IN THE SUPREME COURT OF THE STATE OF DELAWARE

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| DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE, | § | |
| | § | No. 53, 2019 |
| Appellee Below, Appellant, | § | Court Below: Superior Court of the State of Delaware |
| v. | § | |
| | § | C.A. No. N16A-11-001 |
| BRUCE GROSSINGER, D.O., | § | |
| Appellant Below, Appellee. | § | |

Submitted: October 23, 2019
Decided: January 8, 2020

Before **SEITZ**, Chief Justice; **VALIHURA**, **VAUGHN**, and **TRAYNOR**, Justices; **RYAN**, Judge,* constituting the Court *en Banc.*

Upon appeal from the Superior Court of the State of Delaware. **REVERSED IN PART.**

Patricia A. Davis, Esquire (*argued*), and Zoe Plerhoples, Esquire, Department of Justice, Wilmington, Delaware, *Counsel for Appellant.*

Paul A. Logan, Esquire (*argued)*, Post & Schell, P.C. Wilmington, Delaware; James J. Kutz, Esquire, Harrisburg, Pennsylvania, *Counsel for Appellee*.

* Sitting by designation under Del. Const. art. IV § 12.

**TRAYNOR**, Justice:

The Delaware Board of Medical Licensure and Discipline (the "Board") reprimanded Dr. Bruce Grossinger ("Dr. Grossinger"),[1] a physician, for violating various regulations governing the use of controlled substances for the treatment of pain. In particular, the Board adopted the detailed report and recommendation of a Division of Professional Regulation hearing officer, who had found that Dr. Grossinger, in his care of a heroin-addicted patient ("Michael"), had not complied with the Board's rules and regulations. Specifically, the Board found that Dr. Grossinger failed to, among other things, document Michael's history of substance abuse, discuss with Michael the risks and benefits of treatment with controlled substances, order urine samples or require pill counts, and keep accurate and complete treatment records.[2]

After conducting a two-day evidentiary hearing, the hearing officer recommended that the Board find Dr. Grossinger guilty of unprofessional conduct and discipline him by placing his medical license on probation for six months and requiring him to complete additional medical education and pay a $2000 fine.[3] The

[1] Although there are two doctors named Grossinger involved in this case, this opinion will only refer to Appellee Dr. Bruce Grossinger as "Dr. Grossinger." References to Dr. Steven Grossinger will always include his first name.
[2] *See* Ex. A to Opening Br. at 4 n.6.
[3] App. to Opening Br. at A347–48 (hereinafter "A___"). The hearing officer also found that Dr. Grossinger's partners at GNS violated the Board's regulations and recommended discipline. The Board agreed, but only Dr. Grossinger has appealed the Board's order.

Board adopted the hearing officer's findings but reduced Dr. Grossinger's discipline from probation to a letter of reprimand.

Dr. Grossinger appealed the Board's decision to the Superior Court, which reversed on all but one of the five findings. The Superior Court's reversal of the Board rested on several legal conclusions, including that some of the regulations that Dr. Grossinger was said to have violated were unconstitutionally vague as applied to him, that expert testimony was required to establish the standard of care under the regulations, and that Dr. Grossinger's due process rights were violated because the Board relied on evidence—its own expertise—outside the record. The parties cross-appealed. The Board appeals the Superior Court's reversal of all but one of the findings, and Dr. Bruce Grossinger appeals the Superior Court's failure to reverse the final finding. We disagree with the Superior Court's reversal of the Board's decision and, therefore, we reverse.

## I. FACTS

The factual record before the Board was developed at an evidentiary hearing conducted by the hearing officer. Under the statute governing such hearings, the Board was bound by the officer's factual findings.[4] The hearing officer heard

[4] A365; 29 *Del C.* § 8735(v)(1)(d).

testimony of five witnesses, including Dr. Grossinger, his two partners who were charged with the same violations, and an expert called to testify on their behalf.

As the following treatment history shows, the last few years of Michael's life, which came to a tragic end on December 12, 2014 as a result of a heroin overdose, were marked by pain and addiction. Although Michael died while under the care of Grossinger Neuropain Specialists ("GNS"), the medical practice with which Dr. Grossinger is associated, it is important to emphasize here that the Board did not charge Dr. Grossinger or his partners with causing Michael's death. Michael's death did, however, provide the impetus for his grieving mother's complaint to the Division of Professional Regulation and the resulting investigation and disciplinary proceeding. We will therefore begin our discussion with a rudimentary history of Michael's pain-management treatment and its inter-relationship with his opiate addiction.

### A. Michael's medical history

Michael had been in two or three motor vehicle accidents: one in 2008 and one in either 2010 or 2011.[5] After the 2008 collision, Michael sought treatment for his accident-related pain with Dr. Ross Ufberg.[6] After the second accident, Michael

[5] The record is unclear as to whether Michael was involved in two or three accidents between 2008 and 2011. A318. Dr. Steven Grossinger noted in his initial report, written the day Michael presented to GNS, that Michael had been in an accident in 2008 and 2011. A157. In his July 11 report, however, Dr. Steven Grossinger only mentions a collision in 2008 and on April 1, 2010. A216.

[6] A215; A319.

continued to see Dr. Ufberg, who prescribed Lyrica and Oxycodone.[7] Lyrica is not an opiate, but Oxycodone is.[8] In March 2011, Dr. Ufberg discharged Michael "due to inconsistencies in his urine drug screen."[9]

Shortly thereafter, Michael again sought treatment for pain, this time with Dr. Damon Cary.[10] Dr. Cary prescribed Roxicodone and MS Contin,[11] both of which are opiates.[12] Michael continued to follow-up with Dr. Cary through July 17, 2012.[13]

At some point during his pain treatment, Michael became addicted to opiates—specifically, heroin. In December of 2013, Michael sought treatment for his addiction with Dr. Irwin L. Lifrak, who prescribed Suboxone "to assist in [Michael's] detoxication from opioids, such as heroin, Percocet, oxycontin, oxycodone[,] or hydrocodone."[14] Suboxone is the brand name for a combination of buphrenorphine, an opiate, and naloxone, an opiate antagonist.[15] Its only use is for

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[7] A216; A319.

[8] *Is Lyrica a Narcotic?*, HEALTHLINE, https://www.healthline.com/health/is-lyrica-a-narcotic (last visited Nov. 11, 2019); *Oxycodone HCL Solution*, WEBMD, https://www.webmd.com/drugs/2/drug-1025-5278/oxycodone-oral/oxycodone-oral/details (last visited Nov. 11, 2019).

[9] A216; A319.

[10] A216; A319.

[11] A216; A319.

[12] *MS Contin*, WEBMD, https://www.webmd.com/drugs/2/drug-1507/ms-contin-oral/details (last visited Nov. 11, 2019). Roxicodone is simply another name for Oxycodone. *Roxicodone*, WEBMD, https://www.webmd.com/drugs/2/drug-3499/roxicodone-oral/details (last visited Nov. 11, 2019).

[13] A217.

[14] A263–264; A320.

[15] *Opioid Overdose Reversal with Naloxone (Narcan, Evzio)*, NATIONAL INSTITUTE ON DRUG ABUSE (Apr. 2018), https://www.drugabuse.gov/related-topics/opioid-overdose-reversal-

treating opiate addictions—it is not used to treat pain.[16] Michael's treatment with Dr. Lifrak abruptly ended after one month, on January 14, 2014, when Michael tested positive for heroin, as a result of which he was discharged from Dr. Lifrak's care.[17]

### B. Michael presents to GNS

Two weeks later, on January 29, 2014, Michael presented to GNS, a medical practice located in Wilmington that specializes in pain treatment.[18] GNS has three principals: Dr. Steven Grossinger, Dr. Grossinger (the Appellee), and Dr. Jason Brajer.[19] Dr. Allen Silberman also works with GNS, and his name appears on GNS's letterhead, but he is considered an "independent psychologist."[20] Dr. Silberman performs psychosocial studies and evaluates pain status for GNS patients—a service he also provides to Dr. Lifrak.[21]

When Michael presented to GNS, he signed a pain-management agreement, which provided that: (a) he would comply with "any random drug test" that GNS physicians felt was necessary, and (b) if he broke the agreement, GNS "*will* stop prescribing" pain-control medicines and "*will* discharge [him] from the practice."[22]

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naloxone-narcan-evzio; *Suboxone*, DRUGS.COM (Nov. 4, 2019), https://www.drugs.com/suboxone.html.

