WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST

KHUSHBOO S. MODI, RESPONDENT. FINAL DECISION AND ORDER WITH VARIANCE

DHA Case No. SPS-15-0042 DLSC Case No. 14 PHM 062

0004596

BACKGROUND

On December 16, 2015, Administrative Law Judge Jennifer Nashold (ALJ), Division of Hearings and Appeals, issued a Proposed Decision and Order (PDO) in the above referenced matter. The PDO was mailed to all parties. On January 4, 2016, the Division of Legal Services and Compliance (Division) filed an objection to the PDO as to the conclusion reached and requested the Pharmacy Examining Board (Board) find a violation for failing to give a consultation. The Division recommended Respondent be issued a reprimand, \$100.00 forfeiture, and pay investigative costs. Respondent did not file a response to the Division's objections. On February 24, 2016, the Board met to consider the merits of the PDO and the Division's objection. The Board voted to approve the PDO with variance. The PDO is attached and incorporated in its entirety into this Final Decision and Order with Variance (Order).

VARIANCE

Pursuant to Wis. Stat. §§ 450.03 and 450.10, the Board is the regulatory authority and final decision maker governing disciplinary matters of those credentialed by the Board. The matter at hand is characterized as a class 2 proceeding, pursuant to Wis. Stat. § 227.01(3)(b). The Board may make modifications to a PDO, in a class 2 proceeding, pursuant to Wis. Stat. § 227.46(2), provided the Board's decision includes an explanation of the basis for each variance.

In the present case, the Board adopts the "<u>PROCEDURAL HISTORY</u>" and "<u>FINDINGS OF FACT</u>" found in the PDO. The Board also adopts the paragraph titled "<u>Burden of Proof</u>" found in the "<u>DISCUSSION</u>" section on page four (4).

The Board varies the remainder of the "<u>DISCUSSION</u>" section as follows:

Violation

The Pharmacy Examining Board (Board) may revoke, limit, suspend, or deny renewal of the license of a pharmacist if that pharmacist engages in unprofessional conduct. Wis. Stat. § 450.10(1)(b)1. Unprofessional conduct is defined, in part, as a violation of any statute or rule which substantially relates to the practice of pharmacy. Wis. Stat. § 450.10(1)(a)2.

Pursuant to Wis. Admin. Code § Phar 7.01(1)(e), a pharmacist *must* give "appropriate consultation relative to the prescription." Except under certain exceptions inapplicable here, "[t]he consultation requirement applies to original and renewal prescription orders" and "is not satisfied by only offering to provide a consultation." *Id.*

There is no dispute that the Respondent did not provide a consultation to Patient A. Therefore the Respondent violated the mandate of Wis. Admin. Code § Phar 7.01(1)(e) by failing to provide the requisite appropriate consultation relative to Patient A's six (6) prescriptions. The fact that the pharmacy technician handed out the prescriptions, contrary to Wis. Admin. Code §§ Phar 7.015(3)(a) and (c), and contrary to the pharmacy policy, does not excuse the pharmacist's failure to provide a consultation. All pharmacists are strictly liable for complying with the mandate of Wis. Admin. Code § Phar 7.01(1)(e).

Moreover, pharmacists are responsible for providing general supervision over pharmacy technicians. See Wis. Admin. Code § Phar 7.015(2). Pharmacy technicians are explicitly prohibited from providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order, and are prohibited from providing patient counseling and consultation. Wis. Admin. Code § Phar 7.015(3). Rather, these responsibilities lie solely with the pharmacist. See Wis. Admin. Code §§ Phar 7.01(1)(d), 7.01(1)(e) and 7.015(4).

There is no exception which excuses a pharmacist from their responsibility to consult because a pharmacy technician handed out the prescription, no matter the circumstances. The pharmacist is responsible for supervising the pharmacy technicians. The pharmacist is responsible for providing consultations for each prescription to ensure the protection of all patients. The Respondent must therefore be held strictly liable for failing to provide Patient A with appropriate consultation relative to her prescriptions, as required by Wis. Admin. Code § Phar 7.01(1)(e).

