

BEFORE THE WYOMING STATE BOARD OF PHARMACY

IN THE DISCIPLINARY MATTER OF)
CITY DRUG,)
RESIDENT RETAIL PHARMACY LICENSE)
NO. R10215)
)
AND) Docket No. 2024-06 and 2024-08)
)
IN THE DISCIPLINARY MATTER OF)
KELSEY MARIE JAMES,)
WYOMING PHARMACIST LICENSE)
NO. 4122)

SETTLEMENT AGREEMENT, STIPULATION, AND ORDER FOR DISCIPLINARY ACTION

COME NOW, the Executive Director, Matthew R. Martineau (hereinafter “Petitioner”), of the Wyoming State Board of Pharmacy (“Board”) and City Drug, Resident Retail Pharmacy (“City Drug”), and Kelsey James RPh. (“Dr. James”), hereby enter into this *Settlement Agreement, Stipulation, and Order of Discipline* (“Agreement”), subject to approval by the Board.

JURISDICTION

1. Pursuant to the Wyoming Pharmacy Act (“Act”) “there is created a state board of pharmacy whose duty is to carry out the purposes and to enforce the provisions of this act.” Pursuant to the Act, one of the purposes of the Board is to seek disciplinary action against a pharmacy licensee:

(d) The board may deny, suspend, revoke or refuse to renew a license issued under this section, may issue a letter of admonition to a resident pharmacy licensee and may assess an administrative penalty, not to exceed two thousand dollars (\$2,000.00) per violation, against a resident pharmacy licensee on any of the following grounds:

- (i) Failure to comply with any requirement of this chapter or the Wyoming Controlled Substances Act;
- (ii) *Failure to comply with rules and regulations of the board;*
- (iii) Conviction of a pharmacy owner, pharmacist in charge, staff pharmacist or pharmacy technician for a felony under any state or federal law, if the conviction is related to the practice of pharmacy;
- (iv) *Obtaining any remuneration by fraud, misrepresentation or deception;*
- (v) Suspension or revocation of a pharmacy license or any other disciplinary action against the licensee by a board of pharmacy in any other state;
- (vi) Knowing submission of false, misleading or fraudulent information to the board in connection with an initial or renewal application for a resident pharmacy license;
- (vii) Purchase or receipt of a prescription drug, controlled substance or medical device from a source other than a manufacturer, wholesaler or pharmacy licensed by the board;
- (viii) Purchase or receipt of a prescription drug, controlled substance or medical device that is not approved by the federal food and drug administration;
- (ix) Keeping the pharmacy open for business without a licensed pharmacist in charge on site;
- (x) Allowing a person who is not licensed by the board to perform duties as a pharmacist, pharmacy technician or pharmacy technician in training.

(e) Before any final adverse administrative action is taken against a pharmacy licensee, the licensee is entitled to a hearing by the board of pharmacy upon due notice of the time and place where the hearing will be held. The accused may be represented by legal counsel, is entitled to compulsory attendance of witnesses and may appeal to the district court of the county in which the pharmacy is situated, in accordance with the Wyoming Administrative Procedure Act.

(emphasis added)

Wyo. Stat. Ann. § 33-24-113(d)-(e) (West 2024).

2. Pursuant to Wyo. Stat. Ann. § 33-24-122, the Board has been given the following authority by the Wyoming State Legislature:

(a) *The license and registration of any pharmacist may be revoked or suspended by the board of pharmacy or the board may issue a letter of admonition, refuse to issue or renew any license or require successful completion of a rehabilitation program or issue a summary suspension for any one (1) or more of the following causes:*

(i) Conviction of a felony or high misdemeanor that relates to the practice of pharmacy or to the ability to practice pharmacy, in which case the record of conviction or a copy thereof certified by the clerk or judge of the court in which the conviction is had shall be conclusive evidence;

(ii) For renting or loaning to any person his or her license or diploma to be used as a license or diploma for such person;

(iii) *For unprofessional conduct;*

(iv) For knowingly submitting false or misleading information to the board in the application for a license or renewal of a license;

(v) *For knowingly submitting false or misleading information to the board or its representative regarding the professional practice of the internship or professional practice of pharmacy by any other person;*

(vi) Willful violation of any provision of this chapter or any willful violation of any of the provisions of the Wyoming Controlled Substances Act of 1971 or any amendments thereto;

(vii) *Willful violation of any rules or regulations promulgated by the board in accordance with this chapter* or the Wyoming Controlled Substances Act of 1971;

(viii) If the person's registration or license to practice has been refused, lapsed for cause, expired for cause, revoked

for cause, or suspended for cause in this or any other jurisdiction or if the person has otherwise been disciplined by a board of pharmacy in this or any other jurisdiction;

(ix) For senility or mental impairment which impedes the pharmacist's professional abilities or for habitual personal use of morphine, cocaine or other habit forming drugs or alcohol;

(x) For physical impairment which unnecessarily impedes the pharmacist's professional abilities and for which there can be no reasonable accommodation.

(xi) For violating W.S. 35-4-1001.

(b) *If a person accused of violating subsection (a) of this section admits the violation, or the board finds the causes alleged to be true and determines that a letter of admonition or revocation or suspension of a license or registration is an inappropriate remedy, the board may assess an administrative penalty against that person of not more than two thousand dollars (\$2,000.00) for each violation of this act or rule promulgated under this act, to be paid into the county treasury to the credit of the public school fund of the county in which the violation occurred.* In addition to the penalty imposed under this subsection, the board may impose a license probation period upon that person, a violation of which is grounds for license revocation or suspension under subsection (a) of this section.

(c) The board may summarily suspend the license of any person holding a pharmacist license without a hearing if the board finds probable cause to believe that there is imminent danger to the public health or safety. The board may meet by telephone to consider summarily suspending a license if a quorum of the board is not available to meet in person under exigent circumstances. Summary suspension shall occur if the board determines there is probable cause to believe that continued practice by the licensee constitutes an imminent danger to the public health or safety. Proceedings for a disciplinary hearing shall be instituted simultaneously with the summary suspension. If the board does not commence the disciplinary hearing within thirty (30) days of the suspension order, the suspension shall be automatically vacated. At the written request of the suspended licensee in order to prepare for a hearing, the thirty (30) day period may be extended and the temporary suspension continued for an additional period not to exceed thirty (30) days.

