

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Pharmacy License and CSA Registration of</p> <p>WALGREENS 05721 License No. 355 Registration No. 1106816 Respondent</p>	<p>CASE NOS. 2020-0178 & 2021-0236</p> <p>SETTLEMENT AGREEMENT AND FINAL ORDER</p>
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Pursuant to Iowa Code sections 17A.12(5) and 272C.3(4), and 657 Iowa Administrative Code (IAC) 35.24, the Iowa Board of Pharmacy (“Board”) and Walgreens 05721 (“Respondent”) enter into the following Settlement Agreement and Final Order (“Order”) to settle two contested cases currently pending before the Board.

The allegations contained in the Notices of Hearing and Statements of Charges shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. The Board issued a Notice of Hearing and Statement of Charges in case number 2020-0178 on May 3, 2022.
2. The Board issued a Notice of Hearing and Statement of Charges in case number 2021-0236 on May 3, 2022.
3. The Board has jurisdiction over Respondent and the subject matter of these proceedings.
4. The Factual Circumstances contained in the two Notices of Hearing and Statements of Charges are hereby incorporated into this Order. Respondent denies the allegations contained in both sets of Factual Circumstances and denies the allegations contained in both Statements of Charges, however, for purposes of settlement, Respondent acknowledges that the allegations contained in the Factual Circumstances in the two Notices of Hearing and Statements of Charges, if proven in a contested case proceeding, may constitute grounds for the discipline agreed to in this Order. Respondent further acknowledges that the Factual Circumstances, by virtue of their incorporation into this Order, are now public and are available for inspection and copying in accordance with Iowa Code chapters 22 and 272C.
5. Execution of this Order constitutes the resolution of the two identified contested cases. Respondent has a right to a hearing before the Board on the charges, but Respondent waives the right to a hearing and all attendant rights, including the right to appeal or seek judicial review of the Board’s actions, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.
6. Respondent acknowledges that it has the right to be represented by counsel on this

matter.

7. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

8. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

9. This Order constitutes disciplinary action. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

10. This Order shall not be binding as to any new complaints received by the Board.

11. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

12. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

13. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

14. Respondent's pharmacy license and CSA registration are hereby placed on **PROBATION** for a period of two (2) years, subject to the following terms:

- a. Within ten (10) days of this Order, Respondent must share this Order with all permanent employees of the pharmacy. For the duration of the probationary period, any newly hired permanent pharmacy employees must be given a copy of this Order prior to working in the pharmacy.
- b. Respondent shall be assessed a civil penalty in the amount of twenty two thousand dollars (\$22,000), with payment of ten thousand dollars (\$10,000) stayed as set forth in this Order. Respondent shall submit payment in the amount of twelve thousand dollars (\$12,000) within thirty (30) days of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.
- c. Within sixty (60) days of this Order, all permanent pharmacists and technicians must complete two (2) hours of additional education on

inventory management. During the period of probation, any new permanent pharmacists and technicians working at the pharmacy after sixty (60) days, must also have completed two (2) hours of additional education on inventory management. Respondent must maintain documentation verifying compliance with this requirement.

- d. Respondent commits to implementing its new inventory management system by September 30, 2022. If the new inventory management system is not operational by October 1, 2022, Respondent must submit one thousand five hundred dollars (\$1,500) of the stayed civil penalty for each month that implementation is delayed by the end of the month. To illustrate, if the inventory management system is not operational by October 1, 2022, Respondent must submit a civil penalty of \$1,500 by October 31, 2022; if the inventory management system is still not operational by November 1, 2022, Respondent must submit an additional civil penalty of \$1,500 by November 30, 2022; if the inventory management system is still not operational by December 1, 2022, Respondent must submit an additional civil penalty of \$1,500 by December 31, 2022; and if the inventory management system is still not operational by January 1, 2023, Respondent must submit an additional civil penalty of \$1,500 by January 31, 2023. Respondent agrees to provide training to pharmacy employees to ensure they understand how to use the inventory management system. Prior to transitioning to the new inventory management system, Respondent must perform a complete physical inventory of all controlled substances and must utilize these counts for the starting inventory in the new system.
- e. During the probationary period, any required inventories or counts must be exact counts (no estimates).
- f. During the period of probation, Respondent agrees to immediately provide the expected quantity of specified controlled substances listed in the inventory management system and the actual on-hand quantity after a physical count to a Board compliance officer upon request. If there is a discrepancy between the expected quantity and the actual quantity of any controlled substance in Schedules III-V, Respondent has three (3) business days from the date the count was requested to reconcile the discrepancy and report back to the Board compliance officer. Respondent shall be assessed one thousand dollars (\$1,000) of the stayed civil penalty each time there is a discrepancy between the expected quantity and actual quantity of any controlled substance in Schedule II and each time there is an irreconcilable discrepancy between the expected quantity and the actual quantity of any controlled substance in Schedules III-V when

