SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND DAWN B. BARNES, INC. d/b/a BEST BUY PHARMACY OF SHELBINA

Come now Dawn B. Barnes, Inc. d/b/a Best Buy Pharmacy of Shelbina ("Permittee" or "Respondent") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Permittee's permit as a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") regarding cause to discipline the Permittee's permit, and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo.

Permittee acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Permittee knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Permittee acknowledges that it has received a copy of the draft complaint, the investigative report, and other documents relied upon by the Board in determining there was cause to discipline its permit.

For the purpose of settling this dispute, Permittee stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Permittee's permit, numbered 2007016983, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by Section 338.110, RSMo, for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, Dawn B. Barnes, Inc. d/b/a Best Buy Pharmacy of Shelbina is permitted by the Missouri Board of Pharmacy as a registered pharmacy, as defined in Section 338.010 RSMo. Respondent's permit, numbered 2007016983, is current and active and was so at all times material herein.

3. At the time of the events alleged herein, R.H. was the pharmacist-in-charge ("PIC") of Dawn B. Barnes d/b/a Best Buy Pharmacy of Shelbina ("Best Buy" or "Best Buy Pharmacy"), 201 North Center, Shelbina, Missouri 63468.

July 29, 2008 Investigation By Inspector Smith

4. On or about June 24, 2008, the Board received information that Best Buy was open for business without a licensed pharmacist on duty and that prescription medications were compounded, prepared or dispensed to pharmacy customers by non-pharmacist personnel.

5. Based on the information received, Board Inspector Steve Smith visited Best Buy Pharmacy on July 29, 2008 and conducted an investigation.

6. Best Buy Pharmacy is housed within a grocery store and a drive through window services the pharmacy area.

7. During his investigation on July 29, 2008, Inspector Smith observed the pharmacy's drive-thru window and witnessed a female pharmacy technician (initials W.E.) dispense prescription medication to a pharmacy customer at 8:24 a.m., prior to the pharmacist's arrival.

8. After witnessing this occurrence, Inspector Smith entered the store, approached a pharmacy technician and determined that the pharmacist was not on duty when prescription medications were dispensed from the pharmacy at 8:24 a.m.

9. Upon entering the pharmacy, Inspector Smith observed that the pharmacy was not displaying a "No Pharmacist On Duty" sign.

10. During his investigation on July 29, 2008, Inspector Smith reviewed the pharmacy's patient signature log which contained three patient signatures on July 29, 2008 prior to the arrival of a licensed pharmacist on that date.

11. 20 CSR 2220-2.700(1) states:

> A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgment in connection with the receiving, preparing, compounding, distribution or dispensing of medications.

12. At the time of Inspector Smith's visit on July 29, 2008, two female pharmacy

technicians were on duty and working without the direct supervision of a licensed pharmacist to wit: K.E. and W. E.

13. Inspector Smith conducted an interview of Best Buy pharmacy technician K.B. on July 29, 2008. The interview revealed that Respondent's pharmacy technicians

a. open the pharmacy at 8:00 a.m. and the pharmacist arrives around 9:00 a.m.

b. dispense medications to the patient before the pharmacist arrives,

c. transported filled prescriptions off the pharmacy premises to the grocery store's customer service counter for pick up after the pharmacy closes.

14. Inspector Smith conducted an interview of Best Buy pharmacy technician W.E. on July 29, 2008. The interview revealed that

a. W.E. had dispensed a prescription from the drive-thru window on July 29, 2008 prior to the arrival of the pharmacist,

b. if the prescriptions have been processed the day before and checked by the pharmacist, pharmacy technicians will dispense medications to patients without a pharmacist on duty,

c. filled prescriptions are transported off the pharmacy premises to the grocery store's customer service counter for pick up after the pharmacy closes,

d. Respondent knew or should have known that the pharmacy technicians at Best Buy are providing medications to pharmacy patients before the pharmacist's arrival, and

e. Respondent knew or should have known that the pharmacy technicians at Best Buy are transporting prescription medications to the grocery store's customer

service counter.

15. Inspector Smith's investigation on July 29, 2008, also revealed that technicians were performing the following functions before the pharmacist arrives:

a. taking prescriptions orders from pharmacy customers

b. entering prescriptions into the computer system,

c. filling prescriptions, and

d. answering the phones and take messages off the machine.

