IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

LAURIE ANN SPRAGA, D.O.,	)	
	)	
Appellant,	)	
	)	
v.	)	C.A. No. N16A-10-008 CEB
	)	
DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE,	)	
	)	
Appellee.	)	

Submitted: May 2, 2017
Decided: August 7, 2017

MEMORANDUM OPINION.

Upon Consideration of
Appeal from Administrative Order.
REVERSED and REMANDED.

Daniel A. Griffith, Esquire and Kaan Ekiner, Esquire, WHITEFORD TAYLOR & PRESTON, LLC, Wilmington, Delaware. Attorneys for Appellant Laurie Ann Spraga, D.O.

Carla A.K. Jarosz, Esquire, STATE OF DELAWARE DEPARTMENT OF JUSTICE, Wilmington, Delaware. Attorney for Appellee Delaware Board of Medical Licensure and Discipline.

BUTLER, J.

The State has a legitimate concern for maintaining high standards with respect to physicians practicing medicine within its borders. Physicians have a legitimate interest in maintaining their license in good standing. The State's disciplinary action against the physician in this case, while conducted within a framework designed to assure procedural fairness, fell short of the mark. The Court will therefore reverse the decision below and remand for such further proceedings as the administrative board deems appropriate.

FACTUAL BACKGROUND

The facts of this case, as found by the Hearing Officer below, are ugly. Unfortunately, the issues are far too nuanced to respond in knee jerk fashion, despite the temptation to do so. The story is essentially this.

There was a patient at the Delaware Correctional Center who had hepatitis C and was prescribed a very expensive medication by his infectious disease doctor. When we say "expensive" we mean it; each pill cost $1,000 and the manufacturer only sold it in lots of 28.

The administration of this medicine involves some bureaucracy that matters. The Department of Corrections ("DOC") has two vendors that factor in here. Connections Community Support Programs, Inc. ("Connections") provides medical care for DOC patients. DOC has a separate contract with CorrectRX Pharmacy Services, Inc. ("CorrectRx") to run the pharmacy operations for DOC. The actual

location we will be discussing in this case is not technically a pharmacy. It is a "medicine room" where medicines are administered to patients.

Inside these two medical organizations there are a number of actors that play parts in this incident. Connections employed administering nurses Megan Bowerson, Roxanna Gonzalez, nursing supervisor Christine Francis and Director of Nursing Angela DeBenedictis. They were all on site at the James T. Vaughn Correctional Center ("JTVCC") for some or all of the incident to be discussed. Then there is the Respondent Dr. Spraga, who is the Chief Medical Officer for Connections. She was not on site at the time of the incident.

CorrectRx maintains a pharmacy warehouse in Maryland and delivers medications to the various DOC facilities, including JTVCC. The two employees that figure into this story are Dr. Jamie McGee, a pharmacist located at the prison, and her boss, Dr. Valerie Barnes, located at the corporate office in Maryland.

As noted above, the infectious disease medication in question – Sovaldi – was quite expensive. The treatment called for the patient to receive 1 tablet per day for 84 days. The manufacturer only sold these tablets in lots of 28, so that 3 containers of the pills was a full regimen. Although the pills are not narcotics, because of their expense, their count and distribution is tightly controlled.

On March 17, 2015, Nurse Gonzalez was coming off her shift at the JTVCC and was to be replaced by Nurse Bowerson. As required, they counted the Sovaldi

tablets and, in the course thereof, Nurse Bowerson spilled 12 of the tablets onto the floor. Employing a bit of advice she says she learned in nursing school, Bowerson "wasted" the pills into the "sharps" container – a box intended for "biohazard" materials. Because this caused the pill count to be 12 tablets fewer than had been previously counted and, because the prescribed course of treatment of the patient required the patient to ingest the 12 pills over 12 days, the pills needed to be replaced quickly.

Nurse Bowerson contacted the onsite CorrectRX pharmacist, Dr. McGee, to request a refill of the Sovaldi pills. Dr. McGee, in turn, contacted her boss in Maryland, Dr. Barnes. What followed next was the subject of disputed testimony at the hearing, so we will hew closely to the specific fact findings by the Hearing Officer.

