THE COLLEGE OF PHARMACISTS OF MANITOBA

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

And in the matter of: **Robert R. Nieman, a pharmacist registered with the College of Pharmacists of Manitoba**

DECISION AND ORDER OF THE DISCIPLINE COMMITTEE

Pursuant to the Amended Notice of Hearing (the "Notice") dated August 22, 2019, a hearing was convened by the Discipline Committee of the College of Pharmacists of Manitoba (the "College") at the College offices, 200 Tache Avenue, Winnipeg, Manitoba, on March 28, 2022, with respect to charges formulated by the College alleging that Mr. Robert R. Nieman ("Mr. Nieman"), 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 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, at Health Plus Pharmacy (the "Pharmacy"), 1075 Autumnwood Drive, Winnipeg, Manitoba, Mr. Nieman:

1. [STAY];

2. between February 2017 and April 2019, on approximately 14 acquisitions of controlled substances from a licenced dealer, delegated the task of ordering and receiving controlled substances to individuals who were neither qualified nor authorized to do so, in contravention of subsection 65(3) of the *Pharmaceutical Regulation*, Man Reg 185/2013 (the "Regulation");

3. between January 2017 and April 2019, failed to manage and control the controlled substances inventory, in that he:

    a. failed to enter inventory upon receipt of a controlled substance from a licenced dealer in contravention of section 30 of the NCRs, sections G.03.001 and G.03.012 of the *Food and Drug Regulations*, C.R.C. c. 870 (the "FDRs"), and Statement I of *The Code of Ethics* (the "Code"), or any of them;

    b. failed to maintain accurate inventory records by operating the pharmacy with an electronic inventory record of zero controlled substances on-hand, and an inaccurate manual inventory log, which did not reconcile with the actual physical on-hand inventory, in contravention of sections 30 and 43 of the NCRs, and sections 2.3.1, 2.3.2, 2.3.2.1, 2.3.2.3, and 2.3.2.4 of the *Practice Direction – Drug Distribution and Storage* (the "DDS Practice Direction"), or any of them;

    c. failed to investigate discrepancies in contravention of section 2.3.2.3 and 2.3.2.4 of the DDS Practice Direction, or either of them;

    d. on nine separate occasions between January 2017 and March 2019, 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, subsection 7(1)(b) of the *Benzodiazepines and Other Targeted Substances Regulations*, SOR/2000-217, and section 2.3.2.5 of the DDS Practice Direction, or any of them;

e. on nine separate occasions between January 2017 and March 2019, failed to submit Loss and Theft Reports for Controlled Substances and Precursors to the College, in contravention of section 2.3.2.5 of the DDS Practice Direction, and Statement I of the Code, or either of them;

4. failed to implement policies and/or procedures necessary to protect controlled substances essential to the oversight of a pharmacist with sanctions imposed by the Discipline Committee in contravention of section 43 of the NCRs, and sections 2.3.1 and 2.3.2 of the DDS Practice Direction, or any of them;

5. [STAY];

6. in his role as a pharmacist, between January 2019 and April 2019, dispensed narcotics in excess of the prescriber's directions, in both the quantity and interval, with no or insufficient documentation of authorization from the prescriber, in contravention of subsection 31(2)(b) of the NCRs, subsection 69(1) of the Regulation, and Statements 2 and 7 of the Code, or any of them; and

7. in his role as a pharmacist, on December 13, 2018, failed to fulfill his duties in dispensing ketamine 10% compound for a patient, in contravention of section 43 of the NCR, in that he:

    a. failed to receive the ketamine powder and maintain accurate inventory records in contravention of section 30 of the NCR, and sections 2.1.1 and 2.3.2.1 of the DDS Practice Direction, or any of them; and,

    b. failed to safely dispense and label the ketamine 10% compound in contravention of subsections 70(1)(j), and 71(1)(d), (f), (g) of the Regulation, or any of them.

The hearing into the charges convened on March 28, 2022. Mr. Jeffrey Hirsch ("Mr. Hirsch") and Ms. Sharyne Hamm appeared as counsel on behalf of the Complaints Committee. Mr. Nieman appeared unrepresented before the Discipline Committee (the "Panel"). Mr. Joseph Pollock appeared as counsel on behalf of the Panel.

