

BEFORE THE IOWA BOARD OF PHARMACY

<p>RE: Controlled Substances Act Registration of</p> <p>KAREN POTACZEK, DDS Registration No. 1419453 Respondent</p>	<p>CASE NO. 2020-0082</p> <p>COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER</p>
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COME NOW the Iowa Board of Pharmacy ("Board") and Karen Potaczek, DDS, ("Respondent"), 3401 Hwy 71, Spirit Lake IA 51360, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10, 124.305, and 272C.3(4). The Board has jurisdiction over Respondent pursuant to Iowa Code chapters 17A, 124, and 272C, and 657 IAC chapter 10.

A. STATEMENT OF CHARGES

COUNT I

1. Respondent is charged with failure to maintain registration pursuant to 657—Chapter 10, and may be disciplined pursuant to Iowa Code sections 124.303(1)(b) and 124.304(1)(d), and 657 IAC 10.10(1)"d", 10.10(2)"b" and 10.44(4).

COUNT II

2. Respondent is charged with failing to comply with 657 IAC 10.14(2), 10.16, and 10.19(1) pertaining to controlled substances, and may be disciplined pursuant to Iowa Code section 124.304(1)(d), and 657 IAC 10.10(1)"d", 10.44(5), 36.6(21), and 36.6(32).

B. FACTUAL CIRCUMSTANCES

3. Respondent holds Iowa Controlled Substances Act (CSA) registration number 1419453, which is currently active through March 31, 2022.

4. From April 2017 through April 2020 Respondent maintained a supply of controlled substances at her Spirit Lake office with a lapsed CSA registration.

5. In September 2020, an on-site inspection at Respondent's Spirit Lake office revealed the following deficiencies:

- a. Respondent lacked written policies and procedures for handling controlled substances.
- b. Respondent failed to perform an annual inventory of controlled substances.

- c. Respondent lacked invoices for Schedule II controlled substances distributed between registrants.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

6. The Board has jurisdiction over the parties and the subject matter of this proceeding.
7. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.
8. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to a hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, 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.
9. Respondent acknowledges that she has the right to be represented by counsel on this matter.
10. 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.
11. 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.
12. 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.
13. 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.
14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

15. Respondent's CSA registration is placed on **PROBATION** for a period of one (1) year, subject to the following terms:
 - a. Within thirty (30) days of this Order, Respondent shall pay a **CIVIL PENALTY** in the amount of three thousand dollars (\$3,000). 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.

- b. On a quarterly basis, Respondent shall submit documentation demonstrating compliance with the Board's regulations pertaining to controlled substances including copies of the following: most recent annual inventory, Schedule II perpetual inventory, Schedule II invoices for transfers, and relevant policies and procedures.
- c. 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.
- d. Respondent shall abide by all state and federal laws and regulations governing controlled substance registrants. Respondent shall operate in accordance with applicable policies and procedures.
- e. Respondent shall submit quarterly reports detailing her compliance with this Order.
- f. Respondent is responsible for ensuring all required quarterly reports are submitted to the Board in a timely manner. The quarterly reports are due by March 5th (reporting on December-February), June 5th (reporting on March-May), September 5th (reporting on June-August), and December 5th (reporting on September-November).
- g. 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.

16. Should Respondent violate the terms of this Order, the Board may initiate action to impose other discipline, including registration revocation, as authorized by Iowa Code chapter 124 and 657 IAC chapter 10.

12/26/2020
Date

Karen Potaczek
KAREN POTACZEK, DDS
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on January 12, 2021.



Chairperson
Iowa Board of Pharmacy