

BEFORE THE IOWA BOARD OF PHARMACY

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IN THE MATTER OF THE  
STATEMENT OF CHARGES AGAINST:

CASE NO. 2016-173  
DIA NO. 17IBP002

RICHARD GROTE  
License No. 16187

FINDINGS OF FACT,  
CONCLUSIONS OF LAW,  
DECISION AND ORDER

RESPONDENT

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On May 9, 2017, the Iowa Board of Pharmacy (Board) found probable cause to file a Notice of Hearing and Statement of Charges against Richard Grote (Respondent), which charged him with failure to ensure legal operation of the pharmacy (Count I); failure to maintain policies and procedures (Count II); failure to maintain a continuous quality improvement program (Count III); and failure to maintain records for Schedule V dispensing (Count IV). The hearing was held on October 31, 2017 before the following members of the Board: Sharon Meyer, Chairperson; Edward McKenna; Jason Hansel; Gayle Mayer; Brett Barker; LaDonna Gratiyas; and Joan Skogstrom. Assistant Attorney General Laura Steffensmeier represented the state. Respondent failed to appear for hearing. The hearing was open to the public, pursuant to Iowa Code section 272C.6(1), and was recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with its deliberations.

THE RECORD

The record includes the testimony of Dan Sedlacek and State Exhibits 1-8 (See Exhibit List for description).

FINDINGS OF FACT

**Licensure and Disciplinary History.** The Board has issued Richard Grote (Respondent) pharmacist license number 1618, which will expire on June 30, 2018. At all times relevant to the charges, Respondent was the owner and pharmacist-in-charge of Rick's Pharmacy located in Hampton, Iowa. (Exhibit 1; Sedlacek testimony)

When Rick's Pharmacy was inspected in 2008, the inspection report included a number of deficiencies that required correction. The deficiencies at that time included, in part,

failure to have adequate policies and procedures and failure to have a continuous quality improvement (CQI) program. (Exhibit 5)

Respondent was charged by the Board in June of 2012 in connection with his operation of Rick's Pharmacy. At that time, Respondent was charged with lack of professional competency, failure to maintain and provide records, and violations of controlled substance laws. A routine inspection of Rick's Pharmacy had revealed that the pharmacy's controlled substance inventory was more than a year old, that Respondent was more than 5 months behind in entering Schedule II controlled substance sales into the appropriate log book, and that Schedule II controlled substances were being dispensed from medication orders received from wholesalers before they were checked into the pharmacy's inventory. (Exhibits 4, 7; Sedlacek testimony)

In November 2012, Respondent and the Board entered into a Settlement Agreement and Final Order to resolve the pending Statement of Charges. Respondent's pharmacist license was placed on probation for a period of one year. Respondent agreed to provide policies and procedures for the receiving, handling, and dispensing of controlled substances within 30 days. Respondent also agreed to pay a civil penalty in the amount of \$250 and to complete 2 contact hours of continuing education on controlled substance law. (Exhibit 7)

**2016 Inspection and Charges.** On October 13, 2016, Board Compliance Officer Dan Sedlacek, R.Ph. visited Rick's Pharmacy to perform a routine inspection. Respondent was present at the pharmacy during the inspection. Respondent reported that the pharmacy was open 40 hours per week and that he dispensed an average of 4-5 prescriptions per day. During this inspection, Mr. Sedlacek noted the following deficiencies:

- The pharmacy's perpetual inventory was not current and did not have the required record of changes. Prescriptions that had been filled and dispensed were not recorded.
- Controlled substance invoices were not dated, signed and readily retrievable.
- No policy and procedure manual was present, and Respondent was unable to locate it. Respondent recalled that one had been completed several years before, but he had not been able to locate it since his only pharmacy technician retired two years earlier.
- No CQI program was observed. Respondent reported that he did not have a CQI program because he operated a very low volume pharmacy that had not had any medication errors in a long time.

- The Schedule V log book showed multiple transactions for the same patient over a several week period where the quantity of codeine cough syrup that had been dispensed was not recorded. Respondent's initials had not been recorded on transactions since August 16, 2016.
- The pharmacy was in a cluttered, disorderly and unsanitary condition. The prescription counter was piled with paper. The prescription pickup and drop off counters were piled with merchandise and paper and the secure barrier (metal gate) could not be closed. The sink was piled with clean and dirty glassware and cups. A soiled dishcloth was hanging in the sink, and there was a plastic tote on the floor that contained a dark liquid with objects floating in it.