A Statement of Agreed Facts (the "Statement") was filed in which Mr. Nieman admitted:

1. his membership in the College.

2. valid service of the Notice and the Amended Notice of Hearing dated August 22, 2019, and that the College complied with the requirements of sub-sections 46(2) and 46(3) of the Act.

3. he had no objection to the composition of any of the Panel members or to legal counsel to the Panel on the basis of bias, a reasonable apprehension of bias or a conflict of interest.

4. he graduated with his pharmacy degree from the University of Manitoba in 2002.

5. he has been registered as a pharmacist under the Act since August 14, 2002.

6. he ceased to be a practicing pharmacist on January 1, 2021.

7. at all times material to this proceeding, he was a member of the College as a practising pharmacist in Manitoba.

8. As of June 17, 2009, he, through a numbered company, became a 25% owner of the Pharmacy. He remained an owner until October 2020. He was also the pharmacy manager at the Pharmacy from June 17, 2009 until March 27, 2020.

9. he had no previous discipline history with the College

Plea

Mr. Nieman entered a plea of guilty to counts 2, 3(a) – (e), 4, 6 and 7 as set out in the Notice.

The prosecution entered a stay of proceedings with respect to counts 1 and 5 as set out in the Notice.

The parties further agreed that:

Regarding Count 2:

At all material times, there were two pharmacists employed by the Pharmacy - Mr. Nieman and Mr. Shouren Bose.

The College disciplined Mr. Bose through a decision and order of the College's Discipline Committee dated March 3, 2015. The Discipline Order provided that:

a) Mr. Bose be suspended for one year, commencing July 8, 2014 and ending July 8, 2015;

b) During the time he was suspended, Mr. Bose was required:

   i. to complete a chemical abuse assessment approved by the Registrar and provide the Registrar with the findings;

   ii. to comply with all recommendations from the chemical abuse assessment and provide monthly reports in writing to the Registrar; and,

   iii. to make and maintain contact with the Pharmacists at Risk Committee and instruct the Committee to contact the Registrar should he fail to maintain a satisfactory relationship with the Committee;

c) Upon completion of the period of suspension, Mr. Bose was able to apply for re-instatement of his pharmacist license, subject to all of the re-licensing requirements of the College;

d) Upon relicensing with the College, the following conditions would be placed on Mr. Bose's license:

   i. He could not be a pharmacy manager;

   ii. He could not be a preceptor;

   iii. He could not have ordering / signing authority for drugs covered under the *Controlled Drugs and Substances Act*; and,

   iv. He could not work in a pharmacy without another person present in the dispensary;

e) Upon relicensing with the College, Mr. Bose was required to advise the pharmacy manager in all pharmacies who employed him in some capacity that:

   i. Monthly narcotic inventory verification counts must occur;

   ii. Another pharmacist must verify all calculations for compounding medication before the compounding begins; and,

   iii. He had restrictions placed on his license as set out above.

The Investigator conducted a review of the Pharmacy's narcotic records, and obtained records reflecting the narcotic substances ordered and received by the Pharmacy from the licensed dealer, McKesson Canada ("McKesson"). The McKesson records indicated the order date, quantity and name of the narcotic ordered, and the pharmacist placing the order.

The McKesson website requires a secure online password to place an order for narcotics. As a result of Mr. Bose's conditions, he did not have a narcotic password for the McKesson website. Mr. Nieman was the only pharmacist employed by the Pharmacy with a password for the McKesson website.

It was common practice at the Pharmacy for the pharmacy assistants to access the McKesson website to order narcotics using the secure online password of Mr. Nieman. Pharmacy assistants at the Pharmacy would order the narcotic drugs in question by accessing the McKesson website and finalizing the order with Mr. Neiman's secure online password. This process was followed when Mr. Nieman was not present in the Pharmacy and Mr. Bose was the only pharmacist present.