(emphasis added).

3. Therefore, pursuant to the Act, the Board is the sole administrative agency tasked with deciding disciplinary matters against a pharmacy license or a pharmacist's license. Furthermore, the Board has implied or incidental powers that are reasonably necessary in order to carry out the powers expressly granted. *Voss v. Goodman*, 2009 WY 40, ¶ 11, 203 P.3d 415, 420 (Wyo. 2009)

4. Pursuant to Wyoming Statute § 16-3-107(n) of the Wyoming Administrative Procedure Act (WAPA) "informal disposition may be made of any contested case by stipulation, agreed settlement, consent order or default."

5. Pursuant to Chapter 1, Section 7(c)(iii), *Investigations and Board Action*, of the Board's administrative rules, the Board may accept an offer of conditional terms for settlement and may resolve a complaint, at any time, prior to a contested case hearing by accepting conditional terms for settlement.

6. City Drug holds resident retail pharmacy license, License No. R10215 in the State of Wyoming, which expires on June 30, 2025.

7. Dr. James holds a pharmacist license, License No. 4122 in the State of Wyoming, which expires on December 31, 2024.

8. Dr. James is owner and the designated pharmacist-in-charge for City Drug.

9. Pursuant to the foregoing, the Board has jurisdiction to decide this matter, jurisdiction and authority to settle this matter, and jurisdiction and authority to place conditions or restrictions on a pharmacy license or a pharmacist's license.

PROCEDURAL HISTORY

10. The Parties incorporate by reference the facts and allegations set forth in paragraphs 1 through 9 as if fully set forth herein.

11. On March 4, 2024, Board personnel had been contacted by a member of the public and informed that City Drug was listed as a pharmacy option to complete a prescription for compounded injectable semaglutide, a compounded sterile preparation. City Drug lacked the necessary equipment and facilities to conduct sterile compounding, which included compounding semaglutide. Board inspectors visited City Drug to confirm if semaglutide was being compounded at the pharmacy. Dr. James confirmed that City Drug was compounding injectable semaglutide and directed Board inspectors to her compounding pharmacist who confirmed that semaglutide was being compounded as immediate use with a forty eight (48) hour beyond use date (BUD).

12. Based on these admissions, on March 7, 2024, Board personnel filed an administrative complaint against City Drug alleging that it had been compounding injectable semaglutide in a non-sterile environment which violated Chapter 17 of the Board's rules and regulations.

13. Also, on March 7, 2024, Board personnel sent City Drug and Dr. James, as the owner and pharmacists-in-charge ("PIC"), a *Notice of Complaint*, which included a copy of the administrative complaint and allowing City Drug the opportunity to respond to the administrative complaint within twenty one (21) days.

14. Following the Board serving City Drug with its *Notice of Complaint*, Board personnel became concerned that City Drug would continue compounding semaglutide in a nonsterile environment and without the proper equipment, which could: (1) lead to higher or lower concentrations of the medication – which could have adverse impacts to the patients; or (2)

microbial contamination of the compounded semaglutide could result in the spread of fungal or bacterial infections.

15. Because Board personnel were concerned that City Drug's continued compounding presented an immediate threat to public safety during the pendency of the investigation and contested case, on March 12, 2024, Board personnel sent City Drug its *Notice of Intent to Seek Summary Suspension*, setting a special Board meeting on March 14, 2024 at 7:00 a.m. via teleconference.

16. On March 14, 2024, the Board held a special meeting regarding the Executive Director's recommendation for summary suspension of City Drug's pharmacy license for its practice of compounding semaglutide in a non-sterile environment and without the proper equipment. City Drug and Dr. James appeared at the special meeting with legal counsel, Chris Brennan.

17. Following a presentation of the administrative complaint, a summary of the investigation conducted, the questioning of Dr. James, and based on statements/representations by Dr. James, the Board voted not to summarily suspend City Drug's pharmacy license on the condition that all compounding at City Drug cease immediately.

18. On March 18, 2024, the Board entered an *Order Denying Summary Suspension of City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case Hearing*. While the order denied the summary suspension, it did contain a provision which required City Drug to cease all compounding immediately.

19. Neither City Drug nor Dr. James appealed the March 18, 2024, *Order Denying Summary Suspension of City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case Hearing*.

20. On March 18, 2024, City Drug and Dr. James, through legal counsel, Chris Brennan, petitioned the Board, through an email, to allow City Drug to resume compounding two (2) nonsterile preparations to fulfill City Drug's contractual obligation with a local hospice center.

21. On March 20, 2024, during the Board's regularly scheduled meeting, City Drug, through its legal counsel, petitioned the Board to amend the order allowing City Drug to resume all nonsterile compounding. However, the Board ordered that City Drug be allowed to resume nonsterile compounding for only the two (2) preparations outlined in City Drug's original request on March 18, 2024, pending a follow-up inspection and demonstration that City Drug was in compliance with the Board's nonsterile compounding requirements.

22. On March 21, 2024, City Drug was inspected. During the inspection, dirty compounding dishes were observed by inspectors in the sink.

23. Due to the presence of dirty compounding dishes discovered during the follow-up investigation, on March 29, 2024, the Board held a special meeting, at which, the Board heard the results of the inspection. During the meeting, Dr. James represented that the compounding dishes had been left in the sink since either March 12 or March 13, 2024, when they were served with the Board's *Notice of Intent to Seek Summary Suspension*. City Drug was again ordered to cease all compounding.

24. On May 3, 2024, the Board personnel sent to City Drug and Dr. James, as the owner and PIC, its original *Notice of Intent* to pursue discipline against City Drug for its practice of compounding semaglutide in a nonsterile environment and without proper procedures, safety measures, and equipment in violation of Chapter 17 of the Board's rules and regulations.