Mr. Sedlacek noted that similar deficiencies and issues had been cited in prior inspections. At the conclusion of the inspection, Respondent stated that he was planning to close his pharmacy, but he would not specify a closing date. He told Sedlacek that he was selling his stock but was not planning to sell his files. Following the inspection, Sedlacek provided Respondent with a written Inspection Report and a Report of Deficiencies and Corrections Required. Respondent was required to sign and return the Report of Deficiencies and Corrections Required with a written explanation of the steps he had taken to correct each deficiency. Respondent never returned the required form and never documented that the corrections had been made at the pharmacy. (Sedlacek testimony; Exhibit 3)

Mr. Sedlacek revisited Rick's Pharmacy on December 13, 2016. A notice of closing was attached to the pharmacy's front door and another notice was attached to the pharmacy door. The notice stated that the pharmacy would be closing with an anticipated effective date of December 31, 2016 and that pharmacy records would be maintained by Bloemke Pharmacy in Belmont. The notice further stated that after a short vacation they would reopen as Rick's General Store, selling gifts and nonprescription OTC products. Respondent told Sedlacek that he had sent a letter to each patient on December 2, 2016 and had also sent a notice of his intent to close to the Board. Respondent had not yet notified the Drug Enforcement Agency (DEA). Mr. Sedlacek advised Respondent that Board rules required him to give 30 days' notice of closing to patients, the Board, and the DEA. Respondent agreed to send out new closure notices. Following this visit, Mr. Sedlacek prepared an Investigative Report, which was dated December 14, 2016, and he referred Respondent to the Board for a complaint to be opened. (Sedlacek testimony; Exhibit 6)

Mr. Sedlacek returned to Rick's Pharmacy on January 15, 2017, but the door was locked, the closure sign was on the door, and Respondent was not there. Sedlacek returned to

Rick's Pharmacy again on April 14, 2017. The same closure sign was on the door, the doors were locked, and no one was there. Mr. Sedlacek has been trying to verify that the closure was properly executed, but he has been unable to get inside the building to see if any prescription drugs remain inside. (Sedlacek testimony)

Dan Sedlacek returned to Rick's Pharmacy on August 2, 2017. There was a sign on the door that said the business was open on Monday through Friday, 9:00-5:00. The sign advertised 50% off all over the counter medications. Mr. Sedlacek spoke to a neighbor, who stated that he had not seen Respondent since December 2016 and did not know his whereabouts. (Sedlacek testimony)

*Service of Notice of Hearing and Statement of Charges.* On May 9, 2017, the Board issued a Notice of Hearing and Statement of Charges against Respondent. The hearing was scheduled for June 27, 2017 but was continued twice because Respondent could not be found and served. The Notice of Hearing and Statement of Charge was initially sent to Respondent at his address of record by restricted certified mail, but the mailing was returned to the Board office as undeliverable. The Board then attempted to personally serve Respondent, but the Franklin County Sheriff's office issued a return of service stating that they performed a diligent search but were unable to serve him. The Notice of Hearing and Statement of Charges was then served on Respondent by publication in the Hampton Chronicle, with notice being published once each week for three weeks starting on August 9, 2017. Respondent failed to appear for hearing. (Exhibits 1, 2; Continuance Orders)

#### CONCLUSIONS OF LAW

NOTE: The Board's administrative rules at 657 Iowa Administrative Code (IAC) chapters 35 and 36 were amended effective November 1, 2017. This Decision and Order cites to the prior rules, which were in effect at the time that Respondent was charged and at the time of the hearing.

*Failure to Appear.* 657 IAC 35.5(1) allows a Notice of Hearing and Statement of Charges to be served on a licensee by personal service, certified mail return receipt requested, or publication, as provided in the Iowa Rules of Civil Procedure. In this case, Respondent was properly served with the Notice of Hearing and Statement of Charges by publication when he could not be located and served in any other manner. Respondent failed to appear for hearing.

657 IAC 35.21 allows the Board to proceed with the hearing and render a decision in the absence of the licensee if the licensee fails to appear after proper service of notice. The

Board was authorized to proceed with the hearing when Respondent was properly served by publication but failed to appear.

***Failure to Ensure Legal Operation (Count I).*** Iowa Code sections 147.55(9), 155A.12(1) and 657 IAC 36.1(4)"u" all authorize the Board to revoke, suspend or otherwise discipline a licensee for acts or offenses specified by Board rule. Iowa Code section 155A.12(4) authorizes the Board to discipline a licensee for failing to keep and maintain records required by chapter 155A or for failure to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the Controlled Substances Act.

The preponderance of the evidence established that Respondent failed to maintain supplier invoices of controlled substances, which were properly dated, signed and readily retrievable, as required by the Board's rules at 657 IAC 8.9 and 8.9(1). In addition, Respondent's perpetual inventory of Schedule II controlled substances was not up-to-date with the record of changes required by 657 IAC 10.33. Respondent violated 657 IAC 36.1(4)"ac" by his failure to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the board.

