THE COLLEGE OF PHARMACISTS OF MANITOBA

In the matter of: ***The Pharmaceutical Act,*** **C.C.S.M., c.P60**

And in the matter of: **Sara Haverluck-Watson, a pharmacist registered with the College of Pharmacists of Manitoba**

DECISION AND ORDER OF THE DISCIPLINE COMMITTEE

Pursuant to the Notice of Hearing dated May 1, 2019 (the "Notice"), a hearing was conducted by the Discipline Committee of the College of Pharmacists of Manitoba (the "College") at the law offices of Thompson Dorfman Sweatman LLP, Suite 1700 at 242 Hargrave Street, Winnipeg, Manitoba on November 21, 2022, with respect to charges alleging that Sara Haverluck-Watson, being a pharmacist under the provisions of *The Pharmaceutical Act,* C.C.S.M. c.P60 (the "*Act*") and a registrant of the College, is guilty of professional misconduct, conduct unbecoming a member, or has displayed a lack of skill or judgment in the practice of pharmacy, or operation of a pharmacy, or any of the above, as described in section 54 of the *Act,* in that, between January 2017 and February 2019, at the Dauphin Clinic Pharmacy, located at 622-3rd Street SW, Dauphin, Manitoba, in her capacity as a pharmacist and/or pharmacy manager:

1 That in or about May of 2018 Ms. Haverluck-Watson failed to manage and control the controlled drug inventory, resulting in discrepancies in 10 controlled drugs as counted by Health Canada in contravention of section 43 of the Narcotic Control Regulations, C.R.C. c1041 (the "NCRs"), section G.03.012 of the Food and Drug Regulations C.R.C. c870 (the "FDRs"), subsection 7(1)(b) of the Benzodiazepines and Other Targeted Substances Regulations (the "BOTSRs"), sections 2.3.1 and 2.3.2.4 of Practice Direction: Drug Distribution and Storage (the "DDS") and/or Statement I of the College's Code of Ethics (the "Code"), or any of them.

2 That on nine separate occasions between September 22, 2018 and February 23, 2019 Ms. Haverluck-Watson failed to submit Loss and Theft Reports for Controlled Substances and Precursors to the Office of Controlled Substances, Health Canada, in contravention of section 42 of the NCRs, section G.03.013 of the FDRs, subsections 7(1)(b) of the BOTSRs and/or 2.3.2.5 of the DDS, or any of them.

3 That on nine separate occasions between September 22, 2018, and February 23, 2019 Ms. Haverluck-Watson failed to submit Loss and Theft Reports for Controlled Substances and Precursors to the College, in contravention of 2.3.2.5 of the DDS and/or Statement I of the Code, or either of them.

5 That between January 2017 and February 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "A". with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Pharmaceutical Regulation, 185/2013 (the "Regulation") to the *Act*, sections 2.2.3, 2.2.4, 2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, and 2.5 of the Practice Direction: Ensuring Patient Safety (the "EPS"), Recommendations 8 and 9 of the 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain (the "Guideline") and/or Statements I, II, VII, IX of the Code, or any of them.

6 That between January 2017 and March 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "B" with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Regulation, sections 2.2.3, 2.2.4,

2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, 2.5 of the EPS, Recommendations 8 and 9 of the Guideline and/or Statements I, II, VII, IX of the Code, or any of them.

8 That between January 2017 and February 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "C" with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Regulation, sections 2.2.3, 2.2.4, 2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, 2.5 of the EPS, Recommendations 8 and 9 of the Guideline and/or Statements I, II, VII, IX of the Code, or any of them.

At the hearing, Jeff Hirsch attended as legal counsel to the Complaints Committee, John Myers attended with, and as legal counsel to Sara Haverluck-Watson, and David Marr attended as legal counsel to the Panel of the Discipline Committee (the "Panel").

A Statement of Agreed Facts was filed in which the parties agreed to the following:

I. Jurisdiction, Service and Panel Composition

1. Sara Haverluck-Watson admitted her membership in the College.

2. A Notice of Hearing was issued on May 1, 2019.

3. Ms. Haverluck-Watson admitted valid service of the Notice and that the College has complied with the requirements of sub-sections 46(2) and 46(3) of *The Pharmaceutical Act*, CCSM c. P60.

