

BEFORE THE IOWA BOARD OF PHARMACY

Re:)
Pharmacy License of)
BROADLAWNS MEDICAL)
CENTER OUTPATIENT)
PHARMACY)
License No. 695,)
Respondent.)

Case No. 2008-106

STATEMENT OF CHARGES

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Director for the Iowa Board of Pharmacy and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2009).
3. On November 19, 2008, the Board renewed general pharmacy license number 695 for Broadlawns Medical Center Outpatient Pharmacy (hereinafter, "Respondent"), with Mark D. Hall as the pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 695 is current and active through December 31, 2009.
5. Respondent is currently operating a general pharmacy at 1801 Hickman Road, Des Moines, Iowa 50314.

A. CHARGES

COUNT I – LACK OF COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009) and 657 Iowa Administrative Code § 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by inaccuracies in Respondent's records of controlled substance transactions.

COUNT II – INADEQUATE CONTROLS

Respondent is charged under Iowa Code §§ 124.306, 124.402(1), 155A.15(2)(b) (2009), and 657 Iowa Administrative Code § 6.7, with failing to maintain adequate control over and accountability for drugs, including controlled substances.

B. CIRCUMSTANCES

An investigation commenced on October 10, 2008 which revealed the following:

1. At all times material to this statement of charges, Respondent operated a general pharmacy in the Broadlawns Medical Center, Des Moines, with Mark D. Hall as the pharmacist in charge. Respondent dispensed about 270,000 prescriptions in the 18 ½ month period commencing April 1, 2007 and ending October 15, 2008, which period was the subject of an audit.
2. The audit of Respondent's controlled substance inventory, performed by the Board's compliance officers, revealed material shortages of both Schedule II and Schedule III-V controlled substances. Of 73 Schedule II drugs in the audit, 14 shortages were noted, half of which were greater than 1%. Of 77 Schedule III-IV drugs audited, 44 shortages were revealed, 18 of which were greater than 1%.
3. Respondent conducted its own, separate audit which revealed differences in the size of the shortages, but nevertheless confirmed significant shortages of controlled substances. For example, Respondent's own audit revealed significant shortages of Guaifenesin with Codeine.
4. Respondent's staff audit attempted to reconcile some inventory discrepancies by combining counts of brand name and generic drugs.
5. Respondent's staff also acknowledged its ScriptPro system as a source of "dropped" doses, and the admissions of one former employee regarding her diversion of controlled substances. The discharged employee claims returned drugs were not safeguarded, allowing staff members to easily divert controlled substances.

Wherefore, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.


LLOYD K. JESSEN
Executive Director

On this 18th day of November 2009, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.

A handwritten signature in blue ink that reads "Vernon H. Benjamin Chairperson". The signature is fluid and cursive, with the last name being the most prominent.

VERNON H. BENJAMIN, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

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BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2008-106
Pharmacy License of)	
BROADLAWNS MEDICAL CENTER)	STIPULATION
OUTPATIENT PHARMACY)	AND
License No. 695)	CONSENT ORDER
Respondent)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2009), the Iowa Board of Pharmacy (hereinafter, the “Board”) and Broadlawns Medical Center Outpatient Pharmacy (hereinafter, “Respondent”) enter into the following Stipulation and Consent Order settling a licensee disciplinary proceeding currently pending before the Board.

Allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent’s license to operate a pharmacy in Iowa is evidenced by Pharmacy License Number 695, recorded in the permanent records of the Board.
2. Pharmacy License Number 695 is current and active until December 31, 2011.
3. The Board has jurisdiction over the parties and the subject matter of this disciplinary proceeding.
4. A Statement of Charges was filed against Respondent November 18, 2009.
5. While Respondent disputes the allegations contained in the Statement of Charges, Respondent has chosen not to contest those allegations for the following reason:

Respondent recognizes that under Iowa Code chapters 124 and 155A, and the administrative rules of the Board, Respondent must bear the ultimate responsibility for

the failure of its employees or contractors to successfully comply with Iowa laws and regulation. The fact that Respondent delegated duties to employees and contractors is not a defense to the Board's charges. Respondent therefore acknowledges that the allegations of the Statement of Charges, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

6. Beginning on the date of the Board's approval of this Stipulation and Consent Order, Respondent's license shall be placed on probation for two (2) years, upon the following conditions:

- (a) Respondent agrees to abide by the terms of probation.
- (b) Respondent may petition the Board for termination of probation after successfully completing one (1) year.
- (c) Within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order, Respondent will propose to the Board written pharmacy policies and procedures regarding: (1) use of automated dispensing technology, (2) prevention of drug diversion, (3) security of all prescription drugs, (4) maintenance of accurate records and accountability for controlled substances, (5) destruction and disposal of outdated, returned and/or unwanted controlled substances, and (6) identification of and appropriate responses to substance abuse and impairment in pharmacy employees. Respondent has existing policies and procedures relevant to this requirement, which Respondent may submit to the Board for consideration. Following review and

approval by the Board, Respondent agrees to adopt, implement, and adhere to these policies and procedures.