The Investigator reviewed the prescription files and compared them to the McKesson records. The Investigator determined that on approximately 21 acquisitions of 40 different controlled substances, Mr. Bose was the only pharmacist present in the Pharmacy when those narcotic orders were received.

The combination of DPIN records, prescription verification signatures and work schedules indicate that Mr. Bose was the pharmacist present in the Pharmacy on the dates the McKesson orders were received.

When narcotic drugs and controlled substances were received at the Pharmacy, the drugs would be unpacked by a pharmacy assistant, logged into the manual inventory log and stored in the Pharmacy

safe. Mr. Bose would dispense the drugs to patients before Mr. Nieman could check and sign off on the order.

Regarding Count 3(a)

Section 30 of the Narcotic Control Regulations state that a pharmacist must immediately enter the receipt of narcotic drugs into the pharmacy's inventory system. This entry must include the name and quantity of the narcotic received, the date the narcotic was received, and the name and address of the person from whom the narcotic was received.

During the material time, it was the regular practice of the Pharmacy to only have one pharmacist on duty at a time, either Mr. Bose or Mr. Nieman. Mr. Nieman was present at the Pharmacy most Thursdays, Fridays, and every second Saturday and Sunday for an average of 24 hours per week. Mr. Bose was scheduled to work the remainder of the time. This schedule was at times flexible and subject to change.

Mr. Bose was unable to receive narcotic orders as a result of the sanctions on his practice imposed by the previous discipline committee order.

When Mr. Nieman was not present in the Pharmacy, the pharmacy assistants would receive the narcotic orders, unpack them and fill in the manual inventory logs. Because Mr. Nieman was not present in the Pharmacy on a daily basis, often many days would pass before Mr. Nieman would initial the invoices of narcotics and controlled substances received from McKesson. Mr. Nieman would regularly sign off on received narcotic orders that he had never physically seen.

Regarding Count 3(b)

Pharmacies are required to maintain a perpetual inventory with an accurate on hand count of all narcotic and controlled substances. This is central to the concept of narcotic accountability and works to ensure that there are adequate procedures in place to identify theft, loss or diversion of narcotic and controlled drugs.

During the inspection on April 16, 2019, the Investigator requested a computer-generated printout of the inventory levels of all narcotic drugs at the Pharmacy. The Investigator was informed that the Pharmacy was unable to produce such a printout as all of the counts were reset to zero by the dispensary software supplier approximately four days prior. No physical inventory count was completed prior to the reset.

The Investigator reviewed the manual perpetual logbook and conducted physical counts of five selected high-usage narcotics. There was an extreme variation in the actual and expected quantities in all five drugs, as follows:

Drug	Expected Value	Actual Count	Short (Over)
HydromorphContin® 3mg	186	127	59
HydromorphContin® 12mg	84	60	24
Oxycocet ®	1963	2044	(81)
Apo-Methylphenidate® 10mg	321	139	182
PMS-Oxycodone® 5mg	556	357	199

The manual logbook system was not an effective nor accurate record of the narcotic and controlled substances on hand within the Pharmacy.

During the inspection on April 17, 2019, the Investigator requested a copy of the manual logbook to review. The Investigator was informed that the manual logbook had been taken home by a pharmacy assistant to be reconciled. Accordingly, on that date there was no way to determine the expected on-hand inventory levels of any narcotics or controlled substances.

The inability to check on-hand inventory counts to verify dispensed drugs presented a patient safety issue, as the Pharmacy was unable to accurately identify loss, theft, or potential dispensing errors.

Regarding Count 3(c), 3(d) and 3(e)

Pharmacy Managers are required to investigate discrepancies identified physical counts of narcotic and controlled drugs.

