorneys' fees expended in this matter. Ibid.

On July 10, 2024, after receiving exceptions from both parties, the Board entertained oral argument of counsel. (Ja6). Immediately following these arguments, the Board issued an oral decision on the record, indicating that a more detailed written decision would follow. Ibid.

In its oral opinion, and in the written order filed on August 13, 2024, the Board adopted the ALJ's recommended findings of fact, determinations about Slevin's repeated recordkeeping violations, and his conclusions that there was insufficient evidence to support the remaining allegations in the Complaint. (Ja15-Ja16). After its own review of the evidence, including the patient records, the Board found that the ALJ did not address the portions of count five of the Complaint, that alleged that Slevin secretly altered each of the patient records in his response to the Attorney General's discovery demands. (Ja16). The Board, believing this issue particularly significant, therefore made supplemental findings based upon the record below. Ibid.

The Board noted that,

> in reviewing each of the four patient records, we point out that Respondent's records would seemingly have had little to no utility for subsequent or concurrent treating physicians. Accurate and critical information was repeatedly absent from Respondent's medical records. . . . he needed to ensure that his records comprehensively documented the care that was being provided, and comprehensively documented the basis for prescribing as well as each patient's reactions and tolerance to prescribed Subsys. Clearly, the records failed to come anywhere close to minimally acceptable standards, and fell so far short of normative expectations that it was reasonable for ALJ Buono to conclude that those violations rose to a level that supported findings of repeated acts of negligence.
>
> [Ja20].

The Board further held, "[f]undamentally, there is no question that Respondent in fact altered records, as the two sets of records that were produced differ in significant and material respects from each other." (Ja16). It observed that Slevin's goals in altering the records were obvious, as "[n]one of the changes made by Dr. Slevin were identified, dated and initialed, which we take as a clear manifestation of an intent to alter the records without making the alteration visible to anyone reading the records." Ibid. Thus, the Board supplemented the I.D. to find,

> Respondent altered each of the four patient records. Respondent, a medical educator, knew or should have known after his many years of education, training, and practice of medicine how to properly amend a record.

> We therefore find that, when responding to the AG's supplemental subpoena, Respondent altered each of the four patient records, that the alterations were made in a manner inconsistent with regulatory requirements, and that the alterations were, in each instance, intentional and material. For those reasons, we also amend the conclusions in the ID to add determinations that additional bases for disciplinary sanctions against Respondent exist pursuant to N.J.S.A. 45:1-21(h) [based on his having altered each of the four patient records in a manner in violation of N.J.A.C. 13:35-6.2(b)(2)] and pursuant to N.J.S.A. 45:1-21(e) [based on his having engaged in professional misconduct in each instance when he intentionally and materially altered the four patient records].
>
> [Ja16-Ja17].

After the ruling on liability, the Board held a mitigation hearing on penalty on the same day. (Ja21). It considered oral arguments from both parties and testimony from Slevin. Ibid. After additional deliberations, the Board announced its oral decision to Slevin. The Board informed Slevin that while the seriousness of his misconduct could justify a longer suspension from practice, it would adopt the ALJ's recommended discipline and impose a six-month active suspension of his medical license.[5] (Ja23). To allow for the orderly transfer of Slevin's patients, the Board granted Slevin a 45-day wind-down period, from the date of its oral decision on July 10, 2024. (Ja24). As a result, the active

[5]Slevin has served this term of suspension and returned to the active practice of medicine in New Jersey.

suspension of Slevin's license began on August 25, 2024. Ibid.

The Board also imposed a civil penalty in the amount of $150,000 pursuant to N.J.S.A. 45:1-25, and ordered that upon his return to practice, Slevin will be subject to independent monitoring for a minimum of one year. (Ja26). Lastly, in light of its supplemental findings, the Board increased the ALJ's imposition of costs from twenty percent to fifty percent of the total costs incurred. Ibid. Slevin was thus assessed $96,835 in costs. (Ja27).

Slevin filed a motion for reconsideration and a stay with the Board on August 20, 2024, five days before his active suspension was to go into effect. (Ja5542). On August 23, 2024, the Board issued a written order denying the motion for a stay, finding that Slevin had not satisfied the requirements for a stay – there was no demonstration of irreparable harm, no likelihood of success of the merits of the appeal, and the balancing of the equities did not favor a stay. Therefore, as of August 25, 2024, Slevin's license to practice medicine in New Jersey was suspended.