Dr. Barnes (from CorrectRX) contacted Dr. Spraga (the Medical Director for Connections). Dr. Barnes informed Dr. Spraga that the 12 Sovaldi pills had been wasted and "asked Dr. Spraga to arrange for the retrieval of the pills."[1] Dr. Spraga next contacted Nurse Supervisor Francis and told her to retrieve the Sovaldi pills from the sharps container.

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[1] Board Ex. 1 at 31.

Nurse Francis, accompanied by Director of Nursing DeBenedictis, went to the medication room, located the sharps container, turned it over and shook it until the 12 pills finally fell out. Included in the flotsam and jetsom that came from the container were diabetic syringes with safeties engaged, and an equal number of diabetic test strips and diabetic lancets. There was additional material in the sharps container when it was turned and shaken, but no one knows exactly what it was.

Next, the Sovaldi pills were brought to Nurse Francis' office where they were inspected by Nurses Francis and DeBenedictis. About this time, Dr. McGee, the pharmacist, responding to a request from her boss, Dr. Barnes, came to Nurse Francis' office and inspected the Sovaldi pills herself. Dr. McGee has previously conducted inspections of pills approximately 20-25 times in the past to determine if they had been "tampered with, altered, split or had previously been 'checked' in a human mouth."[2]

The state of knowledge about where the pills came from was hotly contested at the hearing. But the Hearing Examiner found as a fact that Dr. McGee knew that the pills she inspected had come from the sharps container. In sum, each of the relevant actors knew they were about to reuse Sovaldi pills that had been wasted in the sharps container. According to the Hearing Examiner's finding, "Dr. Spraga

[2] *Id.* at 32.

determined to leave to the two pharmacists the decision as to whether the retrieved pills could be administered to the inmate 'as they are the subject matter experts.'"[3]

The visual inspection having been completed and there having been nothing observed leading the nurses or Dr. McGee to believe the pills had been compromised, the decision was made to place the pills back into the container and make them available for administration to the patient. The Hearing Examiner found, as a matter of fact, that Dr. McGee gave her authorization to return the 12 Sovaldi pills to the bottle.[4] He further found that "Dr. McGee approved the administration to DL of the 12 tablets."[5]

The Hearing Examiner did not specifically find that it was Respondent Dr. Spraga that ordered the 12 Sovaldi pills back in to circulation. There was certainly testimony, notably from Supervising Nurse Francis, that Drs. Spraga, McGee and Barnes all discussed the fact that the pills had been wasted in a sharps container. A fair reading of the record would conclude that Dr. McGee authorized the recirculation of the wasted pills and that Dr. Spraga assented to that authorization.

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[3] *Id.* at 33.

[4] *Id.* at 34.

[5] *Id.* at 35.

And so it appears that the patient ultimately ingested pills that had been through the sharps container beforehand. The patient was ultimately so advised – several days afterward – but has suffered no ill effects.

The record includes a statement that indicates that even as the decision was being made to return the pills to circulation, Nurse Bowerson was "not happy" about the decision.[6] On March 26, 2015, about 2 weeks after the incident, Nurse Bowerson lodged a complaint with the Department of State's Division of Professional Regulation ("DPR") against nurses Francis and DeBenedictis. These complaints put the incident on the State's radar and caused the DPR investigators to collect statements from all involved. Nurse Bowerson, meanwhile, was suspended for a period before being reappointed. There is at least a suggestion in the record that her suspension was retaliatory over this incident, but there was no finding below to this effect and whether it was or not, at least we understand how this entire episode came to light.

The matter having been brought to the attention of DPR, it did its job of collecting the various witness statements and submitting the matter to the Department of Justice, which is charged with representing the DPR in board prosecutions involving professional licensing. The Department of Justice lodged a formal complaint against Dr. Spraga.

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[6] Board Ex. 3 at 139.