In addition, the preponderance of the evidence in the record established that Respondent failed to maintain his pharmacy sink in a sanitary condition, as required by 657 IAC 8.5(2). Respondent also failed to keep his pharmacy in an orderly and clean condition as required by 657 IAC 8.5(5). At the time of the October 2016 inspection, the pharmacy was not in a clean and orderly condition and its sink was unsanitary.

***Failure to Maintain Policies and Procedures.*** The preponderance of the evidence in the record established that Respondent failed to have policies and procedures for all operations of the pharmacy, as required by 657 IAC 8.3(5). The pharmacist-in-charge is responsible for establishing, periodically reviewing, implementing, and complying with the pharmacy's policies and procedures. At the time of the October 2016 inspection, Respondent was unable to provide the Board's Compliance Officer with a copy of the pharmacy's policies and procedures, and he admitted that he had not seen the policies and procedures in two years.

***Failure to Maintain CQI Program (Count III).*** 657 IAC 8.26 requires all licensed pharmacies to implement and participate in a continuous quality improvement (CQI) program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and quality of patient care. Pursuant to

subrules 8.26(2) and 8.3(5)"c," the pharmacist-in-charge is ultimately responsible for establishing, implementing and utilizing an ongoing, systematic CQI program for achieving performance enhancement and ensuring the quality of pharmacy services. The preponderance of the evidence established that Respondent violated 657 IAC 8.26(2) and 8.3(5)"c," when he did not have a CQI program for Rick's Pharmacy at the time of the October 2016 inspection. The small size of the pharmacy and the relatively small number of prescriptions being filled does not exempt a pharmacy from the CQI program requirement.

*Failure to Maintain Records for Schedule V Dispensing (Count IV).* The preponderance of the evidence established that Respondent's Schedule V logbook was not complete and was not accurate because the recorded transactions did not include the quantity dispensed or the initials of the pharmacist, as required by 657 IAC 10.31(5).

*Sanction.* Respondent's failure to respond to the Statement of Charges and his failure to keep the Board informed of his current whereabouts leave the Board with few options to address these serious violations in a manner that is consistent with the public health, safety and welfare. It is unknown whether Respondent is currently practicing pharmacy.

#### DECISION AND ORDER

IT IS THEREFORE ORDERED that license number 16187, issued to Respondent Richard Grote, is hereby SUSPENDED effective immediately upon service of this Decision and Order.

IT IS FURTHER ORDERED that Respondent shall pay a civil penalty of five thousand dollars (\$5000).

IT IS FURTHER ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 36.18(2), that Respondent shall pay \$75.00 for fees associated with conducting the disciplinary hearing.

IT IS FURTHER ORDERED that the suspension of Respondent's license shall continue until Respondent:

- 1) has paid the \$5000 civil penalty and hearing fee in full;
- 2) has provided the Board with a current address; and

- 3) has appeared for a reinstatement hearing and has established that the reasons for the suspension of his license no longer exists and that it is in the public interest for his license to be reinstated. Effective November 1, 2017, the Board's reinstatement rules are found at 657 IAC 35.36.

Dated this 16th day of January, 2018.



Sharon Meyer, Chairperson  
Iowa Board of Pharmacy

cc: Laura Steffensmeier, Assistant Attorney General

A default decision or decision rendered on the merits after a party has failed to appear or participate in a contested case hearing shall become final board action unless, within 15 days after the date of notification or mailing of the decision, a motion to vacate is filed and served on all parties or unless an appeal of a decision is timely initiated within the time provided by rule 35.30. A motion to vacate must state all facts relied upon by the moving party which establish good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated shall be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) shall be attached to the motion. 657 IAC 35.27(3). The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate. 657 IAC 35.27(4).

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**

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Re:	)	CASE NO. 2016-173
Pharmacist License of	)	
	)	<b>RESCHEDULING ORDER</b>
<b>RICHARD GROTE</b>	)	
License No. 16187	)	
Respondent.	)	

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The hearing in the above captioned case that was scheduled for August 29, 2017, has been rescheduled for October 31, 2017, at 9:00 a.m. The hearing will be held in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309.



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Andrew Funk, Pharm.D., Executive Director  
Iowa Board of Pharmacy

Copies to:

AAG Laura Steffensmeier via email to [laura.steffensmeier@iowa.gov](mailto:laura.steffensmeier@iowa.gov)

DIA



**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	CASE NO. 2016-173
Pharmacist License of	)	
	)	<b>NOTICE OF HEARING AND</b>
<b>RICHARD GROTE</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 16187	)	
Respondent.	)	

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**COMES NOW** the Iowa Board of Pharmacy ("Board") and files this Notice of Hearing and Statement of Charges against Richard Grote ("Respondent"), 920 Fourth Ave S, Hampton IA 50441, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)(e), and 657 IAC 35.5 and 36.5. Respondent's Iowa pharmacist license number 16187 is currently active through June 30, 2018.

