ALBERTA COLLEGE OF PHARMACISTS

IN THE MATTER OF THE HEALTH PROFESSIONS ACT

AND IN THE MATTER OF A HEARING REGARDING THE CONDUCT OF **COLIN POROZNI**

DECISION OF THE HEARING TRIBUNAL (Stage I - Merit)

November 17, 2014

I. INTRODUCTION

The Hearing Tribunal held a hearing into the conduct of Mr. Colin Porozni. In attendance on behalf of the Hearing Tribunal were Mr. Jim Johnston, Chairperson; Ms. Carin Jensen, Pharmacist; Mr. Naeem Ladhani, Pharmacist and Mr. Peter Kawalilak, Public Member.

The following persons were also in attendance at the hearing: Mr. James Krempien, Complaints Director; Mr. David Jardine, counsel for the Complaints Director; Mr. Colin Porozni, investigated member; and Ms. Katrina Haymond, independent counsel for the Hearing Tribunal. A member of the public was also present as an observer.

The hearing took place on September 10 and 11, 2014 at the office of the Alberta College of Pharmacists (ACP). The hearing was held under the terms of Part 4 of the *Health Professions Act* ("HPA").

II. ALLEGATIONS

The Notice of Hearing was entered as Exhibit 1, and stated the following:

IT IS ALLEGED THAT:

During the period from September 9, 2011 to October 29, 2012, as a pharmacist and as the licensee of St. Paul Value Drug Mart, you:

- 1. Were involved directly, and as licensee of St. Paul Value Drug Mart, in the dispensing and billing of a large number of medications on multiple occasions where there was a failure to create or maintain appropriate and required patient records for prescriptions allegedly received and dispensed.
- 2. Failed to meet the standards of practice reasonably expected of a pharmacist and licensee and as a result created a situation which had the potential to place the public at risk through:
 - a. Missing, incomplete and incorrect patient records;
 - b. Medications being dispensed without authorization, without documented authorization or in error;
 - c. Narcotics being dispensed beyond the 72 hour currency set out by the Triplicate Prescription Program; and or
 - d. Generally creating inappropriate and non-current records that had the potential to have resulted in patient harm.

- 3. Failed to ensure that the pharmacy had an adequate number of staff to provide pharmacy services safely, effectively and in accordance with the laws and standards required of pharmacists and pharmacies.
- 4. Failed to ensure as licensee that staff were adequately trained and supervised in respect to the receipt, creation and filing of prescription records and patient records.
- 5. Acted in a manner that likely breached the pharmacy's agreement with Express Scripts Canada and failed to act ethically or honestly in his dealings with this third party subscriber.
- 6. Acted in a manner that impacted the integrity of the profession of pharmacy and the public's trust in the profession of pharmacy.

IT IS ALLEGED THAT your conduct constitutes a breach of the following statutes, regulations, and standards governing the practice of pharmacy:

- Standards 1, 6, 7 and 18 and subsections 1.1, 1.2, 6.3, 6.7, 6.8, 7.1, 7.16, 7.17, 18.1(b), 18.7(a), and 18.7(b) of the Standards of Practice for Pharmacists and Pharmacy Technicians;
- Standards 1, 3, 6 and 8 and subsections 1.1, 1.2, 3.1, 6.1(a), 6.2, 8.1, 8.3(a), 8.3(b), 8.5(a) and 8.7 of the Standards for the Operation of Licensed Pharmacies;
- Sections 1(1)(pp)(i), 1(1)(pp)(ii), 1(1)(pp)(iii), and 1(1)(pp)(xii) of the *Health Professions Act*;
- Sections 12(1), and 25(c) of the Pharmacy and Drug Regulation;
- Sections 1(1)(p)(i),1(1)(p)(ii), 1(1)(p)(ix), 10(1)(a), 10(1)(d)(i), 10(1)(d)(iv), 11(3) and 31(2)(a) of the *Pharmacy and Drug Act*;
- Sections C.01.041 (4) and C.01.042 of the Food and Drug Regulations of the *Food and Drug Act*; and
- Principle X of the ACP Code of Ethics.

and that your conduct set out above and the breach of some or all of these provisions constitutes unprofessional conduct pursuant to the provisions of sections (1)(pp)(i), 1(1)(pp)(ii), 1(1)(pp)(ii), 1(1)(pp)(ii), 1(1)(pp)(ii), 1(1)(p)(ii), and 1(1)(p)(ix) of the *Pharmacy and Drug Act*.

Mr. Porozni denied these allegations and the hearing proceeded as a contested hearing.

III. PRELIMINARY MATTERS

Mr. Porozni attended the hearing without legal representation. He acknowledged at the outset of the hearing that he was aware of his right to retain legal counsel, and stated that he wished to proceed with the hearing and to represent himself.

There were no objections to the composition of the Hearing Tribunal or the jurisdiction of the Hearing Tribunal to proceed with a hearing.

Mr. Jardine indicated that some of the exhibits would contain patient names and other pieces of personal health information. He requested that the Hearing Tribunal make an order redacting any patient names appearing in the exhibits, and that if any patient names are referred to during the hearing, that information should be redacted from the transcript, and that any information in the exhibits or the transcripts should be treated in a confidential manner. He also requested that if it was necessary to display information on a projector that contained personal health information that the hearing be closed to the public for those portions only. Mr. Porozni was in agreement with these comments.

The Hearing Tribunal agreed with this request, given that the exhibits may contain sensitive personal health information. In the circumstances, the privacy interests of third parties outweigh any interest the public may have in having access to the names of the patients. Accordingly, the Hearing Tribunal ordered that any patient names or other information that could identify a patient will be redacted from the record and will not be disclosed to the public. The Hearing Tribunal also agreed to close the hearing only for the portions in which personal health information would be displayed visibly on a projector so as to protect the privacy of the patients named in the exhibits.

IV. EVIDENCE

Mr. Jardine made a brief opening statement. He mentioned that this matter arose because of a complaint raised by Express Scripts Canada ("ESC") in relation to an on-site audit they conducted at the St. Paul Value Drug Mart (the "Pharmacy") from March 18 to 22, 2013 (the "Audit"). He indicated that Mr. Porozni was licensee and manager of the Pharmacy for the majority of the period covered in the Audit and that he was a staff pharmacist at the pharmacy for the full duration of the time the Audit covered. Mr. Jardine told the tribunal that he would be calling three witnesses: Mr. Krempien, Complaints Director for the College; Mr. Jamie Raisbeck, Investigator for the College and Ms. Patti Clayton, On-Site Supervisor for Pharmacy, Medical, Surgical and Equipment for ESC.

Mr. Porozni was provided with the opportunity to make an opening statement, but stated that he did not wish to do so at this time and reserved his right to do so after the witnesses called on behalf of the Complaints Director had testified.

Jim Krempien, Complaints Director

Mr. Jardine called Mr. Krempien, Complaints Director, as his first witness. Mr. Krempien established the following key points in his direct evidence:

- Mr. Krempien received a letter from Mary Bozoian, Manager, Business Integrity at ESC on July 3, 2013.
- This letter was to file a complaint against the Pharmacy in relation to an on-site Audit that was conducted at the Pharmacy March 18 to 22, 2013.
- Mr. Krempien assigned himself as investigator and also appointed Mr. Jamie Raisbeck to investigate.
- Since no individual pharmacists were named in the original complaint, Mr. Krempien started his investigation with , who was the licensee of the Pharmacy at the time he received the complaint.
- Through follow up with it was established that the Audit that took place in March looked at prescriptions billed between September 9, 2011 and February 13, 2013. Decame licensee on December 1, 2012 and was therefore only the licensee for only the last two and a half months of the time that the Audit was looking at.
- For the period covered by the Audit, Mr. Porozni was licensee from September 2011 to the end of October 2012. , another pharmacist employed at the Pharmacy, was thought to be responsible for the Pharmacy for the month of November but he was not the licensee. was licensee from December 2012 through February 2013.
- Three separate investigations were launched examining the conduct of Mr. Porozni, and and and a separate investigations were launched examining the conduct of Mr.
- On July 23, 2012 ownership of the Pharmacy changed. The previous owners included a few people of which Mr. Porozni was one. The new owner as of July 23, 2012 was Value Drug Mart Limited.
- Mr. Porozni was licensee at the point of the ownership change and for a period of time after this.
- An email from Value Drug Mart indicated that after Mr. Porozni ceased being licensee, would be responsible for the Pharmacy until a new licensee could be found.