25. Following these events, on or about September 6, 2024, Board personnel were contacted by the PIC at South Street Pharmacy located in Wheatland, Wyoming. The PIC, Cindy

Geile (hereinafter “Dr. Geile”) reported a patient seeking to refill a prescription which South Street Pharmacy had no record of the prescription. Additionally, Dr. Geile stated that South Street Pharmacy did not have and does not purchase one of the active ingredients necessary to compound and fulfill this prescription. However, the patient insisted that the label on the prescription bottle contained South Street Pharmacy’s information, i.e., its name and phone number.

26. At the request of South Street personnel, the patient sent a photograph of the prescription bottle and label. The label contained a different logo than the one utilized by South Street Pharmacy, had the initials “KJ” as the pharmacist who filled the prescription, had a prescription number that was unique to and only utilized by City Drug, and utilized a different font than South Street Pharmacy utilizes but the same font as used by City Drug. Board personnel believed that the label had been forged or altered to appear as though the prescription came from South Street Pharmacy. Based on this, Board personnel contacted the patient directly.

27. According to the patient, she had been purchasing her medication from City Drug. The patient also stated that she was informed that City Drug was sending the medications to South Street Pharmacy so they could be compounded but were dispensed, sold, and mailed by City Drug.

28. During the pendency of the investigation and in response to the *Notice of Intent*, City Drug had produced a list of prescriptions which had been transferred to other pharmacies. Each of the prescriptions is identified by a specific number which is generated by and unique to City Drug. Contained on the list was the exact same prescription number which was on the forged label produced by the patient. Additionally, the records provided by City Drug alleged that the prescription had been transferred as of May 8, 2024. The forged label indicated that medication was filled on May 17, 2024. Coincidentally, on the records produced by City Drug, there is also

an entry made after the alleged date of the transfer which corresponds to the same date, May 17, 2024, the prescription was filled.

29. Based on this new information, Board personnel sent to City Drug and Dr. James its *Notice of Intent to Seek Summary Suspension* which provided the Petitioners notice of Board personnel's intent to seek summary suspension of City Drug's pharmacy license at a special meeting to be conducted on September 12, 2024, pursuant to Wyo. Stat. Ann. § 16-3-113(c) of the Wyoming Administrative Procedures Act.

30. Also on September 10, 2024, Board personnel sent an *Amended Notice of Intent* to City Drug and Dr. James, as owner and PIC, which included additional claims for disciplinary action against City Drug. Those additional claims were a result of the newly discovered evidence which showed that City Drug and Dr. James: (1) forged a prescription label for medication containing another pharmacy's name; (2) failed to transfer the prescription as stated; (3) compounded the medication at City Drug, and (4) sold and dispensed the medication, under a forged label, without the knowledge or consent of the other pharmacy.

31. Furthermore, on September 10, 2024, Board personnel sent a *Notice of Intent* to Dr. James, in her individual capacity as a practicing pharmacist, alleging that her conduct violated the following rules and regulations: Chapter 17, Section 3(a) and (e), *Pharmacy Staff Training and Evaluation*; Chapter 17, Section 4(c), *Personal Hygiene and Garbing*; Chapter 17, Section 5(a), *Facilities and Engineering Controls*; Chapter 17, Section 6(a), *Requirements for Certification and Recertification*; Chapter 17, Section 7(a), and 7(i)-iv), and 7(j), *Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas*; Chapter 17, Section 10(a-c), *Master Formulation Records, Compounding Records and Labeling*; Chapter 17, Section 11(a-b) and 11(d), *Quality Assurance and Quality control Programs*; Chapter 17, Section 12(a)(iv), 12(c), and

12(e-f), *Establishing Beyond Use Dates*; Chapter 17, Section 13(b), *Immediate Use CSPs*; Chapter 2, Section 7, *Personal Responsibility and Accountability*; Chapter 2, Section 4(d)(v), *Responsibilities of the Pharmacists-in-Charge (PIC)*; Chapter 2, Section 5(a)(iii), *Responsibilities of the Pharmacy License Holder*.

32. On September 12, 2024, the Board held its special meeting to decide whether summary suspension of City Drug's pharmacy license was appropriate based on the evidence that City Drug had forged a prescription label for medication it had allegedly transferred. Following the hearing, at which City Drug and Dr. James presented their own evidence and called two (2) witnesses, the Board found that the evidence showed that City Drug was continuing to compound and had dispensed a compounded prescription medication under a fraudulent label. Based on this, the Board found that public health, safety, and welfare imperatively required emergency action. Thus, the Board summarily suspended City Drug's pharmacy license pending the full contested case hearing.

33. On or about September 18, 2024, the Board issued its *Amended Order Summarily Suspending City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case* which, in pertinent part, ordered:

IT IS HEREBY ORDERED, based upon the foregoing Findings of Fact and Conclusion of law that City Drug immediately cease dispensing prescriptions. City Drug may continue to dispense prescriptions for hospice patients until September 26, 2024. City Drug has until September 26, 2024 to wrap up any prescriptions in their queue and until October 10, 2024 to wrap up any other outstanding business. The summary suspension shall continue until the filing of a formal *Petition* setting forth in detail the alleged violation of Wyoming Board of Pharmacy rules and the completion of a contested case hearing or other resolution of said action.

34. On or about September 18, 2024, City Drug and Dr. James filed their *Motion for Ex Parte Temporary Restraining Order and Preliminary Injunction* in the District Court, First

Judicial District, Laramie County, Wyoming, (Civil Action 2024-CV-020712) seeking a temporary restraining order and injunction against the Board's September 18, 2024, *Amended Order Summarily Suspending City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case.*

35. Additionally, on September 18, 2024, City Drug and Dr. James filed a *Petition for Review* in the District Court, First Judicial District, Laramie County, Wyoming, (Civil Action 2024-CV-020712) seeking to reverse the Board's *Amended Order Summarily Suspending City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case.*

36. On September 26, 2024, the Board held an emergency meeting whereat the Board ordered to stay its September 18, 20224, *Amended Order Summarily Suspending City Drug, Wyoming Board of Pharmacy License No. R10215, Pending a Contested Case*, for the sole purpose of presenting this Agreement to the Board for approval.

