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IN THE SUPREME COURT OF THE STATE OF DELAWARE

DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE Appellee Below, Appellant,	)	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.	)	Trial Court: Delaware Board of Medical Licensure and Discipline Case No. 10-168-14

APPELLANT DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE'S THIRD AMENDED OPENING BRIEF

STATE OF DELAWARE
DEPARTMENT OF JUSTICE

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TABLE OF CONTENTS

TABLE OF CITATIONS

Statutes

Other Authority

NATURE OF PROCEEDINGS

The General Assembly has charged the Appellant, the Delaware Board of Medical Licensure and Discipline ("BMLD" or "Board"), with administering and enforcing Title 24, Chapter 17 of the Delaware Code ("Chapter 17" or "enabling statute"). 24 *Del. C.* § 1710(a). The Board is the sole authority vested with the power to regulate the practice of medicine in the State in order to protect the public, and was created as "the State's supervisory, regulatory, and disciplinary body for the practice of medicine." *Id.* Appellee Bruce Grossinger is a Board-licensed Delaware physician.

The Board's enabling statute demands that it discipline licensed medical doctors whom it finds guilty of unprofessional conduct, a pattern of negligence in the practice of medicine, incompetence, or gross negligence. 24 *Del. C.* § 1731(b)(11). If the Board finds that a licensed physician is guilty of unprofessional conduct or of violating any portion of the enabling statute, it may impose on that licensee discipline ranging from the issuance of a letter of reprimand to licensure revocation. *Id.* at § 1731(a).

On October 15, 2015, the Delaware Department of Justice ("DDOJ") filed a disciplinary complaint with the BMLD alleging that Dr. Grossinger was guilty of unprofessional conduct in that, while prescribing controlled substances to patient Michael in the year preceding his death, Dr. Grossinger failed to comply with the

Board's regulations governing the uses of controlled substances for the treatment of pain and failed to adequately maintain and properly document patient records in violation of the Board's regulations 8.1.12 and 8.1.13. (A129-131). The DDOJ complaint further alleged that Dr. Grossinger failed to obtain and document a medical history and physical examination of Michael in violation of regulation 18.1.1, failed to discuss the risks and benefits of the use of controlled substances with Michael in violation of regulation 18.3, failed to obtain a treatment agreement with Michael outlining the patient's and prescribers responsibilities in violation of regulation 18.4, failed to conduct periodic reviews of Michael's treatment plan in violation of regulation 18.5, and failed to keep accurate and complete medical records of Michael in violation of Board regulation 18.7. (*Id*.). Accordingly, the DDOJ complaint asserted that Dr. Grossinger's conduct violated 24 *Del. C.* § 1731(b)(3) in that he engaged in dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the public. *Id.* A Division of Professional Regulation ("Division") hearing officer conducted an evidentiary hearing on the DDOJ's complaint against Dr. Grossinger on April 21 and 22, 2016. *See* 29 *Del. C.* § 8735(v)(1)d. During the two day hearing, Dr. Grossinger was represented by counsel, testified on his own behalf, and cross-examined the DDOJ's witness. At the conclusion of the evidentiary portion of the hearing, the hearing officer found a set of facts by which the Board was bound, recommended the Board find Dr.

Grossinger guilty of unprofessional conduct as alleged in the State's complaint due to his inadequate medical recordkeeping and violations of the Board's statute and regulations, and recommended the Board discipline Dr. Grossinger by placing his medical license on probation for six months, requiring him to take additional education, and pay a fine. (A347-348). Dr. Grossinger and the State were provided twenty days to submit to the Board any written exceptions to the hearing officer's recommendation that they wished the Board to consider before determining the appropriate conclusions of law and discipline, if any, to be imposed on Dr. Grossinger. *See* 29 *Del. C.* § 8735(v)(1)d.

The Board received exceptions from Dr. Grossinger. (A349-361). As a result, the Board invited Dr. Grossinger to appear at its September 13, 2016 meeting and present oral argument before it deliberated on the hearing officer's recommendations and written submissions. Dr. Grossinger appeared through his counsel and presented argument to the Board. (*Id*.). The Board considered Dr. Grossinger's written exceptions, his counsel's oral argument, and the written recommendations of the hearing officer and voted to modify the hearing officer's recommended discipline by lessening the recommended probationary term to a simple letter of reprimand. (A365-366). Pursuant to 29 *Del. C.* § 10128(b), the Board memorialized that decision in a written order that it issued on October 4, 2016. *Id*.

Dr. Grossinger filed an appeal of the Board's October 4, 2016 order to the

Superior Court. The Superior Court found: (1) the regulations did not provide Dr. Grossinger with constitutionally adequate notice; (2) standard of care must be superimposed onto the regulations to give them meaning; and that (3) the State's failure to present expert evidence on the standard of care deprived Dr. Grossinger of his constitutional right to confront evidence against him.[1] The Court affirmed the Board's finding that Dr. Grossinger's failure to discuss the risks and benefits of controlled drugs prescribed to Michael in violation of regulation 18.3 was supported by substantial evidence and free from legal error. The Superior Court did not address the Board's findings that Dr. Grossinger violated regulations 18.7 or 8.1.13[2] and remanded the case to the Board to determine discipline on the one expressly affirmed violation.

On February 8, 2019, the Board petitioned this Court for an Interlocutory Appeal of the Superior Court's Order. On April 16, 2019, this Court accepted the appeal and issued a briefing schedule. This is the Board's Opening Brief.

[1] The Superior Court indicated it was reversing one of the Board's findings because the hearing officer and the Board "misinterpreted" some regulation (Ex. A to Op. Br. at 2), but it is unclear to which regulation the Superior Court is referring as there is no further discussion on this point in the Order.

[2] All references to regulations or rules are to the regulations of the Board. 24 *Del. Admin C.* § 1700.