The Investigator reviewed the six most recent narcotic reports demonstrating counts conducted by the Pharmacy. The Investigator identified the following with respect to these narcotic reports:

(a) November 13, 2018: This report indicated that the narcotic count was completed by a pharmacy assistant and initialled by Mr. Nieman. The report showed significant unexplained shortages for eleven separate controlled substances. There was no indication that any of these shortages were investigated by Mr. Nieman. There was no Loss and Theft Report prepared and the shortages were not reported to Health Canada or the College;

(b) December 22, 2018: This report was printed and initialled by Mr. Nieman. There was no evidence of a physical count being conducted in connection with this report;

(c) January 23, 2019: This report indicated that the narcotic count was conducted by a pharmacy assistant. Mr. Nieman initialled the report. The report showed significant unexplained shortages for four separate controlled substances. There was no indication that any of these shortages were investigated by Mr. Nieman. There was no Loss and Theft Report prepared and the shortages were not reported to Health Canada or the College;

(d) February 19, 2019: This report indicated that the narcotic count was conducted by a pharmacy assistant. Mr. Nieman initialled the report. The report showed significant

unexplained shortages for eight separate controlled substances. There was no indication that any of these shortages were investigated by Mr. Nieman. There was no Loss and Theft Report prepared and the shortages were not reported to Health Canada or the College;

(e) March 21, 2019: This report indicated that the narcotic count was conducted by a pharmacy assistant. Mr. Nieman initialled the report. The report showed significant unexplained shortages for eight separate controlled substances. There was no indication that any of these shortages were investigated by Mr. Nieman. There was no Loss and Theft Report prepared and the shortages were not reported to Health Canada or the College; and

(f) April 1, 2019: This report indicated that the narcotic count was conducted by a pharmacy assistant. Mr. Nieman initialled the report. There were no marks, amounts or any written indication that the stock was actually counted.

The Investigator reviewed count sheets maintained by the Pharmacy. In total, there were 23 instances on 9 separate occasions where there was a significant shortage in a narcotic or controlled substance and no Loss and Theft Report was provided to Health Canada or the College.

Following counts that indicated variation in the narcotic and controlled substances on hand in the Pharmacy, totals in the inventory log were simply adjusted, and no documentation existed to explain discrepancies. There is no evidence or documentation to indicate that an investigation of these discrepancies was ever conducted.

During the course of the investigation, Mr. Nieman stated that he had never submitted a Loss and Theft Report to either Health Canada or to the College except in two instances after break-ins at the Pharmacy on December 27, 2018 and February 22, 2019. In both of these break-ins, narcotic and controlled substances were stolen.

Regarding Count 4

In October of 2015, Mr. Bose began his employment at the Pharmacy under Mr. Nieman's management. Both Mr. Bose and Mr. Nieman signed a document which acknowledged that each was aware of the conditions set out in the Discipline Order.

The Investigator reviewed the Pharmacy's Policy and Procedures Manual (the "Manual") with respect to the provisions surrounding narcotic accountability. The sections of the Manual which dealt with narcotic policies, reporting and inventory management were inadequate. The Manual contained no information regarding ordering, receiving, signing and storage of documents, or investigating and reporting of shortages.

Due to the employment of Mr. Bose and his accompanying College discipline sanctions, it became a requirement of the Pharmacy Manager to conduct monthly rather than quarterly narcotic and controlled substance inventory counts.

The Investigator conducted a review of the Pharmacy's narcotic records. These records were stored in multiple locations throughout the Pharmacy and were not easily retrievable.

It was a regular practice at the Pharmacy for the pharmacy assistants to conduct the monthly counts and have the counts signed or initialled by Mr. Nieman at a later date. There existed a record of several recent monthly narcotic count reports being printed, but there was no evidence that a physical inventory count was also conducted. There was no evidence that Mr. Nieman was involved in the monthly counts.

Regarding Count 6

Prescriptions received at a pharmacy indicate, in writing, the quantity and interval of the drug prescribed by the healthcare practitioner. A pharmacist is not permitted to adapt a prescription to increase the number of milligrams dispensed or the interval on which they are dispensed without authorization from the prescribing healthcare practitioner. When verbal authorization is provided and permittable, the pharmacist is required to maintain a written record of such authorization, in accordance with the Regulation.

The Investigator reviewed the prescription files at the Pharmacy to evaluate whether proper narcotic dispensing practices were being followed.

Patient "A", was prescribed a tapering dose of opioid drugs. A prescription, dated January 10, 2019, for HydromorphContin 12mg capsules was observed, with the physician's instructions to provide one capsule three times per day, to be dispensed on Mondays, Wednesdays and Fridays.