- In discussions with **b** it was discovered that he was not aware that he was responsible for the Pharmacy. He was a floater pharmacist helping out in the transition between Mr. Porozni and **b**.
- After examining the details of this case the investigations into the conduct of and were dropped and the investigation focused solely on Mr. Porozni.
- Mr. Porozni was licensee for 14 to 15 months of the period of time the Audit covered. For the remainder of the time he was working at the pharmacy as a staff pharmacist.
- There are two ESC agreements that covered the span of the Audit. One that was signed in 2009 by Mr. Porozni of St. Paul Drugs Ltd. The newer one was signed by Stacey Berger, director with Value Drug Mart on July 10, 2012. The newer one listed Mr. Porozni as manager of the Pharmacy. Mr. Krempien received copies of the initial audit report, the audit spreadsheet and supporting pictures and letters from ESC detailing their findings in the Audit.
- The initial Audit report summarized findings and classified them by recovery codes. The audit spreadsheet had details on each finding and the pictures were available to support each finding.
- The *Food and Drug Act* and the Regulations do permit prescriptions to be phoned to the pharmacy by the prescriber but it is incumbent upon the pharmacist to reduce that prescription to writing to create a written record.
- As part of the Audit, ESC mailed prescriber verification letters to physicians or other prescribers to confirm whether they prescribed a medication for the same patient matching the claim the Pharmacy submitted.
- Several letters from physicians indicated they did not prescribe the product that was claimed listing them as the prescriber.
- As part of the Audit, ESC also mailed client verification letters to patients to confirm if they had received the product as claimed by the Pharmacy.
- Only one patient responded out of a total of more than 60 letters sent that she did not remember receiving the product that was claimed.
- With the exception of the patients not receiving the product that was claimed, Mr. Krempien felt that there was evidence to support the complaints made by ESC. The most significant findings in the Audit relate to the inability to locate records or the lack of records.
- The total number of missing records and the percent of missing records compared to the total that were requested were very large. Two of the claims selected in the

Audit were for triplicate prescriptions that were filled outside of their 72 hour window without sufficient documentation.

• While each of the claims identified by the Audit may be small or minor in nature, the fact that there are so many of them has resulted in this case being referred to a hearing.

During the course of Mr. Krempien's testimony, a number of exhibits were entered into evidence, including the Record of Decision (Exhibit 2) and a binder of documents (Exhibit 3) which included the Sequence of Events Report prepared by Mr. Krempien, the letter of complaint from Ms. Bozoian, and documentation from ESC summarizing the Audit results.

After Mr. Jardine was finished questioning Mr. Krempien, Mr. Porozni was then asked if he wished to cross-examine Mr. Krempien. He indicated that he had no questions. The Hearing Tribunal then asked Mr. Krempien some questions of clarification. Mr. Krempien was asked if he could clarify and specifically point out the evidence he submitted that supported Allegations 3 and 4 which referenced the Pharmacy being understaffed and the staff being inadequately trained. Mr. Krempien referenced the letters from in Tabs 5 and 20 of Exhibit 3 which included comments that since is started as licensee, he began making changes in the Pharmacy such as hiring more people and improving policies and procedures. 's letters also talk about inheriting record keeping deficiencies, and explained that one of the reasons for the claims against the pharmacy from ESC for missing records were due to staff not knowing how to file or not knowing how to search for filed records.

Jamie Raisbeck

Mr. Jardine called Mr. Raisbeck as the next witness. Mr. Raisbeck established the following key points in his direct evidence:

- Mr. Raisbeck was asked by Mr. Krempien to conduct investigations on three complaint files, one each for Mr. Porozni, and . Mr. Raisbeck was supplied with copies of the complaint as well as the CD-ROM with audit documentation and pictures.
- Mr. Raisbeck did some analysis on the Audit file from ESC and looked at the different recovery codes that were used in preparing their claim. He analyzed the number of recovery codes that made up the total 2698 claims and then broke it down further to examine how many of the claims were made while Mr. Porozni was licensee vs. the time when was licensee and vs. the month where it was thought that was licensee.
- Mr. Raisbeck attempted to review about 250 to 300 of the pictures provided by ESC and compare them to the claims but at that time he did not have access to the

cross-reference spreadsheet later provided by ESC to identify which pictures supported which claims.

Mr. Raisbeck's analysis of the Audit determined that:

- Code 20 (original prescription or hard copy not found on-site) was 63 percent of the rejected claims and 77 percent of the total dollars to be recovered;
- Code 21 (unauthorized prescription refills) made up 11 percent of the rejected prescriptions;
- Code 3 (incorrect quantity/days supply) made up 3.4 percent of the rejected prescriptions;
- Code 4 (unauthorized prescription splitting) made up 2.8 percent of the rejected prescriptions;
- Code 18 (filled too soon) made up 0.33 percent of the rejections;
- Code 25 (directions on hard copy do not match prescription) made up 0.96 percent of the rejections;
- Code 9 (incorrect person's name) made up 0.33 percent of the rejections; and
- There were several other codes that he felt were more of a contractual issue rather than concerns the College may be interested in.

Mr. Raisbeck conducted an interview with an on December 1, 2013. His analysis on the ESC audit showed a small percentage of the claim rejections were from the onemonth period where it was thought that was responsible for the Pharmacy. During the interview stated that he did not know he was responsible and he actually thought Mr. Porozni was the licensee during that month that he worked there.

Mr. Raisbeck conducted an interview with **b** on January 17, 2014. His analysis of the Audit showed a small percentage of the claim rejections were from the period of time in which **b** was the licensee.

Mr. Raisbeck conducted an interview with Mr. Porozni on January 17, 2014. Mr. Raisbeck focused on Code 20 to inquire as to why prescriptions could not be found. He indicated that Mr. Porozni told him there were many reasons, some of which were:

• Inadequate cross-referencing of multiple prescriptions on the same paper. For example narcotics and regular prescriptions on the same original prescription.

- Daily fills of one prescription. Mr. Porozni said that a hard copy was generated but that it was not linked back to the original prescription.
- One staff member was not as good at filing and that could have created problems in finding prescriptions.
- There had been a previous audit with ESC and he indicated that files that were looked at in that audit could then not be found in the second Audit.

Mr. Raisbeck also testified that:

- During an audit the auditors take pictures of the prescriptions and that nothing leaves the premises of the pharmacy so therefore the prescriptions from the first previous audit should still be in the Pharmacy.
- At the time of the interview those prescriptions still had not been found.
- St. Paul is a small town. Mr. Porozni told him he knows most of his physicians and most of his patients. Because he knows them so well he did not write things on the prescription because his patients and the physicians knew what he was doing.
- Mr. Raisbeck felt that when you are dealing with as many missing prescriptions as were found in Code 20 it indicates that would be due to a nonchalant attitude during the time of the Audit.
- Mr. Raisbeck stated his impression of the Pharmacy was that it was very busy, very small and very disorganized.
- The biggest areas of concern in the Audit were the large amount of missing prescriptions and the amount of missing documentation.
- Mr. Porozni explained to Mr. Raisbeck that one of the likely reasons that physicians signed letters back to ESC claiming they did not prescribe certain drugs is that those prescriptions were given verbally to Mr. Porozni over the phone and that the physician likely did not remember that conversation.

Mr. Porozni was then provided with an opportunity to cross-examine Mr. Raisbeck. On cross-examination:

• Mr. Porozni suggested to Mr. Raisbeck that the interview lasted about an hour, however Mr. Raisbeck's recollection was that it was about two hours. Mr. Porozni asked Mr. Raisbeck how much time they spent talking about personal matters, and suggested that it was the majority of the interview. Mr. Raisbeck could not recall.

• Mr. Porozni asked Mr. Raisbeck whether he recalled telling Mr. Porozni he had nothing to worry about. Mr. Raisbeck said that he might have told him that the allegations were unfounded until the complaint was finished, and that some of the conduct in issue was frivolous.

Mr. Jardine had no further questions after Mr. Porozni's cross-examination but the Hearing Tribunal did ask some clarifying questions, and Mr. Raisbeck provided the following additional testimony:

- Mr. Raisbeck indicated he did not investigate how ESC conducts their on-site audits but he did feel the Audit results were valid.
- Mr. Raisbeck reiterated which codes he felt were the biggest concerns, primarily Code 20 and 21. He referenced that Code 20 was for 1684 claims and that 1450 of those were from the time that Mr. Porozni was licensee.
- Mr. Raisbeck explained which codes he felt were insignificant such as Code 18, filled too soon, which was nine prescriptions out of the total 2698.
- Mr. Raisbeck recollected that Mr. Porozni indicated that for the triplicates that were filled outside of 72 hours there was a conversation between him and the physician and the physician authorized release outside the 72 hours.
- Mr. Raisbeck did not physically look at the filing system at the Pharmacy and did not specifically look at their cross-referencing.

