

ALBERTA COLLEGE OF PHARMACY

IN THE MATTER OF
THE HEALTH PROFESSIONS ACT

AND IN THE MATTER OF A HEARING REGARDING
THE CONDUCT OF

RAJEH ABU ZAHRA

Registration number: 7676

DECISION OF THE HEARING TRIBUNAL

I. INTRODUCTION

The Hearing Tribunal held a hearing into the conduct of Rajeh Abu Zahra. In attendance on behalf of the Hearing Tribunal were Rick Hackman (pharmacist and chair), Hugo Leung (pharmacist), Sarah Gutenberg (pharmacist), and Pat Matusko (public member). The hearing took place on June 10 and 11, 2019 at Edmonton, Alberta. The hearing was held under the terms of Part 4 of the *Health Professions Act*.

In attendance at the hearing were: David Jardine representing the Complaints Director; James Krempien, the Complaints Director of the Alberta College of Pharmacy (the “ACP”); Rajeh Abu Zahra, the investigated person; Simon Renouf, Q.C., representing Mr. Abu Zahra; and James T. Casey, Q.C., independent legal counsel to the Hearing Tribunal.

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

II. ALLEGATIONS

The allegations considered by the Hearing Tribunal as set out in the Notice of Hearing are as follows:

IT IS ALLEGED THAT, between January 1, 2018 and May 3, 2018, while you were both a licensed Alberta pharmacist and the licensee of Boyle McCauley Pharmacy & Home Health Care (ACP License #2498), you:

1. Knowingly dispensed or as the licensee permitted your staff to dispense approximately 1395 Type 1 Triplicate Prescription Program medications from one physician prior to, and without ever, receiving a Triplicate Prescription Program form from that physician for the Type 1 medications;
2. Failed to comply with the Triplicate Prescription Program requirement to dispense Type 1 medications pursuant to a Triplicate Prescription Program prescription over an extended period of time;
3. Inappropriately created procedures to facilitate the ongoing dispensing of Type 1 Triplicate Prescription Program medications without requisite Triplicate Prescription Program prescriptions; and
4. Failed to ensure that required pharmacy records, in particular all Triplicate Prescription Program prescriptions or prescriptions required to be filled under the Triplicate Prescription Program, received by Boyle McCauley Pharmacy & Home Health Care were properly maintained and stored.

IT IS ALLEGED THAT your conduct in these matters:

- a. Breached your statutory and regulatory obligations to the Alberta College of Pharmacy as an Alberta pharmacist and a pharmacy licensee;
- b. Undermined the integrity of the profession;
- c. Created the potential for patient harm; and
- d. Failed to exercise the professional and ethical judgment expected and required of an Alberta pharmacist and a pharmacy licensee.

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

- Alberta Triplicate Prescription Program Guide, which states that dispensers must be presented with the top two copies of the Triplicate Prescription Program form for Type 1 medications;
- Standards 1 (1.1 and 1.2) and 8 (8.1 and 8.3) of the Standards for the Operation of Licensed Pharmacies;
- Principle 10(1) of the Alberta College of Pharmacy's Code of Ethics;
- Sections 10(1)(d)(iv) and 10(1.1) of the *Pharmacy and Drug Act*;

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(1)(pp)(i), 1(1)(pp)(ii), 1(1)(pp)(iii), and 1(1)(pp)(xii) of the *Health Professions Act* and misconduct pursuant to the provisions of sections 1(1)(p)(i), 1(1)(p)(ii), and 1(1)(p)(ix) of the *Pharmacy and Drug Act*.

Mr. Abu Zahra denied the allegations.

III. PRELIMINARY MATTERS

Given that the records to be tendered into evidence at the hearing included patient names, the Hearing Tribunal directed that any information provided to a member of the public under section 85 of the *Health Professions Act* should have any patient names redacted. To ensure privacy, the Hearing Tribunal will not use any patient names in this decision.

IV. EVIDENCE

James Krempien

James Krempien testified about the investigation, the referral of the complaint to a hearing and the Triplicate Prescription Program (the “TPP”). The College of Physicians and Surgeons of Alberta (the “CPSA”), the ACP, and other organizations participate in the TPP. The TPP has a list of medications classified as “Type 1” that includes narcotics that are subject to misuse, abuse, and diversion. A prescriber prescribing one of the medications on the list is required to use a secure prescription pad issued by the CPSA. Pharmacists are expected to understand and comply with the TPP. The requirements of the TPP at the relevant times are set out in the document “Triplicate Prescription Program (TPP) - Information for the Prescriber and the Dispenser” (revised February 2012; referred to as the “TPP Document.”) The TPP Document states that dispensers must be presented with the top two copies of the TPP prescription for Type 1 medications.