4. Ms. Haverluck-Watson had no objection to any of the Panel members nor to legal counsel to the Panel on the basis of bias, a reasonable apprehension of bias, or a conflict of interest.

II. Practice and Discipline History

5. Ms. Haverluck-Watson graduated with her pharmacy degree from the University of Manitoba in 2001.

6. Ms. Haverluck-Watson had been registered as a pharmacist under the *Act* commencing on July 3, 2001.

7. At all times material to this proceeding, Ms. Haverluck-Watson was a member of the College as a practising pharmacist in Manitoba.

8. Ms. Haverluck-Watson's employment history was as follows:

   a) beginning in April 2002, Ms. Haverluck-Watson was employed by Shoppers Drug Mart;

   b) September 2003 to May 2006: Ms. Haverluck-Watson was employed at The Canadian Pharmacy;

   c) beginning in June 2006, Ms. Haverluck-Watson was employed at Dauphin Clinic Pharmacy;

   d) beginning in March 2009, Ms. Haverluck-Watson was employed at Winnipegosis Clinic Pharmacy;

   e) as at November 2011 Ms. Haverluck-Watson was employed at Dauphin Clinic Pharmacy (the "Pharmacy"); and,

   f) as at December 2012 Ms. Haverluck-Watson was employed as the pharmacy manager at the Pharmacy.

9. Ms. Haverluck-Watson has no previous discipline history with the College.

III. Admissions and Plea

10. Ms. Haverluck-Watson had reviewed the Notice as well as this Statement of Agreed Facts. She admitted the truth and accuracy of the facts in this Statement and that the witnesses and other evidence available to the College would, if called and otherwise tendered, be substantially in accordance with these facts.

11. Ms. Haverluck-Watson tendered no evidence and admitted that the conduct described in this Statement demonstrates professional misconduct as described in section 54 of the *Act*.

12. Ms. Haverluck-Watson agreed to enter a plea of guilty to counts 1, 2, 3, 5, 6, and 8 as set out in the Notice.

13. Ms. Haverluck-Watson agreed that her guilty plea is voluntary, unequivocal, and informed.

14. The College will be entering a stay of proceedings with respect to counts 4 and 7 of the Notice.

IV. Facts and Background

15. On or about September 19 and 20, 2017, the Health Canada Office of Controlled Substances ("Health Canada") conducted a controlled substances inspection at the Pharmacy. During the inspection, the Health Canada inspector counted 24 controlled substances and 22 of the substances were deemed unacceptable variances. The Health Canada inspector was unable to complete section C2 Accountability Reconciliation of the inspection form as there was no reliable sales data available.

16. Health Canada sent a copy of its Inspection Report to Ms. Haverluck-Watson on or about October 2, 2017.

17. On October 16, 2017, Ms. Haverluck-Watson replied in writing to Health Canada's Inspection Report.

18. On November 8, 2017, Health Canada sent correspondence to the College advising it of the inspection and identifying its findings and the identified narcotic accountability issues.

19. On May 22 and 23, 2018, Health Canada and the College conducted a joint controlled substances inspection as a follow up on the September 2017 inspection. On July 3, 2018, the College sent the Inspection Reply report to Ms. Haverluck-Watson.

20. On July 12, 2018, Ms. Haverluck-Watson replied in writing to Health Canada.

21. On July 30, 2018, Ms. Haverluck-Watson sent the completed inspection reply form to the College.

22. On August 14, 2018, Ms. Susan Lessard-Friesen, the then-Registrar of the College, made a referral to the College's Complaints Committee (the "Committee").

23. On or about February 14, March 7 and 20, 2019, Mr. Ken Zink, a College Investigator (the "Investigator") conducted telephone interviews with Ms. Haverluck-Watson.

24. On or about March 11, 2019, Ms. Haverluck-Watson forwarded certain information from the Pharmacy including narcotic reports for January 2019.