Patti Clayton

Mr. Jardine called Ms. Patti Clayton as his third witness. During Ms. Clayton's testimony she established the following key points:

- Ms. Clayton was the onsite supervisor responsible for the Audit which led to this complaint.
- Ms. Clayton reports to Ms. Bozoian who filed this complaint and Ms. Clayton is very familiar with the details of the Audit and the complaint.
- The ESC Pharmacy Agreement with the numbered company 1663106 Alberta Ltd. that was signed by was the agreement in place at the time of the Audit.
- The ESC Pharmacy Agreement references the Claims Submission Kit (the Kit). A copy of the Claims Submission Kit was entered as Exhibit 4.
- Exhibit 4 contains additional terms and conditions that must be followed with respect to claims submitted under the ESC Pharmacy Provider Agreement. The

terms, conditions and procedures outlined in this document must be adhered to as outlined in the signed agreement. Of particular interest is Section 8 which refers to Provider Audits.

- Pharmacy providers are not randomly selected for on-site audits. There are a variety of components of the audit program which may result in an audit.
- Health Canada has a profiling tool which looks at all claims billed to the NIHB program. The profiler compares billings from one provider to other providers in the same area and looks for patterns around prescriber IDs, drugs, DINs, number of clients and others.
- Once a pharmacy is identified as being required to undergo an on-site audit, a two year report is run. This report lists all prescriptions billed to the program in that time frame. Then, a sample of 1 percent plus 150 claims is pulled from the total. In the case of St. Paul Value Drug Mart this total was 1345 claims.
- The sample is made up of approximately 40 percent random claims and 60 percent risk based claims.
- Once a sample is created the provider is contacted to arrange a date for an audit.
- In most audit situations the provider is given 25 percent of the claims two weeks in advance so they have time to start pulling information prior to the auditors arriving on site. In this particular case an exception was made and they were given 40 percent of the claims to pull in advance.
- When the auditors arrive on-site the remainder of the claims are given to the provider so the staff can pull the records while the auditors start looking at the first group.
- The audit staff takes pictures, front and back, of the documentation and none of the original documents ever leave the pharmacy.
- The auditors never use the pharmacy dispensing software nor do they pull records themselves. They have a dedicated staff member from the pharmacy to help them.
- The auditors look at both hardcopy records as well as certain electronic documentation such as Drug Utilization Review codes that may have been entered on claims.
- After collecting samples, the auditors conduct a high level exit interview.
- In the case of the Pharmacy the Audit was initiated as a result of the outcome of a 2011 audit at the same Pharmacy. In the 2011 audit there were very high OTC billings and that pattern did not appear to change in the 2013 Audit.

- For this Pharmacy there had also been an audit in 2008.
- The 2013 Audit was not within two years of the 2011 audit so the typical two year sample was amended. The sample was derived from claims filled between September 9, 2011 and February 13, 2013.
- The previous audit covered September 9, 2009 to September 8, 2011 so there was no overlap in audits.
- For this particular audit, the auditors contacted Ms. Clayton because the first 40 percent of claims that were provided did not have any original prescriptions pulled. They only had reprints of electronic records as they thought that was sufficient. This is not usually accepted but ESC decided to accept these records unless there were problems and then they would request the original prescription. In the case of refill prescriptions, the original prescription from which the refills originate was required.
- Based on the auditors' observations while onsite, they will take notes as to prescriptions which should be followed up with a prescriber verification letter and a client verification letter.
- Back at the office a report is completed by comparing the auditors' findings with pricing schedules as well as compiling all exceptions found.
- After the report is completed, an initial recovery letter is sent to the provider with a breakdown of claims under each rejection code. The provider also receives the workbook detailing each of the claims.
- In the case of this Audit, the initial sample was 1345 claims. If an issue was found with a prescription in this sample that also had refills that occurred within the time frame the audit was sampling from, then those refills also became claims. Because of this, the initial sample of 1345 was expanded to a total of 3129 claims.
- The expanded sample of 3129 claims found 2698 errors which is an 86.2 percent error rate.
- Specific claim numbers in each of the recovery codes were broken down for the Hearing Tribunal. Code 20, prescription not available, was the most significant problem, and this was 1684 claims. 595 were from the on-site sample and the remaining 1089 were from the expansion refills.
- After the initial report is sent, the provider is given an opportunity to respond and provide additional information.

- After the provider responds, a final report is sent with the total recovery amount required to be paid. In the case of this audit, the provider provided very little information back and the final audit report actually resulted in an increase in the recovery amount.
- In this case, for Code 20, prescription not available, the provider did not provide any more information on these claims between the initial and final audit report.
- Recovery amounts vary by code. Some codes recover the total cost billed, others recover the dispensing fee and others the cost of the drug. In addition, for certain codes, when there is no patient safety impact, there may be no recovery but rather a warning issued. An example of this is Prescriber ID. This warning is on the first audit but any exceptions found in subsequent audits are subject to recovery. In this particular instance, Prescriber ID was identified in a previous audit and the behaviour did not change so a recovery was listed.
- During the Audit, the auditors witnessed labels with Latin abbreviations that were given to patients which had the potential to cause harm. Medications were dispensed prior to receiving authorization, triplicate standards were not adhered to and there were a high number of negative verification letters returned. These issues, in addition to the very high error rate were the reason for initiating the complaint.
- There were three audits at this pharmacy within 5 years.
- Concerns found in the 2013 Audit were similar to concerns found in the previous two audits.

Mr. Porozni was given the opportunity to cross-examine Ms. Clayton. During his questioning the following information was obtained:

- ESC conducts about 70 on-site audits per year on behalf of NIHB.
- The average size of an audit is about 650 claims. Some are as large as 4000 claims.
- There is no correlation between the size of the audit and the error rates in the audits.
- The Audit was initially conducted completely under the provider agreement number that was in effect at the time of the Audit. After the Audit was completed, the claims were broken down to represent which ones were from which provider.
- Ms. Clayton was not present for the Audit.

- The two auditors who were conducting the Audit did speak with Mr. Porozni but the majority of the time they were there they were dealing with and and the second second
- If a claim identified in the Audit originated from a prescription from the previous audit the pharmacy would need to find the original prescription from that time period.
- According to Health Canada's profiling there were a high number of OTC add-ons that were billed to the program.
- Other insurance providers require a dentist claim to be submitted with a license number of 88111, ESC requires the actual dentist license number. This issue was identified in previous audits but was not corrected in this Audit.
- At the end of each day the auditors cross reference their spreadsheets and create a missing list so they can give staff at the Pharmacy ample opportunity to find documents that are still needed.

Mr. Jardine asked Ms. Clayton several questions in re-direct in relation to the claims resulting from the filling of triplicate prescriptions after 72 hours. She testified that the provider did submit a note that they contacted the physician to fill these triplicate prescriptions beyond the 72 hour limit but that physician contact happened after the claim had already been filled. There was no documentation on the prescription itself indicating that the physician was contacted to authorize the late filling.

The Hearing Tribunal asked some clarification questions to Ms. Clayton as well as asking to use the projector to actually review some of the claim lines and the corresponding pictures to better understand how to interpret the documentation provided as part of the audit. For the period of time that the projector was being used, the hearing was closed and the observer in the room was asked to leave to ensure that the personal health information of third parties was not disclosed. The following information was obtained or clarified during this time:

- In the response to the Audit the provider did not provide any of the original prescriptions that were missing during the Audit.
- Lines 1 and 10 were looked at on the screen as examples of prescriptions that were missing the originals.
- Line 1 was a prescription for Tylenol with Codeine. The picture to support the claim showed a reprinted hard copy from the computer system but there was no picture of the original prescription.
- Line 10 showed a claim for a prescription for patient . The documentation was a reprinted hard copy of a prescription for but the transaction numbers did not match. No original prescription was shown.

