BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:	)	
	)	Docket No. 2017-146
Pharmacist License of	)	DIA No. 19PHB0002
CHRISTOPHER BETTS	)	
License No. 19918,	)	**FINDINGS OF FACT,**
	)	**CONCLUSIONS OF LAW,**
Respondent.	)	**DECISION, AND ORDER**
	)	

STATEMENT OF THE CASE

On July 24, 2018, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing and Statement of Charges against Respondent Christopher Betts, alleging one count: Failure to Ensure Legal Operation.

The hearing was held on September 18, 2018. The following members of the Board presided at the hearing: Sharon Meyer, Chairperson; LaDonna Gratias; Edward McKenna; Jason Hansel; Gayle Mayer; Brett Barker; and Joan Skogstrom. Assistant attorney general Laura Steffensmeier represented the State. Respondent Christopher Betts appeared and was self-represented. The hearing was open to the public at Respondent's request, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

THE RECORD

The record includes the Notice of Hearing and Statement of Charges. The record also includes hearing testimony of Jean Rhodes and Christopher Betts. State's Exhibits 1 through 8 were admitted as evidence. Respondent's Exhibit A was also admitted as evidence. At the State's request, State's Exhibits 3 and 4 and Respondent's Exhibit A are subject to a protective order based on patient information contained therein.

FINDINGS OF FACT

Respondent Christopher Betts is a pharmacist licensed in the state of Iowa. At all times relevant to this matter, Respondent was the pharmacist in charge (PIC) at CVS Pharmacy #10162, located in Des Moines, Iowa.

In June 2017, Patient A filled a prescription for temazepam, a controlled substance, at Respondent's pharmacy. The prescription label reflected that Dr. Jennifer Gerrietts was the prescriber, which was incorrect. The actual prescriber was Nguyen-Ly Huynh, PA-C. At the time that the prescription was initially filled, CVS's computer system used a drop-

down menu to show prescribers who had previously written prescriptions for a particular patient; the person inputting the prescription into the CVS system selected from this menu in order to indicate who the current prescriber was. As Dr. Gerrietts was the primary care provider for Patient A, she showed up in the drop down menu and was incorrectly selected as the prescriber. (Exh. 3; Betts testimony).

When Patient A requested a refill of the prescription in September 2017, pharmacy personnel discovered that the prescription had initially been filled with the wrong prescriber, Dr. Gerrietts, listed in the computer system and on the label. At the time of refill, the CVS computer system does not allow the prescriber field to be edited. When Respondent was made aware of the error regarding Patient A, he contacted CVS management and asked how to edit the prescription in order to reflect the correct prescriber. Respondent was told that editing the prescriber was not possible and that he would need to delete the original entry and input the original prescription again with the correct prescriber information. Respondent did this, and made a note in the computer record that the fill on June 3, 2017 was done with the wrong doctor listed.[1] (Betts testimony; Exh. A).

In October 2017, Dr. Gerrietts became aware of the error when Patient A came in to see her to refill medications and brought the bottle of temazepam with her name on it. Dr. Gerrietts contacted the pharmacy and spoke with Respondent, who acknowledged the error and informed her that the system had been changed to remove her name as the prescribing doctor. Dr. Gerrietts subsequently filed a complaint with the Board. (Exh. 5, pp. 8-10).

As part of the Board's investigation of the complaint, Board compliance officer Jean Rhodes requested that Respondent provide her a copy of the continuous quality improvement (CQI) program report that was completed regarding this error. The pharmacy had a computer program that existed to document errors at the time, but there was no specific category for an error that resulted in the wrong prescriber being listed on the medication label; such an error was labeled an error and recorded in the pharmacy's computer system only if it had an adverse effect on the patient. Owing to the configuration of the computer system, Respondent did not make a report regarding the labeling error immediately upon discovering the error.

When Rhodes contacted Respondent and inquired about the CQI report, Respondent agreed with Rhodes that a labeling error was a dispensing error that needed to be reported under the pharmacy's CQI program. At that time, he made a report in Respondent's computerized error recording system. He informed Rhodes of this, but was not able to print a copy for her of the report as the system did not allow the option to print. When Respondent tried to print the report, all fields blacked out; he was

[1] After being instructed by corporate management that editing the original prescription was impossible, Respondent considered making a duplicate entry so that the original information would not be lost. Respondent rejected this idea, however, out of concern that it could cause problems under the prescription monitoring program with Patient A's providers believing he was obtaining the same controlled substance from two different providers at the same time.

likewise unable to copy and paste the report into another document in order to make it available to Rhodes. Respondent made the pharmacy's management aware of this issue and Respondent's immediate supervisor informed him that he did not believe the Board was entitled to the CQI report. (Betts testimony).