STATEMENT OF FACTS

On December 11, 2013, "Michael" began Suboxone treatment with Dr. Irwin L. Lifrak for his heroin addiction. (A320, 264-68). Michael reported using "over a bundle of Heroin per day . . . for 6 years with some period of sobriety," and admitted to using heroin that very day. (A320, 265). One month into his treatment, on January 14, 2014, Michael tested positive for heroin. (A19, 78, 270). Dr. Lifrak discharged Michael, recommended inpatient treatment, and did not prescribe additional Suboxone "in view of the positive drug screen." (A320, 19, 78).

Two weeks after his discharge from Dr. Lifrak's care, Michael presented to Grossinger Neuropain Specialists ("GNS") with complaints of neck and shoulder pain. (A322, 157). Dr. Steven Grossinger initially evaluated Michael on January 29, 2014. (*Id.*). The initial evaluation documents neck and back pain, prior care under Dr. Cary, but no record of any pain care over the preceding year. (*Id.*). Michael was under the care of Dr. Ross Ufberg in 2008, but he was discharged "due to inconsistencies in his urine drug screen." (A319, 216). Neither Dr. Grossinger nor any GNS physician requested records from or communicated with any of Michael's prior physicians. (A319, 18, 20-21, 100-101, 124-25). When Michael presented to GNS, the practitioners had no idea whether Michael had been compliant with his prior providers. (A295, 20-21).

At the initial evaluation, Michael stated he was "not looking to have medications prescribed." (A324, 158, 13-15). Dr. S. Grossinger documented a review of the Prescription Monitoring Program ("PMP") and identified Michael had recently been prescribed Suboxone from Dr. Lifrak, but did not document any inquiry with Michael as to why the Suboxone was prescribed, why the prescription ended, or why Michael had been treating with Dr. Lifrak. (A324, 13-17, 79-81, 158, 278). Dr. S. Grossinger did not ask Michael about any illegal drug use, and no baseline drug screen was completed. (A25-29).

On January 29, 2014, Dr. Allen Silberman, an "independent psychologist" who works with GNS, evaluated Michael and prepared a report to provide "psychosocial insight" on Michael to the GNS practitioners. (A292, 165-166). The report noted that Michael "suffers an opiate addiction that started five years ago" and incorrectly identified current treatment with Dr. Lifrak "who manages his Suboxone which is used for opiate dependence." (*Id*.). The report does not document any communication with Dr. Lifrak. (*Id*.). The report encourages "compliance with [Michael's] drug treatment program" that Dr. Silberman appeared to believe had been occurring since the time Dr. Lifrak discharged Michael from care. (*Id.*, A321, 323, 29, 158, 165-166). Dr. Silberman diagnosed "opiate dependence" noting that Michael "will be seen again in approximately two weeks." (A323, 166). Michael was a "no show" for a follow-up appointment with Dr. Silberman on February 5,

2014. (A286). During the next year that Michael treated with GNS, there were no additional appointments with Dr. Silberman. (A322-23). There was no follow-up during the year by any GNS practitioner, including Dr. Grossinger, regarding Michael's opiate "addiction," his "dependence," the incorrectly assumed ongoing treatment with Dr. Lifrak, or Michael's failure to attend his follow-up appointment with Dr. Silberman. (A323, 25-29, 90, 108-09, 154-259).

Michael executed a Pain Management Agreement ("the Agreement") with GNS on January 29, 2014. (A282-283). The Agreement mandates compliance with its provisions, including any random drug tests ordered by the practitioners. (*Id.*, A324). Michael attested that he understood that if he broke the Agreement, his doctors "*will* stop prescribing these pain-control medicines and *will* discharge [him] from the practice." (A282). Dr. Grossinger signed a second Pain Agreement on June 13, 2014 with Michael, again mandating cooperation with urine testing and specifically prohibiting illegal drug use. (A324-325, 284-285).

In February 2014, Dr. S. Grossinger performed an EMG test and Dr. Jason Brajer performed a cervical injection. In March 2014, Dr. Brajer performed a second cervical injection and began prescribing medications to Michael. (A171-188). Dr. Brajer began prescribing Hydrocodone, an opioid and controlled substance, to Michael on April 9, 2014 without first reviewing the charting of prior providers and without reviewing the charting of his own practice. (A33, 85-90). He began

prescribing without reviewing the initial evaluation, the psychotherapy evaluation, or the PMP. He did not request a baseline urine drug screen and did not question Michael on his illegal drug use. (A87-90, 93, 103). Dr. Brajer was not aware that Michael suffered an opioid addiction, was recently prescribed Suboxone for detoxification treatment, or that Michael requested he not receive medication. (A85, 88, 94, 165).

Dr. Brajer prescribed Hydrocodone again on May 8, 2014. (A278). On May 28, 2014, Dr. Brajer performed a cervical injection and adjusted Michael's medications to prescribe morphine sulfate in addition to hydrocodone, because Michael reported it worked before. (A203). Dr. Brajer still had not reviewed his practice's records and had no knowledge of Michael's history of opiate addiction.

On June 9, 2014, Dr. S. Grossinger prescribed Hydrocodone and Morphine Sulfate to Michael. (A278). A June 18, 2014 computer note contains reference to "UDS!!" or urine drug screen. Michael did not appear for the screen. (A43-45, 287).

On July 9, 2014, Dr. Grossinger wrote prescriptions for Michael for controlled substances with no appointment encounter and without requiring any urine drug screen. (A154-259, 278). Michael had an appointment with Dr. Brajer on July 30 and there was no discussion on why the drug screen was not completed and no follow-up request for Michael to comply. (A219-220, 287).