<u>Discipline</u>

As a result of the Respondent's unprofessional conduct as detailed above, Respondent is subject to discipline, pursuant to Wis. Stat. § 450.10(1)(b)1. The three purposes of discipline are: (1) to promote the rehabilitation of the licensee; (2) to protect the public from other instances of misconduct; and (3) to deter other licensees from engaging in similar conduct. State v. Aldrich, 71 Wis. 2d 206, 237 N.W.2d 689 (1976).

The Division recommends a reprimand and \$100.00 forfeiture as appropriate discipline in this matter.

Respondent admits she did not provide a consultation to Patient A regarding Patient A's six (6) prescriptions, however the Respondent relies on the actions of the pharmacy technician and the circumstances relating to this particular prescription delivery to excuse her failure to consult. In blaming the pharmacy technician, Respondent fails to understand the importance of the consultation and fails to understand her responsibilities as a pharmacist. Wisconsin Administrative Code § Phar 7.01(1)(e) places a mandate on the pharmacist – the pharmacist shall

give the patient appropriate consultation. This is a serious matter of public safety and Respondent must understand that a consultation *shall* be given for each prescription. Further, the pharmacist is responsible for the general supervision of the pharmacy technicians and is responsible for ensuring each technician only performs the technical dispensing functions that may properly be delegated to a technician.

A reprimand and \$100 forfeiture is appropriate discipline in this case. This will serve to rehabilitate the Respondent and protect the public by ensuring all future prescriptions will only be delivered to the patient after the Respondent has exercised her responsibility to provide appropriate consultation. The proposed discipline will also ensure all pharmacists are on notice that the law requires one hundred percent compliance. The law is clear and pharmacists will be held strictly liable as having committed unprofessional conduct for any instance where an appropriate consultation is not given, regardless of the circumstances.

Costs

The Board has authority to assess all or part of the costs for disciplinary proceedings, taking into account the particular facts of each case. Wisconsin Statute § 440.22(2) states, in relevant part:

In any disciplinary proceeding against a holder of a credential in which the department or an examining board, affiliated credentialing board or board in the department orders suspension, limitation or revocation of the credential or reprimands the holder, the department, examining board, affiliated credentialing board or board may, in addition to imposing discipline, assess all or part of the costs of the proceeding against the holder.

The Board is not required to go through any particular analysis when determining whether to assess all or part of the costs of this proceeding against the Respondent. Nevertheless, guidance can be found in *Noesen v. State Department of Regulation & Licensing, Pharmacy Examining Board*, 2008 WI App 52, ¶¶ 30-32, 311 Wis. 2d 237, 751 N.W.2d 385. In *Noesen*, the Court opined:

Under Wis. Stat. § 440.22(2), the Board may, in its discretion, "assess all or part of the costs of the proceeding" against the licensee if the Board takes disciplinary action as a result. We give due weight to the Board's exercise of discretion. Wis. Stat. § 227.57(10). In reviewing the exercise of discretion, we look to determine whether the decision maker examined the relevant facts, applied the proper standard of law, and reached a reasonable conclusion. *Doersching*, 138 Wis. 2d at 328.

In addition to the above mandatory authority, in previous orders, the Board has considered the following non-mandatory factors to aid in determining if all or part of the costs should be assessed against a Respondent:

- 1. The number of counts charged, contested, and proven;
- 2. The nature and seriousness of the misconduct;
- 3. The level of discipline sought by the parties;
- 4. The respondent's cooperation with the disciplinary process;
- 5. Prior discipline, if any;
- 6. The fact that the Department of Safety and Professional Services (DSPS) is a "program revenue" agency; and
- 7. Any other relevant circumstances.

In the Matter of Disciplinary Proceedings against Elizabeth Buenzli-Fritz (LS 0802183 CHI). In considering these factors, the Board has the discretion to give each factor the weight appropriate given present circumstances. In this case, the Board finds that the imposition of one hundred percent (100%) of the costs is warranted.