[16] *Suboxone*, DRUGS.COM (Nov. 4, 2019), https://www.drugs.com/suboxone.html.

[17] A270; A321.

[18] A12; A157–158; A322.

[19] A322.

[20] A322

[21] A322.

[22] A170 (emphasis added); A324.

That same day, two doctors, Dr. Steven Grossinger and Dr. Silberman, evaluated him and produced written reports regarding their evaluation.[23]

Dr. Silberman's report provided details about Michael's recent care. Among other things, it noted that Michael "suffers an opiate addiction that started five years ago as the result of Oxycodone and Morphine prescriptions from his physician" and that Michael was treating with Dr. Lifrak, "who also manages his Suboxone[,] which is used for opiate dependence."[24]

Dr. Steven Grossinger's report took the form of a letter to Michael's primary care doctor and described the results of Michael's examination, which consisted of an MRI,[25] an EMG,[26] and nerve-conduction studies.[27] In this report, Dr. Steven Grossinger noted that Michael had "not had treatment of his pain over the last year" but "had gotten Suboxone last month though it was not refilled."[28] The report did not, however, mention why Michael was taking Suboxone.[29] When questioned

[23] A157–158 (emphasis added); A165–166 (emphasis added); A322.
[24] A165.
[25] MRI stands for "magnetic resonance imaging," which "is a medical imaging technique that uses a magnetic field and computer-generated radio waves to create detailed images of the organs and tissues in [the] body." MRI, Mayo Clinic, https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768 (last visited Dec. 3, 2019).
[26] A326; A110. EMG stands for "electromyography," which "is a diagnostic procedure to assess the health of muscles and the nerve cells that control them (motor neurons). EMG results can reveal nerve dysfunction, muscle dysfunction or problems with nerve-to-muscle signal transmission." Electromyography (EMG), https://www.mayoclinic.org/tests-procedures/emg/about/pac-20393913 (last visited Dec. 3, 2019).
[27] A22; A157.
[28] A158; A324.
[29] A15; A157–58.

about Michael's Suboxone treatment, Dr. Steven Grossinger testified that he only found out about Michael's heroin addiction a few days prior to testifying.[30] Accordingly, the hearing officer found that Dr. Steven Grossinger "did not know why Michael was treating with Dr. Lifrak with Suboxone," which strongly suggests that Dr. Steven Grossinger did not read Dr. Silberman's report.[31]

Dr. Steven Grossinger also testified, and the hearing officer found, that he did not obtain Michael's medical records from either Dr. Lifrak or Dr. Cary; therefore, he was ignorant of whether Michael had been compliant with Dr. Lifrak or Dr. Cary's treatment.[32] Nor did Dr. Steven Grossinger obtain Michael's medical records from Michael's primary care physician, Dr. Yezdani, who had referred Michael to GNS.[33] Dr. Yezdani's records indicated that he had been prescribing Alprazolam and Xanax for Michael—prescriptions that Dr. Steven Grossinger conceded he would consider in treating Michael due to the "potential ill effects of multiple medications."[34]

### C. Michael's Treatment at GNS

The record shows that Dr. Brajer and Dr. Steven Grossinger, but not Dr. Grossinger, met with Michael to treat his pain several times between his initial

[30] A17.
[31] A293.
[32] A18–20; A294–295
[33] A22; A295.
[34] A22; A295

presentation and his death on December 12, 2014.[35] Initially, Michael presented for treatment about once per month and was prescribed oral medications including opiates, such as Hydrocodone and Morphine Sulfate, during that time.[36] Notably, however, a June 18, 2014 appointment with Dr. Brajer, at which a urine drug screen was to be conducted—the first such screen scheduled during the five months Michael had been, at that point, under GNS's care—was cancelled due to a "lapse in insurance."[37] After this missed urine drug screen, Dr. Grossinger, who had never previously met Michael, refilled Michael's prescriptions for Hydrocodone and Morphine Sulfate on three separate occasions.[38]

A follow-up visit was scheduled for July 30, 2014. Michael showed up for this visit, during which Dr. Brajer increased Michael's Hydrocodone dosage, but his scheduled injection was cancelled because his insurance carrier denied coverage.[39] The missed urine drug screen from June 18 was not performed at this follow-up visit.[40]

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[35] A171–A222; A271; A325–326. Although Dr. Grossinger never met with Michael, the hearing officer noted that Dr. Grossinger's "involvement with Michael's treatment consisted in writing . . . and . . . refill[ing] prescriptions for Michael." A326.
[36] A33, A325. Hydrocodone is also an opiate-based medication. A33.
[37] A43–44; A325.
[38] A107–08; A326.
[39] A287.
[40] A43–45; A326.

Michael then cancelled his next appointment, scheduled for September 3, claiming illness.[41] Despite the outstanding urine drug screen and the recently missed appointment, Dr. Grossinger refilled Michael's Hydrocodone and Morphine Sulfate prescriptions again.[42] Michael then canceled another appointment, which was scheduled for October 27.[43] On November 12, Dr. Grossinger again refilled Michael's prescriptions, even though Michael's treatment record as of that date showed that the June urine screen had not been rescheduled and that Michael had recently missed or cancelled two appointments. The doctor noted, however, that any further refills were contingent upon making—and keeping—an appointment at the GNS offices.[44]

Michael showed up to his next appointment on December 8, when he was seen by Dr. Steven Grossinger, and provided a urine sample for screening.[45] On December 12, 2014, Michael passed away from a heroin overdose.[46] GNS, unaware of his death, discharged Michael as a patient on December 14, 2014, because the urine sample "was abnormal which is indicative of Heroin metabolite."[47]

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[41] A326.
[42] A326.
[43] A326.
[44] A87; A326.
[45] A326.
[46] A271; A327.
[47] A50–51; A327.

### D. Board Proceedings.

After Michael's death, in response to a complaint his mother filed with the Division of Professional Regulation against GNS and its three physicians, the State investigated and filed separate formal complaints against Dr. Brajer, Dr. Steven Grossinger, and Dr. Grossinger. The State charged Dr. Grossinger with violating 24 *Del. C.* § 1731(b)(3) and 24 *Del. C.* § 1731(b)(11).[48] Those two subsections of § 1731 allow the Board to discipline practitioners for unprofessional conduct or misconduct; such misconduct is defined in Board Regulation 8.1 as including "[f]ailure to adequately maintain and properly document patient records," which encompasses violations of other Board Regulations, including the ones at issue in this case.

Because the complaints arose out of the same set of operative facts, the parties agreed to a consolidated evidentiary hearing in front of a single hearing officer. After a two-day evidentiary hearing, the hearing officer found all three doctors guilty of regulatory violations.[49] Drs. Brajer and Steven Grossinger did not appeal. Accordingly, we only concern ourselves with the findings as they relate to Dr. Grossinger.

[48] A130–31.
[49] Ex. A. to Opening Br. at 4.

### 1. Violation of Board Regulation 18.1.1.

The hearing officer first found that Dr. Grossinger violated Board Regulation 18.1.1, which requires physicians prescribing controlled substances for the treatment of pain to "obtain[], evaluate[], and document[]" a "medical history and physical examination." That medical history must include a "history of substance abuse."[50]

The hearing officer found as a matter of fact that, before refilling Michael's prescriptions, Dr. Grossinger reviewed Michael's abnormal MRI's and EMG's. Dr. Grossinger did not, however, recall reviewing Michael's Prescription Monitoring Program ("PMP") report.[51] The PMP is a state-wide system "that collects information on all controlled substance (schedules II-V) prescriptions."[52] Thus, though Dr. Grossinger would have or should have been aware that Michael had been treated with Suboxone in the past, he did not review Michael's history with prescribed opiates. The hearing officer also found, based on Dr. Grossinger's testimony, that Dr. Grossinger did not request a copy of Dr. Lifrak's chart on Michael at any time, nor did he call Dr. Lifrak or communicate with him to discuss Michael's treatment immediately prior to presenting at GNS.[53]

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[50] 24 *Del. Admin. C.* 1700-18.1.1.1.
[51] A113; A326–327.
[52] Delaware Prescription Monitoring Program, Division of Professional Regulation, https://dpr.delaware.gov/boards/pmp/ (last visited Dec. 3, 2019).
[53] A124–125; A330. In what appears to emphasize the hearing officer's wariness of Dr. Grossinger's credibility, the hearing officer noted that, even though Dr. Grossinger did not request or review Dr. Lifrak's charts, he "nonetheless state[d] that Dr. Lifrak should have reported 'heroin addiction' specifically in [his] charts." A327.