On August 28, 2024, Slevin sought leave of this court to file an emergent motion on short notice to stay the Board's final decision, which was denied the same day. Slevin then submitted a motion for a stay to this court on September 30, 2024. That motion was denied on October 17, 2024.

This appeal followed.

ARGUMENT

POINT I

THE BOARD'S DECISION ON LIABILITY SHOULD BE AFFIRMED BECAUSE IT IS SUPPORTED BY THE CREDIBLE EVIDENCE IN THE RECORD AND IS NOT ARBITRARY, CAPRICIOUS OR UNREASONABLE.

The Board's determination that Slevin violated N.J.S.A. 45:1-21(h) and N.J.S.A. 45:1-21(e) was reasonable because it was based upon the undisputed evidence in the record that Slevin's record keeping was sloppy; he did not produce a complete record in response to a Board subpoena; and that he extensively and improperly altered the patient records that were ultimately produced to the Board. As the Board's decision was amply supported by the evidence in the record it should be affirmed.

An agency decision must be affirmed unless it is arbitrary, capricious, or unreasonable, or not supported by substantial credible evidence in the record as a whole. In re Stallworth, 208 N.J. 182, 194 (2011) (internal citations omitted). A "reviewing court may not substitute its own judgment for the agency's even though the court might have reached a different result." Ibid. This deference is appropriate "because of the expertise and superior knowledge of agencies in their specialized field." In re Zahl, 186 N.J. 341, 353 (2006).

Given the critical importance of patient records, the Board has promulgated specific regulations for how they must be maintained. Under N.J.A.C. 13:35-6.5(b), "Licensees shall prepare contemporaneous, permanent professional treatment records. . . All treatment records . . . shall accurately reflect the treatment or services rendered." These regulations also set forth in detail what should be contained in a patient record including a progress note, orders for tests and medical impressions. Ibid. While a physician may correct a patient record when necessary, the regulations clearly state "[c]orrections/additions to an existing record can be made, provided that each change is clearly identified as such, dated and initialed by the licensee." N.J.A.C. 13:35-6.5(b)(2).

Recognizing that unlike handwritten records, electronic records are vulnerable to clandestine modification, the Board's regulations also set forth specific requirements for their use. Here the regulations require that the physician entries be contemporaries with the treatment rendered and that the system used contain an internally activated date and time recording feature. N.J.A.C. 13:35-6.5(b)(3). Electronic records must "be designed in such manner that, after "signing" by means of the CPC, the existing entry cannot be changed in any manner." Id. at 13:35-6.5(b)(3)(v). And while a physician may subsequently modify or change a prior entry, that change must be in the form of

a new entry with its own date and time. Ibid. The record below demonstrates that Slevin failed to adhere to these standards in a host of ways.

As detailed above, Slevin's record keeping violations took three forms. First, Slevin's admissions and the testimony of the experts agreed that he failed to include pertinent information. For example, when testifying about information he considered pertinent to his treatment of N.P., Slevin admitted it should have been included in the patient record. (5T91:5-10). Also, in the records for T.O., he admitted that he failed to document communication with other physicians. (5T59:19-60:2).

Second, Slevin's production of the first set of records, which he certified to be accurate and complete, were in fact missing numerous records that then appeared in set 2. Despite the many additional documents in set 2, Slevin told no one about the dozens of omissions from set 1.

Finally, and most egregiously, Respondent admitted that he altered his records, years after the treatment was rendered. He did so without indicating changes as required by the Board's regulations. And because he altered these electronic records, it showed that the records were not locked to prevent subsequent alteration, also required by the regulations related to electronic records. The Board found that each of the patient records had been extensively altered. (Ja16). Respondent, who also serves as a medical educator, should have

known how to amend a patient record. Ibid. His failure to properly do so was intentional and material. Ibid.

This misconduct by Slevin is on its face is a clear violation of the standards for record keeping set forth in the Board's regulations. Moreover, his omissions and alterations render the entire patient record for each of the four patients fundamentally unreliable. For these reasons, the Board's conclusion that Slevin engaged in repeated acts of negligence, professional misconduct and violations of the record keeping regulations (N.J.A.C. 13:35-6.5) in violation of N.J.S.A. 45:1-21(d),(e) and (h) was reasonable, supported by the record, and should be affirmed.

