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IN THE SUPREME COURT OF THE STATE OF DELAWARE

DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE Appellee Below, Appellant/ Cross-Appellee.	)	No. 53,2019
v.	)	On Interlocutory Appeal from: The Superior Court of the State of Delaware C.A. No. N16A-11-001 JAP
BRUCE GROSSINGER, D.O. Appellant Below, Appellee/ Cross-Appellant.	)	Trial Court: Delaware Board of Medical Licensure and Discipline Case No. 10-168-14

APPELLANT DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE'S REPLY BRIEF ON APPEAL AND CROSS-APPELLEE'S ANSWERING BRIEF ON CROSS-APPEAL

STATE OF DELAWARE
DEPARTMENT OF JUSTICE

Zoe Plerhoples, I.D. No. 5415
Patricia A. Davis, I.D. No. 3857
Deputy Attorneys General
820 North French Street, 6th Floor
Wilmington, Delaware 19801
(302) 577-8368
Zoe.plerhoples@delaware.gov
PatriciaA.davis@delaware.gov
Attorneys for Appellant/Cross-Appellee, Board of Medical Licensure and Discipline

Dated: August 2, 2019

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SUMMARY OF ARGUMENT ON CROSS-APPEAL

I. *Denied*. Substantial evidence exists in the record to support a violation of Board Regulation 18.3 based on the evidence submitted at the hearing.

ARGUMENT

I. THE BOARD DID NOT CREATE EVIDENCE OUTSIDE OF THE RECORD AND DID NOT DEPRIVE DR. GROSSSINGER OF HIS DUE PROCESS RIGHTS.

A. Question Presented

Did the Board deny Dr. Grossinger due process by considering the factual record in light of its own duly promulgated regulations to determine Dr. Grossinger's record keeping did not meet the requirements? This question was not fully briefed below, as the Superior Court raised it *sua sponte* in correspondence preceding oral arguments[1]; and the interests of justice exception to Supreme Court Rule 8 is applicable.

B. Scope of Review

This Court reviews a Superior Court ruling that, in turn, has reviewed a ruling of an administrative body by directly examining the Board's decision to determine whether the decision is supported by substantial evidence and is free from legal error.[2] Questions of law are reviewed *de novo*.[3] In determining whether substantial evidence supports the agency decision, the Court "shall take due account of the experience and specialized competence…" of the Board, and the purpose of the law

[1] (A415).
[2] *Del. Dep't. of Health & Soc. Servs. v. Jain*, 29 A.3d 207, 211 (Del. 2011).
[3] *Prunckun v. Del. Dep't. of Health & Soc. Servs.*, 201 A.3d 525, 540 (Del. 2019).

under which the Board acted,[4] recognizing that the Board has the necessary expertise to determine violations based upon the factual record alone and it does not need expert testimony to establish standards of care.[5]

C. Merits of Argument

The Board did not deny Dr. Grossinger due process by finding that his record keeping did not meet the requirement of its regulations, nor did it create evidence outside of the record. A professional Board evaluating a licensee's conduct in light of the requirements of its regulations is not creating evidence; it is applying the governing law to the facts presented. The evidence in this case came from Dr. Grossinger's own treatment records. The Board's Regulation 18 plainly states that when prescribing controlled substances for the use of chronic pain, a patient's medical record must include documentation of a medical history and physical examination documenting the etiology, nature and intensity of the patient's pain, the patient's current and past treatments for pain, the patient's underlying or coexisting diseases or conditions, the effect of the pain on the patient's physical and psychological function, any history of substance abuse, the presence of one or more recognized medical indications for the use of a controlled substance (Rule 18.1); a

[4] 29 *Del. C.* § 10142(d).
[5] *Bilski v. Del. Bd. of Med. Lic. & Discipline*, 2014 WL 3032703 (Del. Super. Jun. 30, 2014); *aff'd* 115 A.3d 1214 (Table) (Del. 2015).

written agreement that the practitioner "must use" that outlines patient responsibilities including submitting to urine drug screens "when requested" (Rule 18.4); documented periodic reviews to include any new information about the etiology of the pain or the treatment goals and objectives, an indication of whether the treatment modality is improving function, and the appropriateness of the continued use of controlled substances (Rules 18.5 & 18.7). The evidence submitted made clear, and Dr. Grossinger does not dispute, at the time he provided prescriptions to patient Michael, all of this information was not documented in patient Michael's file. Evidence of "standard of care" was not created by the Board, as the Answering brief insists. Rather, the Board's rules spell out what documentation is required and Dr. Grossinger's medical file does not contain this documentation. Due process was not violated.