The Investigator reviewed the dispensing records for Patient "A". and determined that the physician's orders were not being adhered to. Mr. Nieman, without first consulting the prescribing physician, switched the patient to daily dispensing and dispensed outside of the healthcare practitioner's instructions as the patient had consumed his entire supply of the narcotic on the first day. Mr. Nieman advised the prescribing healthcare practitioner of this change to the prescription at a later date.

As a result of this change in the prescription by Mr. Nieman, the patient was to receive three capsules of HydromorphContin 12mg each day. A review of the dispensing records from January of 2019 showed one instance where the patient was supplied with seventeen capsules of HydromorphContin 12mg by Mr. Nieman, instead of three. The dispensing records from February of 2019 show two instances where the patient was supplied with six capsules of HydromorphContin 12mg on a daily basis by Mr. Nieman, instead of three, and one instance where the patient was supplied with four capsules of HydromorphContin 12mg on a daily basis by Mr. Nieman, instead of three.

The dispensing records for Patient "A" did not show any written record of the prescribing physician authorizing the change from three capsules daily to seventeen, six or four capsules daily.

Regarding Count 7

On December 13, 2018, the Pharmacy received a prescription for 150g of ketamine 10% compound from Patient "A". The Pharmacy did not regularly stock ketamine.

In an effort to avoid ordering excess ketamine, the Pharmacy contacted another community pharmacy (the "Pharmacy 2") to confirm whether they had ketamine in stock. It was confirmed that Pharmacy 2 had an inventory of 15g of ketamine. Mr. Nieman wrote a prescription for the ketamine to be transferred to the Pharmacy from Pharmacy 2.

A pharmacy assistant prepared labels for the ketamine while at the Pharmacy, and then drove to Pharmacy 2 to pick up the ketamine prescription. The pharmacy assistant then brought the ketamine to a third pharmacy ("Pharmacy 3") where she compounded it in the presence of another pharmacist who applied the labels. The other pharmacist performed the final check on the prescription.

Mr. Bose went to Pharmacy 3 where he picked up the prescription and delivered it to the patient.

The ketamine compound was not entered into the inventory of the Pharmacy for over one month from when the prescription was dispensed. Mr. Nieman played no role in the dispensing and labelling of the ketamine 10% compound

Submission on Penalty

Counsel for the Complaints Committee and Mr. Nieman made a joint recommendation on disposition, that in accordance with section 54, 55 and 56 of the Act that Mr. Nieman:

a) pay a fine of $5,000.00;

b) upon resumption of practice, be prohibited from being a pharmacy manager or preceptor for a period of ten years, commencing upon the date of relicensure; and,

c) pay a contribution to the costs of the investigation and hearing in the amount of $8,000.00.

The parties submitted that the joint recommendation on disposition appropriately balanced the protection of the public interest and fairness to Mr. Nieman and would not bring the administration of justice into disrepute or be otherwise contrary to the public interest.

After reviewing the authorities, documentary evidence, the agreed facts and the joint recommendation of disposition, the Panel found Mr. Nieman guilty of professional misconduct, having displayed a lack of knowledge or lack of skill or judgment in the practice of pharmacy, and conduct unbecoming a member in accordance with section 54 of the Act. pertaining counts 2, 3(a) – (e), 4, 6 and 7.

After having reviewed the authorities provided to the Panel regarding joint recommended dispositions and the joint recommendation submitted by the parties, the panel ordered that Mr. Nieman:

a) pay a fine of $5,000.00;

b) upon resumption of practice, be prohibited from being a pharmacy manager or preceptor for a period of ten years, commencing upon the date of relicensure; and,

c) pay a contribution to the costs of the investigation and hearing in the amount of $8,000.00.

In arriving at its decision, the Panel considered Mr. Nieman's admissions of guilt and the cooperative discussions between the parties.

Based on the foregoing, the Panel is satisfied that this disposition should serve to act as a deterrent, both general and specific, while at the same time ensuring that the public's interest is protected and the public's confidence is maintained.

DATED at Winnipeg, Manitoba this 14th day of June, 2022.