In May of 2018 Mr. Krempien received information from two employees of the CPSA: Dr. Monica Wickland-Weller, Senior Medical Advisor, and Ed Jess, Director, Prescribing and Analytics. The concerns expressed were that the Boyle McCauley Pharmacy & Home Health Care (the “Boyle McCauley Pharmacy”) may have dispensed up to 1,000 TPP prescriptions to patients of Dr. Visconti without first, or ever, receiving a TPP prescription from Dr. Visconti. Mr. Abu Zahra is the licensee for the Boyle McCauley Pharmacy. Dr. Wickland-Weller explained to James Krempien that Dr. Visconti was under suspension by the CPSA and that she had recent conversations with both Dr. Visconti and Mr. Abu Zahra. She indicated that Dr. Visconti had recently called her and asked the CPSA to send him 20 sets (50 prescriptions per set) of TPP prescriptions so he could clear up the backlog of TPP medications he had prescribed, and which had been dispensed by the Boyle McCauley Pharmacy without the TPP prescriptions. Dr. Wickland-Weller explained that she refused to provide Dr. Visconti with the TPP prescription sets given that he was under suspension. Dr. Wickland-Weller also explained that Mr. Abu Zahra had contacted Dr. Wickland-Weller about three months previously asking the CPSA to intervene with Dr. Visconti in the backlog situation. After the conversation between Ms. Wickland-Weller and Mr. Krempien, it was agreed that the CPSA would provide him with a spreadsheet that showed the dispensing events for the Boyle McCauley Pharmacy since January 1, 2018 for TPP medication prescribed by Dr. Visconti. James received and reviewed the spreadsheet. He decided to treat the information as a complaint under section 65 of the *Health Professions Act*.

Mr. Krempien had an initial conversation with Mr. Abu Zahra advising him of the nature of the concerns and explaining the investigation process. On May 8, 2018 Mr. Krempien sent Mr. Abu Zahra a letter setting out the concerns and enclosing the spreadsheet received by the CPSA. The letter indicates that the spreadsheet lists all dispensing events from the pharmacy between January 1, 2018 and May 7, 2018 for prescriptions written by Dr. Visconti for medications requiring a TPP prescription. The letter notes that there are approximately 8,100 separate dispensing events. Mr. Abu Zahra is asked to provide a written response to the concerns and to identify on the spreadsheet all dispensing events where his pharmacy did not receive an authorizing TPP prescription.

On May 14, 2018 Mr. Krempien met with Mr. Abu Zahra who explained that some time ago Dr. Visconti had started directing patients to the Boyle McCauley Pharmacy because he did not have a good relationship with the pharmacists in Sherwood Park, where Dr. Visconti practiced. Mr. Abu Zahra explained that prior to August/September 2017 the pharmacy would regularly dispense TPP medications without a TPP prescription. The pharmacy would then contact Dr. Visconti's office and get him to issue the missing TPP prescriptions. Prior to the Fall of 2017 the Boyle McCauley Pharmacy did not have too much trouble getting Dr. Visconti to send in the TPP prescription after the fact. After August/September 2017 Mr. Abu Zahra noticed the number of missing TPP prescriptions was increasing. Mr. Abu Zahra suggested that the pharmacy may be missing between 500 to 1,000 TPP prescriptions.

In August 2018 Mr. Abu Zahra submitted his written response and the marked-up spreadsheet showing the dispensing events where the pharmacy did not have a prescription for TPP medications. Included with the response was a statement signed by staff of the Boyle McCauley Pharmacy setting out their attempts to get Dr. Visconti to catch-up on issuing the TPP prescriptions. Mr. Abu Zahra indicates that once he began to realize the number of missing TPP prescriptions, he began to regularly follow-up with Dr. Visconti and contacted the CPSA. Mr. Abu Zahra was not aware that Dr. Visconti was going to be suspended from his practice.