In his appeal, Slevin claims that the Board and the ALJ did not sufficiently review the patient records and did not reference the standards applied. (Ab15-Ab19). Slevin then cherry picked certain patient visits for which he did provide appropriate detail. Ibid. However, the Board did not review only a few records but "the entire record, the ID, exceptions filed thereafter, and consideration of oral argument of counsel." (Ja3). The Board then used its collective medical expertise to find that Slevin's record keeping violations were in plain violation of its record keeping regulations. The fact that Slevin can point to some records that are complete does not alter the Board's finding that numerous records

contained alterations and omissions such that his records did not "accurately reflect the treatment or services rendered." N.J.A.C. 13:35-6.5(b)

Slevin also takes issue with the Board's finding that "Respondent's records fail to adequately detail 'why' he chose to prescribe Subsys to each of the four patients, and similarly fail to document 'how' each patient reacted to taking Subsys," (Ja20), claiming that such a level of detail is not required. He is wrong. The plain language of the regulations require detailed information about the treatment rendered and medical impressions for every patient encounter. N.J.A.C. 13:35-6.5.

And while Slevin argues that the Board ignored his expert's testimony that not every patient encounter needs to be recorded in the medical records, that is not accurate. Rather, the Board, relying on its members' collective expertise as physicians, independently reviewed each of the four patient records and concluded that for each of the exemplar patients, Slevin's records would be of little use as they were missing critical information. (Ja20). That was particularly significant as Slevin was prescribing a fast acting formulation of fentanyl that brought with it significant risks for patient harm. Ibid. This court should defer to the Board in this exercise of its medical expertise.

Slevin also claims that the experts found his records to be sufficient. But the opposite is true. The Board specifically found that both the Attorney

General's expert, Dr. Gharibo, and Slevin's expert, Dr. Gudin, opined that the records lacked detail at times. (Ja20 at Fn. 7). Dr. Gharibo testified about a series of discrepancies between the two sets of records. (3T105:16 to 114:11). He concluded, based on his expert review, that the two sets of records had been altered and that this occurred with multiple patients at issue in the complaint. Ibid. Even Respondent's own expert, Dr. Gudin, could not justify these amendments to the record: "I cannot justify what Dr. Slevin did. I would turn back to his testimony to look for his justification as to why the records were amended to add what he felt were important details." (7T38:3-6). He further admitted that Slevin's alterations do not meet the standard set out in Board regulations adding "clearly**,** I have agreed to the deficiencies in the records." (7T121:20-122:6).

The Board's final decision reflects its unique expertise on the practice of medicine and appropriate medical record keeping. The record below contains ample evidence to support these findings. As such, this court should not disturb the Board's well-reasoned findings on liability.

POINT II

THE PENALTIES WERE IMPOSED AFTER CONSIDERING MITIGATION AND ARE FAIR GIVEN THE SIGNIFICANT RECORD KEEPING VIOLATIONS.

Given the many record keeping violations proven by the Attorney General, the Board's imposition of a short suspension, a monetary penalty and costs was reasonable and should be affirmed.

In reviewing sanctions imposed by an agency, the court should uphold the penalty unless the punishment "is so disproportionate to the offence, in light of all the circumstances, as to be shocking to one's sense of fairness." In re Zahl, 186 N.J. at 354; see also In re Hermann, 192 N.J. at 29. Courts will set aside an administrative sanction only when the court is "satisfied that the agency has mistakenly exercised its discretion or misperceived its own statutory authority." In re Polk, 90 N.J. 550, 578 (1982) (internal citations omitted); see also Matter of Hendrickson, 235 N.J. 145, 158-59 (2018) (quoting Hermann, 192 N.J. at 28). This standard "gives the agency a wide berth of discretion" and "[o]nly a patently unreasonable sanction would call for the appellate court's intervention." Ibid.

After adopting with modification, the I.D., the Board held a separate mitigation hearing at which Slevin presented testimony, written evidence, and

legal argument. (Ja21-Ja22). After considering this mitigation evidence, separate and apart from liability, the Board decides on the appropriate penalty.

Slevin attempts to mitigate his behavior by claiming that the extensive alterations he made to his records did not result in patient harm and were someone else's fault (his staff, his prior counsel and even the Attorney General). (Ja21). But the Board rejected these excuses, stating unequivocally that he alone bears the responsibility for his transgressions. Slevin's decision making, in particularly the "deliberative actions he took to change the records" are solely the result of his flawed decision making. Ibid.

Each case before the Board is unique and is treated as such. Here, the Board found that Slevin's record keeping deviated from the standard of care and its long standing regulations. Specifically, the Board used its collective expertise to find that Slevin's record keeping violations included alterations and omissions that were "substantial and pervasive" (Ja25).