In lieu of Dr. Lifrak's charts, Dr. Grossinger purported to rely instead on Dr. Silberman's reports. The hearing officer noted that Dr. Grossinger thought he recalled reviewing both Dr. Steven Grossinger's and Dr. Silberman's January 29, 2014 reports, but was not sure.[54] On this and other points, the hearing officer was skeptical of Dr. Grossinger's credibility.[55] Specifically, the hearing officer noted that Dr. Grossinger testified that he "believes Silberman did not mention Suboxone in his evaluation" and that, had Dr. Grossinger been aware of Michael's opiate dependence, he would have asked Michael about treatment for that dependence.[56] But the hearing officer points out that Dr. Silberman used the phrase "opiate addiction" in his report and "also reported that Michael was, in January 2014, being managed with Suboxone."[57] Thus, it appears to us that the hearing officer was skeptical that Dr. Grossinger had even read Dr. Silberman's report, despite Dr. Grossinger's testimony that "within a reasonable degree of reasonable probability . . . [he] believe[d] [he] did."[58]

The hearing officer, despite his doubts, took Dr. Grossinger's word, but concluded as a matter of law that:

> If Dr. Bruce Grossinger's admitted 'obsessiveness' led him to read the Silberman report (as he admits), and if that report fairly informed him

[54] A327. This comports with Dr. Grossinger's testimony that he did not recall if he reviewed Dr. Silberman's and Dr. Steve Grossinger's January 29 reports. A110–12.
[55] A327.
[56] A124; A327.
[57] A327 (emphasis added); A165 (emphasis added).
[58] A119.

> that Dr. Lifrak had been treating [Michael] with Suboxone for 'opiate addiction' within weeks or days of his presentation at GNS, in [the hearing officer's] view[,] the reasonable physician practicing under the strictures of Bd. Reg. 18 would have inquired further in order to develop a complete, timely, pertinent medical history.[59]

Board Regulation 18.1.1 requires by its plain text that practitioners engaged in the prescription of controlled substances for pain treatment must "document . . . [the] history of substance abuse."[60] The hearing officer concluded that a reasonable physician would understand such a history to include the patient's treatment for substance abuse—a history which Dr. Grossinger did not obtain.[61]

**2. Violation of Board Regulation 18.3.**

The hearing officer also found that Dr. Grossinger violated Board Regulation 18.3, which requires the practitioner to "discuss the risks and benefits of the use of controlled substances with the patient."[62] The hearing officer ultimately found as a matter of fact that such discussions did not occur.

To begin with, the hearing officer noted that Dr. Grossinger's expert, Dr. Staats, opined that Dr. Grossinger had complied with Regulation 18.3 because "Dr. Steven Grossinger had informed him that 'these communications occurred' and because an 'opiate consent form was signed.'"[63] But the hearing officer did not find

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[59] A331–332. The hearing officer's conclusions of law begin on A328; conclusions stated before that page are findings of fact.
[60] 24 *Del. Admin C.* §18.1.1
[61] A332.
[62] 6 *Del. Admin. C.* 1700-18.3.
[63] A334.

this opinion credible. Specifically, he noted that, after reviewing "both iterations of Michael's GNS chart," he could not "find *any* documentation that *anyone* had the 'talk' with Michael," Dr. Steven Grossinger or anyone else.[64] Nor did the hearing officer find that the "consent form" was proper documentation of the occurrence of a "risk and benefits" discussion, as Dr. Staats opined.[65] Instead, the hearing officer pointed out that none of the forms that Michael signed contained a disclosure of a risks-and-benefits discussion for oral medication or any acknowledgment that they had been explained to him.[66]

Additionally, the hearing officer pointed to April 9, 2014, as a key treatment date for Michael, because Dr. Brajer switched Michael's medications from Tramadol[67] to Hydrocodone at that appointment.[68] Critically, although Dr. Brajer testified that he had "thorough talks" with Michael on "risks and benefits" that day,[69]

[64] A335 (emphasis added).
[65] A335.
[66] A336.
[67] Dr. Steven Grossinger described Tramadol as an opiate-based medication that was not a controlled substance at the time GNS prescribed it to Michael. A32.
[68] Transcript of Evidentiary Hearing before Hearing Officer Roger Akin, C.A. No. 16A-11-001 FWW, at 81; A335.
[69] The hearing officer attributes this testimony to Dr. Steven Grossinger, but that is incorrect. The testimony regarding a "thorough talk" came from Dr. Brajer. A89. Dr. Steven Grossinger's testimony corroborates that Dr. Brajer tends to give such talks. A47. While such confusion would normally cast suspicion on the hearing officer's determinations of credibility, that is not the case here. The hearing officer based his finding of a violation of Regulation 18.3 on the fact that no documentation of a discussion of risks and benefits exists. The fact that there is no documentation of the discussion is not undermined by confusion as to who testified that the discussion occurred.

the hearing officer did not find that statement credible either, finding that "there is no documentation in either GNS chart that such a discussion was had on April 9."[70]

Although the hearing officer found as a matter of fact that Dr. Grossinger never met with Michael, he also noted that Board Regulation 18.3 "imposes a mandatory 'duty' on practitioners regarding . . . 'the talk' with patients." Given the lack of documentation that any risk-benefit discussion was held with Michael, the hearing officer concluded that, "[h]ad [Dr. Grossinger] reviewed Michael's chart prior to writing his first prescription for him in July 2014, he would have determined that the [risk-benefit] discussion had not occurred. Neither Dr. Steven Grossinger nor Dr. Jason Brajer had documented any such discussion."[71] Noting that, "[i]n the past, this Board has often applied the adage that 'if it's not in the chart, it didn't happen,'" the hearing officer concluded that Dr. Grossinger had violated his duty to discuss the risks and benefits of oral opiate-based medication with Michael, because he ignored the lack of documentation of such discussion in Michael's charts and, despite that absence, did not undertake the discussion with Michael himself.[72]

**3. Violation of Board Regulation 18.4.**

The hearing officer then found that Dr. Grossinger had violated Board Regulation 18.4, by failing to enforce the pain-management agreements that Michael

[70] A335–36.
[71] A336.
[72] A336.

had signed. Regulation 18.4 requires the use of a written agreement between the practitioner and the patient that outlines the patient's responsibilities, including a "urine/serum medication levels screening when requested."[73]

Michael signed two such agreements over the course of his treatment at GNS. The first was signed on January 29, the day he presented.[74] The second was signed on June 13, 2014.[75] Both contain clauses requiring Michael to submit to urine testing when requested. Additionally, Michael acknowledges in both agreements that his "doctor *will* stop prescribing these pain-control medicines" if Michael breaks the agreement.[76] The hearing officer found as a matter of fact, that Dr. Grossinger did not enforce the agreement, emphasizing the absence of any urine screens for the five-month period following the cancelled screen in June 2014—a period during which Dr. Grossinger refilled Michael's opiate prescriptions three times.[77] As previously mentioned, a urine drug screen was requested on June 18, 2014, that drug screen was not given (for insurance reasons), it was not rescheduled (until December), and yet Dr. Grossinger continued to refill Michael's opiate prescriptions during that time

[73] 6 *Del. Admin. C.* 1700-18.4.
[74] A324; A336–37; A170. The Board's appendix contains only one page of this agreement, but the language is substantially similar to the pain-management agreement signed in June, 2014. The hearing officer noted that the second agreement differed by adding a condition that Michael was prohibited from seeking prescriptions for controlled substances from any other physician, and adding that Michael must "bring all unused pain medicine to every office visit." A337.
[75] A209–210.
[76] A170 (emphasis added); A209 (emphasis added).
[77] A338.

period.[78] The hearing officer concluded that this lack of enforcement did not satisfy Rule 18.4's mandate that physicians "use" the written agreement.[79]