- Line 1685 was viewed as an example of one of the triplicate prescriptions. The triplicate prescription for patient was dated June 11, 2012. The bottom of the prescription shows pharmacist writing indicating the prescription was dispensed June 11, 2012 yet the hardcopy of the dispensing record created in the dispensing software indicates it was filled June 18, 2012. There was no documentation on the prescription indicating why it was filled beyond the 72 hour and no note of contacting the physician to receive authorization to do this.
- Line 1715, a triplicate prescription for patient was also examined along with the corresponding pictures. It was written on August 10th and dispensed on August 17th with no documentation as to why the delay.
- Line 467, a prescription for patient for 30 tablets of pantoprazole filled on November 22, 2011 was examined. In this case the original prescription was provided but it was written on June 17, 2011. The prescription was written for a total of 60 tablets but the fill on November 22 was for the fifth refill. The total prescription quantity appeared to be amended after the initial 60 were filled so the November 22 fill was invalid and fell under Code 20 as an incorrect original prescription.

After reviewing the pictures and sample line items there were more questions asked to Ms. Clayton to further clarify the breakdown of missing original prescriptions vs. incorrect original prescriptions in recovery Code 20. Ms. Clayton required some time to obtain this information. The parties agreed that she could be re-called to provide this information once she had made further inquiries. Mr. Jardine then indicated that, subject to any further testimony from Ms. Clayton, or the need to call rebuttal evidence, the evidence on behalf of the Complaints Director was concluded.

Colin Porozni

Mr. Porozni then testified on his own behalf.

Mr. Porozni explained his history of ESC audits and stated that it had been a frustrating and very stressful experience. He mentioned that his first audit occurred after a pharmacy on the First Nations reserve north of St. Paul shut down and he inherited their files. His billings to the NIHB program increased dramatically as a result of this which triggered his first audit. His second audit was two years later due to high claims of benzodiazepines which he attributed to two new physicians with different prescribing habits. He felt that with the third Audit, he should start budgeting for them since they were such a regular occurrence and despite hundreds of hours of labour to assist with the audits there were still recoveries.

At this point Mr. Porozni introduced Exhibit 5, a letter by Julie Weber, Manager of Store Operations and Acquisitions, Value Drug Mart. The letter shows the breakdown of recovery amounts relating to the provider agreement that was in place for the first part of the audit that Mr. Porozni had signed as well as the provider agreement that was in place after the change in ownership.

The key testimony provided by Mr. Porozni was as follows:

- **100**, **100**'s wife, was the person who was leading the search for information for this on-site Audit. He indicated that all discussions between the auditors and the Pharmacy staff were done through **100**.
- Mr. Porozni was licensee for 86 percent of the Audit period. According to Mr. Raisbeck's analysis in the Sequence of Events Report, 88 percent of the Code 20 claims were from the time he was the licensee.
- After became licensee, Mr. Porozni worked with him for a few weeks and then took a one month holiday. After returning he only worked a few days a week.
- Mr. Porozni highlighted that if a prescription was being dispensed daily for six months and there was a problem with the original prescription then each of the following 179 daily billings were also clawed back.
- He mentioned that many First Nations people go by several names and that the name on the prescription might not match the name on their Indian Status card which might also be different than their Alberta Health Care card.
- Mr. Porozni suggested that for many of the prescriber verification letters, the receptionist would receive the letter, check the appointment schedule to see if the physician had seen the patient on the date specified and then reply negatively if there was no appointment. He also suggested verbal prescriptions or changes might not be charted after the phone call with the pharmacist.
- Locum physicians also led to differences between physician records and Pharmacy records.
- He indicated that he was not comfortable adapting prescriptions as a pharmacist as past experience resulted in claims back from ESC in relation to this practice.
- One physician in town frequently prescribed Advil Cold and Sinus as that was the first product in his prescribing software. This product was not a benefit under the NIHB program and the physician was asked to change his prescriptions to reflect the individual ingredients. He suggested the pharmacy should just substitute whenever this situation arose.
- Mr. Porozni addressed eight specific prescriptions that showed dispensing errors. He felt eight errors out of a sample of almost 2700 claims was not a "large" amount. He shared that he takes errors seriously and always documents the errors.

- Mr. Porozni then focused specifically on some of the six allegations made against him.
- Allegation 1 referred to a large number of records missing or unavailable. Mr. Porozni testified that:
 - The Pharmacy had their files stored in boxes stacked about 20 feet high as well as in Sea Cans across the back alley and these all had to be sorted through.
 - o Due to the number of records required it was painstaking and very time consuming.
 - Mr. Porozni made a business decision to give up looking. He said it was not worth the time and effort.
- Allegation 2(b) referred to medications being dispensed without authorization. Mr. Porozni testified that:
 - The Pharmacy had a workflow for filling bubble packs where they would process and bill all of their prescriptions on a Sunday. They would package them throughout the week and the patient would pick them up the next weekend. There were times when a valid prescription was not available on the Sunday but they would still process and then obtain the prescription sometime during the week that they were packaging but always before the patient picked up.
- Allegation 2(d) referred to inappropriate and non-current records. Mr. Porozni testified that:
 - His filing was sometimes behind by a week but that he felt numerical order for transactions was the appropriate way to file and this took time.
- Allegation 3 referred to inadequate staffing. Mr. Porozni testified that:
 - o mentioned this in his letter back to Mr. Krempien that he felt the Pharmacy needed more staff.
 - Mr. Porozni felt this comment came from inexperience as had only been out of school for one year.
 - o mentioned in his letter that he never felt staffing was a problem.
- Allegation 4 referred to inadequate staff training. Mr. Porozni testified that:
 - o The Pharmacy had both on-site training for new hires as well as a training manual.
 - One staff member who was filing was found to be dyslexic and struggling to place things in order. This individual was removed from this task once this was discovered.

- Allegation 5 referred to breaching the contract with ESC. Mr. Porozni testified that:
 - He chose not to commit any more time or resources. He felt it was a business decision.
 - He prioritized which claims to look for by the value of the claim. If a prescription was for \$1000 it was worth looking for. If it was for \$5 it was not worth looking for.
- Allegation 6 referred to acting in a manner that impacted the integrity of the profession of pharmacy. Mr. Porozni stated that he has always acted with honesty and integrity.

Mr. Porozni summarized his statements by agreeing that there is evidence of a lack of documentation on his part in some of the areas however he feels he has always acted with honesty and integrity. At no time did he act maliciously or with the intent to endanger patient's lives. He chose to no longer look for missing claims as a business decision.

Mr. Jardine then cross-examined Mr. Porozni. The information obtained on cross-examination was as follows:

- Mr. Porozni has been a pharmacist for 22 years with almost all of his career being at the Pharmacy.
- Even though the change in ownership of the Pharmacy happened in July, Mr. Porozni continued as licensee until the end of October and he worked there part time after that.
- 40 percent of the claims required were sent to the pharmacy two weeks in advance. Mr. Porozni said he was not involved in the Audit at that time and was not sure of the details around this.
- Mr. Porozni indicated he did have a numerical filing system.
- Mr. Porozni stated that sometimes prescriptions could be in one of two places, either filed with the regular prescriptions or with the narcotics.
- Mr. Porozni described a filing issue when an original prescription has four or five prescriptions written on it but one of them has an issue that requires contact with the physician. He claims that the original is filed with the last prescription filled and this may be days later so the prescriptions filled initially will not be filed where they should.
- Mr. Porozni indicated that some of the original prescriptions from the previous ESC audit were not re-filed and put where they could be found.

- Even though Mr. Porozni was not actively involved in this Audit or participating in the searching he was still the person responsible for setting up the filing system that was being used to find files in the Audit.
- Mr. Porozni carries a fair amount of information in his head about discussions with physicians but without that information documented on the prescriptions it is not relevant for others who need that information such as auditors.
- After receiving the initial Audit recovery letter there was an opportunity to search for these files again. Once the complaint was being investigated there was also an opportunity to find the files to aid in his defense. At no time were these files ever found. They are still missing.

After Mr. Jardine completed his cross examination the Hearing Tribunal asked Mr. Porozni a few questions of clarification:

- Mr. Porozni was consulted by who was helping with the Audit. He suggested printing reprints of the hardcopies as they would help cross reference the original.
- Mr. Porozni indicated that he gave instructions to stop searching for prescriptions that were associated with the first provider number that he was responsible for. He indicated that **staff** did continue to look for prescriptions under their provider number.
- Mr. Porozni was under the impression that only 150 prescriptions were missing despite having received copies of all Audit materials.

Mr. Porozni indicated that he had no further witnesses to call and had no further evidence to submit.

Patti Clayton

Ms. Clayton was then re-called as a witness to provide further evidence on the information she was asked to find.