Due process in the administrative hearing context requires "the opportunity to be heard, by … testimony or otherwise, and the right to controvert, by proof every material fact which bears on the question of right in the matter involved in an orderly proceeding appropriate to the nature of the hearing and adapted to meet its ends."[6] Here, Dr. Grossinger was well aware of what was, and what was not, in his treatment records for patient Michael. Dr. Grossinger did not believe the law and regulations applied to him, but the Board did not introduce or consider any "expert testimony"

[6] *Vincent v. E. Shore Mkts.*, 970 A.2d 160, 164 (Del. 2009)

that Dr. Grossinger was not able to respond to if he so chose.

Both the Superior Court and Dr. Grossinger presume without cause that there was missing evidence, that the Board somehow created "expert evidence" during its deliberative process, relied on that evidence to meet its decision, and that was fundamentally "unfair" to Respondent. It is unclear what evidence the Board purportedly created as the Board's Order does not cite any evidence not presented by either party. The Superior Court cites the created evidence as "standard of care" evidence and in doing so, improperly conflates the requirements of a tortious malpractice action with this license disciplinary case.[7] Administrative due process has never required "standard of care" evidence, as is used in a malpractice action, to prove conduct inconsistent with licensing laws. Dr. Grossinger may not agree that the requirements of Rule 18 are necessary or important, but his personal belief does not equate to a requirement that the State prove the efficacy of the regulation by expert testimony.

Dr. Grossinger's discipline arises out of his prescribing controlled substances to patient Michael despite the lack of required documentation in his medical records. Dr. Grossinger asserts that the State was required to present expert testimony to establish that he violated the Board Regulations alleged in the Complaint. This directly contravenes the governing statutes and the settled precedent in this area of

[7] Ex. A at 36-37.

the law. The Administrative Procedures Act requires that "[a reviewing court] when factual determinations are at issue, shall take due account of the experience and specialized competence of the agency and of the purposes of the basic law under which the agency has acted."[8] Delaware Courts considering this issue have consistently held that an agency or Board may use its institutional expertise to evaluate evidence,[9] including a determination as to whether a licensee's conduct violates its laws.[10]

Dr. Grossinger's Answering Brief makes much ado of counsel's statement below that the regulations cannot outline "every factual scenario for treatment of a patient." Answ. Br, at 15. It completely subverts the entire licensing system's underlying expectation that professionals possess a certain competence within their field to posit that every treatment decision possible with every patient must be outlined in the Board's regulations or no licensee may ever be disciplined. The

[8] 29 *Del. C.* § 10142(d). In this case, the Board acts under its statutory directives to "protect the public, specifically those persons who are the direct recipients of services," and "to maintain minimum standards of licensee competency." *See* 24 *Del. C.* § 3001(a),(b).

[9] *Olney v. Cooch*, 425 A.2d 610, 614 (Del. 1981); *Turbitt v. Blue Hens Lines, Inc.*, 711 A.2d 1214, 1215 (Del. 1998). Dr. Grossinger relies extensively on the *Turbitt* case while ignoring one of the central holdings of that case: "whatever 'institutional experience' or administrative expertise the Board possesses *may be used as a tool for evaluating evidence*, but not as a source for creating evidence." *Id.* at 1216.

[10] *See e.g., Jain v. Delaware Board of Nursing*, 2013 WL 3389287 (Del. Super. Feb. 13, 2013) *aff'd* 72 A.3d 501 (Del. 2013); *Frazer v. Delaware Board of Nursing*, 2016 WL 6610320 at *3-4 (Del. Super. Nov. 9, 2016);

Board evaluates licensees' conduct in light of the requirements of the profession. The Board is comprised of professional members familiar with the vernacular and practice of medicine in order to evaluate whether a licensee's behavior rises to the level of violating the statutory or regulatory requirements of the Board. However, it is not the case that here such institutional knowledge was even required. Rule 18 is the most detailed rule of the Board, and the plain language of the rule includes numerous mandatory requirements for documenting patient files.[11] The simple fact is that these requirements were not met. The expectation of physician competence within the Board's rules does not make them unconstitutionally vague as applied absent expert testimony, nor would expert testimony have changed the level of notice to Respondent.[12]