FACTUAL ALLEGATIONS FOR DISCIPLINARY ACTION

37. The Parties incorporate by reference the facts and allegations set forth in paragraphs 1 through 36 as if fully set forth herein.

38. According to the documents provided by City Drug, semaglutide was compounded and dispensed to One Hundred Sixty Seven (167) different patients. Furthermore, documents show that injectable semaglutide had been compounded at City Drug a total of Four Hundred Fourteen (414) times.¹

¹ On June 21, 2024, City Drug responded to the *Notice of Intent to Recommend Disciplinary Action*. Included in that response was its assertion that City Drug Pharmacy had filled 308 prescriptions for injectable semaglutide rather than 414 prescriptions and that 7 batches out of the 414 prescriptions, were cancelled, rather than compounded after March 7, 2024.

39. Dr. James and City Drug admitted to compounding semaglutide in a nonsterile environment, without the proper facilities, proper equipment, or training for sterile compounding.

40. Dr. James and City Drug admitted that City Drug never intended to conduct sterile compounding; therefore, it lacked the proper procedures and equipment.

41. Dr. James and City Drug admitted that City Drug never created or implemented a Quality Assurance and Quality Control program until after the complaint was filed against.

42. Dr. James and City Drug admitted that City Drug lacked any written training programs or sterile compounding competencies which include, but are not limited to, appropriate gowning, garbing, handwashing, cleaning, etc.

43. Following a special meeting, the Board found that evidence showed that City Drug was continuing to compound and had dispensed a prescription under a fraudulent label. Based on this, the Board found that public health, safety, and welfare imperatively required emergency action. Thus, the Board summarily suspended City Drug's pharmacy license pending the full contested case hearing.²

44. Based on the investigation and the information outlined herein, the Executive Director, Investigative Board Member, and Board Compliance Officer ("Committee") believe there is clear and convincing evidence that sterile compounding was occurring at City Drug which did not comply with Chapter 17 of the Board's rules. Specifically, City Drug failed to comply with the following: Chapter 13, Section 5(a)and(e), *Drug Compounding Facilities*; Chapter 17, Section 3(a)and(e), *Pharmacy Staff Training and Evaluation*; Chapter 17, Section 4(c), *Personal Hygiene and Garbing*; Chapter 17, Section 5(a-b), *Facilities and Engineering Controls*; Chapter 17, Section

² Dr. James and City Drug in the district court, through their Petition for Review, contest that there was substantial evidence that City Drug was continuing to compound and had issued a fraudulent label.

6(a), *Requirements for Certification and Recertification*; Chapter 17, Section 7(a), and 7(i)(i-iv), and 7(j), *Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas*; Chapter 17, Section 10(a-c), *Master Formulation Records, Compounding Records and Labeling*; Chapter 17, Section 11(a-b) and 11(d), *Quality Assurance and Quality control Programs*; Chapter 17, Section 12(a)(iv), 12(c), and 12(e-f), *Establishing Beyond Use Dates*; and Chapter 17, Section 13(b), *Immediate Use CSPs*.

45. The Committee believes there is clear and convincing evidence that City Drug and Dr. James failed to comply with rules, regulations, and Board orders.

46. The Committee believes there is clear and convincing evidence that Dr. James knowingly provided false or misleading information to Board Staff.

47. The Committee believes there is clear and convincing evidence that Dr. James willfully violated rules or regulations promulgated by the Board.

48. The Committee believes there is clear and convincing evidence that Dr. James should have known sterile compounding was occurring based on her education, that it was against Board rules, and did not take any action to report or otherwise stop the activity. Accordingly, Dr. James committed unprofessional conduct.

49. The Committee believes there is clear and convincing evidence that as Pharmacist-in-Charge, Dr. James failed to maintain records by trusting another pharmacist to maintain said compounding records which were “nonexistent.” According to Chapter 17, Section 10 (a)-(b) of the Board’s administrative rules, there shall be a master formulation record and a compounding record for all CSPs whenever a pharmacy steriley compounds. By entrusting a different pharmacist to maintain those records, Dr. James failed to direct the pharmacy’s operations, its staff, and maintain those records as required by Board rules.

50. The Committee believes there is clear and convincing evidence that City Drug did not operate in compliance of the Board's sterile compounding rules and regulations. Dr. James contributed to this violation by failing to ensure that City Drug operated in compliance with Board rules. Additionally, Dr. James contributed to violations by entrusting a different pharmacist to maintain the compounding records. Thus, Dr. James can be held individually liable as the Pharmacy License Holder. *Board of Pharmacy Rules*, Chapter 2, Section 7(c).

51. Based on the factual allegations set forth above, and incorporated herein by reference, the Committee alleges it can prove by clear and convincing evidence that Dr. James' conduct violated the Act. Specifically, Wyoming Statute § 33-24-122(vii) by failing to comply with Chapter 4, Section 2, *Code of Ethics*, which requires the following: (1) A pharmacist has the duty to observe the law, uphold the dignity and honor of the profession and to accept its ethical principles; (2) A pharmacist shall hold the health and safety of patients to be of first consideration; (3) A pharmacist shall not condone the dispensing, promoting or distributing of drugs or medical devices which do not meet standards required by law or which lack therapeutic value for the patient, (4) A pharmacist shall strive to improve and enlarge professional knowledge and shall utilize that knowledge in accordance with professional judgment; and (5) exhibiting behavior toward a patient, another licensee, or an employee of a pharmacy that exploits the position of trust, knowledge, emotions or influence of the licensee.