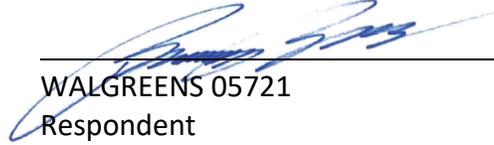
discovered by a Board compliance officer or upon a count done at the request of a Board compliance officer.

- g. During the period of probation, Respondent shall reconcile its inventory management system inventory counts with the on-hand physical inventory count for all controlled substances on a quarterly basis (on or before November 30, February 28, May 31, and August 31 of each year) and document the reconciliation. This may be achieved through a documented audit and reconciliation of all controlled substances once every three months, or by routine documented cycle counts, so long as all controlled substances are counted every 90 days. Respondent must submit the written reconciliation to the Board on or before the identified dates above. Any discrepancies must be investigated and documented. The results of any investigations must be submitted to the Board upon completion of the investigation of the discrepancy, which in no case shall exceed thirty (30) days from the date of the on-hand physical inventory count.
- h. Respondent understands when patient counseling is required and agrees to provide patient counseling when required.
- i. Respondent shall appear before the Board upon request for purposes of evaluating performance of the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- j. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- k. Any documentation required to be submitted to the Board pursuant to this Order should be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.
- l. The probation period may be extended if Respondent is not compliant with the terms of probation. Respondent may request early release from probation after one year. The Board retains the sole discretion to approve or deny any such request for early release, but shall consider Respondent's compliance with the probationary terms when making a decision.

15. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 124, 155A, and 272C and 657 IAC chapters 10 and 36.

By the signature below, signatory acknowledges they are authorized to sign this Settlement Agreement and Final Order on behalf of Respondent.

8/09/2022
Date


WALGREENS 05721
Respondent

This Settlement Agreement and Final Order is approved by the Iowa Board of Pharmacy on
August 24, 2022.


Chairperson
Iowa Board of Pharmacy

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Pharmacy License and CSA Registration of</p> <p>WALGREENS 05721 License No. 355 Registration No. 1106816 Respondent</p>	<p>CASE NO. 2021-0236</p> <p>NOTICE OF HEARING AND STATEMENT OF CHARGES</p>
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COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Walgreens 05721 (“Respondent”), 3140 SE 14th St, Des Moines IA 50320, pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and 272C.3(1)(e), and 657 Iowa Administrative Code (IAC) 35.6 and 35.7.

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A disciplinary contested case hearing shall be held on June 28, 2022, before the Board. The hearing shall begin at 9:00 a.m. and will be held in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines, IA 50309. You may choose to attend the hearing in-person at the Board office or may attend electronically through the Zoom platform. Contact the Board office to obtain participation instructions if you wish to attend electronically.

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

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

Presiding Officer. The Board shall serve as presiding officer at the contested case hearing, but the Board hereby delegates to an Administrative Law Judge from the Department of Inspections and Appeals the authority to make initial rulings on prehearing matters and requests the administrative law judge be present to assist and advise the Board at the contested case hearing.

Hearing Procedures. The procedural rules governing the conduct of the contested case hearing, including prehearing matters, are found at 657 IAC chapter 35. At the hearing, you may appear personally or be represented by counsel at your own expense. You will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf on issues

of material fact, cross-examine witnesses present at the hearing, and examine and respond to any documents introduced at the hearing. The hearing may be open to the public or closed to the public at your discretion, pursuant to Iowa Code section 272C.6(1) and 657 IAC 35.25(10).