The prescribing of controlled substances continued on August 7 (Dr. Brajer), August 11 (Dr. S. Grossinger), September 11 (Dr. Grossinger), October 10 (S. Grossinger), and November 12 (Dr. Grossinger), without Michael appearing for any appointments during that time. (A43-45, 154-259, 278). There was no discussion of why a drug screen was never completed, no follow-up request for Michael to comply with the drug screen, and no enforcement of the Agreement requiring Michael to comply with the drug screen request. (*Id.*, A338). There is no record of any GNS practitioner requiring Michael to comply with the June drug screen request until December of 2014. (A338, 50).

At the time of the administrative hearing, Dr. Peter S. Staats testified as an expert on behalf of Dr. Grossinger and his colleagues. (A301-307). He indicated that the GNS practitioners' care of Michael was consistent with the standard of care and Rule 18. (A63). Dr. Staats admitted he had been misinformed that Rule 18 was not the law in 2014. (A63). Dr. Staats had not reviewed Dr. Lifrak's records and was unaware that Michael had been treating with Suboxone for a heroin addiction only two week before presenting to GNS. (A56-57). He opined that it is much better for a practitioner to have prior provider records; he would have obtained records before prescribing if he had the same information as the GNS practitioners; and he is not sure if he would have prescribed opiates. (A58-60). In his practice, he relies on the PMP, urine drug screens, and prior provider records. (A70-71). His opinion

is that it is not reasonable to prescribe opiates to a known heroin addict. (A61). He admitted the GNS doctors would have known Michael was a heroin addict if they reviewed Dr. Lifrak's records. (A60-61). He indicated the informed consents for injections do not document a risks and benefits discussion for controlled substances, nor does the PMA. (A62). He agreed that the "letter of the law" was not followed without that documented discussion, and his report is in error on this point. (A64-68, 77). He opined that if a patient has an addiction disorder, the need for a UDS would stand on its own, and he would have ordered a follow-up urine drug screen for Michael before December 2014. (A73-75).

It was undisputed at the hearing that Michael was at high risk for abuse when he presented to GNS. (A297; 41, 96). Dr. Grossinger denied ever seeing or treating Michael "in any way" at the time of the hearing. (A280-281). When provided with copies of prescriptions bearing his signature, Dr. Grossinger admitted he prescribed to Michael and admitted that his initial written representations to the Division were false. (A107-108, 272-277). While Dr. Grossinger wrote controlled substance prescriptions for Michael, it is undisputed that he did not have any treatment encounters with Michael. (A326, 107-108). Dr. Grossinger testified that "he could not recall" what records he reviewed before prescribing to Michael. (A109-110). Dr. Grossinger authored no records documenting any review of records, encounters, or discussions with Michael. (A114-117).

Before prescribing controlled substances, Dr. Grossinger did not require Michael to submit to a urine drug screen, did not enforce the Agreement, did not discuss the risks and benefits of controlled substances with Michael, did not question Michael on his illegal drug use, did not obtain other provider records, and did not question Michael on his recent Suboxone prescription or why it stopped.

On December 8, 2014, after almost one year of prescribing controlled substances (three times by Dr. Grossinger), Michael finally submitted to his first urine drug screen with GNS. (A50). Positive for heroin, the prescribed Hydrocodone was not found in Michael's system. (A327-328). By letter dated December 15, 2014, GNS discharged Michael due to this inconsistent drug screen. Michael had died of heroin intoxication three days earlier. (A271).

Rejecting Dr. Grossinger's defense that he should not be held responsible as he was not the primary treating physician, the Board specifically held that "[a]ll three doctors should be treated the same [for disciplinary purposes] because a covering doctor who merely refills a prescription is as responsible as the treating doctors." (A365). This appeal followed.

SUMMARY OF ARGUMENT

I. The Superior Court erroneously failed to apply the holding in *Bilski*, in holding that constitutional due process required the State to present expert evidence in the administrative proceeding to prove that Dr. Grossinger's narcotic prescribing to Michael without any visits or documentation violated the Board's record-keeping requirements and its detailed requirements for the prescribing of controlled drugs for pain.

II. The Superior Court erred in superimposing a malpractice standard of care requirement onto the Board's controlled drug prescribing regulations and finding the regulations unconstitutionally vague as applied to Dr. Grossinger.

III. Substantial evidence supports the Board's finding that Dr. Grossinger's narcotic prescribing to Michael did not comply with its laws.

ARGUMENT

I. THE SUPERIOR COURT ERRED IN HOLDING THAT EXPERT EVIDENCE IS REQUIRED TO ESTABLISH THAT A VIOLATION OF THE BOARD RULES OCCURRED.

A. Question Presented

Was the State required to present expert testimony that a violation of the Board rules had occurred in the administrative 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.[3] Questions of law are reviewed *de novo*.[4] 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 under which the Board acted,[5] 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.[6]

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[3] *Del. Dep't. of Health & Soc. Servs. v. Jain*, 29 A.3d 207, 211 (Del. 2011).
[4] *Prunckun v. Del. Dep't. of Health & Soc. Servs.*, 201 A.3d 525, 540 (Del. 2019).
[5] 29 *Del. C.* § 10142(d).
[6] *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).

C. Merits of Argument

1. The Administrative Procedures Act applies to the Board and contemplates case decisions do not require expert testimony.

Disregarding all citations made by both parties to the Delaware Administrative Procedures Act ("APA"), the Superior Court erroneously held that "the APA plainly did not apply at the time of the hearing or at the time of the board's decision." Ex. A to Op. Br. at 16. The Board has been an enumerated agency, subject to the APA's provisions for determining case decisions since 1984.[7]

Nevertheless, the Superior Court *sua sponte*[8] held that the APA did not apply to the Board until 2017, citing a revision of the Board's statute that struck surplusage hearing process provisions in the Board's enabling statute, substituting "[h]earings shall be conducted pursuant to the Administrative Procedures Act."[9] But the 2017 bill did not apply the APA to the Board's proceedings for the first time. Disregarding the clear language in 29 *Del. C.* § 10142(d) that "[t]he Court, when factual determinations are at issue, shall take due account of the experience and specialized competence of the agency of the purposes of the basic law under which the agency has acted,"[10] the Superior Court also disregarded the experience and competency of

[7] 29 *Del. C.* § 10161(a)(22); 64 Del. Laws. C. 477, § 5; 29 *Del. C.* § 8735(g).
[8] Both parties relied upon the APA in arguments before the Superior Court. (Ex. A to Op. Br. at 16).
[9] Ex. A to Op. Br. at 16-17.
[10] Ex. A to Op. Br. at 16-17, fn. 46 (citing 29 *Del. C.* § 10142(d)).

the BMLD, and found expert testimony was required to prove a violation of the Board's rules. The APA was applicable to the Board, it controlled this case decision, it makes clear the Board can utilize its own experience and specialized competence without the need for expert testimony, and the Superior Court's decision to disregard both parties' arguments regarding the APA was in error.