25. On or about March 15, 2019, Ms. Haverluck-Watson advised the Investigator by email that the Pharmacy had started a fentanyl exchange program in 2017 and provided narcotic reports for December 2018 and February 2019.

26. Mr. Zink submitted his Investigation Report to the Committee on March 21, 2019.

27. The Notice was issued on May 1, 2019.

Count 1

1.1 That in or about May of 2018 Ms. Haverluck-Watson failed to manage and control the controlled drug inventory, resulting in discrepancies in 10 controlled drugs as counted by Health Canada in contravention of section 43 of the Narcotic Control Regulations, C.R.C. c1041 (the "NCRs"), section G.03.012 of the Food and Drug Regulations C.R.C. c870 (the "FDRs"), subsection 7(1)(b) of the Benzodiazepines and Other Targeted Substances Regulations (the "BOTSRs"), sections 2.3.1 and 2.3.2.4 of Practice Direction: Drug Distribution and Storage (the "DDS") and/or Statement I of the College's Code of Ethics (the "Code"), or any of them.

1.2 During the inspection conducted by Health Canada and the College in May 2018, the inspectors oversaw a physical inventory count of 18 controlled substances within the Pharmacy. Numerous discrepancies were noted in the count.

1.3 During the same inspection, Health Canada conducted an Accountability Reconciliation and determined that nine drugs had unacceptable variances.

1.4 At the time of the May 2018 inspection, the Pharmacy lacked the means to maintain an accurate inventory and had difficulty accounting for all narcotics, controlled drugs and targeted substances stored within the Pharmacy. The inability to maintain an accurate inventory presents a patient safety issue, as the Pharmacy is unable to accurately identify loss, theft, or potential dispensing errors.

1.5 Prior to the May 2018 inspection, the pharmacy conducted advance billing of bubble packed controlled substances, employed software that was inadequate for tracking controlled substance brand changes, and stored controlled substances in automated filling machines, all of which impaired the ability of Ms. Haverluck-Watson to conduct an accurate inventory.

Counts 2 and 3

2.1 That on nine separate occasions between September 22, 2018 and February 23, 2019 Ms. Haverluck-Watson failed to submit Loss and Theft Reports for Controlled Substances and Precursors to the Office of Controlled Substances, Health Canada, in contravention of section 42 of the NCRs, section G.03.013 of the FDRs, subsections 7(1)(b) of the BOTSRs and/or 2.3.2.5 of the DDS, or any of them.

3.1 That on nine separate occasions between September 22, 2018, and February 23, 2019 Ms. Haverluck-Watson failed to submit Loss and Theft Reports for Controlled Substances and Precursors to the College, in contravention of 2.3.2.5 of the DDS and/or Statement I of the Code, or either of them.

3.2 All discrepancies in the inventory of narcotics, controlled drugs and targeted substances should be investigated and reconciled. Any losses that cannot be reconciled or explained must be

reported to Health Canada and to the College within 10 days of discovery.

3.3 In the inspection report dated October 2, 2017, Health Canada inspectors indicated that the Pharmacy had not submitted a loss/theft report within the last year, despite negative balances being found in the drug inventory reports with no explanation.

3.4 On October 31, 2017, Ms. Haverluck-Watson was emailed a notice from Health Canada outlining the importance of reporting all unexplained negative discrepancies, even if the shortage was a single tablet.

3.5 After the initial Health Canada inspection of September 2017, Ms. Haverluck-Watson conducted 16 narcotic and controlled drug audits within the Pharmacy. The first seven of these showed very significant shortages and were reported to Health Canada and the College.

3.6 Despite every one of them revealing unexplained missing narcotics or controlled substances, the subsequent nine counts were not reported at all.

Count 5

5.1 That between January 2017 and February 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "A" with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Pharmaceutical Regulation, 185/2013 (the "Regulation") to the *Act*, sections 2.2.3, 2.2.4, 2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, and 2.5 of the Practice Direction: Ensuring Patient Safety (the "EPS"), Recommendations 8 and 9 of the 2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain (the "Guideline") and/or Statements I, II, VII, IX of the Code, or any of them.