52. Based on the factual allegations set forth above, and incorporated herein by reference, the Committee alleges that it can prove by clear and convincing evidence that Dr. James allowed the compounding semaglutide at City Drug in a nonsterile environment with little or no equipment, the lack of proper equipment and garbing, the lack of any procedures or safety measures, the lack of appropriate trained and certified individuals, the lack of the required

documentation, the lack of quality control, lack of training, and the lack of a secure and sterile environment to perform the compounding which violated the Act. Furthermore, by creating a fictitious label, attempting to conceal compounding occurring at City Drug, and failing to transfer the prescription as required the Committee alleges it can prove by clear and convincing evidence that Dr. James' conduct violated the Act. Specifically: Wyoming Statute § 33-24-122(a)(iii) for unprofessional conduct; Wyoming Statute § 33-24-122(a)(v) for knowingly submitting false or misleading to the Board; and Wyoming Statute § 33-24-122(a)(vii) by failing to comply with the following rules: Chapter 17, Section 3(a)and(e), *Pharmacy Staff Training and Evaluation*; Chapter 17, Section 4(c), *Personal Hygiene and Garbing*; Chapter 17, Section 5(a), *Facilities and Engineering Controls*; Chapter 17, Section 6(a), *Requirements for Certification and Recertification*; Chapter 17, Section 7(a), and 7(i)(i-iv), and 7(j), *Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas*; Chapter 17, Section 10(a-c), *Master Formulation Records, Compounding Records and Labeling*; Chapter 17, Section 11(a-b) and 11(d), *Quality Assurance and Quality control Programs*; Chapter 17, Section 12(a)(iv), 12(c), and 12(e-f), *Establishing Beyond Use Dates*; Chapter 17, Section 13(b), *Immediate Use CSPs*; Chapter 2, Section 7, *Personal Responsibility and Accountability*; Chapter 2, Section 7, *Personal Responsibility and Accountability*; Chapter 2, Section 4(d)(v), *Responsibilities of the Pharmacists-in-Charge (PIC)*, which requires a pharmacist-in-charge to maintain all pharmacy records required by state and federal law in a readily retrievable format; Chapter 2, Section 5(a)(iii), *Responsibilities of the Pharmacy License Holder*, which requires the pharmacy license holder to ensure the pharmacy operates in compliance with all state and federal laws, rules and regulations.

53. Based on the factual allegations set forth above, and incorporated herein by reference, the Committee alleges that it can prove by clear and convincing evidence that City Drug engaged in the practice of compounding semaglutide in a nonsterile environment with little or no equipment, the lack of proper equipment and garbing, the lack of any procedures or safety measures, the lack of appropriate trained and certified individuals, the lack of the required documentation, the lack of quality control, lack of training, and the lack of a secure and sterile environment to perform the compounding which violated the Act. Furthermore, by creating a fictitious label, attempting to conceal compounding occurring at City Drug, and failing to transfer the prescription as required the Committee alleges it can prove by clear and convincing evidence that City Drug's conduct violated the Act. Specifically, Wyoming Statute § 33-24-113(d)(ii) for failing to comply with the Board's rules and Wyoming Statute § 33-24-113(d)(iv) for obtaining any remuneration by fraud, misrepresentation or deception. Additionally, the Committee alleges the conduct occurring at City Drug violated the following rules: Chapter 13, Section 5(a)and(e), *Drug Compounding Facilities*; Chapter 17, Section 3(a)and(e), *Pharmacy Staff Training and Evaluation*; Chapter 17, Section 4(c), *Personal Hygiene and Garbing*; Chapter 17, Section 5(a-b), *Facilities and Engineering Controls*; Chapter 17, Section 6(a), *Requirements for Certification and Recertification*; Chapter 17, Section 7(a), and 7(i)(i-iv), and 7(j), *Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas*; Chapter 17, Section 10(a-c), *Master Formulation Records, Compounding Records and Labeling*; Chapter 17, Section 11(a-b) and 11(d), *Quality Assurance and Quality control Programs*; Chapter 17, Section 12(a)(iv), 12(c), and 12(e-f), *Establishing Beyond Use Dates*; and Chapter 17, Section 13(b), *Immediate Use CSPs*.

GROUNDS FOR DISCIPLINARY ACTION

54. The Parties incorporate by reference the facts and allegations set forth in paragraphs 1 through 53 as if fully set forth herein.

55. The Parties have hereby agreed and stipulated to the fact that sufficient evidence exists to demonstrate, by clear and convincing evidence, that Dr. James and City Drug have violated the Act. Therefore, disciplinary action is warranted and within the Boards jurisdiction.

56. Dr. James and City Drug represent they read this Agreement in its entirety, have had an opportunity to consult with their respective legal counsel, fully understand the contents and requirements herein, and agree to abide by the *Order* set forth herein *in lieu* of a contested case hearing.

57. Dr. James and City Drug represent that by executing this Agreement, they waive any right to any applicable administrative contested case hearing or appeals in this matter pursuant to the Wyoming Administrative Procedures Act, Wyoming Statute §§ 16-3-107 through 115, the Act, the Board's rules, or any other applicable law or constitutional right. Dr. James and City Drug represent that they shall seek dismissal with prejudice, within five days, following entry of this *Order*, in the following matters: (1) *Motion for Ex Parte Temporary Restraining Order and Preliminary Injunction* in the District Court, First Judicial District, Laramie County, Wyoming, (Civil Action 2024-CV-020712); and (2) *Petition for Review* in the District Court, First Judicial District, Laramie County, Wyoming, (Civil Action 2024-CV-020712).

58. Dr. James and City Drug represent that due and proper notice of this matter have been afforded to them, they agree they have not been subjected to undue influence, pressure, or coercion by the Petitioner, the Board, its staff, or the Office of the Attorney General, and they are

entering into this Agreement under their own free will after having the opportunity to obtain advice from legal counsel regarding the consequences of entering into this Agreement.

59. Dr. James and City Drug represent that they do not contest the Board's jurisdiction and authority to enter this Order or any of the provisions herein.

60. Dr. James and City Drug understand this Agreement shall be submitted to the Board, which may either approve or reject the Agreement. Should the Board reject the Agreement, the Parties shall have an opportunity to request a contested case hearing in accordance with the Wyoming Administrative Procedures Act, the Act, and the Board's rules. If the Board does not approve this Agreement and a contested case hearing takes place as a consequence, Dr. James and City Drug further represent and agree they do not object to the Board's hearing the case on the basis the Board has become disqualified due to its review and consideration of this Agreement and its contents.