- Ms. Clayton produced three documents that she obtained. Mr. Jardine and Mr. Porozni both stated that they had no objection to allowing these documents to be admitted into evidence, hearing and they were marked as Exhibits.
- Exhibit 6 was an email from Zenobia Roussel, QA Analyst at ESC, dated September 11, 2014. It contained further clarification on some of the information Ms. Clayton testified about earlier in the hearing.
- Exhibit 7 was a copy of the Initial Audit Report dated February 3, 2012 that was provided to Mr. Porozni in response to the 2011 audit.

- Exhibit 8 was an email from Zenobia Roussel dated September 11, 2014 with a break-down of the data on the 2011 audit.
- Ms. Clayton then clarified some of her previous testimony concerning the results of the 2013 Audit, based on the information contained in Exhibit 6.
- With respect to the audit from 2011, the following points were made in relation to Exhibit 7 and 8:
 - o The 2011 audit had a total claim sample of 1500 claims. In that audit 362 of the claims were a result of original samples not being provided and of those, 110 were examples of original prescriptions not provided.

Both parties indicated that they did not intend to call any further witnesses.

V. SUBMISSIONS

Submissions on Behalf of the Complaints Director

Mr. Jardine began his submissions by defining the burden of proof as being based on the balance of probabilities. In addition he re-emphasized that the Hearing Tribunal must conduct a two-step analysis. The Hearing Tribunal must first determine if the allegation is factually proven based on the balance of probabilities and second, if it is proven, the tribunal must determine whether the conduct is unprofessional conduct.

Mr. Jardine summarized the allegations and the evidence in relation to each of the allegations. He provided the Hearing Tribunal with a book of Statutory Authorities, including excerpts from the ACP's Standards of Practice, the HPA, the *Pharmacy and Drug Act*, and the Food and Drug Regulation.

Mr. Jardine submitted that the definition of unprofessional conduct as defined in the HPA highlights that unprofessional conduct can be displaying a lack of knowledge or lack of skill or judgment in the provision of professional services whether or not it is disgraceful or dishonourable. While Mr. Porozni had indicated during the hearing that he did not act maliciously or with bad intent, Mr. Jardine emphasized that it was not necessary to prove that a member acted maliciously or with bad intent to be found guilty of unprofessional conduct.

Mr. Jardine submitted the evidence in this case is clear that there is an ineffective system for finding and retrieving records. He also submitted that there was no system in place to maintain the records. The legislation and Standards governing pharmacists clearly requires pharmacists to keep and maintain adequate records. Mr. Jardine submitted that Allegations 1 and 2 were clearly proven and the conduct in issue constitutes unprofessional conduct. Allegation 3 was about an adequate amount of staff. Mr. Jardine indicated that there was a discrepancy between seven is evaluation of staffing levels and Mr. Porozni's evaluation. He indicated that clearly the filing was not being done in an appropriate manner and that this could be due to inadequate staffing levels. Mr. Jardine submitted that the Hearing Tribunal would have to consider the evidence in order to determine whether the allegation is proven based on the evidence.

Allegation 4 was about adequate training and supervision and again Mr. Jardine indicated that the filing was clearly not being done properly and this is a logical reason as to why it was not.

Allegation 5 is about breaching the agreement with ESC. Mr. Jardine submitted that there is no doubt that the Agreement was breached. Mr. Jardine submitted that the allegation indicates that Mr. Porozni failed to act ethically or honestly in his dealings with ESC. Mr. Jardine indicated that the College is not claiming that there was intent to defraud or that there were fictitious records created. However, there was an ethical obligation to meet the terms of the contract entered into with ESC, and Mr. Porozni failed to meet this requirement.

Allegation 6 deals with impacting the integrity of the profession. Mr. Jardine submitted that Allegation 6 was also proven. He indicated that both the public and other members of the profession need to be confident that regulations and standards put in place regarding the profession are adhered to.

In summary, Mr. Jardine felt that, with the possible exception of Allegation 3, the facts were proven and that the conduct was clearly unprofessional conduct, given the degree and magnitude of the breaches.

Closing Submissions by Mr. Porozni

Mr. Porozni indicated that he already addressed the six allegations in his defense and therefore he did not have any further comments with respect to them. He did indicate that once he determined there was closer to 500 missing records, instead of only 150, he had considered asking for a delay of the hearing so he could search for them. However he also mentioned he realized it would likely not have an impact on the issues mentioned.

At this point the Hearing Tribunal asked a few clarifying questions about the wording of the allegations. The parties were advised that the Hearing Tribunal would adjourn to deliberate, and would provide a written decision in due course.

VI. FINDINGS

The Hearing Tribunal carefully considered the evidence provided during the course of the hearing in relation to each of the allegations made. The tribunal also reviewed the

material presented in the CD-ROM and looked at specific examples of different types of prescriptions and claims which will be referenced below in relation to each allegation.

While the evidence will be referred to in further detail below, the Hearing Tribunal did review the ESC Audit results, in conjunction with the information upon which the results were based. Based on its review, the Hearing Tribunal was satisfied that the Audit results were accurate, and that the findings of the auditors in Exhibit 3, Tab 8 and as further explained by Ms. Clayton are supported by the evidence.

<u>Allegation 1: During the period of September 9, 2011 – October 29, 2012, you were</u> involved directly, as licensee, in the dispensing and billing of a large number of medication where there was a failure to create or maintain appropriate and required patient records for prescriptions allegedly received and dispensed.</u>

The Hearing Tribunal finds that Allegation 1 was proven on the balance of probabilities. The evidence clearly established that there were numerous prescriptions that were not produced during the Audit, nor were they produced at any time by Mr. Porozni during the course of the investigation or the hearing. The Hearing Tribunal concludes that even if Mr. Porozni did create the prescriptions initially, there is no doubt that he failed to "maintain" the prescriptions as required.

There was a great deal of testimony and evidence submitted that looked at the numbers in the Audit. Of particular interest was Code 20 in the Audit, Original prescription or hard copy not found on site. For the initial Audit there were 1345 claims looked at and, of these, there were 507 original prescriptions that could not be found. There were several reasons given as to why these could not be found including issues with cross referencing to narcotics, cross-referencing to prescriptions filled at different times of the day or week therefore giving non-sequential transaction numbers and files from the 2011 audit that were not refilled after that audit. While these reasons would contribute to not being able to find the 507 records they also support the allegation itself. Had there been an appropriate filing system including cross-referencing, the files could have been found and presented to the auditors.

The allegation indicates there was both a failure to create appropriate records as well as to maintain them. Creating and maintaining are two different issues and can be addressed individually.

During the course of the hearing, Mr. Porozni testified that he created the records; however, he could not access them during the Audit for a variety of reasons. He stated the prescriptions that had been produced for the 2011 audit had never been re-filed, and were kept in a box. Therefore, if the same records were required for the subsequent Audit, they could not be easily located. Mr. Porozni's decision to keep the 2011 audit records in a box and not re-file them in the appropriate location clearly resulted in an filing system that was ineffective, and was a failure to maintain appropriate and required patient records.

Mr. Porozni also testified that he did not make entries to note the location of the original prescription when doing subsequent re-fills. The issue of cross-referencing prescriptions is another example of not maintaining an effective filing system. The record may have been created but if it is not retrievable then the maintenance of the system is missing. This is another example of Mr. Porozni failing to maintain appropriate patient records.

The evidence clearly establishes that, even if Mr. Porozni created the appropriate records (which will be discussed below), he failed to maintain the patient records that were the subject of the Audit in an appropriate manner, since the records could not be retrieved when they were required.

Allegation 1 states that Mr. Porozni failed to "create" or "maintain" appropriate records. Based on the wording of the allegation, it is not necessary for the Complaints Director to prove that Mr. Porozni failed to create <u>and</u> maintain the records. Proof that Mr. Porozni failed to create <u>or</u> maintain the records is sufficient proof of the allegation.

Nevertheless, since failing to create or maintain the records are two distinct issues, the Hearing Tribunal also considered whether Mr. Porozni failed to create the records as required.

There were numerous examples in the evidence presented where no original prescription was provided. Claim line 1 and Claim line 10 were viewed as examples where there was no original prescription produced.

Another more obvious example of a failure to create patient records is the lack of appropriate documentation on verbal prescriptions and with respect to changes in prescriptions. Claim line 467 as outlined in the evidence is an example where a prescription was filled for a quantity greater than that originally prescribed with no documentation as to when or why or by whom it was renewed.