Rhodes then attempted to obtain the CQI report through CVS's corporate management. The pharmacy's corporate management ultimately sent Rhodes an e-mail on February 13, 2018 that contained information regarding the incorrect labeling event that occurred on June 3, 2018. Respondent testified at hearing that what was sent to Rhodes in the e-mail was not the text from the CQI report he completed; it appeared to him to be a paraphrase of information that he input into the computer record. Rhodes noted that the CQI report did not include a date and time that the event was discovered. That information was part of the CQI report that Respondent filled out electronically; he does not know why it was not included when the pharmacy's corporate management sent the report to the Board. (Betts, Rhodes testimony; Exh. 4, p. 27).

Since this error occurred, Respondent has learned through experience that a prescription entry can be edited at the time of refill by refunding the refill at the register, which allows him to edit the original entry. Respondent was unaware of this process at the time, and CVS management, from whom he sought assistance, did not provide him this information. This process is how Respondent will deal with any future errors, so that the original information is preserved in the computer system for review. (Betts testimony).

The pharmacy has also changed its CQI policies and procedures to include the maintenance of a paper record of reportable events that can be immediately available to the Board for inspection. The paper record is reviewed quarterly by Respondent, as PIC, and by Respondent's district manager, to ensure that appropriate remedial steps have been taken for any errors and to improve performance going forward. (Betts testimony).

Additionally, the pharmacy has now changed its computer system so that there is no option to autopopulate the prescriber on a new prescription. The prescriber must be entered manually each time a new prescription is input, thus reducing the opportunity for labeling errors such as the one that occurred here. (Betts testimony).

Board Action against CVS Pharmacy #10162

In July 2018, the Board charged CVS Pharmacy #10162, the pharmacy at which Respondent works as PIC, with failing to have a CQI program that complies with the requirements of 657 Iowa Administrative Code 8.26. The factual allegations in the Statement of Charges against the pharmacy are nearly identical to the factual allegations in the Statement of Charges against Respondent. As part of a settlement agreement, the pharmacy admitted the factual allegations contained in the Statement of Charges. The pharmacy was cited for having a noncompliant CQI program and ordered to pay a $2,500 civil penalty. The pharmacy was also required to retrain all pharmacy staff on its updated CQI program policies and procedures. (Exh. 7).

CONCLUSIONS OF LAW

Pursuant to Iowa Code section 155A.12(1), the Board may impose discipline on a pharmacist's license in the event that the licensee violates any provision of Chapter 155A or any rules of the Board adopted under Chapter 155A.[2] Under the Board's rules, a pharmacist in charge is tasked with working cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure the legal operation of the pharmacy, including meeting requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.[3]

Continuous Quality Improvement Program

The Board's regulations require that a pharmacy, its PIC, and all staff pharmacists share responsibility for establishing, implementing, and utilizing an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services. The rules identify the pharmacy and the PIC as sharing responsibility for establishing the CQI program.[4] The CQI program is an ongoing, systematic program of standards and procedures aimed at detecting, identifying, evaluating, and preventing medication errors with the ultimate goal of improving medication therapy and the quality of patient care.[5]

Under a CQI program, any preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient must be recorded. Such events include, but are not necessarily limited to:

a. An incorrect drug;
b. An incorrect drug strength;
c. An incorrect dosage form;
d. A drug received by the wrong patient;
e. Inadequate or incorrect packaging, labeling, or directions; or
f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.[6]

The Board's regulations require that all CQI records be maintained on site at the pharmacy or be accessible at the pharmacy and available for inspection and copying by the Board or its representative for at least two years from the date of the record.[7]

The specific allegation against Respondent in this case is that he failed to ensure legal operation of a pharmacy by failing to have a continuous quality improvement program

[2] *See also* 657 Iowa Administrative Code (IAC) 36.6(21).
[3] 657 IAC 8.3(1).
[4] 657 IAC 8.3(5)(c).
[5] 657 IAC 8.26.
[6] 657 IAC 8.26(1).
[7] 657 IAC 8.26(5).

that complies with the requirements of 657 Iowa Administrative Code 8.26. Under the circumstances, the Board concludes that Respondent has not committed the violation alleged. Under the Board's regulations, the PIC and the pharmacy share responsibility for ensuring legal operation of the pharmacy, which includes establishing the CQI program. The Board appreciates the realities of a PIC who is working inside a corporate structure over which he or she does not exert direct control. In this situation, Respondent took immediate action after learning the error had been committed and promptly sought input from management as to how to properly identify the error in the pharmacy's computerized systems. The limitations of the computerized reporting system led to a delay in Respondent making a written CQI report of the error, but he took steps to ensure that the issue was addressed, including changing the label on the refill to reflect the correct prescriber and ensuring that the fill history, including the error, was documented in the pharmacy's prescription system.