The Board imposed a six month active suspension from practice. It noted that while the nature of Slevin's conduct could have justified a longer active suspension, it would accept the ALJ's recommendation even though the Board made additional findings. (Ja23). In imposing this active suspension from practice, the Board found that Slevin's "intentional, material, and repeated acts of altering all four patient records, which we find to constitute professional

misconduct, warrants significant sanctions." Ibid. The Board further found that such a suspension from practice "is an appropriately measured penalty for the violations established." Ibid.

As to the civil monetary penalty, the amount chosen by the Board was well within statutory limits. The Board found that the content and omissions of Slevin's records violated the Board's regulations under N.J.S.A. 45:1-21(h). Further, his many alterations of the patient records were found to be professional misconduct under N.J.S.A. 45:1-21(e). (Ja17). As this finding was not made by ALJ Buono, an increase of the penalty imposed was warranted. Ibid.

Under N.J.S.A. 45:1-25, the Board can impose a $10,000 penalty for the first violation and $20,000 for each subsequent violation. This statute specifies that "each act in violation of any regulation or statute administered by the Board shall constitute a separate violation." Thus, the Board could have counted each alteration or omission as a separate violation and imposed a penalty every time. For example, if one patient's record contained 10 omissions and 10 alterations, the Board could have counted each violation separately (20 violations) and imposed a penalty of $390,000 for just this one patient. (1 violation @ $10,000 + 19 violations @ $20,000 each.)

The Board, however, took a much more measured approach counting violations per patient not per occurrence. In calculating a monetary penalty, the

Board apportioned only two violations per patient (professional misconduct & record keeping).. Ibid. The total amount imposed for the first patient was $30,000 ($10,000 for an initial violation and $20,000 for a subsequent violation) and for each of the three other patients $40,000 (two penalties of $20,000 each for subsequent violations). Ibid. The total penalty imposed using this method was $150,000. This amount is significantly lower than the statute authorizes and amply supported by the record below.

Finally, under N.J.S.A. 45:1-25(d), when a violation is found, the Board is empowered to order payment of all costs, "including, but not limited to, costs of investigation, expert witness fees and costs, attorney fees and costs, and transcript cost." As record keeping violations were found the Board had the discretion to impose the payment of all costs. Recognizing that portions of the allegations against Slevin were not proven, the Board used its discretion and reduced the costs sought, $193,670, by 50% to $96,835. (Ja27). Given that the statute permitted imposition of all costs, this reduction was reasonable and should be affirmed.

The Board's role to protect the health, safety, and welfare of the public, is "paramount to the rights of the individual practitioner claiming the privilege to pursue his or her medical profession." Polk, 90 N.J. at 566. The Board here crafted a sanction that reflects a fair and reasoned assessment of Slevin's

conduct in light of the harm and/or potential harm to his patients and to the public interest.

CONCLUSION

For these reasons, the Board's decision should be affirmed.

Respectfully submitted,

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IN THE MATTER OF THE SUSPENSION OR REVOCATION OF THE LICENSE OF KIERAN SLEVIN, M.D. LICENSE NO. 25MA8620600 TO PRACTICE MEDICINE AND SURGERY IN THE STATE OF NEW JERSEY	SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION, Docket No. A-000168-24 Civil Action On Appeal From: State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, State Board of Medical Examiners OAL Docket No. 05046-21 Sat Below: Hon. Dean Buono, A.L.J.

REPLY BRIEF OF APPELLANT

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PRELIMINARY STATEMENT

The Attorney General ("AG") seeks to portray Appellant, Kieran A. Slevin, M.D. ("Dr. Slevin"), as a careless and inattentive physician. However, this characterization is both inaccurate and unsupported by the record.

Like many dedicated medical professionals, Dr. Slevin encountered significant administrative challenges—particularly with his electronic medical records system, OmniMD (the "EMR System").

While designed to streamline healthcare operations by assisting providers with patient records, billing, and scheduling, the EMR System, in practice, created substantial obstacles that hindered Dr. Slevin's ability to efficiently manage his practice. Despite these systemic issues, the AG failed to acknowledge the burdens imposed by this flawed technology, instead unjustly attributing its shortcomings to Dr. Slevin's professional conduct.

Furthermore, when Dr. Slevin recognized the shortcomings of the EMR System he attempted to supplement his patient records to ensure that they were complete and accurate. Dr. Slevin made an additional production of records to the AG and was upfront and honest regarding these amendments. Nevertheless, the State Board of Medical Examiners (the "Board"), grasping at any potential liability attributable to Dr. Slevin, and without supporting evidence, found these amendments to be intentional and material. Worse, based on the findings by the

administrative law judge ("ALJ") and the Board, neither the AG, the ALJ, nor the Board appear to have reviewed the supplemental record production.