The complaint against Spraga charged that she engaged in "any dishonorable, unethical, or other conduct likely to deceive, defraud, or harm the public."[7] She was further charged with violating 24 *Del. C.* §1731(b)(11) which prohibits "unprofessional conduct" if the licensee engages in "misconduct, including…incompetence…in the practice of medicine."

Proceedings Before the Hearing Examiner

The fact finding before the Hearing Examiner included testimony from the nurses and doctors previously mentioned. The State proceeded on the theory, consistent with the prehearing interviews conducted by the DPR investigators, that Dr. Spraga acted unilaterally in making the decision and the pharmacists were unaware that the pills had been placed in the sharps container.

In addition to her own testimony, Dr. Spraga offered the testimony of 2 expert witnesses: nursing expert Kathryn Wild and physician expert Dr. Paul Axelson. Dr. Axelson had "impressive credentials in the subspecialty of Infectious Diseases."[8] Dr. Axelson testified that in his opinion, administration of the wasted Sovaldi pills to the patient was acceptable despite the pills' "adventure" in the sharps container.[9]

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[7] 24 *Del. C.* §1731(b)(3).

[8] Board Ex. 1 at 39.

[9] *Id.*

Both experts testified that they personally would have ingested the wasted Sovaldi tablets. The State presented no expert testimony at all.

The most hotly contested issue at the hearing was whether the pharmacists were unaware of their "adventure" in the sharps container or were complicit in the decision to reuse the pills. The State's theory, placing all responsibility for the decision on Respondent, supposed that the pharmacists were unaware of the pills' travels.

But the hearing did not go that way. The Hearing Examiner found as a fact that both pharmacists were aware that the pills had been removed from the sharps container. He further found that Dr. Spraga relied on the advice of the pharmacists to put the pills back in circulation. This was a dramatic departure from the State's theory of liability and left both the Hearing Examiner and the State in a rather awkward position: to sustain a sanction against Respondent, a new or different theory of liability was needed.

The Hearing Examiner's Conclusions of Law

Unlike the Hearing Examiner's findings of fact, which the Board (and the Court) are bound to follow, the Examiner also made proposed conclusions of law to which neither are similarly bound.

With respect to the State's charge under subsection (b)(11) that Spraga engaged in "unprofessional conduct" by engaging in "misconduct,

including...incompetence...in the practice of medicine," the Hearing Examiner refused to make any such finding, repudiating the argument that Dr. Spraga's conduct was incompetent.[10]

The Hearing Examiner did find, however, that "although evidence of [the inmate's] condition post-March 17 indicates that consumption of the returned pills did not cause or exacerbate health problems, *that is not the standard by which the Board should make the 'likelihood of harm' analysis.*" [Emphasis Added] "Dr. Spraga had the authority to overrule Dr. McGee's conclusion but chose not to do so."[11] It was in her failure to overrule the pharmacist that the Hearing Examiner concluded that Respondent caused a "risk of harm" – the necessary predicate to a finding of liability under the charge as levied against Dr. Spraga.

The Hearing Examiner thus held Dr. Spraga to a "standard" that would require her to overrule the pharmacist whom the Hearing Examiner found had advised Dr. Spraga that reusing the pills would be medically safe.[12] What makes this holding even more remarkable is that the Hearing Examiner nowhere explains what this "standard" is to which the Respondent was being held or where in the record any

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[10] *Id.* at 42.

[11] *Id.* at 41.

[12] *Id.*

such standard was fleshed out. If doctors are indeed to be held to a standard requiring them to overrule the pharmacist, one would think there would have been some further evidence and argument on the point. But since the State's case was predicated on its belief that the pharmacists never did know that the pills had been through the sharps container, the State made no such argument.

Proceedings Before the Board of Medical Practice

Dr. Spraga appealed the Hearing Examiner's proposed findings to the Board of Medical Practice. In such proceedings, findings of fact are not subject to review.[13] But the conclusions of law are subject to review and in the Board's decision, the Hearing Officer's conclusions of law were manipulated in important respects.