2. The Superior Court erred by failing to apply this Court's controlling precedential ruling that expert testimony is not required.

In *Bilski v. Del. Bd. of Med. Licensure & Discipline*,[11] the Superior Court held a BMLD decision is supported by substantial evidence and free from legal error where, as here, the record includes detailed factual findings based on patient records and the licensee's testimony, and expert testimony as to standard of care is not required.[12] This Court affirmed the *Bilski* decision[13] and it has been controlling precedent ever since. The arguments in *Bilski* were substantially similar to those presented on appeal in this case and its analysis should control. The Superior Court distinguished *Bilski* and its progeny on misstatements of fact.

During the evidentiary hearing in *Bilski*, the State admitted the patient records into evidence and extensively questioned Dr. Bilski about those records. The State did not use an expert witness or present "standard of care evidence." The Board

[11] 2014 WL 3032703 (Del. Super. Jun. 30, 2014).
[12] *Id.* at *5
[13] *Bilski*, 115 A.3d 1214 (Table).

found a "pattern of negligence" in Dr. Bilski's record keeping.[14]

Dr. Bilski appealed arguing legal error because the State did not introduce expert testimony on standard of care at the hearing.[15] The Superior Court held the record did not have to include expert testimony for the Board to find a violation of the Medical Practice Act. Rejecting Dr. Bilski's argument, the Court declined to apply the "technical requirements" of medical negligence claims to the administrative disciplinary process.[16] This Court affirmed, adopting the rationale of the Superior Court.

This case concerns Dr. Grossinger's prescribing of controlled drugs to one patient and the Board's finding that the prescribing did not conform to the Board's laws and regulations. The facts are strikingly similar to *Bilski*, but the Superior Court distinguished the case at bar because different *far more detailed* regulations are at issue here than were in *Bilski*. In *Bilski*, the Board found a "pattern of negligence" without expert testimony. Here, the Board found that Dr. Grossinger's record keeping practices failed to meet the detailed requirements of the Board's rules that outline exactly what documentation must be contained in a patient's chart when controlled substances are prescribed.[17]

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[14] *Bilski*, 2014 WL 3032703, at 3.
[15] *Id.*
[16] *Id.* at 4-5.
[17] *See, e.g.*, Rule 18.1.1; 18.3; 18.4; 18.5 *et seq.*, 18.7 *et seq.*

The Superior Court has employed the *Bilski* analysis in subsequent cases, including *Centers v. Del. Bd. of Med. Licensure & Discipline*[18] and *Denham v. Del. Bd. of Mental Health and Chemical Dependency Professionals*,[19] where the evidence and administrative process were akin to both this case and to *Bilski*.

In *Centers*, the State alleged inadequate and negligent record keeping. The Board found violations of 24 *Del. C.* § 1731(b)(3) and Regulation 8.1.13 for failing to adequately maintain and properly document records.[20] The Board made those determinations following a fact-finding hearing where Dr. Centers was the only witness. On appeal, Dr. Centers argued a lack of substantial evidence because the State did not introduce "standard of care" evidence or rebut his testimony. Applying *Bilski*, the *Centers* Court rejected that argument and held that standard of care evidence is not required to prove a violation of Board regulations.[21]

The Superior Court in this case distinguished *Centers* stating Dr. Centers had "conceded that his conduct amounted to a violation of the standard of care."[22] However, the Superior Court completely disregarded the fact that Dr. Grossinger did the same in this case. On May 22, 2015, in response to the initial complaint filed by

[18] 2017 WL 2558266 (Del. Super. June 12, 2017).
[19] 2017 WL 5952763 (Del. Super. Nov. 30, 2017).
[20] The same Code section and regulation are implicated in this case.
[21] *Id.* at n. 69.
[22] (Ex. A. to Op. Br. at 49); *but see Centers*, 2017 WL 2558266, at *3 ("Appellant argues his testimony reveals he met, and even exceeded the standard of care with respect to his record-keeping practices.").

Michael's mother, Dr. Grossinger submitted a letter to the Division, admitting that the treatment of Michael "did not comply with Rule 18 in certain ways" and outlining changes GNS had therefore made. (A149).

In *Denham*, the State proved multiple Ethics Code violations and the Board of Mental Health revoked Denham's license. Denham appealed, arguing that she was denied a meaningful hearing due to the lack of expert testimony. The Superior Court again considered the question of what evidence was necessary to establish violations in a disciplinary proceeding.[23] The Superior Court held it was a function of the Board to draw upon its institutional expertise to evaluate evidence in reaching its decision.[24] Citing *Bilski*, the Superior Court held the State was not "obligated to present expert testimony to establish Denham's violations of the Ethics Code, nor did the Board's findings of violations of the Ethics Code Directive require expert testimony."[25] The factual record was substantial evidence for the Mental Health Board to apply its expertise and impose discipline, without the need for expert testimony.