5.2 During the May 2018 inspection conducted by Health Canada and the College, Ms. Rani Chatterjee-Mehta, Assistant Registrar – Quality Assurance, reviewed a number of prescriptions filled at the Pharmacy to ensure prescription validity and proper dispensing practices and identified four patients of the Pharmacy who had been using high-dose opioids for prolonged periods of time of at least 1400 MEQ/day.

5.3 The Guideline recommends a dosage of not more than 90mg MEQ/day as a watchful dose of opioids, where the balance between benefits and harms often becomes unfavorable. When the use of a medication or its dosage is outside of standard practice, there is a risk of serious harm to the patient. In such circumstances, pharmacists should include documentation with each dispensation that records:

a) Counselling points provided to the patient related to safety;

b) Discussion with the patient of any adverse effects experienced;

c) Determination with the patient if the goals of therapy are being met;

d) Any early refill requests;

e) Upon an initial concern and when new or repeated concerns arise, discussion with the prescriber about concerns related to lack of benefit and/or potential for harm, appropriate tapering plan options, considerations for referral as appropriate and the prescriber's subsequent response; and

f) The pharmacist's plan for follow up.

5.4 In addition, when communicating concerns with the prescriber, the discussion ought to include

clarification of the dose, current standards of practice or Guideline recommendations, the specific safety implications, options for the best course of action, and the pharmacist's recommendation based on the discussion.

5.5 Patient "A" was prescribed opioids from a physician at the Dauphin Medical Clinic since 2002 for multiple orthopedic injuries affecting his neck, low back and chest. In 2011, patient "A" was switched from oral narcotics to fentanyl patches.

5.6 In July 2012, the dose was titrated to 500mcg per hour every three days which equates to approximately 1800-2020 MEQ/day.

5.7 On July 5, 2012, the Pharmacy contacted the prescribing physician at which time the physician indicated that they were aware that the dosage exceeded the guidelines in place at that time.

5.8 In February 2017, through a new prescriber, the dosage for patient "A" was tapered to 300mcg per hour every three days. This represents a 40% reduction in dose, while 10% would be standard practice for an initial taper of opioids.

5.9 By July 2017, patient "A's" dosages were increased to 500 mcg per hour every three days. The Pharmacy confirmed the dose and filled the patient's prescription. Patient "A's" dosage was decreased from 500mcg per hour to 400mcg per hour in or around October of 2017.

5.10 Between January 2017 and February 2019, Ms. Haverluck-Watson only intervened once, on July 16, 2018, advising of the high dose and suggesting a taper. This was subsequent to the July 3, 2018, Inspection Reply Form distributed to her from the College.

5.11 On February 23, 2019, patient "A" presented to the hospital emergency and the emergency physician stopped all fentanyl prescriptions and provided the patient with drugs to alleviate withdrawal symptoms and indomethacin (non-steroidal anti-inflammatory) used to treat patient "A's" pain.

5.12 Ms. Haverluck-Watson admits that she did not meet her professional obligations in having and documenting conversations with patient "A's" prescribers about the dosages provided to patient "A" between January 2017 and February 2019.

Count 6

6.1 That between January 2017 and March 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "B" with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Regulation, sections 2.2.3, 2.2.4, 2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, 2.5 of the EPS, Recommendations 8 and 9 of the Guideline and/or Statements I, II, VII, IX of the Code, or any of them.

6.2 Patient "B" was injured in 2004 and was prescribed opioids for pain in 2005. A number of narcotics were prescribed to control patient "B's" pain, and he was ultimately prescribed oxycodone in February 2009.

6.3 Between November 2013 and November 2017, the dose of oxycodone was increased and reached as much as 600 OxyNeo 80mg tablets every 28 days, or approximately 2520 MEQ/day.

6.4 The Pharmacy contacted the prescriber to express concerns about the high dosages on January

27, 2012 and November 20, 2013.