Recall that the charge in the complaint sustained by the Hearing Examiner was a violation of 24 *Del. C.* § 1731(b)(3): "dishonorable or unethical conduct likely to deceive, defraud, or harm the public." This was the case noticed and litigated before the Hearing Examiner.

But the Board has the authority, granted at 24 *Del. C.* 1713(f), to promulgate regulations for the imposition of discipline against practitioners. Pursuant to that authority, the Board has passed Regulation 8: "Dishonorable or Unethical Conduct (24 *Del. C.* 1731(b)(3)). This regulation, after cataloguing a number of sanctionable

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[13] 29 *Del. C.* § 8735(v)(1)(d).

behaviors such as fraudulent billing or advertising, improper sexual activity with patients or improper financial conduct, the regulation ends with Rule 8.1.16, a catchall prohibiting "any other act tending to bring discredit upon the profession."[14]

In Dr. Spraga's case, the Board ruled as follows:

> "The Board found that the conclusions of law must be modified, *to add a finding* that Dr. Spraga violated Board Rule 8.1.16 in that by ordering the retrieval of wasted medication out of the sharps container, she engaged in an act tending to bring discredit upon the profession." [emphasis added]

This finding of a violation of a Board regulation against bringing "discredit upon the profession" makes its first appearance in the record at the Board level: it was not in the charging documents and was no part of the proposed findings or conclusions of the Hearing Officer. In fact, it was not even argued by either side at oral argument before the Board.

ANALYSIS

I. A FINDING OF PUBLIC HARM IS NOT SUPPORTED BY THE EVIDENCE

Dr. Spraga was well aware that the charge against her was under 24 *Del. C.* §1731(b)(3) – conduct "likely to deceive, defraud, or harm the public." She directed her entire defensive effort to this charge, securing two expert witnesses to testify to the absence of harm to the public. The State presented no evidence, expert or

[14] 24 *Del. Admin C.* § 1700 (8.1.16.).

otherwise, in rebuttal. In his fact findings, the Hearing Examiner did not point to any testimony that supported the proposition that dispensing pills that had previously been in the sharps container caused or was likely to cause harm to the public.

Perhaps the Hearing Examiner and the Board did not wish to sanction the idea of reusing pills that had an "adventure" through a prison sharps container because the alternative was simply unpalatable. But the Court is concerned here with evidence, not with supposition, stereotype or superstition. On this score, the Court must agree with the Respondent that the Hearing Examiner's legal conclusion that Dr. Spraga engaged in conduct "harmful to the public" was not supported by the evidence. The Hearing Examiner essentially conceded as much, finding instead that Dr. Spraga breached a duty to overrule the pharmacist, a duty neither charged nor proven up at the hearing. Indeed, the record is at best confusing over which medical professional had the responsibility to make the call as to whether the pills could or should be reused. The Hearing Examiner apparently concluded that Dr. Spraga had a duty to overrule Dr. Barnes, the pharmacist, but that conclusion is not supported by anything more than supposition. To the extent it reflects some conclusion of law,

it is not one to which the Court can subscribe on the record testimony.[15]

In its briefing to the Court, the State does not really argue that the finding of a risk of public harm is supported by the record before the Hearing Examiner. The State goes so far as to fault Respondent for "incorrectly" attacking the finding that she engaged in conduct likely to cause public harm despite the fact that the Board did indeed affirm that finding by the Hearing Examiner that she did so, albeit without discussion. While it may be too much to hold that the State has waived any argument that public harm was proven below, the State has presented no argument of public harm and instead argues here that regardless of a finding of public harm, the Board could fairly conclude that Respondent violated a regulation against conduct tending to bring discredit on the profession.

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[15] The State argues that the Respondent's conduct met the requirement of "risk of public harm" because the evidence of "public harm" may include non-physical, or emotional, or psychic harm to the public. State's Brief at 15. Thus, the argument goes, the State's charge for which the Respondent received notice was substantiated by the evidence.