In *Bilski*, *Centers*, *Denham*, and this case, the State presented documentary evidence, including patient records and witness testimony, including the treating professionals' own testimony, but no expert testimony. The boards each made

[23] *Denham*, 2017 WL 5952763, at *6.
[24] *Johnson v. Chrysler Corp.*, 213 A.2d 64, 66-67 (Del. 1965).
[25] *Denham*, 2017 WL 5952763, at *5.

findings of fact, and using their institutional expertise, determined violations. All three prior cases address patient care and documentation, the boards' role in evaluating findings of fact on that care, and determining a violation of its laws from those findings *without* the need for expert testimony. Notably, these cases involved the same or more nebulously defined violations ("pattern of negligence," "failure to adequately maintain and properly document") than violations applied in this case. Indeed, Rule 18 is one of the most detailed regulations of any professional board.

Dr. Grossinger did not create *even one record* documenting his treatment and prescribing to Michael; he simply signed prescriptions for controlled substances and admitted the same in his testimony. This Court's ruling in *Bilski* controls and the Board can determine that a complete absence of documentation from Dr. Grossinger when an opioid dependent patient receives highly addictive controlled substances is a failure to comply with its rules that require specific—and here missing—documentation. It does not need a different physician expert to confirm.

II. THE BMLD'S REGULATIONS ARE NOT UNCONSTITUTIONALLY VAGUE AS APPLIED TO DR. GROSSINGER IN THIS CASE.

A. Question Presented

Are the Board's regulations unconstitutionally vague as applied to Dr. Grossinger, requiring evidence of the standard of care as the Superior Court held? This question was not fully briefed below, as the Superior Court raised it *sua sponte* in correspondence preceding oral arguments[26] 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 board by directly examining the Board's decision to determine whether the decision is supported by substantial evidence and is free from legal error.[27] Questions of law are reviewed *de novo*.[28]

C. Merits of Argument

Finding a due process violation occurred during the Board proceedings, the Superior Court determined that the Board's regulations were unconstitutionally vague as applied to Dr. Grossinger. It then found it "necessary to superimpose the standard of care onto the regulations in order to give them meaning" to cure the

[26] (A415).
[27] *Jain*, 29 A.3d, at 211.
[28] *Prunckun*, 201 A.3d at 540.

vagueness.[29] Continuing down this path, the Court held that because the State failed to offer "standard of care" evidence, the Board must have created it after the evidentiary hearing had closed, depriving Dr. Grossinger of his due process right to confront the evidence against him and further, denying Dr. Grossinger of adequate notice of what the regulations required of him.

The Superior Court's analysis is flawed. The Board's Order does not cite to any evidence not presented by either party. Counsel's statement during one of the three oral arguments below that "the regulations do not put practitioners on notice of every factual scenario for treatment of a patient" is not, as the Superior Court described, a concession that "nothing in the language of the regulations expressly provided notice to Dr. Grossinger of most of the things the Board ultimately found was required of him."[30]

The Superior Court deemed the evidence it believes the Board created as "standard of care" evidence but, in doing so, improperly conflated the requirements of a tort/malpractice action with a license disciplinary case. Administrative due process has never required "standard of care" evidence, as is used in a malpractice action, to prove conduct inconsistent with licensing laws.

The Superior Court cites to *Turbitt v. Blue Hen Lines, Inc.*[31] in support of its

[29] (Ex. A to Op. Br. at 2).
[30] (*Id.*)(quoting Tr. Of Oral Arg., D.I. 44, at 20 (Aug. 17, 2018)).
[31] 711 A.2d 1214 (Del. 1998).

conclusion that the Board supplied missing evidence. *Turbitt* concerns the Industrial Accident Board's ("IAB") creation of a 15% permanency rating based on its experience, and not upon evidence presented by either party. On appeal, this Court held that the IAB could not find a permanency rating of 15% when the only evidence presented at the hearing was that the claimant suffered a rating of 34%.[32] The IAB had relied on a prior case in which it awarded 23% permanent partial impairment to a claimant with a spinal injury that it considered more severe. The IAB improperly created a new rating on an issue requiring professional expertise, where it lacked support for that rating in the record, and after improperly utilizing prior cases to form its finding without notice to the parties.[33] Here, the Board evaluated the detailed factual findings on Dr. Grossinger's conduct supported by evidence in the record, or more properly, what was *missing from* Dr. Grossinger's records. The Board neither created evidence, nor was required to consider or rely upon expert testimony to determine a violation of its rules.

The make-up of the IAB compared to that of the Board of Medical Licensure and Discipline is also instructive when distinguishing *Turbitt*. The General Assembly purposefully created the BMLD to include a majority of licensed,

[32] *Id.* at 1215-16.
[33] *Id.*; *see also Roberts v. Homes,* 1999 WL 1222699, at *2 (Del. Super. Nov. 8, 1999) (The issue in *Turbitt* was one "requiring expert testimony.").

practicing physicians.[34] By comparison, the IAB is made-up of residents from the State with no particular training or expertise requirements.[35] Unlike the IAB, the Board's specialized competence consisting of practicing physicians makes it uniquely qualified to evaluate Dr. Grossinger's conduct in prescribing to Michael, and apply those factual findings to its disciplinary laws without reliance on expert testimony.