During the investigation Mr. Abu Zahra provided Mr. Krempien with a copy of an undated fax that Mr. Abu Zahra had sent to Dr. Visconti indicating that the Boyle McCauley Pharmacy had an inspection from Health Canada which concluded that the pharmacy was very behind in obtaining TPP prescriptions. The letter indicates that Health Canada sent some examples of missing TPP prescriptions to the CPSA. The letter asks Dr. Visconti for his suggestions on how to address the missing TPP prescriptions and asks when he could provide the missing TPP prescriptions. The letter notes that Mr. Abu Zahra needs to inform Health Canada about the missing TPP prescription. The fax imprint with the date is March 8, 2018. Dr. Visconti faxed a copy of the letter back to Mr. Abu Zahra with a handwritten note on the fax: "We have ordered more. Tell them the printer [has] been late to deliver them."

Mr. Krempien met with Mr. Abu Zahra on August 10, 2018 to review the spreadsheet with the annotations from Mr. Abu Zahra and a staff pharmacist. From the review Mr. Krempien concluded that the pharmacy was missing approximately 1,309 TPP prescriptions for narcotics dispensed to patients between January 1, 2018 and May 7, 2018. Mr. Abu Zahra reiterated the information about his contact with the CPSA and the attempts to get Dr. Visconti to clear-up the backlog. At the meeting Mr. Abu Zahra explained the practice adopted by the Boyle McCauley Pharmacy. Dr. Visconti would see his patients that required TPP medications every week. Then Dr. Visconti's office would fax a written prescription (not a TPP prescription) to the pharmacy after the patient's weekly appointment. At some point afterwards Dr. Visconti was to send the corresponding original TPP prescription to the pharmacy. The staff would maintain a list of the missing TPP prescriptions and regularly send it to Dr. Visconti's office to try to get him to issue the missing TPP prescriptions.

After discussion about the number of missing TPP prescriptions, it was agreed that Mr. Abu Zahra was going to provide some additional information concerning the accuracy of the

marked-up spreadsheet. James Krempien received this information at the end of August 2018 which indicated that in addition to the 1,309 missing TPP prescriptions, there were an additional 86 missing TPP prescriptions identified. There would be additional “dispensing events” associated with each missing TPP prescription but it was verified that there were 1,395 missing TPP prescriptions.

On November 6, 2018 Mr. Krempien made a decision to refer the matter to a hearing. The Record of Decision indicates that the Triplicate Prescription Program document requires dispensers be presented with the top two copies of the TPP form for Type 1 medications. He concludes that between January 1, 2018 and May 3, 2018 the Boyle McCauley Pharmacy dispensed approximately 1,395 Type 1 TPP medications for Dr. Visconti without ever receiving a TPP prescription. Mr. Krempien testified about the reasons for referring the matter to a hearing. The number of missing TPP prescriptions was very large- almost 1,400 in 120 days. This means that the pharmacy was dispensing medication 10 or 11 times every day without the required TPP prescriptions and for which no TPP prescription was ever received. Mr. Abu Zahra and the staff had taken some steps to try and address the issue, but they were ineffective, and the pharmacy kept dispensing the TPP medication even as the problem of missing TPP prescriptions got worse and worse. As a licensee, Mr. Abu Zahra was responsible for compliance with the TPP Program.

Mr. Krempien gave evidence about the TPP which has been in existence since about 1986. It is a mandatory program for pharmacists, physicians and other health professional prescribers whose regulatory bodies are part of the program. The TPP is addressed in the education for pharmacists. The TPP helps ensure the appropriate prescribing, dispensing and security of narcotics. The TPP is described on the College website and is noted as being mandatory for pharmacists. James Krempien testified that pharmacists are aware of the program and that compliance is mandatory. On cross-examination, James Krempien did not identify any statute, regulation, or bylaw that explicitly stated that the TPP program was mandatory for pharmacists.

Originally pharmacists had to receive two copies of TPP prescriptions. The pharmacist would maintain one copy at the pharmacy and send the other copy to the CPSA. This was changed on July 1, 2017 so that, with a few exceptions, pharmacists did not need to send a copy of the TPP prescription to the CPSA since information about TPP prescriptions are provided to the CPSA from dispensing events that are loaded to Alberta Netcare.