61. Dr. James and City Drug understand this Agreement is a disciplinary action and shall become a permanent part of their record with the Board, and that certain conditions will be placed on City Drugs' pharmacy license, and that these actions against her pharmacist license and City Drug's license shall be subject to publication on the Board's website.

62. Dr. James and City Drug understand this Agreement constitutes a public record within the meaning of the Wyoming Public Records Act [Wyoming Statute §§ 16-4-201 through -205], and, upon proper request, shall be subject to disclosure, inspection, and dissemination in accordance with or except as otherwise provided by applicable federal and state laws.

63. Dr. James and City Drug understand this Agreement shall be reported in accordance with applicable federal and state law.

CONCLUSIONS OF LAW

64. The Board hereby incorporates by reference the facts and allegations set forth in paragraphs 1 through 64 as if fully set forth herein.

65. The Board is the sole, exclusive, and duly-authorized licensing, regulatory, and administrative agency in the State of Wyoming regarding the practice of pharmacy as authorized by the Act, Wyoming Statute §§ 33-24-101 through 301.

66. Pursuant to Wyo. Stat. Ann. § 33-24-113(d), the Board has been given the following authority over a pharmacy license:

(d) The board may deny, suspend, revoke or refuse to renew a license issued under this section, may issue a letter of admonition to a resident pharmacy licensee and may assess an administrative penalty, not to exceed two thousand dollars (\$2,000.00) per violation, against a resident pharmacy licensee on any of the following grounds:

(i) Failure to comply with any requirement of this chapter or the Wyoming Controlled Substances Act;

(ii) Failure to comply with rules and regulations of the board;

(iii) Conviction of a pharmacy owner, pharmacist in charge, staff pharmacist or pharmacy technician for a felony under any state or federal law, if the conviction is related to the practice of pharmacy;

(iv) Obtaining any remuneration by fraud, misrepresentation or deception;

(v) Suspension or revocation of a pharmacy license or any other disciplinary action against the licensee by a board of pharmacy in any other state;

(vi) Knowing submission of false, misleading or fraudulent information to the board in connection with an initial or renewal application for a resident pharmacy license;

- (vii) Purchase or receipt of a prescription drug, controlled substance or medical device from a source other than a manufacturer, wholesaler or pharmacy licensed by the board;
- (viii) Purchase or receipt of a prescription drug, controlled substance or medical device that is not approved by the federal food and drug administration;
- (ix) Keeping the pharmacy open for business without a licensed pharmacist in charge on site;
- (x) Allowing a person who is not licensed by the board to perform duties as a pharmacist, pharmacy technician or pharmacy technician in training.

(emphasis added)

67. Pursuant to Wyo. Stat. Ann. § 33-24-122, the Board has been given the following authority by the Wyoming State Legislature over a pharmacist's license:

- (a) *The license and registration of any pharmacist may be revoked or suspended by the board of pharmacy or the board may issue a letter of admonition, refuse to issue or renew any license or require successful completion of a rehabilitation program or issue a summary suspension for any one (1) or more of the following causes:*
 - (i) Conviction of a felony or high misdemeanor that relates to the practice of pharmacy or to the ability to practice pharmacy, in which case the record of conviction or a copy thereof certified by the clerk or judge of the court in which the conviction is had shall be conclusive evidence;
 - (ii) For renting or loaning to any person his or her license or diploma to be used as a license or diploma for such person;
 - (iii) *For unprofessional conduct;*
 - (iv) For knowingly submitting false or misleading information to the board in the application for a license or renewal of a license;
 - (v) *For knowingly submitting false or misleading information to the board or its representative regarding the*

professional practice of the internship or professional practice of pharmacy by any other person;

(vi) Willful violation of any provision of this chapter or any willful violation of any of the provisions of the Wyoming Controlled Substances Act of 1971 or any amendments thereto;

(vii) *Willful violation of any rules or regulations promulgated by the board in accordance with this chapter* or the Wyoming Controlled Substances Act of 1971;

(viii) If the person's registration or license to practice has been refused, lapsed for cause, expired for cause, revoked for cause, or suspended for cause in this or any other jurisdiction or if the person has otherwise been disciplined by a board of pharmacy in this or any other jurisdiction;

(ix) For senility or mental impairment which impedes the pharmacist's professional abilities or for habitual personal use of morphine, cocaine or other habit forming drugs or alcohol;

(x) For physical impairment which unnecessarily impedes the pharmacist's professional abilities and for which there can be no reasonable accommodation.

(xi) For violating W.S. 35-4-1001.

(emphasis added).

68. The Wyoming Supreme Court has held that administrative agencies have implied powers necessary for carrying out there statutory purposes:

[A]dministrative agencies have certain implied powers necessary to fulfillment of their statutory purposes. Of course, those implied powers are only those derived by necessary implication from express statutory authority granted to the agency. A more comprehensive statement of the concept of implied powers in this setting is this:

Generally administrative agencies have the implied or incidental powers that are reasonably necessary in order to carry out the powers expressly granted. The reason for implied powers is that, as a practical matter, the legislature cannot foresee all the problems

incidental to carrying out the duties and responsibilities of the agency. However, the inherent or implied power of an administrative agency is not boundless.

Voss v. Goodman, 2009 WY 40, ¶ 11, 203 P.3d 415, 420 (Wyo. 2009) (quoting, *BP Am. Prod. Co. v. Dep't of Revenue*, 2006 WY 27, ¶ 28, 130 P.3d 438, 466-67 (Wyo. 2006)). Therefore, the Board has implied authority to condition a license held by a licensee.

CONCLUSIONS

69. The Board hereby incorporates by reference the facts and allegations set forth in paragraphs 1 through 69 as if fully set forth herein.

70. City Drug holds a pharmacy license, License No. R10215 in the State of Wyoming, which expires on June 30, 2025.

71. Dr. James holds pharmacist's license, License No. 4122 in the State of Wyoming, which expires on December 31, 2024.

72. Dr. James is the pharmacist-in-charge at City Drug.

73. The Board has jurisdiction in this matter over Dr. James, City Drug, and their respective licenses.

74. The Board concludes that Dr. James' conduct, as set forth herein, if established by clear and convincing evidence at a contested case hearing, constitutes violations of the Act and the Board's rules as set forth above.