Dr. Grossinger's reliance on cases from the state courts of New Jersey and Pennsylvania is reliance misplaced. Dr. Grossinger cites *New Jersey Bd. of Optometrists v. Nemitz*, 90 A.2d 740 (N.J. Super. 1952) for the proposition that a board of experts cannot be silent witnesses as well as judge. In *Nemitz*, the New

[11]For example, 18.1 states the "following criteria *must* be used when evaluating the treatment of chronic pain." 18.7 specifies what the medical record *must* include, 18.1.1 specifies what the evaluation *must* document; 18.5 specifies a practitioner *shall* periodically review the course of pain treatment; the agreement for treatment in Rule 18.4 *must* be used "if a patient is at high risk for medication abuse."

[12] Respondent argued forcefully in the administrative hearing that Rule 18 was not the law, did not apply to him, and did not apply to his prescribing to Michael. Rule 18 has applied to Dr. Grossinger, and all Delaware licensed doctors, since 2012.

Jersey Court found that a very slight variance in the lens of an eyeglass was not enough for that Board to find gross incompetence in the practice of optometry absent some evidence that the variance was not within the "standard of tolerance." *Nemitz*, 90 A.2d at 745. However, the New Jersey court recognized that the board members' "value as experts in the judging process contemplated by the statutory disciplinary proceeding, consists in the application of their special knowledge to the factual controversy appearing within the record made at the hearing." *Id*. Here, Dr. Grossinger argues that he could not have possibly known how frequently he was supposed to require his patient to obtain a urine drug screen because there was no "standard of care" evidence submitted by the State. Answ. Br. at 36. However, Dr. Grossinger's own practice signed a pain management contract with patient Michael, pledging to stop prescribing controlled substances if urine drug screen requests were not complied with.[13] Michael was ordered to submit for a urine drug screen in June of 2014.[14] He refused, and Dr. Grossinger wrote him a prescription for controlled substances anyway.[15] The Board did not require silent expert witness testimony on the standard of care to determine that Dr. Grossinger's flagrant disregard for the terms of the pain management contract his own firm utilized was a failure to "use" that pain management contract in violation of Rule 18.4 and a failure to "require"

[13] A170, 209-210, 282-283, 324-325
[14] A43-45, 287
[15] A154-259, 278

urine drug screens in violation of Rule 18.4.1.

The Pennsylvania case cited by Dr. Grossinger is similarly unhelpful to his argument. Dr. Grossinger provides a single quote from *Lyness v. Commonwealth of Pennsylvania*, 605 A.2d 1204 (Pa. Super. 1992): "commingling of prosecutorial and adjudicative functions within a single multi-member administrative board . . . is not consistent with the notion of due process . . . ." Answ. Br. at 20-21. In *Lyness*, the issue was whether an administrative Board could both institute a disciplinary case after determining probable cause exists, and then hear the case at the resultant disciplinary hearing. Contrary to the assertion of Dr. Grossinger, the Pennsylvania Court was not opining on the board members' use of expertise in analyzing facts during a hearing. Rather, that Court held the due process violation was that the Board would "wear the hat of the prosecutor and make the determination that probable cause exists to bring formal charges; and then the same board—with a number of members identical—later wears the robe of the judge to make a presumably impartial adjudication which will determine the fate of a physician's license to practice medicine in this Commonwealth." *Lyness*, 605 A.2d at 1208. Here, Dr. Grossinger was investigated by the Division of Professional Regulations, prosecuted by the Department of Justice, and a violation of the rules was found by the Board of Medical Licensure and Discipline. There is no credible claim of commingling of prosecutorial and adjudicative roles.