**A. TIME, PLACE, AND NATURE OF HEARING**

Hearing. A disciplinary contested case hearing shall be held on June 27, 2017, before the Board. The hearing shall begin at 9:00 AM and shall be located in the Board conference room located at the Iowa Board of Pharmacy Office, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

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 35.11. 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 at the following address: Iowa Board of Pharmacy, 400 S.W. 8<sup>th</sup> Street, Suite E, Des Moines, Iowa, 50309-4688.

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.

Pre-hearing Conference. Any party may request a prehearing conference in accordance with 657 IAC 35.15 to discuss issues related to the hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing 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. If you need to request an alternative time or date for the hearing, you must

comply with the requirements in 657 IAC 35.16. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The Office of Attorney General is responsible for representing the public interest (the State) in this proceeding. Copies of pleadings should be provided to counsel for the State at the following address:

Laura Steffensmeier  
Assistant Attorney General  
Iowa Attorney General's Office  
2<sup>nd</sup> Floor, Hoover State Office Building  
Des Moines, Iowa 50319

Ms. Steffensmeier can also be reached by phone at (515) 281-6690 or by e-mail at [laura.steffensmeier@iowa.gov](mailto:laura.steffensmeier@iowa.gov).

Communications. You may contact the Board office at (515) 281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. 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 with the Board office 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 (2015).

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 35.21.

## **C. CHARGES**

### **COUNT I**

#### **FAILURE TO ENSURE LEGAL OPERATION**

Respondent is charged with failing to ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy in violation of 657 IAC 8.3, specifically by violating 657 IAC 8.5(2), 8.5(5), 8.9(1), and 10.33, and may be disciplined pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), (4), and (5), and 657 IAC 36.1(4)"u" and "ac".

**COUNT II**  
**FAILURE TO MAINTAIN POLICIES AND PROCEDURES**

Respondent is charged with failing to establish, periodically review, implement, and comply with policies and procedures for all operations of the pharmacy in violation of 657 IAC 8.3(5)"a", and may be disciplined pursuant to Iowa Code sections 147.55(9), 155A.12(1), and (3), and 657 IAC 36.1(4)"u".

**COUNT III**  
**FAILURE TO MAINTAIN CQI PROGRAM**

Respondent is charged with failing to implement or participate in a continuous quality improvement program in violation of 8.26(2) and 8.3(5)"c", and may be disciplined pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), and (4), and 657 IAC 36.1(4)"u".

**COUNT IV**  
**FAILURE TO MAINTAIN RECORDS FOR SCHEDULE V DISPENSING**

Respondent is charged with failing to maintain a bound record book for dispensing of Schedule V controlled substances containing the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist who approved the dispensing of the substance to the purchaser in violation of 657 IAC 10.31(5), and may be disciplined pursuant to Iowa Code sections 147.55(9), 155A.12(1), (3), (4), and (5), and 657 IAC 36.1(4)"u" and "ac".

**D. FACTUAL CIRCUMSTANCES**

1. At all times relevant, Respondent served as pharmacist in charge at R & D Apothecary, d/b/a Rick's Pharmacy, in Hampton, Iowa. Rick's Pharmacy closed effective December 31, 2016.
2. In October 2016, Rick's Pharmacy underwent a routine inspection. The following deficiencies were discovered during the inspection:
  - a. The sink area was not in a sanitary condition.
  - b. The pharmacy area was generally cluttered and disorganized.
  - c. The pharmacy's controlled substance invoices were not dated, signed, or readily retrievable.
  - d. The pharmacy's perpetual inventory was not up-to-date and did not have the required record of changes.
  - e. The pharmacy did not have a policy and procedure manual available.


- f. The pharmacy did not have an operational continuous quality improvement program.
  - g. The Schedule V logbook contained transactions without the quantity dispensed and without the initials of a pharmacist.
3. Respondent was disciplined by the Board in 2012 for similar conduct.

**E. SETTLEMENT**

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 IAC 36.6. If you are interested in pursuing settlement in this matter, please contact Assistant Attorney General Laura Steffensmeier at (515) 281-6690.

**F. FINDING OF PROBABLE CAUSE**

On this 9th day of May, 2017, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



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Chairperson  
Iowa Board of Pharmacy

Copy to:

Laura Steffensmeier  
Assistant Attorney General  
Office of the Attorney General of Iowa  
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).