75. The Board concludes that City Drug's conduct, as set forth herein, if established by clear and convincing evidence at a contested case hearing, constitutes violations of the Act and the Board's rules as set forth above.

76. The Board concludes the violations of the statutory and rule provisions identified herein, are grounds for disciplining Dr. James and City Drug. Based on Petitioner's

recommendation, and pursuant to the Agreement entered into by the Parties, the Board concludes the following:

- (1) Dr. James agrees to a revocation of her pharmacist's license for a period of three (3) years, after which Dr. James may apply for reinstatement of her revoked license, subject to the Board's rules and review process under the said rules;
- (2) Dr. James agrees to a Ten Thousand Dollar (\$10,000.00) fine;
- (3) Dr. James shall complete (1) the CPEP's Probe: Ethics & Boundaries Program; and (2) CriticalPoint: Best Practices for Sterile and Hazardous Drugs Compounding - Virtual Training; Dr. James shall be solely financially responsible for payment of said courses.
- (4) City Drug will release a proper recall notice, approved by the Board, and issued in accordance with the Board's rules;
- (5) City Drug agrees to a three (3) year suspension of its pharmacy license, but that suspension will be stayed for three (3) years upon compliance with the following conditions:
 - (a) City Drug will name a new pharmacist-in-charge other than Dr. James. Dr. James may not be the PIC unless approved by the Board and only after once again obtaining her pharmacist's license.
 - (b) City Drug shall be required to pay for and complete an annual Verified Pharmacy Program inspection through the National Association of Boards of Pharmacy for a period of

three (3) years with the first inspection to be schedule before the pharmacy license renewal term. City Drug shall provide the VPP inspection reports to the Board, and any deficiencies identified in the inspections shall be corrected/rectified within ninety (90) days. City Drug shall further provide the Board with certification that any deficiencies have been corrected. If City Drug or Dr. James fail to comply with these provisions then the stay on the suspension against City Drug's pharmacy license shall be lifted and the pharmacy license immediately suspended.

- (c) City Drug will not be allowed to compound any medication, either sterile or nonsterile during the three (3) year stayed suspension period. However, after one (1) year, City Drug may petition the Board for permission to resume nonsterile compounding, which will require Board approval and be subject to all pharmacists completing their compounding competencies.
- (d) City Drug shall be required to be disclose the conditions on its pharmacy license to any purchaser of City Drug with said purchaser agreeing in writing to continue to abide by the conditions on City Drug's pharmacy license.
- (e) City Drug shall pay the amount of Thirty Eight Thousand Three Hundred Eighty Six (\$38,386.00) Dollars which

represents the net profit obtained by City Drug in dispensing semaglutide as disgorgement damages.

- (f) City Drug shall pay a Ten Thousand Dollar (\$10,000.00) fine.
- (g) City Drug will provide monthly reports to Board personnel for all items dispensed at City Drug for a period of three (3) years.

(6) Dr. James will cause City Drug to be sold to a third-party within six (6) months. In the event Dr. James is unable to cause the sale of City Drug within the six (6) month period, the stay upon the three (3) year suspension against City Drug will be lifted and the suspension will go into immediate effect. Prior to the expiration of the six (6) month deadline to sale, Dr. James and City Drug may petition the Board for additional time, upon a showing of good cause.

(7) The Board will hold a special meeting pursuant to notice requirements, as soon as reasonably possible, in order to approve or deny this Agreement. Upon approval of this Agreement the summary suspension shall be lifted thereby allowing City Drug to operate under the Board's March 18, 2024, Order with a new PIC and until City Drug is sold to a third-party.

(8) All fines and monetary penalties set forth herein shall be payable within ninety (90) days.

ORDER FOR DISCIPLINARY ACTION

IT IS THEREFORE HEREBY STIPULATED AND ORDERED AS FOLLOWS:

1. **Board Approval of Agreement.** The Board approves this Agreement, and hereby incorporates the proceeding paragraphs herein, which constitutes disciplinary action for the conduct set forth in this Agreement.
2. Dr. James pharmacist's license, License No. 4122, is hereby **REVOKE**D for a period of three (3) years, after which Dr. James may apply for reinstatement of her revoked license, subject to the Board's rules and review process under the said rules
3. Dr. James shall pay, individually, a Ten Thousand Dollar (\$10,000.00) fine;
4. Dr. James shall complete: (1) the CPEP's Probe: Ethics & Boundaries Program; and (2) CriticalPoint: Best Practices for Sterile and Hazardous Drugs Compounding - Virtual Training. Dr. James shall be solely financially responsible for payment of said courses.
5. City Drug will release a proper recall notice, approved by the Board, and be issued in accordance with the Board's rules;
6. City Drug agrees to a three (3) year suspension of its pharmacy license, but that suspension will be stayed for three (3) years upon compliance with the following conditions: (a) City Drug will name a new pharmacist-in-charge other than Dr. James. Dr. James may not be the PIC unless approved by the Board and only after once again obtaining her pharmacist's license; (b) City Drug shall be required to pay for and complete an annual Verified Pharmacy Program inspection through the National Association of Boards of Pharmacy for a period of three (3) years with the first inspection to be schedule before the pharmacy license renewal term; (c) City Drug shall provide the VPP inspection reports to the Board, and any deficiencies identified in the inspections shall be corrected/rectified within ninety (90) days; (d) City Drug shall further provide

the Board with certification that any deficiencies have been corrected; (e) If City Drug, Dr. James, or a subsequent purchaser fail to comply with these provisions then the stay on the suspension against City Drug's pharmacy license shall be lifted and the pharmacy license immediately suspended; (f) City Drug will not be allowed to compound any medication, either sterile or nonsterile during the three (3) year stayed suspension period; (g) After a one (1) year period, City Drug may petition the Board for permission to resume nonsterile compounding, which will require Board approval and be subject to all pharmacists completing their compounding competencies.