16. Inspector Smith conducted an interview of Respondent's PIC on July 29, 2008 and Respondent's PIC admitted that

a. pharmacy technicians at Best Buy process prescriptions without a pharmacist on duty in order to help the pharmacy "stay ahead" all day,

b. he does not usually arrive for work until after 8:00 a.m.

c. temporary pharmacists do not usually arrive for work until 9:00 a.m.

d. the pharmacy has gotten lax in putting up its "No Pharmacist On Duty" sign.

17. Inspector Smith conducted an interview of Best Buy pharmacy technician C.G. on July 29, 2008. The interview revealed that prescription medications are left at the grocery store's customer service counter for patient pick up after pharmacy hours.

18. Inspector Smith conducted an interview of grocery store employee, Karen Farrell on July 29, 2008. The interview revealed that

a. Prescriptions from Best Buy Pharmacy have been held at the customer service counter for customer pick up for as long as the pharmacy has been open.

b. Non-pharmacy personnel including grocery store employees provided prescription

medications to two different customers at the customer service counter.

19. Inspector Smith conducted an interview of grocery store employee, Barb Edmundson on July 29, 2008. The interview revealed that,

a. prescriptions from Best Buy Pharmacy had been held at the customer service counter for customer pick up for the at least one and one-half (1 ½) years.

b. every night, pharmacy staff personnel bring out a cardboard box containing prescription medications for customer pick up after hours and that the next morning, the box would be picked up and taken back to the pharmacy, and that

c. Non-pharmacy personnel including grocery store employees provided prescription medications to pharmacy customers from the grocery store's customer service counter.

20. On July 29, 2008, Board Inspector Smith requested that Respondent provide a written response to the alleged violations identified by Inspector Smith during his inspection.

21. Respondent provided a written response dated August 4, 2008 wherein Respondent's PIC states that,

a. "In the past the technicians would…dispense…prescriptions…that had been filled on a previous day."

b. "…the pharmacy will no longer be opened until the pharmacist on duty arrives".

c. "We are no longer leaving prescriptions at the C&R grocery."

No Pharmacist On Duty

22. Respondent's conduct of operating a pharmacy without a pharmacist on duty and

failing to display its "No Pharmacist On Duty" sign is in violation of 20 CSR 2220-2.010(1) which states in part:

> (A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law.
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> When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").
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> (B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold.

23. Respondent's conduct of allowing pharmacy technicians to receive, prepare, process, and fill prescription medications without the direct supervision of a licensed and registered pharmacist is in violation of Section 338.010, RSMo, which states in relevant part:

> . . . This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his duties. This assistance in no way is intended to relieve the pharmacist from his responsibilities for compliance with this chapter and he will be responsible for the actions of the auxiliary personnel acting in his assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, podiatry, or veterinary medicine, or the practice of

> optometry in accordance with and as provided in sections 195.070 and 336.220, RSMo, in the compounding or dispensing of his own prescriptions.

24. Best Buy Pharmacy's conduct of allowing prescriptions to be picked up after hours at the grocery store customer service counter is in violation of 20 CSR 2220-2.190(1) which provides that:

> Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient.

25. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by operating Best Buy Pharmacy without a pharmacist on duty.

26. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to display the pharmacy's "No Pharmacist On Duty" sign.

27. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by dispensing prescription medication without a pharmacist on duty.

28. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by allowing pharmacy technicians to receive, prepare, process, and fill prescription medications without the direct supervision of a licensed and registered pharmacist.

29. Respondent violated Missouri rules and regulations governing the practice of

pharmacy by failing to supervise Best Buy Pharmacy and its pharmacy personnel to ensure compliance with state and federal pharmacy laws and regulations.

30. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to ensure the safety of Best Buy pharmacy customers and its legend drug inventory.

31. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to comply with all state and federal patient counseling requirements.

32. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to ensure compliance with all state and federal drug laws and rules.

33. Respondent and the pharmacy employees violated state and federal privacy laws by exposing confidential and protected health information outside the pharmacy premises without written authorization of the patient.

Dispensing Of Legend Drugs By Non-Pharmacy Personnel

34. Best Buy Pharmacy is located within the premises of C & R grocery store in Shelbina, Missouri.

35. The Board does not license or permit the entire C & R grocery store location; but only the pharmacy premises located therein.