Lastly, when attempting to justify the penalty imposed by the Board, the AG points only to the statutory maximums that the Board *could* impose rather than addressing the arguments that Dr. Slevin's conduct was not gross in nature. The Board, therefore, failed to consider mitigating circumstances, or that there was no harm to the patient's health, safety, or welfare.

Dr. Slevin, therefore, respectfully asks this Court to reverse the Board's decision. In the alternative, Dr. Slevin asks that the matter be remanded to the ALJ for consideration of the materials that were overlooked at the time the ALJ issued his order.

LEGAL ARGUMENT

I. The Board's Decision Is Arbitrary, Capricious, and Unreasonable and Not Supported by the Record (JA4).

A. Slevin's corrections to the record.

The AG harps on the fact that Dr. Slevin "admitted that he altered his records." (Rb15). However, Dr. Slevin does not deny that the patient records were corrected, and, in fact, Dr. Slevin was upfront and honest regarding any and all corrections made. (4T54:20 to 55:11). What Dr. Slevin is arguing, and the AG failed to address, is that the Board, without any proof, concluded that the alleged alterations were "intentional and material" and in violation of N.J.A.C. 13:35-6.5(b)(2). (JA4).

Dr. Slevin made the corrections knowing that the AG would review the modifications, which demonstrates that Dr. Slevin was not concealing the adjustments. (4T54:9-17). Dr. Slevin testified that "[he] never added anything that wasn't true, or [he] never deleted anything that . . . was substantive and should have remained in the record." (5T87:17-20). In sum, the corrections were not intended to strengthen Dr. Slevin's case and were neither intentional nor material.

Additionally, the AG failed to address Dr. Slevin's chain-of-custody argument regarding the Virtua records that Dr. Slevin provided to the AG's office prior to the ALJ hearing. As previously stated, an unknown person presumably within the AG's office redacted those records at some point after Dr. Slevin provided them to the AG's office and the hearing before the ALJ. The AG's office did not return the redacted Virtua records to Dr. Slevin's counsel until the eve of the hearing. Thus, Dr. Slevin's counsel had no opportunity to review the AG's redactions. Nevertheless, the AG failed to acknowledge this chain-of-custody issue and instead makes sweeping statements about alterations to the medical records that are not supported by the record below.

B. Dr. Slevin adequately detailed the "why" and "how" in his patient records.

Dr. Slevin argued that the Board's contention that Dr. Slevin's records violated the Medical Records regulation overlooked the extensive documentation of why Dr. Slevin prescribed Subsys and how the patients responded. Specific

examples of that documentation were recounted, and numerous records admitted into evidence demonstrating that documentation are in the joint appendix. (See JA1305, 2224, 2757, 4909; See generally JA126-2857).

In response to Dr. Slevin's arguments, the AG ignored the documentation, making broad statements about how the Board reviewed the entire record in rendering its decision. The problem with this argument, as with the Board's finding of inadequacy, is that it never identifies what omissions existed. Although the AG quoted the Board when it stated it reviewed "the entire record," the record shows that this was not the case. (JA3). The record contains numerous explanations of why Dr. Slevin prescribed Subsys and documentation of how the patients reacted to taking the medication—all contained in his medical records. (See JA126-2857). Both the ALJ and the Board failed to adequately review these records, and, because of this failure, the Board wrongfully adopted the ALJ's decision.

Additionally, the Court should note that while the AG claimed there were missing documents, Dr. Slevin submitted two different productions. Based on the findings by the ALJ and the Board, those documents could not have been reviewed by the AG, ALJ, or the Board due to the AG's disorganized presentation. Certain records were left out of the binders that the AG provided to the ALJ and the redactions to the documents within those binders were made by some unknown

person with the AG's office. Worse yet, the binders were not turned over to Dr. Slevin's counsel until the eve of the hearing.

It is fundamental that in deciding a case, an agency such as the Board must provide the facts that support its conclusion of wrongdoing. State Department of Health v. Tegnazian, 194 N.J. Super. 435, 450-451 (App. Div. 1984); Application of Holy Name Hospital, 301 N.J. Super. 282, 292 (App. Div. 1997) (stating agency must find the facts and "provide notice of those facts to all interested parties").