7. City Drug shall be required to be disclose the conditions on its pharmacy license to any purchaser of City Drug with said purchaser agreeing in writing to the conditions on City Drug's pharmacy license.

8. City Drug shall pay the amount of Thirty Eight Thousand Three Hundred Eighty Six (\$38,386.00) Dollars which represents the net profit obtained by City Drug in dispensing semaglutide as disgorgement damages.

9. City Drug shall pay a Ten Thousand Dollar (\$10,000.00) fine.

10. City Drug will provide monthly reports to Board personnel for all items dispensed at City Drug for a period of three (3) years.

11. Dr. James will cause City Drug to be sold to a third-party within six (6) months. In the event Dr. James is unable to cause the sale of City Drug within the six (6) month period, the stay upon the three (3) year suspension against City Drug will be lifted and the suspension will go into immediate effect. Prior to the expiration of the six (6) month deadline to sale, Dr. James and City Drug may petition the Board for additional time, upon a showing of good cause.

12. The Board will hold a special meeting pursuant to notice requirements, as soon as reasonably possible, in order to approve or deny this Agreement. Upon approval of this Agreement

the summary suspension shall be lifted thereby allowing City Drug to operate under the Board's March 18, 2024, Order with a new PIC and until City Drug is sold to a third-party.

13. All fines and monetary penalties set forth herein shall be payable within ninety (90) days.

14. **Further Cooperation.** Dr. James and City Drug shall fully cooperate with any further investigation by the Board or Petitioner.

15. **Discipline for Violation.** A significant violation of the terms of this Agreement shall constitute independent grounds for Petitioner to seek further disciplinary action. No action or inaction occurring before the entry of this Order shall be a basis for finding a violation of this Agreement or Order.

16. **Publication of Discipline.** This Agreement shall be subject to publication on the Board's website.

17. **Reporting by Board of Discipline.** This Agreement constitutes authorized disciplinary action of the Board and, as such, shall be reported in accordance with applicable federal and state law.

18. **Public Record of the Board.** This Agreement, as well as the information that is part of Docket No. 2024-06 and Docket No. 2024-08, constitutes public records within the meaning of the Wyoming Public Records Act [Wyoming Statute §§ 16-4-201 through 205], and, upon proper request, shall be available for inspection and dissemination in accordance with applicable federal and state law.

19. **Continuing Jurisdiction.** The Board shall retain continuing jurisdiction in this matter to take further action as may be necessary to conclude this matter or other actions permitted by law.

20. **Waiver of Contested Case Hearing.** Dr. James and City Drug's execution of this Agreement includes their full waiver of any contested case hearing or appeal to which they may be entitled to pursuant to the WAPA, the Act, the Board's rules, or any other applicable law or constitutional right.

21. **Effective Date.** This Agreement shall become effective upon full and complete execution by all signatories below. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts. Each counterpart when so executed shall be deemed to be an original and all of which together shall constitute one and the same agreement. Signatures, originally signed by hand, but transmitted via e-mail or fax, shall also be deemed valid and binding original signatures.

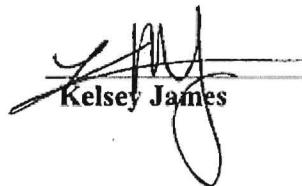
22. **Enforcement.** This Agreement shall be enforceable in the Laramie County District Court in and for the State of Wyoming according to the laws of the State of Wyoming.

23. **Entire Agreement.** This Agreement constitutes the full and entire understanding between the Parties and the Board. Dr. James and City Drug's execution of this Agreement includes their representation and acknowledgement have read and understand the terms and conditions of this Agreement, has been given an opportunity to consult and/or has consulted with counsel of their choice, and accordingly voluntarily enter into this Agreement of their own choosing and shall be bound by the terms and conditions thereof, until the Board issues any order to the contrary. Dr. James and City Drug have been given no additional inducement to enter into and execute this Agreement. Should any portion of this Agreement be judicially determined to be void, illegal or unenforceable, the remainder of the Agreement shall continue in full force and effect, and either party may renegotiate the terms affected by the severance.

[SIGNATURES APPEAR ON FOLLOWING PAGE]

AGREED TO AND ACCEPTED BY KELSEY JAMES AND CITY DRUG, LLC:

I, Kelsey James, individually, as pharmacists-in-charge for City Drug and as owner of City Drug, swear I have read the foregoing Agreement and agree to its terms and conditions as provided above on behalf of myself and City Drug.



Kelsey James

10-2-24

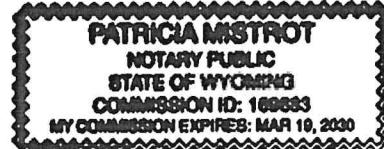
Date

STATE OF Wyoming)
COUNTY OF LARAMIE) SS

The foregoing document was subscribed and sworn to before me by Kelsey James, personally known to me or having established their identity by means of sufficient documentation, purporting to be the person signing the document, and the signature on the foregoing document was made in my presence, on the 2nd day of October, 2024.

My Commission Expires: 3/19/2030


Notary Public



APPROVED AS TO FORM:



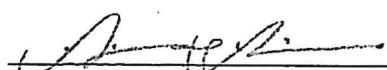
Thomas Rumpke
Attorney for City Drug, LLC and Kelsey
James, RPh.

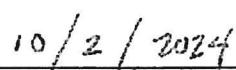
10-2-2024

Date

[ADDITIONAL SIGNATURES ON FOLLOWING PAGE]

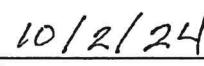
AGREED TO AND ACCEPTED BY PETITIONER, EXECUTIVE DIRECTOR:


Matthew R. Martineau


Date 10/2/2024

APPROVED AS TO FORM:


Brian J. Marvel
Senior Assistant Attorney General
Prosecuting Attorney for Petitioner


Date 10/2/24

APPROVED BY AND FOR THE WYOMING STATE BOARD OF PHARMACY


L. Williamson
President or President's Designee


Date 10-2-24