**4. Violation of Board Regulation 18.5.**

Next, the hearing officer found that Dr. Grossinger violated Board Regulation 18.5, which requires the "licensed practitioner [to] periodically review the course of pain treatment." That review requires the physician to evaluate "continuation or modification of controlled substances for pain management therapy depending on the practitioner's evaluation of the patient's progress."[80]

The hearing officer found as a matter of fact that Dr. Grossinger had not met or seen Michael, nor was he involved in planning or executing Michael's course of pain treatment.[81] As a matter of law, however, the hearing officer concluded that Board Regulation 18.5.1 "imposes an affirmative duty on the practitioner who *prescribes* controlled substances to conduct periodic chart reviews in order to determine whether progress toward treatment goals . . . warrants continuation of modification of then-current drug regimens."[82] Dr. Grossinger did not recall reviewing Dr. Steven Grossinger's reports or Michael's medical records, other than

[78] A338.
[79] A337 ("[T]he regulation states that the pain physician 'must use' such agreements. . . . In other words, the physician who promises or threatens toxicology screening must in fact implement that threat from time to time or the agreement is just another piece of paper.").
[80] 6 *Del. Admin. C.* 1700-18.5–1700-8.5.1.
[81] A339.
[82] A340 (emphasis added).

his abnormal MRI's and EMG's;[83] instead, he "relied on the prescriptive history established by Dr. Brajer and Dr. Steven Grossinger" in refilling Michael's prescription.[84] Consequently, the hearing officer found that Dr. Grossinger did not conduct *any* review of Michael's treatment plan, much less a periodic one, thus "fail[ing] to conduct the sort of 'periodic review' required of the prescriber in Board Regulation 18.5."[85]

**5. Violation of Board Regulation 18.7.**

Additionally, the hearing officer concluded that Dr. Grossinger violated Board Regulation 18.7, which requires the practitioner to "keep accurate and complete records," including "medical history and physical examination," "discussion of risks and benefits," and "periodic review."[86] The hearing officer noted that he had already concluded that Dr. Grossinger violated Board Regulations 18.1.1 (which required medical records and medical history), 18.3 (which required a discussion of risks and benefits), and 18.5 (which required periodic review). Those violations, the hearing

[83] A340.
[84] A340.
[85] A340.
[86] 6 *Del. Admin. C.* 1700-18.7–1700-18.7.11.

officer concluded, were sufficient to also constitute a violation of Board Regulation 18.7's requirement of documentation.[87]

### 6. Violation of 24 *Del. C.* § 1731(b)(3).

Finally, the hearing officer concluded that Dr. Grossinger's multiple violations of regulations requiring documentation also supported the legal conclusion that Dr. Grossinger had violated 24 *Del. C.* § 1731(b)(3). Section 1731 authorizes the Board to discipline licensed practitioners for unprofessional conduct—which is defined as "[a]ny dishonorable, unethical, or other conduct likely to deceive, fraud, or harm the public." Board Regulation 8.1 defines "[t]he phrase 'dishonorable or unethical conduct likely to deceive, defraud, or harm the public'" as, among other things, "[f]ailure to adequately maintain and properly document patient records."[88] The hearing officer therefore concluded that, in addition to violating Board Regulations 18.1, 18.3, 18.4, 18.5, and 18.7, Dr. Bruce Grossinger

[87] A340–41.
[88] 6 *Del. Admin. C.* 1700-8.1.13.

had also engaged in unethical behavior as defined under Board Regulation 8.1 and was thus subject to discipline under 24 *Del. C.* §1731(b)(3).[89]

**7. The hearing officer's disciplinary recommendation and the Board's order.**

As sanctions for Dr. Grossinger's violations, the hearing officer recommended that the doctor's medical license be placed on probation for six months, and that he complete nine continuing-medical-education hours and pay a $2,000 fine.[90] After Dr. Grossinger received a copy of the hearing officer's recommendations, he submitted written exceptions. Those exceptions included a breakdown of Michael's treatment from Dr. Grossinger's perspective, an interpretation of the evolution of the Board's regulations, and arguments that the penalty recommended by the hearing officer was too harsh.[91] The written exceptions also included an argument that the State offered no expert testimony, which "forced [Dr. Grossinger] to shadowbox against a non-existent opponent,"[92] and attached a letter from Dr. Jackson Snyder of Potomac, Maryland.[93] The State moved to strike

[89] A341–42.
[90] A347–48.
[91] A349–61; A363–64.
[92] Exhibit A to Memorandum of Respondent Bruce Grossinger, D.O. in Opposition to the July 13, 2016 Report and Recommendation of the Hearing Officer, C.A. No. N16A-11-001 FWW, at 4.
[93] Exhibit B to Memorandum of Respondent Bruce Grossinger, D.O. in Opposition to the July 13, 2016 Report and Recommendation of the Hearing Officer, C.A. No. N16A-11-001 FWW.

the letter as factual evidence not presented at the evidentiary hearing. Both Dr. Grossinger's attorney and the State also presented exceptions orally to the Board.

The Board issued its final order on October 4, 2016, granting the Board's motion to strike and affirming the hearing officer's conclusions of law regarding Dr. Grossinger's violations. Yet it also reduced the hearing officer's recommended penalty, "finding it too harsh given that [the State's] Complaint involve[d] one patient and there is an established successful practice."[94] Instead of placing Dr. Grossinger's license on probation for six months, the Board decided to subject the license to a letter of reprimand, but retained the fine and continuing medical education requirements.[95] Dr. Grossinger appealed the order to the Superior Court.

**E. The Superior Court's decision.**

The Superior Court, after briefing and oral argument, issued a memorandum opinion reversing all of the Board's conclusions except for its determination that Dr. Grossinger had violated Regulation 18.3, regarding discussions of the risks and benefits of Michael's oral opiate-based medications. The Superior Court first noted that the Administrative Procedures Act[96] ("APA") did not apply to the Board—even

[94] A365.
[95] A366.
[96] 29 *Del. C.* 10100.

though neither party disputed that the APA applied.[97] On appeal, the Board argues that the APA does apply, and Dr. Grossinger does not dispute that.[98]

The Superior Court reversed all but one of the Board's remaining findings because, in its view, the Board Regulations in question were unconstitutionally vague as applied to Dr. Grossinger and, more particularly, that they did not give him adequate notice that his conduct was prohibited. It noted that, for example, Regulation 18.1.1 did not specify from whom GNS needed to acquire medical records, nor did it specify what time periods such medical records needed to cover.[99] The Superior Court also held that Regulation 18.4 was vague because it did not specify the required frequency of the mandated urine drug screens.[100] Similarly, Regulation 18.5 was vague, in the court's view, because it did not specify the frequency of the required "periodic review."[101]

This purported vagueness, in the court's view, could only be cured by the application of a standard of care, and there was no evidence presented by the State in this case regarding such a standard. According to Appellee and the Superior Court, that lack of evidence implicated Dr. Grossinger's due process rights, and,

[97] Ex. A to Opening Br. at 16–17;
[98] Opening Br. 14–15; Answering Br. 27–28 (arguing that the Superior Court would not have reached a different conclusion had it applied the APA, but not arguing whether the APA does or does not apply).
[99] Ex. A to Opening Br. at 26–27.
[100] Ex. A to Opening Br. at 28–29.
[101] Ex. A to Opening Br. at 30–31.

more specifically, his rights to notice and confrontation. Put another way, the court held that the Board's reliance on a reasonable-physician standard of care derived from its own expertise rather than expert testimony deprived Dr. Grossinger of *ex ante* notice of what standard of care his conduct would be judged by and also deprived him of the opportunity to cross-examine and confront the evidence used to derive that standard.

## II. STANDARD OF REVIEW

Where, as here, the Superior Court has reviewed an administrative agency decision without receiving any evidence other than that presented to the agency, we do not review the Superior Court's decision directly. Instead, we examine the agency's decision to determine whether the agency's ruling is supported by substantial evidence and free from legal error.[102] Our review of issues involving statutory construction and the application of the law to undisputed facts is plenary.[103]

## III. ANALYSIS

The Board raises three claims on appeal. First, it submits—contrary to what the Superior Court held—that expert evidence is not required to establish that Dr. Grossinger violated the standards to which he is subject under the Board's rules and regulations. Second, the Board argues that the lack of expert testimony does not

[102] *Stoltz Mgt. Co. v. Consumer Affairs Bd.*, 616 A.2d 1205, 1208 (Del. 1992).
[103] *Dept. of Health and Social Services v. Jain*, 29 A.3d 207, 211 (Del. 2011).

render its rules and regulations unconstitutionally vague as they were applied to Dr. Grossinger and does not violate his due process rights of notice and confrontation. Third, the Board contends that the Board's factual findings are supported by substantial evidence. In his cross-appeal, Dr. Grossinger argues that the Board's finding that he did not discuss the risks and benefits of opioid treatment with his patient, in violation of Board Regulation 18.3, was not supported by substantial evidence. We address each of these issues in turn.