Nearly all board regulations in licensing prosecutions involve some practitioner discretion when applied to the care of a patient, including the Board's pain prescribing and documentation regulations. Rule 18 is the most detailed rule of the Board, and the plain language of the rule includes numerous mandatory requirements.[36] The existence of some discretion 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 Dr. Grossinger. Moreover, the expert that testified on Dr. Grossinger's behalf stated that he relies on the very documents and information Dr. Grossinger did not obtain when prescribing Michael controlled substances. As applied to Dr. Grossinger, the expert testimony in this

[34] 24 *Del. C.* § 1710(b).
[35] 19 *Del. C.* § 2301A(a).
[36]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."

case is that the standard of care in his practice is to obtain and review prior treating records, review the PMP, and require patients to submit to urine drug screens.[37] The Superior Court found the Boards regulations unconstitutionally vague because the regulations do not specify how often urine drug screens should be requested, but as applied to Dr. Grossinger, no urine drug screens were ever requested despite his writing three separate prescriptions for controlled substances.[38]

There is a strong presumption that a statute is constitutionally valid.[39] Dr. Grossinger has the burden of rebutting this presumption, and "[a]ll reasonable doubts as to the validity of a law must be resolved in favor of the constitutionality of the legislation."[40] "The standards of certainty in statutes punishing for [criminal] offenses is higher than in those depending primarily upon civil sanction enforcement."[41] The nature of the enactment guides fair notice and enforcement under the due process clause.[42] When a law is challenged as unconstitutionally void for vagueness, the provision must be reviewed as it applies to the particular conduct at issue.[43] A statute is unconstitutionally vague if "it fails to give a person of ordinary

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[37] A70-71.
[38] A43-45, 154-259, 278.
[39] *McDade v. State*, 693 A.2d 1062, 1065 (Del. 1997).
[40] *Id.* (citing *Wilmington Med. Ctr., Inc. v. Bradford,* 382 A.2d 1338, 1342 (Del. 1978)).
[41] *Winters v. New York*, 333 U.S. 507, 515 (1948).
[42] *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982).
[43] *McDade*, at 1065; *See also Crissman v. Delaware Harness Racing Comm'n,* 791

intelligence fair notice that his contemplated behavior is forbidden by the statute, or if it encourages arbitrary or erratic enforcement."[44] Unprofessional conduct in professional discipline must be viewed in light of its primary purpose to protect the public and the "common understanding and practices" of the particular profession.[45]

A void for vagueness challenge as applied to Dr. Grossinger's conduct in prescribing to Michael is analyzed in the context of his knowledge as a practicing and prescribing physician, the Board's knowledge as members of the same profession, and the purposes of professional discipline to protect the public – and it fails. As a practicing physician, licensee of the Board, and controlled substance registrant with the power to prescribe addictive narcotics, Dr. Grossinger is required to know what is required of him, as is every prescribing physician in the State.[46]

A.2d 745, 747 (Del. 2002).

[44] *Wien v. State,* 882 A.2d 187, 187 (Del. 2005) (quoting *State v. Baker,* 720 A.2d 1139, 1147-48 (Del. 1998)).

[45] *See Lynch v. Ellis*, 2003 WL 22087629, at *7 (Del. Super. July 22, 2003) (citing *Molden v. Mississippi State Dept. f Health*, 730 So.2d 29 (Miss.1998)); *Perez v. Holbrock*, 368 F.3d 166 (2004) (finding that required specificity may be provided by the common knowledge and understanding of the community to which the regulations apply); *Haley v. Medical Disciplinary Bd*., 818 P.2d 1062, 1074 (Wash. 1991) (common knowledge and understanding of members of the particular profession to which a statute applies many also provide the needed specificity to withstand a vagueness challenge).

[46] Dr. Grossinger argued forcefully in the administrative process that Rule 18 was not the law and did not apply to his prescribing to Michael, but his ignorance of the laws applicable to his profession is not a defense to his violations. He similarly mislead his expert into his belief that Rule 18 was not in effect in 2014 when Dr. Grossinger was treating Michael. As a licensee, he is charged with knowledge of the laws, which set forth the requirements of Rule 18, which has been in effect since

Consistent with this standard, the Superior Court acknowledged below that "[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."[47] Yet, it held the regulations unconstitutionally vague as applied to Dr. Grossinger because they did not put him on notice of "what was required of him under the facts of this case."[48]

The Superior Court seeks a level of detail to the Board's regulations as would be required in a criminal statute. Professional standards couched in terms more general than those at issue here are frequently upheld by courts.[49] The regulations cannot conceivably address every factual treatment scenario and cannot tell Dr. Grossinger every required step when caring for Michael, nor should they.[50] Boards

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early 2012. (A349-353).

[47] (Ex. A to Op. Br. at 20).

[48] (Ex. A. to Op. Br. at 2).

[49] *San Filippo v. Bongiovanni*, 961 F.2d 1125, 1137 (1992) ("standards of sound scholarship and competent teaching" standard not vague as applied and held to encompass a "wide range of conduct" to which professors can evaluate their behavior's conformity); *Perez*, 368 F.3d at 176 (finding that required specificity may be provided by the common knowledge and understanding of the community to which the regulations apply); *Bell v. Bd. of Regents of Univ. of State of NY*, 295 N.Y. 101, 108-09 (Ct. App. 1945) (upholding language of "unprofessional" conduct as it applies to the dentistry profession and as can be determined by professionals in the same practice); *Chastek v. Anderson*, 416 N.E. 247, 249-50 (Ill. 1981) (collecting cases where broader language was upheld).

[50] *See Bd. of Med. Examiners v. Mintz*, 378 P.2d 945, 948 (Or. 1963) ("The fact that it is impossible to catalogue all of the types of professional misconduct is the very reason for setting up the statutory standard in broad terms and delegating to the board the function of evaluating the conduct in each case."); *In re Chase*, 987 A.2d

routinely interpret their own regulations and apply them to similar factual records. That after-the-fact application of the facts to the law does not equate to a lack of notice. The Superior Court acknowledged the Board could not craft regulations detailed enough to predict all scenarios, but then held them unconstitutionally vague as applied because they did not do just that.