6.5 The next contact was made after the first Health Canada inspection, on October 30, 2017, when Ms. Haverluck-Watson contacted the prescriber and suggested a taper and/or referral to an opioid addition clinic. A taper was initiated on November 3, 2017.

6.6 Between January 2017 and March 2019, Ms. Haverluck-Watson only intervened twice with the prescriber, (on October 30, 2017, and July 24, 2018) related either to the appropriateness, risks of the dosage, or any request for a tapering plan. These two interventions followed the inspections conducted by Health Canada and the College.

6.7 Ms. Haverluck-Watson admits that she did not meet her professional obligations in having and documenting conversations with patient "B's" prescriber about the dosages provided to patient "B". between January 2017 and March 2019.

Count 8

8.1 That between January 2017 and February 2019 Ms. Haverluck-Watson dispensed or authorized the dispensing of opioids for patient "C" with either no or insufficient intervention with the prescribing physician, taking into account the high dosages of the opioids ordered and the frequency of administration, in contravention of section 83(a), (e) and (i) of the Regulation, sections 2.2.3, 2.2.4, 2.3, 2.4.1, 2.4.2, 2.4.3, 2.4.6, 2.4.7, 2.5 of the EPS, Recommendations 8 and 9 of the Guideline and/or Statements I, II, VII, IX of the Code, or any of them.

8.2 Patient "C" has been using opioids since 1998 and suffers from chronic TMJ arthritis.

8.3 As of January 2017, patient "C" was receiving 400 tablets of OxyNeo 80mg tablets every 20 days, approximately 2400mg MEQ/day.

8.4 On March 8, 2017, Ms. Haverluck-Watson expressed her concern to the prescriber and suggested a taper for the patient due to the high dosages provided to this patient. This engagement with the prescriber was documented on the patient's profile and a slow taper was implemented in April 2017.

8.5 Over the span of one year, between March 8, 2017, and March 15, 2018, the total dosage of OxyNeo 80mg dispensed to patient "C" dropped from 20 tabs per day (approximately 2400mg MEQ/day) to 17 tabs per day (approximately 2040mg MEQ/day). Ms. Haverluck-Watson made no request for a specific or more rapid taper regimen in the months following the commencement of the taper, despite patient "C" receiving refills approximately every 20 days.

8.6 Ms. Haverluck-Watson contacted the prescriber on July 25, 2018, to ask if patient "C's" dosage was still appropriate.

8.7 Patient "C's" dosage decreased on October 15, 2018 by one tablet per day, and again on February 13, 2019 by one tablet per day. There is no documentation of a suggestion by Ms. Haverluck-Watson to speed up the taper during this 4-month period.

8.8 Patient "C" ceased being a patient of the Pharmacy in March 2019.

8.9 Ms. Haverluck-Watson admits that she did not meet her professional obligations in having and documenting conversations with patient "C's" prescriber about the dosages provided to patient "C" between January 2017 and February 2019.

Upon considering the Agreed Statement of Facts, this Panel found pursuant to section 54 of the *Act* that Sara Haverluck-Watson was guilty of professional misconduct and accepted the joint recommended disposition of legal counsel for the Complaints Committee and Sara Haverluck-Watson and ordered that Sara Haverluck-Watson:

a) pay a fine of $10,000.00;

b) have a prohibition on her license that she not act as a preceptor for a period of two years;

c) successfully completes a five-day Quality Assurance program at her sole cost and to the satisfaction of the Registrar; and

d) pay a contribution to the costs of the investigation and hearing in the amount of $25,000.00.

In arriving at its decision, the Panel considered Ms. Haverluck-Watson's admission of guilt, which alleviated what would have been a very lengthy and complicated hearing, and her lack of any prior history of discipline, and is satisfied that this disposition will serve to act as a deterrent to her and in general, while at the same time balances the protection of the public interest and fairness to Ms. Haverluck-Watson, and would not bring the administration of justice into disrepute or be otherwise contrary to the public interest.

DATED at Winnipeg, Manitoba this 3rd day of January, 2023.

THE COLLEGE OF PHARMACISTS OF MANITOBA

Per Martha Mikulak, Chair, Discipline Panel