The Division charged the Respondent with a single count, which was contested, and proven. Furthermore, as discussed above, the failure to provide the requisite consultation for the prescriptions at hand is serious, warranting a reprimand and \$100 fine. Dispensing prescription medications is a great responsibility, which requires strict compliance with the law in order to help ensure the safety of the public for each and every prescription.

Additionally, the Department of Safety and Professional Services (Department) is a program revenue agency, meaning the Department is funded by the revenue received from all licensees. This is a fact that also weighs heavily into the calculation of the appropriate amount of costs to be borne by the Respondent. As a program revenue agency, any costs not paid by the Respondent are shared by all other pharmacy profession licensees. Therefore, the Board gives serious consideration as to whether the costs associated with this action should be paid by the Respondent or shared by other non-culpable licensees.

The Respondent's lack of prior discipline and appearance at required conferences and proceedings, are significantly outweighed by the other factors discussed herein. Based on all of the above, it is appropriate for the Respondent to bear one hundred percent (100%) of the costs associated with this matter.

CONCLUSIONS OF LAW

- 1. The Board has jurisdiction in this matter, pursuant to Wis. Stat. § 450.10.
- 2. The Division met its burden, of establishing by a preponderance of the evidence, that Respondent engaged in unprofessional conduct, as defined in Wis. Stat. § 450.10(1)(a)2., by failing to give Patient A the mandated consultations for each prescription required in Wis. Admin. Code § Phar 7.01(1)(e).
- 3. The facts of record and the criteria delineated in *Aldrich* warrant that Respondent be reprimanded and assessed a \$100 forfeiture.

4. Imposition of one hundred percent (100%) of the costs of these proceedings on Respondent is appropriate under the facts of this case, and the guidance of *Noesen* and *Buenzli-Fritz*.

ORDER

For the reasons set forth above, it is hereby ORDERED:

- 1. Respondent is REPRIMANDED.
- 2. Respondent shall pay a FORFEITURE of \$100.00.
- 3. Respondent shall pay one hundred percent (100%) of the recoverable costs in this matter in an amount to be established, pursuant to Wis. Stat. § 440.22(2) and Wis. Admin. Code § SPS 2.18. After the amount is established, payment shall be made by certified check or money order payable to the Wisconsin Department of Safety and Professional Services and sent to:

DEPARTMENT MONITOR

Department of Safety and Professional Services
Division of Legal Services & Compliance
1400 East Washington Ave., P.O. Box 7190
Madison, WI 53707-7190

- 4. The terms of this Order are effective the date the Final Decision and Order is signed by the Board.
- 5. IT IS FURTHER ORDERED that the above-captioned matter is hereby closed as to Respondent Khushboo S. Modi.

Dated at Madison, Wisconsin this \\\^t\triangle day of March, 2016.

A Member of the Board

State Of Wisconsin DIVISION OF HEARINGS AND APPEALS

In the Matter of Disciplinary Proceedings Against Khushboo S. Modi, R.PH., Respondent

DHA Case No. SPS-15-0042 DLSC Case No. 14 PHM 062 00045 9 6

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

Khushboo S. Modi, by

Attorney Vincent J. Bobot Bobot Law Offices 5414 S. 13th Street Milwaukee, WI 53221-4420

Wisconsin Pharmacy Examining Board P.O. Box 8366 Madison, WI 53708-8366

Department of Safety and Professional Services, Division of Legal Services and Compliance, by

Attorney Cody Wagner
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

PROCEDURAL HISTORY

The above-captioned matter was initiated on April 20, 2015, when the Department of Safety and Professional Services (Department), Division of Legal Services and Compliance (Division), filed and served its Complaint against Respondent, Khushboo S. Modi, R.PH. (Respondent). The Complaint alleged that Respondent was subject to discipline pursuant to Wis. Stat. § 450.10(1)(a)2 for failing to provide appropriate consultation relative to a prescription as required by Wis. Admin. Code § Phar 7.01(1)(e). Telephone conferences were held between the undersigned administrative law judge (ALJ) and counsel for the parties on June 5 and July 8,

2015. Consistent with discussions held at the telephone conferences, a Scheduling Order was issued on July 8, 2015, setting a hearing date and related deadlines.