Simply stating that medical records are inadequate without providing the factual underpinning for that alleged omission is insufficient. And, indeed, in this case, the alleged deficiency did not exist as is proved by the numerous records cited to in the record.

Additionally, the AG mischaracterizes Dr. Slevin's argument regarding the level of detail needed for the patient records pursuant to N.J.A.C. 13:35-6.5(b). Dr. Slevin is not arguing that the records should not be detailed. Rather, Dr. Slevin argues that the level of detail required is not delineated within the statute, and the AG failed to present evidence as to the standard of proof and the detail that must be provided.

The only expert testimony on this subject was offered by Dr. Slevin's expert, Dr. Gudin. He explained that not every encounter finds its way into the medical record. (7T155:10-14). He cited examples of those types of encounters, such as

phone calls between visits, patients raising issues related to prescriptions, and lab reports which sometimes arrive when the record is not available. (7T193:24 to 194:5).

Additionally, while the AG attempts to cherry pick and couch Dr. Gudin's testimony to portray it in support of the AG's position, this is not accurate. For example, when the AG asked Dr. Gudin: "the regulations says contemporaneous, permanent professional treatment records. These records do not meet that standard, do they?" Dr. Gudin responded: "The way you portrayed the records, they do not." (7T38:17-24).

Lastly, to the extent the AG wanted to prove a case based on insufficient detail, it was obligated to present a standard through documentary evidence or expert testimony. The AG has done neither. Thus, the Board's conclusion that Dr. Slevin failed to "adequately detail" the "why and "how" is arbitrary and capricious because no standard to make that determination was set forth by statue or by expert testimony. The AG cannot discipline a physician based on unexpressed rules.

II. Dr. Slevin's Punishment Is Disproportionate to the Offenses Found (JA4).

Dr. Slevin argues that without a finding of gross negligence or gross malpractice, Dr. Slevin's license should not have been suspended. Once again, the AG failed to address Dr. Slevin's argument. In the ALJ's findings, which the Board adopted "in their entirety," he concluded that "the charges proven regarding [Dr.

Slevin's] preparation of treatment records and lack thereof constitute negligence but not of a gross nature." Therefore, based upon the precedent cited by the ALJ, In Re Suspension or Revoc. License of Kerlin, 151 N.J. Super. 179, 186–87 (1977), Dr. Slevin's license should have been suspended because 1) Dr. Slevin did not personally participate in the record keeping violations and 2) the ALJ found that his lack of record keeping was negligence "but not gross in nature."

Instead of addressing the issue above, the AG chose to focus on the monetary penalties that the Board *could* impose based upon the statute. However, the monetary penalties imposed by the Board are also unsupported by the record as the Board provided no justification for increasing the fine by fifty percent, since that figure does not correlate to any findings against Dr. Slevin. Thus, the substantial increase of the fine is not supported by the record. Additionally, Dr. Slevin should not have to bear the extra expense of the AG's unorganized and failed investigation. That burden should fall upon the AG.

Although the AG states that Dr. Slevin has not taken responsibility for making corrections to the record, this, again, is inaccurate. Dr. Slevin provided explanations about how the events transpired and took full responsibility. Dr. Slevin took has been forthright and truthful regarding all corrections made to the records. (5T84:14 to 85:7).

Lastly, the AG argues that the Board "took a much more measured approach." However, the Board's approach was not measured because it failed to take mitigating factors into account when assessing whether Dr. Slevin's license should be suspended. Specifically, it failed to consider Dr. Slevin's previously unblemished record, as he has never been fined or otherwise disciplined by the Board; that the alleged record-keeping violation stemmed from a clerical error rather than deliberate misconduct; and Dr. Slevin's proactive response upon discovering the error, including accepting full responsibility and promptly providing all requested documentation. These considerations should have been weighed to ensure a fair and balanced evaluation of the circumstances.

CONCLUSION

The record on appeal does not establish that Dr. Slevin failed to comply with his record keeping obligations under N.J.S.A. 45:1-21(e) and N.J.S.A. 45:1-21(h). Dr. Slevin, therefore, respectfully submits that the decision of the Board should be reversed, and the suspension of Dr. Slevin's license should be vacated, and the monetary fines should be rescinded. In the alternative, Dr. Slevin submits that the matter be remanded to the ALJ for consideration of the materials that were overlooked at the time the ALJ issued his order.

Respectfully submitted,
MANDELBAUM BARRETT PC

Dated: April 14, 2025

By: */s/ Andrew Gimigliano*
Andrew Gimigliano