The Hearing Tribunal also looked at a sample of prescriptions in the claim file along with the corresponding pictures. In this random sample there were examples such as prescriptions numbered 7547346 and 7547347 that were claimed for patient for Aviane and Zovirax. These two medications were written on the original prescription in black ink where the rest of the prescription was written in blue ink with the physician's signature in blue. It appears the Zovirax and Aviane were written on the prescription by someone other than the physician but there is no record of whom. There is also no indication of signature or authorized quantity. Clearly it is a record that was not created properly.

Standard 6.8 of the Standards of Practice for Pharmacists and Pharmacy Technicians addresses the need for a pharmacist or pharmacy technician to reduce a verbal prescription to writing which must also include the pharmacist's signature or initials. Standard 6.7 of the same Standards describes the various pieces of a prescription that are necessary for it to be complete. Quantity and directions for use are two of those requirements that were not displayed in the specific example listed above. No matter who

wrote "Aviane" and "Zovirax" on the prescription, the quantity and the directions should have been clarified with the prescriber by the pharmacist and this clarification should have been documented on the prescription with the pharmacist's initials. This was all missing and therefore a proper record was not created. This is just one example of many that were looked at.

The other factor that was considered by the Hearing Tribunal with respect to Allegation 1 was the sheer volume of problems. The final audit had 2698 exceptions with an overall error rate of 86.2 percent. 63 percent of the rejected claims were due to missing original prescriptions or hard copies and another 11 percent were due to unauthorized prescription refills. These numbers are from a claim that started by looking at a 1 percent plus 150 claim sample of prescriptions filled in the time period the audit looked at. This is an extremely high error rate with numbers that are well beyond a few misplaced prescriptions. It was also revealed that in the 2011 audit there were 362 claims as a result of original samples not being provided from a total claim sample of 1500 claims. It is evident that the issue of missing claims was not just a one-time problem that arose in the March 2013 Audit but that it was an ongoing concern at the Pharmacy.

While Mr. Porozni testified that he believes that he created the appropriate prescriptions, but made a business decision not to continue to search for the records, the Hearing Tribunal finds that, on a balance of probabilities, Mr. Porozni failed to create the patient records for the specific prescriptions referenced above.

The Hearing Tribunal also considered whether Mr. Porozni failed to create the remainder of the patient records that were the subject of the Audit. The Hearing Tribunal considered Mr. Porozni's explanation that although the records did exist, he made a business decision not to retrieve the records that were sought. It was clear to the Hearing Tribunal that Mr. Porozni had ample time to search for the records. The Pharmacy was given 40 percent of the initial claim sample two weeks in advance of the audit to search for them. The auditors created a list of missing prescriptions at the end of each day of the Audit to help staff find the files. The provider was given 30 days after receiving the initial Audit report to find files and submit for consideration before the final Audit could be produced and we heard that there were no original prescriptions submitted back to them. In addition, he had an opportunity to obtain and submit the records during the course of the investigation by the Complaints Director, or to obtain them and submit them as evidence during the course of the hearing. To date, the patient records have still never been produced.

Although the Hearing Tribunal has concerns with respect to whether the patient records were "created," as indicated above, Allegation 1 alleges that Mr. Porozni failed to create <u>or</u> maintain the appropriate and required patient records. The Hearing Tribunal finds that Mr. Porozni failed to maintain the appropriate and required patient records in relation to the prescriptions that were the subject of the Audit, which are listed in Exhibit 2, Tab 8, at pages 33-138. In addition, the Hearing Tribunal finds that Mr. Porozni failed to create the specific patient records referenced above (i.e., claim lines 1, 10, 467 and Prescriptions 754346 and 7547347). Allegation 1 is therefore factually proven.

<u>Allegation 2: During the period of September 9, 2011 – October 29, 2012, failed to</u> meet the standards of practice reasonably expected of a pharmacist and as a result created a situation which had the potential to place the public at risk

The Hearing Tribunal finds that Allegation 2 was also proven on the balance of probabilities.

There are four different particulars associated with Allegation 2. The Hearing Tribunal examined each of the four particulars individually, but also looked at the general wording of the allegation.

Particular (a) in Allegation 2 relates to missing, incomplete and incorrect patient records. Particular (a) is very similar to Allegation 1 and the evidence that supports Allegation 1 also supports 2(a).

In addition to the evidence listed for Allegation 1 the Hearing Tribunal also finds that the following evidence supports 2(a):

• Prescription 7527430 was filled on September 13, 2011 for Zyprexa Zydis for patient . The actual prescription provided to support this claim was dated November 11, 2011 for Zyprexa Zydis for patient . A prescription hardcopy was also reprinted from the computer with prescription number 7527430 dated September 13, 2011 but it listed patient as the patient. Unsure why the original prescription provided does not match the patient name or the dates of fill.

Another factor to consider in relation to 2(a) is the physician verification letters that were sent out by ESC to the prescriber to verify they did indeed prescribe the product that was being claimed. There were more than 40 of these letters sent out and many of them came back with a negative response. Mr. Porozni addressed these negative responses in his letter to Mr. Krempien about the complaint and had reasons why he thought they were sent back as negative. Mr. Porozni felt that the receptionist at the office would have indicated a negative response if they did not see that specific patient having an appointment with the physician around the time of the prescription and he also felt that some of the verbal discussions between him and the prescriber were not charted and therefore were not recalled when they received the letter. Given that the patient records are missing, Mr. Porozni's explanation is somewhat speculative. Nevertheless, there are only two potential reasons for these negative responses, either the prescriber did not prescribe the medication and it was not a valid prescription, or there was missing and unclear documentation to refute the response. In both cases these are examples of missing, incomplete or incorrect patient records.

Particular (b) of Allegation 2 relates to medications being dispensed without authorization or without documented authorization or in error. The following are a few examples of evidence the Hearing Tribunal found during its review that support Allegation 2(b):

- Patient had nine medications filled on November 13, 2011 for 28 days of each. A report was printed from the computer system on November 23, 2011 and was used as the "original prescription" for these medications. There was some handwriting on this report that looks like it was backdated to November 13 but there was no indication it was a verbal order or any initials to show who even wrote this.
- Patient as outlined in above in relation to Allegation 1 where the Aviane and Zovirax were not adequate prescriptions.
- Patient was prescribed Toradol 10 mg tid for 30 tablets. Prescription was filled for ibuprofen 600 mg tid for 30 tablets. There was a handwritten note on the prescription indicating "change to ibuprofen 600 mg tid" but there was no indication of who wrote this, who authorized it, and when that discussion happened.
- Patient had prescription for Senokot filled along with many other medications. The Senokot was not written on the original prescription anywhere. There was also a prescription for omeprazole for this patient which was prescribed as one daily for 180 tablets but was filled for 1 twice daily for a total of 336 tablets.

There are numerous other examples of prescriptions where the documentation was very weak. It was unclear whether they were verbal orders or changes as the documentation was ineligible or missing. There were also examples where it appeared prescriptions had been filled for quantities greater than that originally prescribed but the quantity was just altered on the original rather than creating a new prescription with a verbal prescription record to show it was authorized as a refill.

Particular (c) of Allegation 2 referred to narcotics being dispensed beyond the 72 hour currency as outlined in the Triplicate Prescription Program. There were two prescriptions identified which prove this allegation. Prescription 2777904 was written for patient on August 10, 2012 yet it was first filled on August 17, 2012. There is no documentation on the original prescription indicating why it was filled beyond the 3 days and if the physician had authorized this late release. Prescription 2775000 was written for patient on June 11, 2012 yet it was first filled June 18, 2012. There is no documentation on the original prescription indicating why it was filled beyond the 3 days and if the physician had authorized this late release. The final audit response indicates that they received a response to these initial claims in the form of some documentation to indicate that these prescriptions were authorized by the physician to be released after the 3 day expiry but this response was not accepted as ESC claimed the dating on the authorization was after the prescription had been released.

There are only these two specific examples of prescriptions to support this allegation. The Hearing Tribunal considered whether particular (c) was proven, given that there were only two examples. While this would not be sufficient, on its own, to prove Allegation 2,

the Hearing Tribunal finds that it is illustrative of a general pattern of conduct, and further demonstrates Mr. Porozni's failure to meet the Standards of Practice. Not much weight would be put on only two prescriptions to support an allegation but since this is a part of Allegation 2 it certainly does help to prove the allegation as a whole.