### A. Expert evidence was not required to establish Dr. Grossinger's violations of the Board's Regulations.

The Board's Regulations set forth standards of conduct to which licensed practitioners are held; they require, for example, periodic review of the patient's course of treatment. The parties do not dispute that those standards of conduct must be interpreted using some standard of care[104]—a metric that, for example, would determine how frequent the mandated "periodic review" must be. Rather, they dispute whether the State was required to present expert evidence to establish that level of care.

According to the Board, it does not need to hear expert testimony as to the level of care, because it is composed of a mix of experts and laymen and has

[104] That the Regulations require a standard of care to interpret the mandated conduct is implicit in the preface to the Regulations, which provides that "the Board will consider the inappropriate treatment of pain to be a departure from *standards of practice*" and "[t]he Board *may* refer to current clinical practice guidelines and/or expert review." 24 *Del. Admin. C.* 1700-18.0 (emphasis added).

specialized competence in the field of medicine. Dr. Grossinger disagrees, arguing that the Board's exercise of its expertise in determining the scope and applicability of the Board Regulations under the reasonable-physician standard violates his due process rights of adequate notice and confrontation of the evidence against him. Necessarily at the heart of this dispute is the nature of the standard of care implicit in the Regulations—in short, whether its interpretation is a matter of fact to be determined with the aid of expert evidence or a matter of law to be decided using the Board's expertise.

As a preliminary matter, though, we address the applicability of the APA to the Board's order—not because the parties disputed the issue but because the Superior Court addressed it.

**1. The APA applies to the Board of Medical Licensure and Discipline.**

The applicability of the APA is important to this case because it mandates deference by the courts to Board decisions. In particular, 29 *Del. C.* § 10142(d) states that, when reviewing the Board's decisions, "[t]he 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."

The Superior Court found that the APA did not apply to the Board until 2017—after the Board issued its order regarding Dr. Grossinger. It based its

decision on a 2017 amendment to 24 *Del. C.* § 1734(d),[105] which added language making it clear that Board hearings "shall be conducted pursuant to the Administrative Procedures Act."[106] But, as Appellant correctly points out, that bill was not the first time that the General Assembly made the Board subject to the APA. The Board has been an enumerated agency subject to APA provisions since 1984.[107]

As noted, the parties do not dispute the applicability of the APA to the Board's decision. Because the APA explicitly listed the Board as an agency it governs prior to 2016, and because the APA addresses hearings and decisions by the Boards it governs, we conclude that the Board's order in this case was governed by the APA.[108] The Board's factual determinations are therefore subject to substantial deference under § 10142(d).

**2. The standard of care implicit in the Board Regulations is an issue of law that does not require expert evidence to establish.**

As noted, whether the resolution of an issue requires expert evidence depends in part on whether that issue is a question of law or fact; the latter requires either witness or expert testimony, and the former does not.[109] Thus, whether expert

[105] 24 *Del. C.* § 1734 is part of the Medical Practice Act and covers hearings by the Board.
[106] 2017 Del. Laws. C. 97.
[107] 29 *Del. C.* § 10161(a)(22); 64 Del. Laws. C. 477, §5.
[108] 29 *Del. C.* §§ 10121–10129, 10142.
[109] *E.g., United Rentals, Inc. v. RAM Holdings, Inc.*, 2007 WL 4465520, at *1 (Del. Ch. Dec. 13, 2007) ("This Court, however, has made it unmistakably clear that it is improper for witnesses to opine on legal issues governed by Delaware law. It is within the exclusive province of this Court to determine such issues of domestic law."); *United States v. Curtis*, 782 F.2d 593, 599 (6th Cir. 1986) ("Experts are supposed to interpret and analyze *factual* evidence. They do not testify about

testimony is required to establish the standard of care incorporated in the Board Regulations depends on whether the determination of the standard of care implicit in the Regulations is an issue of law or fact.

According to Dr. Grossinger and the Superior Court, the determination of this standard is a question of fact, an important categorization in light of the nature of administrative disciplinary proceedings governed by the APA. In such cases, a hearing officer of the Division of Professional Regulation[110] conducts an evidentiary hearing and makes findings of fact.[111] Those findings are then binding upon the Board, even though, as was the case here, the hearing officer is not medically trained. The Board may not consider additional evidence and "shall affirm or modify" the hearing officer's recommended conclusions of law and proposed sanctions.[112]

The Board does not explicitly address whether the determination of the standard of care is a question of fact or law. Rather, it argues that it is not only empowered to determine the standard of care itself, but also that it need not hear

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the law because the judge's special legal knowledge is presumed to be sufficient, and it is the judge's duty to inform the jury about the law that is relevant to their deliberations.") (emphasis added); *Marx & Co. v. Diners' Club Inc.*, 550 F.2d 505, 509–10 (2d Cir. 1977) ("It is not for witnesses to instruct the jury as to applicable principles of law, but for the judge. . . . [E]xpert testimony on law is excluded because 'the tribunal does not need the witness' judgment.' . . . The special legal knowledge of the judge makes the witness' testimony superfluous.") (quoting VII Wigmore on Evidence § 1952, at 81).

[110] The Division oversees numerous state agencies, boards, and commissions, including the Board of Medical Licensure and Discipline, of which the Director of the Division is a voting member. *Board of Medical Licensure and Discipline*, DIVISION OF PROFESSIONAL REGULATION, https://dpr.delaware.gov/boards/medicalpractice/ (last visited Dec. 6, 2019); 24 *Del. C.* § 1710(b).

[111] 29 *Del. C.* § 8735(v)(1)(d).

[112] *Id.*

expert evidence in order to do so, because of its "experience and specialized competence"—competence which requires deference on judicial review.[113]

We disagree with the Superior Court's conclusion that the standard of care applicable to a determination of whether a physician has complied with the Board's regulations is purely a question of fact. Although Appellee and the Superior Court cite several cases purporting to hold that the determination of the standard of care applicable to medical treatment is a question of fact, all of the cited cases arise in the context of medical malpractice or other forms of negligence—a context that differs in material respects from administrative proceedings.[114] In tort cases, the jury decides the specific level of care required in each situation, i.e., the level of care required of the specific defendant in the tort case. Such a determination is necessarily a question of fact because the standard of care is different for every set of different facts; it is uncodified, case-specific, and necessarily tailored to the situation at hand.[115] That is not the case in administrative disciplinary cases, where

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[113] 29 *Del. C.* § 10142(d).

[114] For example, Appellee's Answering Brief cites *Di Filippo v. Preston*, 173 A.2d 333 (Del. 1961), an action for personal injuries and medical expenses arising out of alleged medical malpractice, as well as *Davis v. Maute*, 770 A.2d 36 (Del. 2011) and *Campbell v. DiSabatino*, 947 A.2d 116 (Del. 2008), both of which are negligence cases. Similarly, the Superior Court cited *Robelen Piano Co. v. Di Fonzo*, 169 A.2d 240 (Del. 1961), a negligence action against a storekeeper for injuries, and a litany of other tort cases. Ex. A to Opening Br. at 36 n94.