Dr. Grossinger did not *create even one record* documenting his treatment and prescribing to Michael; he simply signed prescriptions for controlled drugs and admitted the same in his testimony.[16] In this case, the lack of records justifying his prescriptions for potent narcotics is the evidence evaluated by the Board. There was no silent expert testimony considered by the Board. The fact that some of the Board's rules and regulations do not impose the same detailed or specific requirements as others does not mean that the regulations are vague, or that they require expert evidence to prove a violation. It means that medical care or medical practice in some cases may be strictly delineated and prescribed, and in some cases, a practitioner will be confronted with patient care that requires a more nuanced approach, which they are expected to be able to give while complying with the basic tenets of the law. The Preamble language to Rule 18 does not impose a requirement that the Board have expert testimony to prove a violation, it imposes a requirement that physicians act within at least the bare minimum required by the profession and do what the Rule requires. In fact, as Judge Parkins noted: "[p]resumably, all licensed physicians are familiar with the standard of care and, therefore, they are charged with knowledge of the standard of care as applied to the regulations."[17]

Because the Board did not create evidence and instead relied upon a factual

[16] A107-108, 114-117, 280-281, 272-277
[17] (Ex. A to Op. Br. at 20).

record created at a hearing, Dr. Grossinger was not deprived of his due process rights. It is respectfully requested that the decision of the Board be affirmed.

II. THE SUPERIOR COURT INAPPROPRIATELY IMPOSED A MEDICAL NEGLIGENCE STANDARD OF CARE ON AN ADMINISTRATIVE PROCEEDING

A. Question Presented

Did the Superior Court err in imposing a medical negligence standard and using civil tort and medical malpractice precedent to determine that expert testimony is necessary to determine the standard of care in as a matter of fact an administrative Board proceeding? (A388, 391).

B. Scope of Review

This Court reviews a Superior Court ruling that, in turn, has reviewed a ruling of an administrative board by directly examining the Board's decision to determine whether the decision is supported by substantial evidence and is free from legal error.[18] Questions of law are reviewed *de novo*.[19]

C. Merits of Argument

Dr. Grossinger incorrectly asserts that the "requirement of expert testimony for medically related administrative matters naturally flows from that same requirement in medical negligence cases." Answ. Br. at 30. This is simply incorrect. An administrative licensing prosecution is not a medical malpractice case, and the requirements are not analogous. The Superior Court incorrectly applied a standard

[18] *Jain*, 29 A.3d at 211.
[19] *Prunckun*, 201 A.3d at 540.

of care analysis from malpractice jurisprudence to the professional disciplinary process, and extensively cited medical malpractice cases, even though it acknowledged that the proceedings were different because "the standard of care lies at the heart of any negligence claim against a physician" (Ex. A. to Op. Br. at 38), and Dr. Grossinger adopts that flawed reasoning. This is not a negligence case, this is a case concerning whether a licensee complied with a detailed regulation regarding chronic pain management. In a disciplinary proceeding, the Board considers claims "distinguishable from the legal processes of a typical medical negligence case."[20] While it can consider expert testimony, that testimony is not required to establish standard of care in the administrative proceeding.[21] As the *Bilski* Court noted, "to require such testimony – akin to that which is required in a medical negligence action – would frustrate the Board's proper administrative and adjudicative functions."[22]

The issue for the Board was not whether "standard of care," as applied in a malpractice, was violated, but whether Dr. Grossinger's prescribing to Michael, as evidenced from his patient records and the testimony of Dr. Grossinger and his colleagues, complied with the Board's law and regulations. The question of whether

[20] *Bilski*, 2014 WL 3032703, at *4 (citing *Jain*, 2013 WL 3389287).
[21] *Id.*
[22] *Bilski*, 2014 WL 5282115, at *2 (Del. Super. Oct. 16, 2014); *See also Del. Bd. of Nursing v. Francis*, 195 A.3d 467, 475 (Del. 2018) (reversing the Superior Court's finding that actual harm is a requisite element of a disciplinary action against a nurse by that board).

a licensee's conduct violates a law or regulation is a legal determination statutorily vested with the Board.[23] The Superior Court and Dr. Grossinger both erroneously analogize administrative licensing proceedings to jury trials where the jury sitting as trier of fact determines what the standard of care is as a factual issue prior to making a decision as to whether the defendant has breached that standard; that is simply not the case in administrative proceedings. The Superior Court's order requiring expert testimony to determine the standard of care, and thus, a violation of Board regulations, is in direct conflict with *Bilski* and its progeny.

Dr. Grossinger is expected, as a duly licensed medical doctor under Delaware law, to know the requirements of the Medical Practice Act and the Board's regulations. All of the malpractice cases cited in his brief are inapposite to the situation at bar, as they concern lay juries using an expert supplied standard to evaluate conduct and remediate harm. Here, a Board is using its institutionalized expertise to determine if conduct proven at a hearing violates its regulations in order to regulate the profession. The violations are statutory and regulatory requirements established by the Board and not controlled by malpractice law or evidentiary standards.