- (d) Respondent has provided the Board with evidence that authorized, but unfilled pharmacy staff positions, have been available to the pharmacist in charge during the past two calendar years. Respondent shall continue to make adequate pharmacy staff positions available and shall assist the pharmacist in charge in complying with all Iowa pharmacy laws and board rules, including 657 I.A.C. § 6.2(2) ("Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy").
- (e) Respondent shall file eight sworn quarterly reports with the Board, signed by the pharmacist in charge, attesting to Respondent's compliance with the terms and conditions of this Stipulation and Consent Order. The reports shall be filed not later than December 5, March 5, June 5 and September 5 of each calendar year and *shall include a description of Respondent's most recent efforts to comply with this Stipulation and Consent Order*. Respondent's quarterly reports shall identify the person who has primary responsibility for assuring that Respondent is in compliance with Iowa law, as well as any other information deemed to be necessary, from time to time, by the Board.
- (f) Respondent shall obey all federal and state laws, rules, and regulations substantially related to the operation of an Iowa outpatient pharmacy.

7. Pursuant to 657 Iowa Administrative Code § 36.1(2)(i), Respondent shall remit

payment of two-thousand, five hundred dollars, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. The payment shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the remittance ordered pursuant to 657 Iowa Administrative Code § 36.1(2)(i), this disciplinary proceeding shall be concluded without further order of the Board.

8. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate further action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2009), and 657 Iowa Administrative Code § 36.1.

9. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

10. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

11. The State's counsel may present this Stipulation and Consent Order to the Board.

12. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Iowa Board of

Pharmacy for its consideration on this 26 day of Oct 2010.


BROADLAWNS MEDICAL CENTER
OUTPATIENT PHARMACY, Respondent
By Vincent Mandracchia, DPM, MHA
Senior Vice President; Chief Medical
Officer

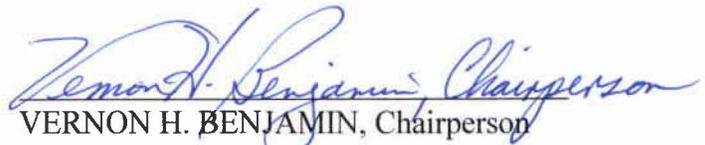
Subscribed and sworn to before me by Vincent Mandracchia, who has stated to me that he is authorized to sign this Stipulation and Consent Order on behalf of Broadlawns Medical Center Outpatient Pharmacy on this 26 day of October 2010.



Michelle A. Phillips
Iowa Notarial Seal
Commission No.: 737386
My Commission Expires:
10/28/2011


NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 3rd day of November 2010.


VERNON H. BENJAMIN, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Connie Diekema
699 Walnut Street, Suite 1900
Des Moines, Iowa 50309

BEFORE THE BOARD OF PHARMACY STATE OF IOWA

**IN THE MATTER OF THE STIPULATION AND CONSENT ORDER AGAINST
BROADLAWNS MEDICAL CENTER OUTPATIENT PHARMACY,
RESPONDENT**

2008-106

TERMINATION ORDER

DATE: March 7, 2012

1. On November 3, 2010, a Stipulation and Consent Order was issued by the Iowa Board of Pharmacy placing the license to operate a pharmacy, number 695 issued to Broadlawns Medical Center Outpatient Pharmacy on probation for a period of two years under certain terms and conditions.

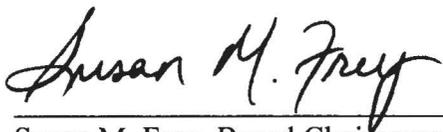
2. Respondent petitioned the Board for early termination of probation.

3. The Board directed that the probation placed upon the Respondent's license to practice pharmacy should be terminated.

IT IS HEREBY ORDERED:

That the probation placed upon the Respondent's license to operate a pharmacy is terminated, and the license is returned to its full privileges free and clear of all restrictions.

IOWA BOARD OF PHARMACY



Susan M. Frey, Board Chairperson
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688