Particular (d) of Allegation 2 refers to creating inappropriate and non-current records that had the potential to have resulted in patient harm. There is some overlap between Allegation 2(d) and 2(a) especially with respect to "inappropriate" records. Examples cited in Allegation 1, 2(a) and 2(b) could all be defined as inappropriate as they fail to meet the standards outlined in Standard 18 of the Standards of Practice for Pharmacists and Pharmacy Technicians around creating and maintaining patient records and as outlined in Standard 6.7 of the same Standards around the requirements of a prescription to make it complete.

With respect to non-current records there are two different issues that arise based on a review of the Audit. One is the examples of prescriptions where a report was generated after a prescription was filled and this record was then backdated in handwriting and looks to be used as the original prescription. One example is patient described in 2(b) above. The other issue is around the practice that was described by Mr. Porozni with respect to filling blister packages in the computer on a Sunday and using the week to obtain necessary prescriptions to support these fills if there were not adequate refills on file. While these prescription was obtained, the NIHB Claims Submission Kit (Exhibit 4) stipulates in Section 5.4 A that the claim submission sent to ESC must have the date of service and that this date cannot be a future date. By billing the prescription on Sunday before there was a valid prescription, this requirement is not being met and it supports the definition of a non-current record.

Mr. Porozni testified that this practice was in place to deal with workflow issues, and that no prescriptions were actually provided to patients until the prescription was received. The Hearing Tribunal understands the workflow issues around filling blister packs and the need to spread the work out over several days. However, the Hearing Tribunal nevertheless finds that prescriptions should not be filled in the computer and billed to the third party payer without first obtaining a prescription to support this claim.

The Hearing Tribunal finds that there is a significant amount of evidence, as outlined above, which demonstrates that Allegation 2, including particulars (a) – (d) are proven on a balance of probabilities.

The Hearing Tribunal also considered whether Mr. Porozni's failure to meet the standards of practice had the potential to put the public at risk, as alleged. There were no examples provided of actual patient harm, but it is easy to envision cases of possible patient harm that could result from the examples in 2(a) through (d). For example, there were examples of many prescriptions where the total quantity was altered from that originally prescribed in order to extend therapy. There was no evidence that a health care professional, either the pharmacist of the physician, assessed the patient to determine if

their therapy should be continued. This could have negative consequences to the patient if they should not have continued on this medication.

<u>Allegation 3: During the period from September 9, 2011 – October 29, 2012, failed</u> to ensure that the pharmacy had an adequate number of staff to provide pharmacy services safely, effectively and in accordance with the laws and standards of pharmacists and pharmacies.

The Hearing Tribunal finds that the Complaints Director has not proven Allegation 3 on a balance of probabilities.

There was some evidence in stated in Mr. Krempien and in Mr. Raisbeck's notes of their interview where stated he hired more staff as he felt the pharmacy was understaffed. There was contradictory evidence in site interview where he did not feel there were staffing level issues at the Pharmacy.

Although the Complaints Director suggested that the problems referred to above in Allegations 1 and 2 may have arisen due to inadequate staffing levels, the only evidence submitted on behalf of the Complaints Director in relation to this allegation was hearsay evidence. There was no evidence showing work schedules or other interviews with staff to determine the staffing levels. There was no evidence of observation of the pharmacy by a College practice consultant to determine if their day to day practice was not meeting standards due to staff levels. Additional evidence of this nature may have provided the factual foundation to prove the allegation. However, the only evidence that was adduced was minimal and conflicting. Therefore, the Hearing Tribunal finds that Allegation 3 is not proven.

<u>Allegation 4:</u> During the period from September 9, 2011 – October 29, 2012, failed to ensure as licensee that staff were adequately trained and supervised in respect to the receipt, creation and filing of prescription records and patient records.

The Hearing Tribunal finds that the Complaints Director has not proven Allegation 4 on a balance of probabilities.

As the Hearing Tribunal has indicated in its discussion of Allegations 1 and 2, it is clear that the patient records that were the subject of the Audit were not appropriately maintained during the period of time in question. The Complaints Director suggests that one of the reasons for this is that staff was not provided with adequate training or supervision.

The evidence submitted on behalf of the Complaints Director in relation to this allegation was very limited. None of the staff who worked at the Pharmacy were called to provide evidence regarding the nature of the training they had received, or the supervision that was provided. Mr. Porozni testified that there was one staff member who struggled with appropriate filing but after it was determined that she suffered from dyslexia she was removed from the task. Mr. Porozni also indicated that filing procedures were addressed with new hires as part of their on the job training.

Mr. Porozni stated that there was a training manual for the Pharmacy, but that it did not address the filing system they were to use.

The inability to recover so many records indicates that the system in place at the Pharmacy was not sufficient. However it is not evident based on the evidence that the issues arose due to inadequate training or supervision.

In the circumstances, the hearing finds that there is insufficient evidence to prove Allegation 4 on a balance of probabilities.

<u>Allegation 5: During the period from September 9, 2011 – October 29, 2012, acted</u> in a manner that likely breached the pharmacy's agreement with ESC and failed to act ethically or honestly in his dealings with this third party subscriber

The Hearing Tribunal finds that Allegation 5 was proven on a balance of probabilities.

Allegation 5 related to a breach of the Pharmacy's agreement with ESC, and alleges that Mr. Porozni failed to act ethically or honestly in his dealings with this third party subscriber.

The first element of this allegation is easily addressed by looking at both the Pharmacy Provider Agreement and the Claims Submission Kit.

- Section 3.1.1 of the Agreement states that the Provider shall cause its personnel and any pharmacists it employs to comply with the provisions in this Agreement.
- Section 6.2 (c) of the Agreement states that the Provider shall cooperate with any audit or review and shall provide such information as may be required by Express Scripts Canada, including copies of any Client profiles, prescriptions, shipping invoices, internal invoices, manufacturers' invoices, wholesalers' invoices, documentation of item receipt by the Client, and evidence of other or additional drug benefit coverage.
- Section 8.1 of the Agreement states "The Provider" shall maintain pharmacy records relating to Clients and their prescriptions in accordance with all applicable laws, but not less than five (5) years."
- Section 8.3 of the Claims Submission Kit discusses the role of the Provider in an audit and specifically states that the Provider will cooperate with Express Scripts Canada in all audit activities.

• Section 8.4.5.6 of the Claims Submission Kit outlines the documentation required for Audit purposes. One such example of documentation required is the original prescription.

The evidence establishes that there were 507 original prescriptions that could not be found. By virtue of the Agreement that Mr. Porozni signed with ESC, and by virtue of his employment at the Pharmacy as a pharmacist when the second Agreement was signed, Mr. Porozni was required to maintain original prescriptions and to provide them to ESC as part of its audit process.

Mr. Porozni also indicated that he made a business decision to stop searching for prescriptions and that he would rather pay than have staff spend time searching for records. The Hearing Tribunal felt that this statement is evidence of his failing to cooperate with the Audit proceedings, and this too is a breach of the ESC Agreement.

The requirements for documentation outlined in Section 8.4.5.6. are closely related to the requirements for documentation that are outlined in the Standards of Practice and that are explained with respect to Allegations 1 and 2 above. Each of the sections of the Agreement and the Kit identified above were broken and therefore the first part of the allegation is proven.

The second part of the allegation alleges that Mr. Porozni failed to act honestly or ethically with this third party subscriber. There is no evidence that Mr. Porozni was dishonest with ESC and neither Mr. Porozni, the College nor Ms. Clayton ever made this claim.

On the other hand there is evidence to support that by him failing to comply with the Agreement he had signed with ESC that he was acting unethically. Principle 10 of the Alberta College of Pharmacists Code of Ethics relates to acting with honesty and integrity. The Hearing Tribunal finds that Mr. Porozni had an ethical obligation to act in compliance with the Agreement he signed with ESC and to cooperate with the audit. By failing to find records they asked for and then telling them he would no longer participate in their Audit, he was breaching that contract and not fulfilling his responsibilities that he agreed to. In this case the Hearing Tribunal does agree that his dealing with ESC were unethical, although there is no evidence that he was dishonest.

In light of the foregoing, the Hearing Tribunal finds that Allegation 5 is proven.

<u>Allegation 6: During the period from September 9, 2011 to October 29, 2012, acted</u> in a manner that impacted the integrity of the profession of pharmacy and the public's trust in the profession of pharmacy

The Hearing Tribunal finds that Allegation 6 is proven on a balance of probabilities.