[115] *Robelen Piano Co. v. Di Fonzo*, 169 A.2d 240, 244–45 (Del. 1961) ("The standard of care required of all defendants in tort actions is that of a reasonably prudent man. That standard, however, is not a definite rule easily applicable to every state of facts. The details of the standard, of necessity, must be formulated in each particular case in the light of its peculiar facts. In each case the question comes down to what a reasonable man would have done under the circumstances.

regulations are designed to apply across the profession with equal force, and where the standard of care is not *itself* what is violated (as in tort cases), but rather a metric to judge whether a *regulation* is violated. In other words, the Regulations provide standards of conduct—which are typically absent in tort cases—and the level of care that determines the scope of the Regulations is derived from an interpretation of those standards. Therefore, in administrative proceedings, the standard of care is an *element* of the regulation, albeit an implicit one,[116] unlike in tort cases, where the standard of care is itself the governing standard, the specifics of which are determined by the jury, based on the facts, for the specific claim before the court. The interpretation of an element of a regulation is a question of law,[117] and it is not subject to expert testimony or confrontation.[118] Ascertaining the meaning of the implicit standard-of-care element of the Regulations is thus a question of law to be decided by the Board; it becomes a mixed question of fact and law, entitled to

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In close or doubtful cases, . . . that question is to be determined by the jury. This is so because of public insistence that its conduct be judged in large part, at least, by a cross-section of the public.").

[116] We reiterate that neither Dr. Grossinger nor the Board dispute that the reasonable-physician standard of care is implicit in the Board's regulations. In fact, even Dr. Grossinger's brief relies on the assumption that the Board's regulations are interpreted based on a reasonable-physician standard of care. Answering Br. 18 ("[U]se of the standard of care to supply missing critical information is consistent with the letter and intent of the Regulations."). Instead, Dr. Grossinger disputes the *meaning* of the reasonable-physician standard of care, and argues that the meaning requires expert testimony to establish. Answering Br. 16–18.

[117] *E.g.*, *Gill v. Shinseki*, 26 Vet. App. 386, 389 (Ct. Vet. App. 2013), *aff'd sub nom. Gill v. McDonald*, 589 F. App'x 535 (Fed. Cir. 2015) ("The "interpretation of a ... regulation is a question of law."); *In re Cities of Annandale & Maple Lake NPDES/SDS Permit Issuance for the Discharge of Treated Wastewater*, 731 N.W.2d 502, 515 (Minn. 2007) ("[W] hen a decision turns on the meaning of words in an agency's own regulation, it is a question of law.").

[118] *Supra* note 109.

deference,[119] only when applied to the facts of a specific case. That application does not require expert testimony to establish, just as our Vice Chancellors will not admit legal experts' testimony as to whether a specific defendant director has breached her fiduciary duties because such questions, though fact-specific, "concern[] legal issues governed by Delaware law."[120] To hold otherwise would be to allow the hearing officer, a lay person who is charged with making binding findings of fact, to restrict the Board's decision-making regarding the level of care exercised by reasonable physicians statewide, based only on the testimony of experts proffered in a specific proceeding.

This line of reasoning comports with the holding in *Bilski v. Board of Medical Licensure and Discipline*.[121] The argument in *Bilski* is almost identical to Dr.

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[119] The APA provides for deferential judicial review only of factual determinations. The Board's determination of a reasonable-physician standard of care, as incorporated into the Board Regulations, is thus not accorded such deference under the APA. The Board's specific findings of violation in particular proceedings, however, are mixed questions of fact and law and are accorded APA deference. *E.g.*, *Smith v. First State Exxon*, 1997 WL 27397, at *2 (Del. Super. Ct. Jan. 2, 1997) ("[E]ven as to the law or mixed questions of fact and law, it would seem that the Court should be entitled to 'take due account of the experience and specialized competence of the agency' which administers the law on a regular basis.") (quoting 29 *Del C.* 10142(d)); *Taylor v. Harford Cty. Dep't of Soc. Servs.*, 862 A.2d 1026, 1031 (Md. 2004) ("When the agency decision being judicially reviewed is a mixed question of law and fact, the reviewing court applies the substantial evidence test, that is, the same standard of review it would apply to an agency factual finding."); *Browning-Ferris Indus. v. Residents Involved in Saving the Env't, Inc.*, 492 S.E.2d 431, 434 (Va. 1997) (Consideration "of the experience and specialized competence of the administration agency . . . appl[ies] to the review of mixed questions of law and fact, and to the review of purely factual issues," but not to issues of law.).

[120] *Forsythe v. ESC Fund Mgmt. Co. (U.S.)*, 2010 WL 1676442, at *2 (Del. Ch. Apr. 21, 2010) (disregarding an expert report that claimed to testify "about custom and practice in the financial services business" but was actually the expert's "opinions regarding whether the defendants [had] fulfilled their fiduciary duties").

[121] 2014 WL 3032703 (Del. Super. Ct. June 30, 2014), *aff'd* 115 A.3d 1214 (Del. 2015).

Grossinger's due process claim: in *Bilski*, a physician subject to disciplinary proceedings for unprofessional conduct while prescribing controlled substances challenged the Board's disciplinary process by arguing that the lack of expert testimony regarding the standard of care meant that "the Board must have necessarily 'created' the evidence through its own expertise."[122] The Superior Court held—and we affirmed on the basis of its opinion—that the lack of expert testimony at the evidentiary hearing did not mean that the Board "created" evidence through its own expertise.[123] Quite to the contrary, the Superior Court found that the Board's decision was supported by a "robust" factual record.[124] While the court did not explicitly state that the Board may rely on its own expertise in determining whether there was a violation, our holding here is implicit in *Bilski*. The Board could not have made its decision on the robust record without first interpreting the Regulations (and the incorporated reasonable-physician standard of care) and applying that interpretation to the record. Indeed, *Bilski* is entirely on point here. Contrary to Dr. Grossinger's claims, the Board created a robust record, interpreted the Regulations and the incorporated standard of care, and applied that interpretation to the record. Expert testimony as to the meaning of the regulation was not necessary in *Bilski*, and it is unnecessary here.

[122] *Id.* at *1, *4.
[123] *Id.* at *4.
[124] *Id.*

### B. The lack of expert evidence as to the level of care required by the Regulations does not violate Dr. Grossinger's due process rights.

Dr. Grossinger argues, and the Superior Court found, that the lack of expert testimony on the reasonable-physician standard of care violated his due process rights because it deprived him of adequate notice that the Regulations applied to his conduct and deprived him of the right to confront adverse evidence. Because we have decided that the reasonable-physician standard implicit in the Regulations is a determination of law, rather than of fact, both of these arguments fail.

#### 1. The Board Regulations give adequate notice and therefore are not constitutionally vague as-applied.

According to both Dr. Grossinger and the Superior Court, the Board Regulations are unconstitutionally vague because their requirements are general and not specific, and therefore fail to give adequate *ex ante* notice of what conduct is required.[125] For example, according to Dr. Grossinger, Board Regulation 18.5 is vague because the mandated "periodic review" does not specify the frequency required for such reviews.[126] The only way to cure such alleged vagueness is to hold

[125] Ex. A to Opening Br. at 2; Answering Br. 15–16.
[126] Answering Br. 17.

practitioners to a standard of care by which such "periodic review" will be judged sufficient or insufficient.[127]

We note preliminarily that, although Dr. Grossinger frames his argument as an as-applied challenge to the vagueness of the Regulations, his challenge is actually a facial one. A facial challenge alleges that a statute or regulation is not valid under any set of circumstances; an as-applied challenge alleges that a statute or regulation is not valid in the particular circumstances of the case.[128] Dr. Grossinger appears to argue that his challenge is as-applied rather than facial because the lack of expert evidence *at his disciplinary proceeding* failed to give him notice of how he should have acted while treating Michael.[129] According to Dr. Grossinger, such expert testimony would fill the gaps in the Regulations and provide him notice of what conduct is proscribed.

But if a regulation's text fails to give *ex ante* notice of its requirements, it is facially void; a regulation whose meaning only becomes clear in disciplinary proceedings does not give adequate notice to anyone.[130] "The concept of unconstitutional vagueness is derived from a basic notion of fairness; citizens must

[127] Answering Br. 16.
[128] *U.S. v. Salerno*, 481 U.S. 739, 745 (1987); *U.S. v. Powell*, 423 U.S. 87, 92 (1975).
[129] Answering Br. 15–16.
[130] *Crissman v. Delaware Harness Racing Comm'n*, 791 A.2d 745, 747 (Del. 2002) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law.")

be given fair warning *before* being held culpable for conduct deemed to be criminal [or proscribed]."[131] Expert testimony at a disciplinary proceeding to clarify that standard of care would at most provide *ex post* notice and is therefore irrelevant to a fair warning challenge.