Additionally, Respondent took appropriate and prompt action to respond to the Board's inquiries and to make his superiors aware of the inquiries where he was not empowered to provide information directly. Ultimately, Respondent's actions – along with the Board's intervention directly with the pharmacy – resulted in an improved CQI system that more effectively addresses patient safety. Had Respondent taken less robust steps in addressing the error and communicating his concerns to the pharmacy directly, the result may well have been different here.

DECISION AND ORDER

IT IS THEREFORE ORDERED that the Statement of Charges filed against Christopher Betts on July 24, 2018 is hereby DISMISSED.

Dated this 14th day of November, 2018.

Sharon Meyer
Chairperson, Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General
Christopher Betts, Respondent

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.

BEFORE THE IOWA BOARD OF PHARMACY

RE: Pharmacist License of **CHRISTOPHER BETTS** License No. 19918 Respondent	CASE NO. 2017-146 **NOTICE OF HEARING AND STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Christopher Betts ("Respondent"), 4637 84th St, Urbandale IA 50322, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)"e", and 657 IAC 35.6 and 35.7. Respondent's Iowa pharmacist license number 19918 is currently active through June 30, 2019.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on September 18, 2018, before the Board. The hearing shall begin at 9:00 a.m. and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines IA 50309.

Answer. Within twenty (20) days of the date you are served this Notice of Hearing and Statement of Charges, you may file an Answer pursuant to 657 IAC 35.16. The Answer should specifically admit, deny, or otherwise answer all allegations contained in sections C and D of this Notice of Hearing and Statement of Charges.

Filing of Pleadings. Pleadings shall be filed with the Board either by e-mail, if done in compliance with 657 IAC 35.17(2), to Amanda.Woltz@iowa.gov, or by mail/delivery to the following address: Iowa Board of Pharmacy, 400 SW 8th St, Ste E, Des Moines IA 50309.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the Board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

Prosecution. The Office of Attorney General of Iowa is responsible for representing the public interest (the State) in this proceeding. Counsel for the State in this matter is Assistant Attorney General Laura Steffensmeier. Ms. Steffensmeier can be reached by phone at (515) 281-6690. Copies of pleadings should be provided to counsel for the State either by email to Laura.Steffensmeier@ag.iowa.gov, or by mail/delivery to the following address:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines IA 50319

Communications. You may not contact individual Board members in any manner, including by phone, letter, or e-mail, regarding this Notice of Hearing and Statement of Charges. Board members may only receive information about the case when all parties have notice and the opportunity to participate, such as at the hearing or in pleadings you file and serve upon all parties in the case.

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C (2017).

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 147, 155A, and 272C, and 657 IAC chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 IAC 35.27.

C. STATEMENT OF CHARGES

COUNT I
FAILURE TO ENSURE LEGAL OPERATION

Respondent is charged with failure to ensure legal operation of a pharmacy in violation of 657 IAC 8.3(1), specifically by failing to have a continuous quality improvement program that complies with the requirements of 657 IAC 8.26, and may be disciplined pursuant to Iowa Code sections 147.55(9) and 155A.12(1) and 657 IAC 36.6(21).

D. FACTUAL CIRCUMSTANCES

1. At all relevant times, Respondent was the pharmacist in charge at CVS 10162 in Des Moines, Iowa.

2. In 2017, Respondent processed a prescription under the wrong prescriber.

3. When the error was identified, Respondent deleted the original prescription and re-entered it with the correct prescriber.

4. Respondent did not create a CQI report for the error in a timely manner. The CQI report, when created, did not have all of the required information.

5. The pharmacy's CQI policies and procedures did not comply with the Board's rules governing CQI programs.

E. SETTLEMENT

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 35.24. To cancel a scheduled hearing, an executed settlement agreement must be received by the Board at least three (3) business days prior to the scheduled hearing. If you are interested in pursuing settlement in this matter, please contact the Assistant Attorney General identified above.

F. FINDING OF PROBABLE CAUSE

On this 24th day of July, 2018, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.

Sarah K Thompson
_____

Chairperson
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor
1305 E Walnut St
Des Moines IA 50319
ATTORNEY FOR THE STATE

PLEASE NOTE: If you require the assistance of auxiliary aids or services to participate in this matter because of a disability, immediately call 515-281-5944. (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942).