[23] 29 *Del. C.* § 8735(v)(1)d; 24 *Del. C.* § 1713(a)(9); 24 *Del. C.* §§ 1731(a).

ARGUMENT ON CROSS-APPEAL

I. THE BOARD'S DECISION THAT DR. GROSSINGER VIOLATED REGULATION 18.3 IS SUPPORTED BY SUBSTANTIAL EVIDENCE AND FREE FROM LEGAL ERROR.

A. Question Presented

Was the Board's Order finding Respondent in violation of Regulation 18.3 supported by substantial evidence in the record? (A388, 391).

B. Scope of Review

This Court reviews a Superior Court ruling that, in turn, has reviewed a ruling of an administrative board by directly examining the Board's decision to determine whether the decision is supported by substantial evidence and is free from legal error.[24] The appellate court does not weigh the evidence, determine questions of credibility, or make its own factual findings.[25] Questions of law are reviewed *de novo*.[26]

C. Merits of Argument

Substantial evidence exists in the record to support the Board's finding that Dr. Grossinger did not comply with Regulation 18.3 requiring informed consent when refilling prescriptions for Michael.[27] Rule 18.3 requires a practitioner to

[24] *Jain*, 29 A.3d at 211.
[25] *Id*.
[26] *Prunckun,* 201 A.3d at 540.
[27] Rule 18.3 states *in toto* "Informed Consent - The practitioner must discuss the

discuss the risks and benefits of the use of controlled substances with the patient, and Rul**e** 18.7.6 requires documentation of that discussion of risks and benefits.[28] Respondent did not have any "encounters" with Michael; his undisputed role was to "refill prescriptions", and he admits he did not even make any chart notes when he refilled prescriptions for controlled substances for patient Michael. (A114-117). The findings provide ample information for the Board to conclude that Respondent did not discuss risks and benefits with Michael. No practitioner at GNS documented this required discussion in Michael's file. (A335-336). Dr. Grossinger somewhat confusingly asserts that no documentation of any discussion with the patient was required, only a discussion. Answ. Br. at 41. However, while 18.3 mandates a discussion of the risks and benefits, 18.7.6 mandates that the "entire record must include the…discussion of risks and benefits." While Dr. Grossinger is correct that the medical adage "if it's not in the chart, it didn't happen," is not a rule of evidence, the plain language of Rule 18 itself very clearly requires documentation. All that is necessary to prove this violation is Michael's treatment record from Dr. Grossinger's practice, which is completely devoid of any documentation that any discussion of

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risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity."

[28] Rule 18.7 states "Medical Records- The practitioner shall keep accurate and complete records. The entire record must include the . . . 18.7.6 discussion of risks and benefits, ..."

the risks and benefits of the use of controlled substances ever occurred. All practitioners in this practice agreed they did not document this discussion, including Dr. Grossinger, who in fact admits he did not author any records on Michael, and the defense expert agreed it is not documented. The "Informed Consent" forms that Michael signed pertaining to his injections, which did not document a discussion of the risks and benefits of the controlled substances that he was being prescribed, were part of the record, and were discussed in the hearing and in the summary of evidence that the Hearing Officer wrote for the Board (A334-336); as were Steven Grossinger's testimony regarding his discussions with Michael (Id.), and the assertion that the Board was unaware of the existence of these facts is incorrect. *See* Answ. Br. at 42.

CONCLUSION

For the reasons set forth in this Opening Brief, Appellant, the Board of Medical Licensure and Discipline, requests this Court affirm its October 4, 2016 disciplinary Order and reverse the January 23, 2019 decision of the Superior Court.

Respectfully Submitted,

STATE OF DELAWARE
DEPARTMENT OF JUSTICE

/s/ Zoe Plerhoples
Zoe Plerhoples, I.D. No. 5415
Patricia A. Davis, I.D. No. 3857
Deputy Attorneys General
820 North French Street, 6th Floor
Wilmington, Delaware 19801
(302) 577-8368
Zoe.plerhoples@delaware.gov
PatriciaA.davis@delaware.gov
Attorneys for Appellant/Cross-Appellee, Board of Medical Licensure and Discipline

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