But nothing in the argument before the Board or the Board's decision supports the argument pressed by the State here. The Board did nothing to modify the conclusions of law of the Hearing Examiner insofar as the finding of a "risk of public harm" is concerned. Indeed, the Hearing Examiner did not even mention psychic harm, and neither did the Board. Thus, whether "harm" under the Code must be a physical or can include emotional or psychic harm is a question we can leave for another day. The Board having made no such finding, the issue is not properly before the Court.

II. THE BOARD MAY NOT AMEND A CHARGE *SUA SPONTE*

Delaware's Administrative Procedures Act, 29 *Del. C.* §10122(4), requires that when an Agency – in this case the Delaware Board of Medical Practice – "proposes to proceed for a case decision," it shall give 20 days' prior notice to all parties and the notice "shall cite the law or regulation giving the agency authority to act."

The notice provided in this case advised Respondent that she was alleged to have violated 24 *Del. C.* §§1731(b)(3) and 1731(b)(11). She was not notified that she would be expected to defend an allegation that she violated Regulation 8.1.16. The State has directed us to no case in which an administrative agency has *sua sponte* amended the statutory or regulatory provision upon which liability was predicated. This is not a surprise, since such a fundamental change in the State's theory of liability is inconsistent with fair notice and an opportunity to be heard, the touchstones of due process.

The Court's concerns here are not merely technical or procedural. As discussed by the Supreme Court:

> Due process, unlike some legal rules, is not a technical notion with a fixed content unrelated to time, place, and circumstances; rather it is a flexible concept which calls for such procedural protections as the situation demands. As it relates to the requisite characteristics of the proceeding, due process entails providing the parties with the opportunity to be heard, by presenting testimony or otherwise, and the right of controverting, by proof, every material fact which bears on the question of right in the matter involved in an orderly proceeding

> appropriate to the nature of the hearing and adapted to meet its ends. Further, due process requires that the notice inform the party of the time, place, and date of the hearing and the subject matter of the proceedings.[16]

In this case, the Hearing Examiner's finding that the pharmacists were all well aware that the pills had been wasted in the sharps container was a repudiation of the State's case that Respondent had acted alone, or at least without the knowledge of the pharmacists. The Examiner's further finding that Respondent relied on the advice of the pharmacists made the State's case against Respondent virtually untenable, save for the graphically ugly facts. Liability must be shown by a process that gives the party fair notice and an opportunity to be heard, not a *post hoc*, post hearing, duty to overrule the pharmacist that was never presented or argued, or an "oh, by the way" regulatory violation apparently conceived by the Board after the hearing, after the briefing, after the arguments, while the Board deliberated privately. The Court is certain that this finding by the Board cannot stand.

III. REMAND TO THE BOARD IS APPROPRIATE

Where this dispute goes from here is a matter for the Board to take up in the first instance. The Court is not in a position to determine whether the Respondent has evidence she wishes to present, or what that evidence might be. We have no

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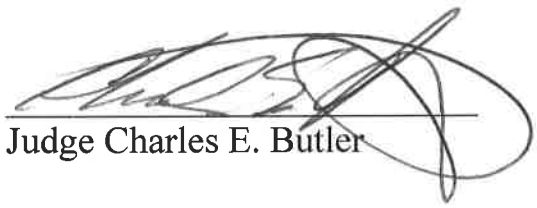
[16] *Vincent v. E. Shore Markets*, 970 A.2d 160, 164 (Del. 2009) (footnotes omitted).

opinion whether reusing pills from a sharps container brings discredit on the profession or should be lauded as a wise use of taxpayer money. Arguments can be made on all sides, none of them were fleshed out below precisely because Respondent was not notified that the conclusion was possible.

The Court believes the appropriate course at this point is to remand this matter to the Board for such further proceedings as it deems appropriate in light of the rulings made herein. At a minimum, the Respondent should be given notice and an opportunity to be heard consistent with both the APA and the Due Process Clause.

IT IS SO ORDERED.



Judge Charles E. Butler