A hearing was held in this matter on September 14, 2015, at which "Patient A," the pharmacy customer on the day at issue, testified for the Division, and Respondent testified on her own behalf. At the close of hearing, the ALJ granted the Division's request to amend its Complaint to clarify that it was Patient A, and not her daughter, who picked up the prescriptions. At the request of the parties, post-hearing briefs were submitted, with the final submission filed on November 30, 2015.

FINDINGS OF FACT

- 1. Respondent is licensed in the State of Wisconsin as a pharmacist, having license number 16963-40, first granted on January 30, 2013, and current through May 31, 2016. (Amended Complaint, ¶ 1, Answer, ¶ 1)
- 2. Respondent has been employed as a pharmacist at a CVS pharmacy in Menomonee Falls, Wisconsin (pharmacy) since October 2013. (Amended Complaint, ¶ 3, Answer, ¶ 3; Hrg. Tr., p. 15)
- 3. On June 2, 2014, Patient A went to the pharmacy drive-up window to pick up some prescriptions. (Hrg. Tr., p. 7)
- 4. Respondent was the only pharmacist on duty at the pharmacy when Patient A came to pick up her prescriptions. There were three pharmacy technicians on duty. (Hrg. Tr., pp. 15-16)
- 5. After Patient A paid for the prescriptions and signed off for them on a clipboard, a pharmacy technician handed Patient A a bag containing six prescriptions and closed the window. This process took approximately three to four minutes. Patient A asked if she would get a pharmacist consultation, as three of the prescriptions were new prescriptions, but the technician turned and walked away without responding. Respondent yelled out her request again but then drove off because there were other vehicles behind her. The time period between receiving the prescriptions and driving away was approximately 30 seconds. (Hrg. Tr., pp. 8, 12-13)
- 6. Patient A did not realize that there was a call button on the drive-up window. (Resp. Ex. A, p. 6; Hrg. Tr., p. 13)
- 7. Patient A later called the pharmacy to complain about the lack of a consultation. (Hrg. Tr., p. 9)
- 8. During the time that Patient A was at the drive-up window, Respondent was on the telephone for business-related reasons. (Hrg. Tr., p. 17)
- 9. While on the telephone, Respondent heard the word "consult," and, after finishing the phone call, went to the drive-up window to conduct the consultation. When she got to the window, she asked asked the technician where the consult was, and the technician responded that

the customer drove away. Respondent asked where the prescriptions were and the technician stated that she had given them to the customer. Respondent asked the technican why she had handed the medications to the patient without a consultation but the technician did not have an answer. (Hrg. Tr., pp. 17-19)

- 10. Respondent did not see or speak to Patient A. Respondent was responsible for supervising the technicians, and was the only person at the pharmacy who would have been able to give a consultation to Patient A. (Hrg. Tr., pp. 22-23)
- 11. Respondent would have provided a consultation had Patient A not driven away. (Hrg. Tr., pp. 16-18, 21-22)
- 12. At the time of this incident, pharmacists at the pharmacy did not have the ability to identify patients in order to attempt to contact them after the fact and provide consultations. Since this incident, the pharmacy has changed its policies to provide a mechanism for contacting the patient. (Hrg. Tr., p. 20)
- 13. Respondent did not hire the technician who dispensed the prescriptions prior to a consultation, nor does Respondent have authority to terminate or discipline the technician. (Hrg. Tr., p. 19)
- 14. Respondent follows a policy of providing consultations on all new prescriptions and attempting to provide consultations on all prescriptions. (Hrg. Tr., p. 23)
- 15. Prior to the June 2, 2014 incident, Respondent had been working with the technician for two to three months and worked with her approximately three shifts per week. The technician had not previously dispensed medication without a required consultation. (Hrg. Tr., pp. 17-19)
- 16. The pharmacy dispenses approximately 2,100 prescriptions per week. During the course of a normal business day, Respondent conducts over 100 consultations. (Hrg. Tr., pp. 18, 21)
- 17. The pharmacy technician violated the pharmacy's policy on June 2, 2014 by providing the prescriptions without waiting for Respondent to provide the consultation. (Resp. Ex. A; Hrg. Tr., pp. 24-27)
- 18. The day before Patient A received the prescriptions at the pharmacy, a hospital nurse went over the new prescriptions with Patient A. Instructions were also contained on the labels. (Hr. Tr., pp. 10, 20)