36. Best Buy Pharmacy personnel did transport, on regular basis, prescription medications off the pharmacy premises to be stored at the customer service counter of C & R grocery store in Shelbina, Missouri.

37. Multiple unlicensed, unregistered and unsupervised employees of C & R grocery store were allowed to dispense prescription medications to patients outside the pharmacy premises and after pharmacy hours, without a pharmacist on duty.

38. Respondent's practice of allowing non-pharmacy staff to dispense prescription medications outside of the pharmacy area to pharmacy patients after pharmacy hours is in violation of 20 CSR 2220-2.010(1) which states in part:

> (A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law.
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> When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").
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> (B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold.

39. Respondent's conduct alleged herein constitutes the unauthorized practice of pharmacy and unauthorized operation of a pharmacy without the appropriate permit and/or licensure by the Board in violation of §338.210, RSMo.

40. Section 338.210, RSMo, states, in part, that:

> 1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:
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> 2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable prescription or drug order shall occur at the pharmacy location where such identifiable prescription or drug order is first presented by the patient or the patient's authorized agent for preparation or dispensing, unless otherwise expressly authorized by the board.
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> 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder of pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

41. Respondent's conduct of dispensing prescriptions outside of the pharmacy area, to be picked up by patients after pharmacy hours is unlawful pursuant to § 338.220, RSMo, which states:

> 1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy.

42. Respondent's practice of allowing non-pharmacy staff to dispense prescriptions outside the pharmacy area to patients after pharmacy hours is also in violation of 20 CSR 2220-2.190(1) which states:

> Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her

> designee shall personally offer to discuss matters which will enhance of optimize drug therapy with each patient or caregiver of each patient.

43. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by transporting prescription medications off of the pharmacy premises to a non-permitted location and authorizing the delivery of prescription medications to pharmacy patients by unregistered, unlicensed and unsupervised non-pharmacy personnel.

44. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by leaving prescription medications in the care of unregistered, unsupervised and unlicensed non-pharmacy personnel by placing and storing prescriptions in a cardboard box outside of the pharmacy area.

45. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by exposing confidential and personally identifiable protected health information to non-pharmacy personnel by packing and delivering a cardboard box of "bagged" prescription medications to C & R grocery store's customer service counter every night.

46. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by allowing non-pharmacy personnel to take custody of, dispense and sell prescription medications outside the pharmacy premises without the direct supervision of a licensed and registered pharmacist.

47. Respondent violated Missouri rules and regulations governing the practice of pharmacy by failing to supervise Best Buy Pharmacy and its pharmacy personnel to ensure compliance with state and federal pharmacy laws and regulations.

48. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to ensure the privacy and safety of Best Buy pharmacy customers and its legend drug inventory.

49. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to comply with all state and federal patient counseling requirements.

50. Respondent and the pharmacy employees violated Missouri rules and regulations governing the practice of pharmacy by failing to ensure compliance with all state and federal drug laws and rules.

51. Respondent and the pharmacy employees over whom Respondent has a duty to supervise, violated state and federal privacy laws by exposing confidential and protected health information outside the pharmacy premises without written authorization of the patient.

JOINT CONCLUSIONS OF LAW

52. Cause exists for Petitioner to take disciplinary action against Respondent's permit under 20 CSR 2220.2-010(O) which states:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

53. Cause exists for Petitioner to take disciplinary action against Respondent's permit under Section 338.285, RSMo, which states:

> The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

54. Cause exists for Petitioner to take disciplinary action against Licensee's permit under Section 338.055 RSMo (Supp. 2002), which states in pertinent parts:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> (5) Incompetency, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter.
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> (6) Violation of, assisting or enabling any person to violate, any provision of this chapter, in the performance of the functions or duties of any profession licensed or regulated by this chapter.
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> (13) Violation of any professional trust or confidence.
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(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo (2000):

1. Respondent's pharmacy permit, Permit No. 005218, is hereby PUBLICLY CENSURED.

2. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

3. Respondent, together with its heirs and assigns, and its attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is

severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ REQUESTS

__dl_____ DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

DAWN B. BARNES, INC. d/b/a
BEST BUY PHARMACY OF SHELBINA

By: Dawn B. Barnes
DAWN B. BARNES
President

Date: 6/01/2009

PETITIONER

MISSOURI BOARD OF
PHARMACY

By:
KIMBERLY GRINSTON
Executive Director

Date: 6/17/09

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