Thus, although Dr. Grossinger's argument attempts to target only his particular situation, his argument that the Regulations do not provide him adequate notice without expert testimony is better seen as alleging that the Regulations on their face do not provide adequate notice.[132] We are not persuaded by this argument. The Regulations implicitly incorporate a reasonable-physician standard of care against which a license-holder's conduct is judged—which Dr. Grossinger does not dispute.[133] The reasonable-physician standard of care, which is an objective standard of care, does not fail to give notice simply because it contains the word "reasonable"

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[131] *Gov't of Virgin Islands v. Steven*, 134 F.3d 526, 527 (3d Cir. 1998) (emphasis added).

[132] Dr. Grossinger's aversion to challenging the Regulations on their face is understandable. As the Superior Court noted, "the Regulations here have been adopted in one form or another by almost every jurisdiction in the state [*sic*]." Ex. A to Opening Br. at 21 (It is unclear whether the Superior Court meant almost every jurisdiction in the state or almost every jurisdiction in the nation. Regardless of whether the term "state" is an error, the widespread use of the regulations does not bear on the constitutionality of the regulations themselves.). A facial challenge would wreak havoc by calling into question every form of regulation that incorporates an implicit standard of care. The Superior Court was cognizant of this potential repercussion. It "emphasize[d] therefore that it [did] not find the regulations vague on their face" without explaining why Dr. Grossinger's challenge was applicable only to his particular set of facts. *Id.* But widespread repercussions cannot make an otherwise unconstitutional regulation constitutional, and due process cannot be circumvented for the convenience of the government.

[133] Answering Br. 18.

and people can differ as to the meaning of that term.[134] Indeed, the adequate notice requirement itself incorporates the reasonableness standard, by requiring that statutes and regulations only give "*the person of ordinary intelligence* a reasonable opportunity to know what is prohibited."[135]

We also note that, even if we were to take Dr. Grossinger's argument as an as-applied challenge, his argument would still fail. For notice to be adequate, it must give reasonable persons clarity as to what conduct is proscribed. To that end, consistency is the key. Basing violations of Regulations on expert testimony on an *ad hoc* basis would result in a patchwork of definitions of the required standard of care, with variations because of differing sets of facts and individual experts' idiosyncrasies. Adopting expert testimony to govern the interpretation of the Regulations would thus provide less notice than subjecting practitioners to the discretion and judgment of the Board. The Board is composed of sixteen people, eight of whom are licensed physicians, one of whom is the director of the Division of Public Health, and seven of whom are laypeople.[136] They "may," but are not required to, "refer to current clinical practice guidelines and/or expert review" when

[134] Similarly, statutes prohibiting reckless conduct do not fail to give notice simply because the challenger is not 100% sure what "reckless" means. *E.g.*, *State v. Boyer*, 512 S.E.2d 605, 701 (Ga. 1999) ("A statute is not unconstitutionally vague if its language provides persons of ordinary intelligence with notice as to what it prohibits so they may conduct themselves accordingly).
[135] *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (emphasis added).
[136] 24 *Del. C.* § 1710(b).

deciding disciplinary cases.[137] The same way that juries, through force of numbers, balance out individual idiosyncrasies,[138] so too does the Board's composition balance out the idiosyncrasies of individual physicians. And practitioners are on notice that the Board's judgment is informed by "current clinical practice guidelines."[139] Determinations of the reasonable-physician standard of care are thus more consistent when made by the Board than by experts in individual proceedings.

Further, even if we accepted Dr. Grossinger's argument that the Regulations do not provide adequate notice as to (1) the required extent of documentation of the patient's history of substance abuse, (2) the required extent and frequency of discussions of risks and benefits of oral opiate-based medication, (3) the required frequency of urine drug screening, or (4) the required frequency of "periodic review," Dr. Grossinger's notice argument would still fail.

Dr. Grossinger and the Superior Court focus on the absence of guidance in Regulation 18.1.1 as to when a prior treating physician's records must be obtained. But the Regulations clearly require documentation of the patient's "history of substance abuse"[140]—which includes a history of treatment of such substance abuse.

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[137] 24 *Del. Admin. C.* 1700-18.0.
[138] *Robelen Piano Co.*, 169 A.2d at 245 ("The standard of care required of all defendants in tort actions . . . must be formulated in each particular case in the light of its peculiar facts . . . by the jury. This is so because of public insistence that its conduct be judged in large part, at least, by a cross-section of the public.").
[139] *Id.*
[140] 24 *Del. Admin. C.* 1700-18.1.1.3.

Dr. Grossinger does not explain how this clear statement in the regulation did not put him on notice that he was required to document Michael's substance-abuse history, something he failed to do in any fashion. This is not a case where Dr. Grossinger obtained some documentation of Michael's history of substance abuse and the Board found it was insufficient; Dr. Grossinger and GNS did not obtain *any* of Michael's history of treatment, because they did not obtain information from the *only* doctor that Michael saw for his addiction. In fact, Dr. Steven Grossinger did not know until a few days before testifying that Michael was addicted to heroin,[141] Dr. Brajer did not know at the time of his testimony that Michael had been treated with Suboxone,[142] and Dr. Grossinger also did not know until after Michael's death that he was addicted to heroin.[143] A notice challenge might have some color if medical records were requested and the Board found them insufficient, but that is not the case here, where none of the GNS doctors were even aware that Michael had a history of substance abuse, despite Dr. Silberman's report explicitly noting an opiate addiction and treatment with Suboxone.[144]

Similarly, Dr. Grossinger did not discuss with Michael the risks and benefits of the medications he was prescribing at all, nor could he rely on documentation that

[141] A17.
[142] A84–88.
[143] A119–20.
[144] A165.

someone had done so, because there was no documentation. Dr. Grossinger fails to explain how a Regulation that mandates a discussion did not give him notice that at least one discussion was required.

Nor did GNS conduct a urine drug screening once the first screening was requested in June. It is the case that Regulation 18.4 does not explicitly mandate a certain frequency of drug screening, but it does require practitioners to "use" their agreements to require urine screening "when requested." GNS requested a urine drug screening in June, it was not completed, and GNS did not reschedule it or discharge Michael.[145] Dr. Grossinger does not explain how Regulation 18.4 did not provide notice that practitioners must enforce their pain-management agreements—something GNS abjectly failed to do.

Finally, as explained later, Dr. Grossinger failed to conduct *any* review of Michael's pain treatment course, much less *periodic* review. Even if we credited Dr. Grossinger's argument that "periodic" as used in Regulations 18.5 and 18.7 is vague, no reasonable person could believe that never conducting any review would satisfy the Regulations.

[145] A urine drug screening was only requested again in December, five months after the first screening was requested and missed.

### 2. The Board Regulations do not violate Dr. Grossinger's due process right to confrontation because the level of care implicit in the Regulations is an issue of law.

Dr. Grossinger's second due process challenge alleges that Dr. Grossinger was deprived of the "opportunity to confront and cross-examine adverse witnesses."[146] As we have held earlier, the Board's determination of the reasonable-physician standard of care based on its own expertise is not a determination of fact, nor is it a determination of mixed fact or law. Instead, it was a purely legal determination, and Dr. Grossinger is not entitled to cross-examine the methods by which such determinations are reached.

## C. Sufficiency of evidence

As a final matter, both parties dispute whether the Board's decision was supported by substantial evidence for each of the alleged violations. "Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. On appeal, this Court will not weigh the evidence, determine

[146] Answering Br. 20.

questions of credibility, or make its own factual findings."[147] We find that each of the Board's findings of violations was supported by substantial evidence.

### 1. Violation of Board Regulation 18.1.1.

The Board concluded that Dr. Grossinger violated Board Regulation 18.1.1 by failing to "obtain[],evaluate[], and document[]" a "medical history and physical examination,"[148] including Michael's "history of substance abuse."[149]

The hearing officer found that none of the GNS physicians, including Dr. Grossinger, obtained Michael's medical charts from or communicated with Dr. Lifrak, who provided Michael's only treatment for heroin addiction.[150] That finding was based on testimony from Dr. Steven Grossinger, Dr. Brajer, and Dr. Grossinger.[151] The testimony from all three doctors reflected that they either did not know, at the time of their treatment, that Michael had recently been treated with Suboxone, or did not obtain Michael's treatment information from either the PMP or Dr. Lifrak.[152] The hearing officer tied that failure to obtain Dr. Lifrak's records directly to a violation of Regulation 18.1.1's requirement that practitioners document the patient's "history of substance abuse." The hearing officer's findings are

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[147] *Jain v. Delaware Bd. of Nursing*, 72 A.3d 501 (Del. 2013) (TABLE).
[148] 24 *Del. Admin. C.* 1700-18.1.1.
[149] 24 *Del. Admin C.* 1700-18.1.1.3.
[150] A330.
[151] Transcript of Evidentiary Hearing before Hearing Officer Roger Akin, C.A. No. 16A-11-001 FWW, at 54, 231, 237, 291, 293.
[152] A17; A84–88; A119–20.

consistent and supported by the doctors' testimony; the Board's conclusion that Dr. Grossinger violated Regulation 18.1.1.3's requirement that practitioner's document the patient's history of substance abuse is therefore supported by substantial evidence.