DISCUSSION

Burden of Proof

The burden of proof in disciplinary proceedings is on the Division to show by a preponderance of the evidence that the events constituting the alleged violations occurred. Wis. Stat. § 440.20(3); see also Wis. Admin. Code § HA 1.17(2). To prove by a preponderance of the evidence means that it is "more likely than not" that the examined action occurred. See State v. Rodriguez, 2007 WI App. 252, ¶ 18, 306 Wis. 2d. 129, 743 N.W.2d 460, citing United States v. Saulter, 60 F.3d 270, 280 (7th Cir. 1995).

Violations

The Pharmacy Examining Board (Board) may revoke, limit, suspend or deny renewal of the license of a pharmacist if that pharmacist engages in unprofessional conduct. Wis. Stat. § 450.10(1)(b)1. Unprofessional conduct is defined, in part, as a violation of any statute or rule which substantially relates to the practice of pharmacy. Wis. Stat. § 450.10(1)(a)2.

Pursuant to Wis. Admin. Code § Phar 7.01(1)(e), a pharmacist must give "appropriate consultation relative to the prescription." Except under certain exceptions inapplicable here, "[t]he consultation requirement applies to original and renewal prescription orders" and "is not satisfied by only offering to provide consultation." *Id*.

There is no dispute that Respondent did not provide a consultation to Patient A. Relying primarily on *Hannigan v. Sunby Pharmacy*, 224 Wis. 2d 910, 593 N.W.2d 52 (Ct. App. 1999), however, Respondent argues that she did not violate the consultation requirement because her conduct was not willful. Respondent's reliance on *Hannigan* is misplaced. Although the *Hannigan* court made reference to professional misconduct under Wis. Stat. § 450.10, the statute at issue in *Hannigan* was Wis. Stat. § 146.84, which imposes liability on a person "who violates s. 146.82 or 146.83 in a manner that is *knowing and willful*." *Id.* at 917, 926. *Hannigan* did not involve interpretation of Wis. Admin. Code § Phar 7.01(1)(e), nor does § Phar 7.01(1)(e) contain the "knowing and willful" language provided in Wis. Stat. § 146.84.

Nevertheless, I agree that under the specific circumstances of this case, Respondent's conduct does not constitute a violation of Wis. Admin. Code § Phar 7.01(1)(e). I base this conclusion on the following facts. During the short interaction between the technician and Patient A, Respondent was engaged in other pharmacy duties, specifically, handling a work-related telephone call. Based on the pharmacy's written policies and Respondent's previous experience with the technician, Respondent had no reason to believe that the technician would provide prescriptions without the required consultation. Pharmacy policies and applicable laws require that a consultation be performed, Respondent routinely followed those policies and laws, and the technician had, prior to the incident in question, likewise followed them when Respondent had worked with her. Respondent would have performed the consultation had she been given the opportunity to do so. When she heard the word "consult," she ended the telephone call and immediately went to provide the consultation. However, when she got to the drive-up window, the prescriptions had been dispensed, Patient A was gone, and Respondent had

no way of attempting to contact Patient A. After receiving her prescriptions, Patient A had driven away within 30 seconds, after observing that the drive-up window had been closed, the technician had walked away, and a car was behind Patient A's car. Patient A did not know there was a call button on the window she could have pressed to receive the consultation. Notably, the pharmacy's policies have since been changed so that customers may be contacted after the fact should a situation like this reoccur.