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

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

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

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 124, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you pursuant to Iowa Code sections 155A.15(2) and 272C.3, and 657 IAC 8.3, 10.44, and 36.

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

C. STATEMENT OF CHARGES

COUNT I

Respondent is charged under 657 IAC 36.6(21) with violating a board rule, specifically 657 IAC 10.18, which makes the registrant responsible for ensuring that the perpetual inventory record for schedule II controlled substances is accurate and matches the actual on-hand inventory at all times.

COUNT II

Respondent is charged under 657 IAC 36.6(21) with violating a board rule, specifically 657 IAC 6.14(1), which requires patient counseling for a new prescription.

D. FACTUAL CIRCUMSTANCES

1. Respondent's pharmacy license number 355 is currently active through December 31, 2022.
2. Respondent's CSA registration number 1106816 is currently active through May 31, 2024.
3. The Board received a complaint alleging that patient counseling was not provided on a new prescription for prednisone.
4. Respondent's security video recordings confirmed that counseling was not provided.
5. Respondent underwent an inspection in September 2021.
6. During the inspection, the on-hand count of hydrocodone/APAP 5-325 mg was short by 247 tablets.
7. A Board compliance officer then requested a full audit of all schedule II controlled substances.
8. The audit was conducted from January 1, 2021, through January 22, 2022. This audit identified a shortage of 44 tablets of oxycodone 20 mg IR and a shortage of 60 capsules of dexamethylphenidate ER 20 mg. The counts for two hydrocodone products resulted in overages.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On May 3, 2022, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

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

BEFORE THE IOWA BOARD OF PHARMACY

RE:

WALGREEN COMPANY, as owner of each Pharmacy License and CSA Registration listed below, and

WALGREENS 07967

License #1257
Registration #1107775, and

WALGREENS 05060

License #1086
Registration #1107613, and

WALGREENS 07454

License #197
Registration #1107331, and

WALGREENS 05721

License #355
Registration #1106816, and

WALGREENS 359

License #778
Registration #1106780, and

WALGREENS 07455

License #1210
Registration #1107732, and

WALGREENS 04714

License #459
Registration #1106755

Respondents.

CASE NOS: 2020-0175, 2020-0176, 2020-0177, 2020-0178, 2020-0179, 2020-0180 & 2020-0181

**NOTICE OF HEARING AND
STATEMENT OF CHARGES**

COMES NOW the Iowa Board of Pharmacy (“Board”) and files this Notice of Hearing and Statement of Charges against Walgreen Company, as owner of the pharmacy licenses and Controlled Substances Act (CSA) registrations captioned above, and each pharmacy identified above (collectively “Respondents”), pursuant to Iowa Code sections 17A.12(2), 17A.18(3), and

272C.3(1)(e), and 657 Iowa Administrative Code (IAC) 35.6 and 35.7. The above-referenced contested case proceedings (2020-0175, 2020-0176, 2020-0177, 2020-0178, 2020-0179, 2020-0180 & 2020-0181) have been consolidated pursuant to 657 IAC 35.14(1).

A. TIME, PLACE, AND NATURE OF HEARING

Hearing. A consolidated disciplinary contested case hearing shall be held on June 28, 2022, before the Board. The hearing shall begin at 9:00 a.m. and will be held in the Board conference room located at the Iowa Board of Pharmacy Office, 400 SW 8th St, Ste E, Des Moines, IA 50309. You may choose to attend the hearing in-person at the Board office or may attend electronically through the Zoom platform. Contact the Board office to obtain participation instructions if you wish to attend electronically.

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

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

Presiding Officer. The Board shall serve as presiding officer at the contested case hearing, but the Board hereby delegates to an Administrative Law Judge from the Department of Inspections and Appeals the authority to make initial rulings on prehearing matters and requests the administrative law judge be present to assist and advise the Board at the contested case hearing.

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

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

Laura Steffensmeier
Assistant Attorney General
Hoover State Office Building—2nd Floor

1305 E Walnut St
Des Moines IA 50319

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

B. LEGAL AUTHORITY AND JURISDICTION

Jurisdiction. The Board has jurisdiction in this matter pursuant to Iowa Code chapters 17A, 124, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you pursuant to Iowa Code sections 124.304, 155A.15(2), and 272C.3, and 657 IAC 8.3, 10.44, and 36.