Tribunal considered whether the public's trust of the profession of pharmacy was impacted. The public relies on a pharmacy keeping a thorough and complete record of

their health information. A big part of this is ensuring that patient records can be retrieved. In addition, ESC entered into an agreement with the Pharmacy, which required the Pharmacy to create and maintain appropriate patient records. Although ESC is the entity that conducted the Audit, ESC is still a member of the public. The evidence referred to for Allegations 1 and 2 established that there were a great deal of records that could not be located. If there is ever a situation where a patient requests their patient record or their original prescription needs to be reviewed due to an error or simply to receive clarification it is paramount that it can be found. The tribunal was concerned about the magnitude of the situation. If 507 original prescriptions out of a claim of 1345 could not be found then chances are very good that other original prescriptions may not be found.

The public, including ESC, also trusts that in general pharmacists will uphold their Standards of Practice of their profession. Since Mr. Porozni has clearly not met the Standards with respect to recordkeeping and documenting there is a breach of the Standards.

In addition, the Hearing Tribunal also considered whether Mr. Porozni's conduct impacted the integrity of the profession. Pharmacy is a self-regulating profession and with that it carries a great deal of responsibility and accountability. If the evidence established that there were only one or two missing documents or one or two triplicates that were dispensed late without documentation, then the evidence would not be sufficient to prove the allegations, or to demonstrate that the integrity of the profession was impacted by Mr. Porozni's conduct. But that is not the case here. The evidence established that the Mr. Porozni had an 86.2 percent error rate based on the Audit results. This cannot be accepted by the profession as a satisfactory practice. Standards and regulations have been broken on many occasions, over several years. Mr. Porozni was audited in the past and should have learned from his past audit results and changed his practice. Instead he chose to make a business decision to not worry about it and just pay a penalty. This is definitely damaging to the integrity of the profession.

Based on these facts the Hearing Tribunal finds that Allegation 6 is proven.

Conduct is "Unprofessional Conduct"

For the reasons outlined above, the Hearing Tribunal finds that Allegations 1, 2, 5 and 6 are proven on a balance of probabilities.

The Hearing Tribunal also considered whether the conduct is "unprofessional conduct". Section 1(1)(pp) of the HPA states that "unprofessional conduct means one or more of the following, whether or not it is disgraceful or dishonourable:

- Displaying a lack of knowledge of or lack of skill or judgment in the provision of pharmacy services;
- Contravention of this Act, a code of ethics or standards of practice;
- Contravention of another enactment that applies to the profession; and

• Conduct that harms the integrity of the regulated profession."

A similar definition can also be found in the Pharmacy and Drug Act.

In this case there are several regulations, standards of practice, and one aspect of the code of ethics that have not been upheld.

- Standard 1 (specifically 1.1 and 1.2) of the Standards of Practice for Pharmacists and Pharmacy Technicians talks about pharmacists' requirement to uphold the law that governs their practice. By breaking other areas of the Standards and various Acts and regulations which will be proven below, this standard is also broken.
- Standard 6 (specifically 6.3, 6.7 and 6.8) of the Standards of Practice for Pharmacists and Pharmacy Technicians deals with the need to determine the appropriateness of each prescription. These sections define what makes a prescription complete. In many of the cases listed in the evidence it was obvious that the prescriptions were not complete as defined here. Standard 6.8 also deals with the need to reduce verbal prescriptions to writing. The evidence shows that this standard was also broken.
- Standard 7 (specifically 7.1, 7.16 and 7.17) of the Standards of Practice for Pharmacists and Pharmacy Technicians addresses the proper procedures to be followed when dispensing. These standards dictate that a prescription must be determined to be correct before dispensing and it also discusses the need to keep clear documentation as to who completed which steps in the dispensing process. In the prescriptions reviewed in the evidence there were many examples of prescriptions lacking appropriate documentation. There were many prescriptions that were not correct identified in the Audit which is clearly a violation of this standard.
- Standard 18 (specifically 18.1(b), 18.7(a) and 18.7(b)) of the Standards of Practice for Pharmacists and Pharmacy Technicians addresses the need to create and maintain patient records. This standard was also broken on many occasions.
- Standard 1 of the Standards for the Operation of Licensed Pharmacies deals with the need to be compliant with the Law and therefore this standard is also broken as in the other standards.
- Standard 8 of the Standards for the Operation of Licensed Pharmacies establishes the need for comprehensive record keeping which was clearly an issue with the Pharmacy during the relevant period of time. This standard discusses the need for an "effective" system which is clearly not the case due to the sheer volume of errors found when trying to recover records.
- Section 12(1) of the Pharmacy and Drug Regulation dictates that a licensee must ensure that records are created and maintained in accordance with the standards

for the operation of licensed pharmacies. Since Standard 8 was breached, there is a correspondence breach of the Pharmacy and Drug Regulation. Section 25(c) of the Pharmacy and Drug Regulation states that licensee must ensure that the pharmacy complies with all enactments applicable to pharmacy. Section 1(1)(p)(i), 1(1)(p)(ii) and 1(1)(p)(ix) of the Pharmacy and Drug Regulations defines "misconduct" in a manner that is similar to the definition of "unprofessional conduct" in the HPA. Mr. Porozni was the licensee for the Pharmacy for part of the Audit period. Therefore, his conduct also constitutes "misconduct" as a licensee.

- Section 10(1)(a) of the *Pharmacy and Drug Act* stipulates that a licensee must ensure the licensee operations in accordance with this Act. There are other areas of this Act such as 10(1)(d)(i) and 10(1)(d)(iv) that establish that drugs must be dispensed pursuant to a prescription and that all required records are maintained in according with the Act. Since original prescriptions could not be found and since there were some prescription verification letters declined by physicians, these provisions have also been breached. Section 11(3) of the *Pharmacy and Drug Act* establishes that a proprietor must ensure all required records are created and maintained in accordance with the Act. Since Mr. Porozni was the proprietor on the first ESC Agreement, his conduct also constitutes a breach of s. 11(3) of the *Pharmacy and Drug Act*.
- Section 31(2)(a) of the *Pharmacy and Drug Act* establishes that Schedule 1 drugs must be dispensed pursuant to a prescription. Again, because of so many missing original prescriptions. In at least some cases (for the reasons outlined above), the Hearing Tribunal found that drugs were dispensed without an original prescription. Therefore, Mr. Porozni's actions also breached s. 31(2)(a) of the *Pharmacy and Drug Act*. Section C.01.041(4) of the Food and Drug Regulations of the *Food and Drug Act* describes how to reduce a verbal prescription to writing. The Hearing Tribunal noted many prescriptions that did not follow the requirements in the regulations. The Audit showed 30 claims under Code 21(f), incomplete verbal documentation.
- Section C.01.042 of the Food and Drug Regulations of the *Food and Drug Act* establishes that a prescription cannot be refilled more times than it was prescribed. The prescription for IC for pantoprazole that was described in the evidence for is clearly a violation of this section. There were other examples of this seen by the Hearing Tribunal as well.
- Principle X of the Code of Ethics establishes the ethical obligations of a pharmacist in dealing with contractors, suppliers and others involved in the business of pharmacy. As seen in the reasons for Allegation 5, Mr. Porozni's actions in breaching the Agreement with ESC constitutes a contravention of Principle X of the Code of Ethics.

Based on the foregoing, the Hearing Tribunal finds that Mr. Porozni clearly breached the Standards of Practice for Pharmacy and Pharmacy Technicians, the Standards for the Operation of Licensed Pharmacies, the ACP Code of Ethics, and a number of enactments that apply to the profession.

In addition, the Hearing Tribunal finds that Mr. Porozni's actions display a lack of knowledge or judgment in the practice of the profession. He should have been aware of his duty to keep thorough and complete records and to maintain an adequate filing system, and to dispense prescriptions pursuant to a complete prescription.

In addition, the Hearing Tribunal finds that Mr. Porozni's conduct impacts the integrity of the profession.

While the Hearing Tribunal is aware that not every breach is sufficient to rise to the level of unprofessional conduct, the sheer magnitude of the errors, and the repetitive nature of the breaches, establishes that Mr. Porozni's conduct is "unprofessional."

VII. CONCLUSION

In conclusion the Hearing Tribunal finds that Allegations 1, 2, 5 and 6 were proven on the balance of probabilities, and that the conduct in issue is "unprofessional conduct" as defined in the HPA.

The Hearing Tribunal finds that Allegations 3 and 4 were not proven.

The Hearing Tribunal will determine what orders should be issued after hearing submissions on penalty from the parties.

Signed on behalf of the Hearing Tribunal by the Chair

Dated: November 17, 2014 Per: Jim Johnston