**2. Violation of Board Regulation 18.3.**

The Board also found that Dr. Grossinger did not discuss the risks and benefits of the use of controlled substances with Michael, nor did he rely on documentation that his partners had done so.[153] In his cross-appeal, Dr. Grossinger points out that Dr. Steven Grossinger testified to discussing the risks and benefits of Michael's oral medication with Michael, and that GNS used informed consent forms indicating that GNS had "fully explained" alternatives, including oral medication, to the injections Michael underwent.[154] Dr. Grossinger argues that the hearing officer "failed to mention these facts in his binding findings of facts," and that the officer may not "simply ignore the existence of evidence and then base a legal conclusion on the lack of such evidence."[155]

Had the hearing officer neglected to mention Dr. Steven Grossinger's testimony or the informed consent forms in relation to Regulation 18.3, Dr. Grossinger's argument might have some merit. But the hearing officer discussed

[153] A334–36.
[154] Answering Br. 41–42.
[155] Answering Br. 42.

both the testimony and the forms in his recommendation regarding Board Regulation 18.3.[156] In particular, the hearing officer rejected the informed consent forms as evidence that a GNS physician had discussed the risks and benefits of the prescribed medications with Michael. The hearing officer noted that the forms did not themselves contain a discussion of the risks and benefits of the oral medications, and that the informed consent forms only stated that GNS physicians had "fully explained . . . potential benefits [and] risks or side effects" of the injection procedures for which the informed consent was obtained.[157] Further, the hearing officer found that the forms' language verifying that GNS had explained the "relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services"[158] did not indicate, without additional evidence, that GNS had explained the risks and benefits of Michael's supplemental (not alternative or substitutional) oral medications.[159] The hearing officer's conclusions are drawn directly from the language of the forms themselves, which were signed before each injection that GNS performed on Michael. The circumstances under which the informed consent forms were signed (right before injections, and not with prescription refills) and the language of the forms support

[156] A334–35.
[157] A335; A188.
[158] A188.
[159] A335.

the hearing officer's factual finding that the informed consent forms for the injections do not indicate that a discussion of the risks and benefits of Michael's supplemental oral medications occurred.

The hearing officer also noted—and questioned the credibility of—Dr. Brajer's testimony about having a risks and benefits discussion with Michael[160] and Dr. Steven Grossinger's testimony about Dr. Brajer's discussions.[161] And the hearing officer found that Dr. Steven Grossinger's mere mention of such discussions was insufficient for Dr. Grossinger to conclude that such discussions had occurred, because no written documentation existed.[162] As we do not make credibility assessments on appeal, we do not disturb the hearing officer's implicit finding that Dr. Brajer's and Dr. Steven Grossinger's testimony was not credible or that it was insufficient for Dr. Grossinger to rely upon regarding his duties under Regulation 18.3. The lack of documentation is therefore sufficient to support the hearing officer's finding that no discussion with Michael of the risks and benefits of his medications occurred.

### 3. Violation of Board Regulation 18.4.

The Board also found that Dr. Grossinger violated Board Regulation 18.4 by failing to make use of Michael's pain-management agreements. The hearing officer

[160] A89.
[161] A47.
[162] A336.

found that, according to the agreements, Michael agreed to comply with random drug testing and understood that any violation of the agreement would result in GNS discharging him as a patient—findings that are supported by the language of the pain-management agreements.[163] The officer then found, based on testimony and GNS's medical charts, that Michael missed a urine drug screen in June, 2014, and that drug screen was not administered until half a year later.[164] In the meantime, GNS, including Dr. Grossinger, not only failed to discharge Michael as a patient, but continued to refill Michael's opiate prescriptions.[165]

The Board held that Regulation 18.4 requires that practitioners use their pain-management agreements by actually requiring urine drug screens at some point, or else "the agreement is just another piece of paper."[166] And the hearing officer found that GNS did not use the pain-management agreements, because it continued to treat Michael and prescribe medication without the requested urine screening. Those factual findings are corroborated by GNS's medical charts and by the doctors' testimony. After reviewing the record before the hearing officer, we hold that the hearing officer's factual findings are supported by substantial evidence and that the

[163] A170 (Pain Management Agreement, signed by Michael, which states, "I will comply with any random drug test" . . . "I understand that if I break this Agreement, my doctor will stop prescribing these pain-control medicines and will discharge me from the practice").
[164] A44–46; A286–87; A336–38.
[165] A278.
[166] A337.

Board's conclusion that Dr. Grossinger violated Regulation 18.4 was not an abuse of its discretion.

**4. Violation of Board Regulation 18.5.**

The Board concluded that Dr. Grossinger failed to conduct any review, much less periodic review, of Michael's pain treatment, in violation of Board Regulation 18.5.[167] The hearing officer found, based on Dr. Grossinger's own testimony, [168] that Dr. Grossinger had not reviewed Dr. Steven Grossinger's reports or Michael's medical records, other than the abnormal MRI's and EMG's.[169] The hearing officer also found that Dr. Grossinger did not independently review Michael's course of treatment, but rather "relied on the prescriptive history" of his partners because "the case seemed routine to him."[170] That finding is also supported by Dr. Grossinger's testimony.[171] As mentioned, we do not make credibility assessments on appeal. Given Dr. Grossinger's uncertainty in his testimony, it was within the hearing officer's discretion to find that Dr. Grossinger did not review any of Michael's medical records or his course of treatment at all, much less periodically.

[167] A339.
[168] A109–14 (testimony of Dr. Grossinger, expressing uncertainty as to whether he reviewed any of Michael's medical charts or reports besides the abnormal MRI's and EMG's, which he "always look[s] at").
[169] A340.
[170] A340.
[171] A111–12.

Accordingly, the Board did not err in finding that such lack of review violated Regulation 18.5.

**5. Violation of Board Regulation 18.7.**

The Board's conclusion that Dr. Grossinger violated Board Regulation 18.7 by failing to keep complete and accurate records is also supported by substantial evidence. As addressed above, the hearing officer found that Dr. Grossinger (a) failed to obtain Dr. Lifrak's medical charts, (b) failed to discuss the risks and benefits of the oral medications with Michael and could not have justifiably concluded that someone else had had such discussion with Michael because there was no documentation of such discussion, and (c) failed to conduct any review of Michael's treatment course, much less document it. These findings were supported by substantial evidence, and it was within the Board's discretion to conclude that Dr. Grossinger had thereby also violated Board Regulation 18.7.

**6. Violation of 24 *Del. C.* § 1731(b)(3).**

The Board's conclusion that it could discipline Dr. Grossinger under 24 *Del. C.* § 1731 is also free of error and supported by substantial evidence. Section 1731 authorizes the Board to discipline a practitioner who has been issued a license for "unprofessional conduct," which is defined in §1731(b)(3) as including "[a]ny dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the

public."[172] That phrase is in turn defined by Board Regulation 8.1.13 as including, among other things, "[f]ailure to adequately maintain and properly document patient records."[173] As we have already decided that the Board's conclusion that Dr. Grossinger's failure to adequately keep medical records for Michael violated Board Regulations 18.1.1, 18.3, 18.5, and 18.7, we do not hesitate to affirm the Board's decision that Dr. Grossinger violated § 1731.

## IV. CONCLUSION

For the foregoing reasons, we **REVERSE** the Superior Court's decision below insofar as it reverses the Board's decision and AFFIRM the Board's decision.

[172] 24 *Del. C.* § 1731(b)(3).
[173] 24 *Del. Admin. C.* 1700-8.1.13.