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

C. STATEMENT OF CHARGES

COUNT I

Respondents are charged under 657 IAC 10.44(5) and 36.6(21) with violating a board rule, specifically 657 IAC 10.14, which states that the registrant shall maintain ultimate accountability of controlled substances and records maintained at the registered location.

COUNT II

Respondents are charged under 657 IAC 36.6(28) with failing to create and maintain complete and accurate records as required by state or federal law or regulation or rule of the board, specifically records required by 657 IAC 10.19(1)“a”, which states that each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

D. FACTUAL CIRCUMSTANCES

1. Walgreen Company holds pharmacy license #1257 and CSA registration #119775 for Walgreens 07967 in Clive. Pharmacy license #1257 is currently active through December 31, 2022. CSA registration #1107775 is currently active through May 31, 2024. Walgreens 07967 is the subject of Case No. 2020-0175.

2. Walgreen Company holds pharmacy license #1086 and CSA registration #1107613 for Walgreens 05060 in Clive. Pharmacy license #1086 is currently active through December 31,

2022. CSA registration #1107613 is currently active through May 31, 2023. Walgreens 05060 is the subject of Case No. 2020-0176.

3. Walgreen Company holds pharmacy license #197 and CSA registration #1107331 for Walgreens 07454 in Ankeny. Pharmacy license #197 is currently active through December 31, 2022. CSA registration #1107331 is currently active through May 31, 2024. Walgreens 07454 is the subject of Case No. 2020-0177.

4. Walgreen Company holds pharmacy license #355 and CSA registration #1106816 for Walgreens 05721 in Des Moines. Pharmacy license #355 is currently active through December 31, 2022. CSA registration #1106816 is currently active through May 31, 2024. Walgreens 05721 is the subject of Case No. 2020-0178.

5. Walgreen Company holds pharmacy license #778 and CSA registration #1106780 for Walgreens 359 in Des Moines. Pharmacy license #778 is currently active through December 31, 2022. CSA registration #1106780 is currently active through May 31, 2024. Walgreens 359 is the subject of Case No. 2020-0179.

6. Walgreen Company holds pharmacy license #1210 and CSA registration #1107732 for Walgreens 07455 in Waterloo. Pharmacy license #1210 is currently active through December 31, 2022. CSA registration #1107732 is currently active through May 31, 2023. Walgreens 07455 is the subject of Case No. 2020-0180.

7. Walgreen Company holds pharmacy license #459 and CSA registration #1106755 for Walgreens 04714 in Des Moines. Pharmacy license #459 is currently active through December 31, 2022. CSA registration #1106755 is currently active through May 31, 2024. Walgreens 04714 is the subject of case number 2020-0181.

8. Each pharmacy identified herein is charged with Count I and Count II, resulting in a total of seven charges of Count I and seven charges of Count II against Respondents.

9. In November 2020, each pharmacy reported losses of controlled substances to the Board, which Respondent attributed to employee pilferage. The reported losses generated the above-referenced complaint numbers.

10. The Board investigations revealed insufficient evidence to attribute the losses to a specific employee.

11. The Board requested that each pharmacy identified herein perform an audit of all controlled substances.

12. Walgreen Company completed an audit for each pharmacy for the time period of June 10, 2019, through June 9, 2021; the start and end dates corresponded with the dates in which the pharmacies completed the required annual inventory for all controlled substances.

13. The audit reports for each pharmacy show a large number of drug products which were found to have losses or overages.

14. Walgreen Company is unable to definitively determine what led to the identified losses of controlled substances.

15. The audit reports for each pharmacy contained ending inventory quantities of zero that were highlighted in yellow, which Walgreen Company indicated meant that a zero quantity was unexpected.

16. Walgreen Company indicated that many of the highlighted ending inventory quantities of zero must have been inaccurately entered at the time of the annual inventory.

E. SETTLEMENT

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

F. FINDING OF PROBABLE CAUSE

On May 3, 2022, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



Chairperson
Iowa Board of Pharmacy

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