Though the Superior Court purportedly applies a vague "as applied" standard, its analysis amounts to a finding that the regulations are void on their face. The Superior Court conflates its vague as applied analysis with the requirement of expert testimony, but expert testimony at the administrative hearing would not change the level of notice to Dr. Grossinger of what was required of him when he actually engaged in the prescribing controlled drugs to Michael. Whether the State presents "standard of care" evidence at a disciplinary hearing after the fact would not guide how practitioners treat their patients. Thus, the Superior's Court's ruling is tantamount to a finding that the regulations are void on their face. For example, the Superior Court found that Dr. Grossinger was not on notice to obtain prior records of Dr. Lifrak because Rule 18.1 requires a prior history but does not specify when prior records must be obtained to complete that history and "without that information in advance it would have been impossible for [Dr. Grossinger] to comply with the

924, (Vt. 2009) ("[W]e defer to determinations that require the Board to apply its expertise or weigh whether certain behavior violated the standard of care pertaining to unprofessional conduct under the statute over which it has authority.")

regulation as applied to him." (Ex. A. to Op. Br. at 28). This analysis ignores the requirement that Dr. Grossinger's conduct be analyzed within the norms of the medical community and the delegated role of the professional Board to evaluate the conduct in each case. The holding is really that the "standard is so vague that it is not standard at all,"[51] and that is an overboard application of constitutional vagueness in the civil context which would render any attempt to regulate professionals for the public health, safety or welfare essentially impossible.

Here, Michael's GNS file reflected an active opiate addiction and no information as to why his Suboxone treatment abruptly ended. Dr. Grossinger never enforced Michaels's Pain Agreement and required him to submit to the ordered urine drug screen, or even to show for an appointment before prescribing to him. Dr. Grossinger chose to write narcotic prescriptions for Michael without laying eyes on him, without documenting a review of Michael's file, without following up on alleged ongoing treatment for an opioid addiction, and without authoring even one patient record for Michael. Dr. Grossinger's record keeping for Michael was so non-existent he initially testified at his hearing that he never treated him. The Board's prescribing and record-keeping requirements require a physician to exhibit some due diligence before prescribing opiates to an opiate addict. If Dr. Grossinger had, he would have been aware that Michael was very recently ingesting a bundle of

[51] *San Filippo*, at 1138.

heroin per day and had failed addiction treatment. The regulations are not impermissibly vague on their face, or as applied.

The Superior Court below erroneously applied a standard of care analysis from malpractice jurisprudence to the professional discipline process, even holding that Dr. Grossinger's due process rights include "a constitutional right to hear and confront evidence against him concerning the *standard of care*." (Ex. A. to Op. Br. at 21, emphasis added). Though it acknowledges the different proceedings, it nevertheless extensively cites medical malpractices cases as apt here because "the standard of care lies at the heart of any negligence claim against a physician" (Ex. A. to Op. Br. at 38), and it erroneously applies that standard to this professional discipline case.

Standard of care in a malpractice case serves a distinctly different purpose than in a license prosecution and evidentiary bases required for malpractice proceedings did not apply in this case. The hearing did not address whether Dr. Grossinger must compensate the patient for subpar medical care, but whether Dr. Grossinger failed to comply with the Board's requirements of his profession.[52] The State presented evidence below, not to prove duty, breach, causation and damages,

[52] This is highlighted by the Court's *sua sponte* discussion on whether the State must "prove harm." (Ex. A. to Op. Br. at 15-16). That is not a required element of proof because this is not a malpractice case and disciplinary proceedings serve the distinctly different purpose of protecting the public, rather than compensating for injury.

but to set forth for the Board Dr. Grossinger's conduct when prescribing opioids to an opiate addict.

In a disciplinary proceeding, the Board considers claims "distinguishable from the legal processes of a typical medical negligence case."[53] While it can consider expert testimony, that testimony is not required to establish standard of care in the administrative proceeding.[54] *Bilski*, at 4. "[T]o require such testimony – akin to that which is required in a medical negligence action – would frustrate the Board's proper administrative and adjudicative functions."[55]

The issue for the Board was not whether "standard of care," as applied in a tort case, 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, violated the Board's laws. That is a legal determination statutorily vested with the Board.[56] While the hearing officer made findings of fact on the evidence for the Board's review and recommended "conclusions of law," the Board was not bound by those legal conclusions.

While Dr. Grossinger argued his care of Michael complied with the Board's laws, the Board was not required to agree with him or review "standard of care"

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[53] *Bilski*, 2014 WL 3032703, at *4 citing *Jain v. Del. Bd. of Nursing*, 2013 WL 3389287 (Del. Super. Feb. 13, 2013).
[54] *Id.*
[55] *Bilski*, 2014 WL 5282115, at *2.
[56] 29 *Del. C.* § 8735(v)(1)d; 24 *Del. C.* § 1713(a)(9); 24 *Del. C.* §§ 1731(a).

evidence to find otherwise. The violations are statutory and regulatory standards set by the Board and not controlled by malpractice law or evidentiary standards.

III. SUBSTANTIAL EVIDENCE SUPPORTS THE BOARD'S FINDING THAT DR. GROSSINGER'S PRESCRIBING OF CONTROLLED SUBSTANCES TO MICHAEL DID NOT COMPLY WITH ITS LAWS.

A. Question Presented

Was the Board's Order finding Dr. Grossinger in violation of its prescribing narcotics to Michael 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.[57] Substantial evidence is more than a scintilla but less than a preponderance of the evidence.[58] The appellate court does not weigh the evidence, determine questions of credibility, or make its own factual findings.[59]

C. Merits of Argument

There was ample evidence regarding the conduct of Dr. Grossinger in prescribing to Michael to support the findings and the Board's final Order. The State introduced the GNS records on Michael, Dr. Lifrak's records on Michael, a PMP report on Michael, the public complaint and the responses, and Michael's death certificate. The State elicited testimony from the three practitioners, and called a

[57] *Jain*, 29 A.3d at 211.
[58] *Johnson*, 213 A.2d at 66-67.
[59] *Id*.

Division investigator for brief testimony.