The transaction at issue was outside of Respondent's knowledge and control and was caused by the technician's failure to comply with pharmacy policy. Strict liability may not be imposed under these unique circumstances.

The three prior Board decisions relied on by the Division do not change the result. These cases involved pharmacists who were reprimanded and fined for failing to provide consultations prior to transferring prescriptions to patients. See In the Matter of Disciplinary Proceedings Against Ronald J. Collard, R.Ph., Order No. LS9902091PHM (Feb. 9, 1999); In the Matter of Disciplinary Proceedings Against Denise A. Bonjour, R.PH., Order No. 0001106 (Sept. 14, 2011); In the Matter of Disciplinary Proceedings Against Roland A. Buchholz, R.Ph., Order No. LS0704041PHM (April 4, 2007). However, these cases are distinguishable from the instant case.

Significantly, all three cases were the result of stipulated agreements where the pharmacists agreed that the facts constituted a violation. They were not the result of a contested case hearing in which the alleged violations were legally disputed. In addition, all of the cases involved multiple instances where the pharmacists knowingly failed to provide consultations. In contrast, this case involves a single aberration from a policy of always providing consultations, and the pharmacist was unaware that prescriptions had been dispensed without a consultation until it was too late to remedy the situation.

In *Collard*, a Department investigator observed "on two occasions" a technician transfer prescriptions to patients without consultation from a pharmacist. The pharmacist was present and on duty at the pharmacy and "allowed" the technician to conduct the transaction.

In *Bonjour*, a Department investigator observed "multiple transactions" during which the pharmacist permitted transfer of prescriptions to patients without consultation with a pharmacist. The pharmacist admitted that she thought consultations were only needed for new prescriptions.

In Buchholz, the pharmacist, Roland Buchholz, was the managing pharmacist at a pharmacy. In May of 2006, a Department investigator witnessed "multiple transactions" at the pharmacy, during which the pharmacist on duty "permitted a clerk to transfer prescriptions to patient without consultation with the licensed pharmacist." The clerk informed the investigator that her typical method of handling prescription transfers was to get the customer's name, retrieve the bag containing the prescription, have the customer sign for the drug and convey the prescription to the customer. If the prescription was new (not a refill), she would arrange for a consultation with the pharmacist. The clerk said she was unaware that a pharmacist was supposed to do consultations and transfer prescriptions. The investigator interviewed the

pharmacist on duty who stated that the work flow had changed with the recent sale of the pharmacy and the change had disrupted systems that had been in place.

In June of 2006, Buchholz completed a Notice of Compliance in which he assured the Board that state laws concerning pharmacy consultations had been reviewed and were being properly implemented. However, over four months later, in October of 2006, a Department investigator observed a clerk at the pharmacy transfer a prescription to a patient without any acknowledgement, contact or communication from the pharmacist on duty, who was Buchholz. Buchholz told the investigator that he had been very busy, the incident was a "mishap" and he did not realize what was going on. However, the Board noted that the patient was the "only customer, and the telephone was not ringing."

All three of these cases involved multiple instances of failing to provide consultations, in which the pharmacists knew the conduct was occurring and allowed them to occur. Here, there was one transaction and Respondent did not permit it. Rather, the record shows that the failure to provide a consultation occurred as a result of the technician's conduct, without Respondent's knowledge or acquiescence. Accordingly, the Division has failed to meet its burden of showing a violation.

CONCLUSIONS OF LAW

The Division has not met its burden of establishing by a preponderance of the evidence that Respondent failed to provide appropriate consultation relative to a prescription as required by Wis. Stat. § 450.10(1)(a)2 and Wis. Admin. Code § Phar 7.01(1)(e).

ORDER

For the reasons set forth above, it is ordered that the Division's Amended Complaint is dismissed.

Dated at Madison, Wisconsin on December 16, 2015.

STATE OF WISCONSIN
DIVISION OF HEARINGS AND APPEALS

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Jennifer E. Nashold

Administrative Law Judge