Dr. Grossinger cannot avoid discipline by relying on his colleagues and casually signing off on prescriptions for controlled substances based on misplaced "trust" of prior providers. Dr. Grossinger is responsible to Michael and to the public for every controlled drug he authorizes. He had an obligation to understand Michael's history, his pain and his addiction before prescribing, and he did not meet that obligation. The rote signing of narcotic prescriptions for Michael with no visits or documented review of his care is a dangerous practice and not consistent with the standards set by the Board. Dr. Grossinger is responsible for his own narcotic prescriptions and cannot escape responsibility under the guise of "covering" for his colleagues. (A365).

Rule 18.1.1 states that a history of substance abuse *must* be obtained, and Rule 18.7.1 requires documentation of that history. Dr. Grossinger failed to obtain any information from Dr. Lifrak regarding Michael's Suboxone treatment for substance abuse despite all of the red flags in the record regarding Michael's opioid addiction and alleged ongoing treatment for the addiction. His practice's evaluation documented that Michael had a history of opiate dependence, presently suffers an opioid addiction, and was purportedly treating for that addiction with Dr. Lifrak. (A326-327). The same evaluation noted that the prescriptions for Suboxone ended only two weeks before Michael presented to GNS. (A324). Dr. Grossinger should

have known that Michael specifically requested that he not receive medication. (A324-325). He would have known had he reviewed the notations in his practice's file on Michael. Dr. Grossinger made no effort to ask Michael why he did not want pain medications, to obtain a complete history from Michael regarding his substance abuse, to ask Michael about illegal drug use, or to follow-up with Dr. Lifrak to obtain that history. (A326-327). Dr. Grossinger "signed off on prescriptions to refill the medications" with no treatment encounters with Michael, and without authoring any records for Michael despite prescribing controlled substances. (A107-108). He relied on other physicians in following their prescriptions, when those physicians did not obtain a complete history either and were also disciplined by the Board. (A320, 327). Dr. Grossinger's "trust" was misplaced and his failure to make his own inquiries was appropriately found by the Board to be a violation of the law.

Rule 18.3 for informed consent states a practitioner must discuss the risks and benefits of the use of controlled substances with the patient, and Rule 18.7.6 requires documentation of discussion of risks and benefits. Dr. Grossinger did not have any "encounters" with Michael, his undisputed role was to "refill prescriptions," and he did not make any chart notes when he refilled prescriptions. (A326-327). The findings provide ample information for the Board to conclude that Dr. Grossinger did not discuss risks and benefits with Michael. The violation is amplified by the findings that no practitioner at GNS documented this required discussion in

Michael's file. (A335-336). This again highlights why it was improper for Dr. Grossinger to rely on his colleagues and simply fill prescriptions.

Rule 18.4 *requires* pain management agreements for patients at high risk for medication abuse and states the agreements *must be used*, and Rule 18.7.11 requires documentation of that review. Michael was a high-risk patient and the practice had him execute a PMA. (A323-324,337). The Board found that Dr. Grossinger, along with the another GNS practitioners, did not use the PMA in any meaningful sense because they did not enforce its provisions. The central issue was not the frequency with which Michael should have been drug screened, but that the requirement that Michael get a urine drug screen to continue receiving prescriptions was not enforced. The PMA required compliance with its provisions and states Michael *will* submit to drug screens as requested, and the practice "*will* stop prescribing" for non-compliance. (A285). A urine drug screen was ordered in June, Michael did not show for the drug screen, and Dr. Grossinger prescribed controlled substances to Michael on three separate occasions after that without requiring Michael to complete the urine drug screen and without enforcing the PMA as required by Rule 18.4. (A337-339). "There is no record . . . that Michael, an opiate addict, had been directed to come to GNS office to provide a urine between June and December 2014." (A338). A treatment agreement is meaningless if not enforced, and the plain language of Rule 18 requires more than just papering of the record.

Rule 18.5.1 *requires* periodic review on the course of paint treatment that *shall* include continuation of controlled substances depending on the practitioner's evaluation of the patient's progress toward treatment goals and objective. As evidenced by Dr. Grossinger's response letters, testimony, and Michael's patient records (A149, 154-259, 280-281), his treatment of Michael consisted of writing refill prescriptions in July, September, and November without any visits. (A326). Dr. Grossinger did not document a discussion or encounter to determine if the prescriptions were actually benefitting Michael during the entire course of treatment. (A108, 114-117). He merely relied on the other physicians to follow the prescriptions and the "warning" form used by GNS. (A327). That form did not include any periodic review or evaluation of the patient's progress. (A327). Dr. Grossinger could not have known Michael's "progress" when he prescribed because, following his July 30 appointment, Michael did not appear for any appointments or drug screens until December 8. (A338, 154-259).

Rule 8.1.13. requires adequately maintaining and properly documenting the patient record. Rule 18.7 as discussed in the summary of substantial evidence above requires documentation of practitioner's compliance with Rule 18. The Superior Court failed to substantively address these violations, when either alone could have resulted in discipline against Dr. Grossinger's license. Rule 8.1.13 is one of the two bases relied upon by the Board in the comparable *Centers* case. Substantial evidence

supports the violations, starting with the lack of any documentation at all by Dr. Grossinger in Michael's file, but also specifically including the absence of a full drug history or inquiry, the absence of Dr. Lifrak's records from Michael's file, and the absence of any Rule 18 compliance by Dr. Grossinger.

The factual record established Dr. Grossinger wrote three prescriptions for controlled substances for a patient he never saw. He established a Pain Management Agreement with this patient, and then Dr. Grossinger completely failed to live up to his end of that agreement. The prescribing practices with this patient were dangerously unsafe to not only that patient, but to the surrounding citizens as pills were being prescribed but, according to the only urine drug screen conducted, not taken by this patient. The Board imposed its lowest level of discipline, a letter of reprimand, against Dr. Grossinger after taking into account his mitigation arguments. That decision is supported by substantial evidence. The Superior Court's finding of errors of law regarding unconstitutional vagueness as applied are simply wrong. It is respectfully requested that the decision of the Delaware Board of Medical Licensure and Discipline be affirmed.

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

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