Mr. Krempien testified that rather than providing a physical copy of the TPP prescription to the patient, a physician might fax the TPP prescription to the pharmacy. It is acceptable for pharmacists to accept the fax. Mr. Krempien addressed whether it was ever appropriate for a pharmacist to fill a TPP medication using a regular prescription form with the TPP prescription to follow. He indicates that pharmacists could do so in exceptional circumstances if the patient needed the medication and the TPP was not available. He said that every pharmacist might come across this situation once or twice a year but that it was exceptional and uncommon. He indicates that in the case of emergencies the TPP does permit pharmacists to dispense relying on a regular prescription with the TPP to follow. From his perspective, the practice at the Boyle McCauley Pharmacy does not fall within the emergency exception and is not acceptable practice in his view.

Shao Lee

Dr. Shao Lee is the Professional Practice Director for the ACP. She has a PhD in clinical practice and patient assessment. Ms. Lee testified about the TPP. She sits on the TPP committee. Those medications identified as Type 1 must be written on a TPP prescription form so that the use can be monitored. Pharmacists are expected to follow the program. Type 2 medications are those with concerns with abuse or misuse. They are monitored but can be written on a regular prescription.

Dr. Lee addressed the TPP prescription form. A particular form is required to be used to help avoid diversion of narcotics. The form itself is difficult to reproduce due to security features. The quantity of the medication must be identified using both numbers and letters to prevent zeros being added to the quantity by patients. Each prescriber is assigned a TPP pad with their own number unique to that prescriber. When the pharmacist is presented with a TPP prescription, the pharmacist must ensure the form is signed by the patient or the patient's agent. The prescription is only current for 72 hours. The prescription is not complete until all information on the TPP prescription form is filled out.

Dr. Lee was asked when it might be appropriate for a pharmacist to dispense a TPP medication with only a regular prescription form. Dr. Lee said this should only happen very rarely. If there was an emergency and a physician was unable to immediately access their TPP prescription pad, then this may be appropriate for a pharmacist to fill the prescription. In an emergency the pharmacist could accept the regular prescription form but the TPP prescription form has to be obtained later. As set out in the TPP document, the obligation on pharmacists is to ensure that the prescription is current, authentic, complete, and appropriate. It is not complete until the TPP prescription form is received. Dr. Lee considers that it is a highly irregular practice for a pharmacist to dispense Type 1 medications using a regular prescription form and then wait until later to get the TPP prescription form. She considers this unacceptable. New graduates are tested on their understanding of the TPP through the jurisprudence module that must be completed. The TPP program is also addressed in the structured practical training that students must undertake prior to licensing.

The ACP Standard 6 requires that each pharmacist must determine that the prescription is "current, authentic, and complete." Dr. Lee does not consider that a prescription covered by the TPP is complete unless the properly completed TPP prescription is received.

Dr. Lee acknowledges that the TPP is not explicitly addressed in the standards of practice, but the standards require compliance with legislation, and she considers that this includes provincial programs such as the TPP. Dr. Lee indicated that there would have been a resolution of the Council of the College deciding to participate in the program. Since 1986 the expectation is that all members would follow the program.

Rajeh Abu Zahra

Mr. Abu Zahra testified about his background, his interactions with Dr. Visconti and about the investigation. Mr. Abu Zahra obtained registration with the ACP and began practicing in 2008. He worked in various roles and then obtained the opportunity to be involved with the

Boyle McCauley Pharmacy. Since 2012 to the present he has been a 100 percent shareholder and the licensee.

Mr. Abu Zahra is aware of the requirements of the TPP. He ensures that the program is followed at the Boyle McCauley Pharmacy. He indicated that many of the patients at the Boyle McCauley Pharmacy are referred by the Boyle McCauley Health Centre. Many of the patients are drug or alcohol dependent. Most are on pain management or opioid dependence programs.

Mr. Abu Zahra addressed his business relationship with Dr. Visconti. He indicated that many of Dr. Visconti's patients live in the Boyle McCauley area. Dr. Visconti wanted to deal with one pharmacy for his patients, so he began sending patients with triplicate prescriptions to the Boyle McCauley Pharmacy. Mr. Abu Zahra indicated that Dr. Visconti wanted to restrict his patients to one pharmacy, so they were easier to monitor. The general volume of prescriptions for Dr. Visconti's patients on a daily basis might be 15, 20, or 30 prescriptions to be filled. Quite a few of Dr. Visconti's patients would need to have prescriptions filled every week. Sometimes the patients would come to the pharmacy and for other patients the pharmacy would deliver to them. Dr. Visconti would fax prescriptions to the pharmacy. Sometimes they were TPP prescriptions and sometimes regular prescriptions. Most were regular prescriptions with the understanding that the TPP prescriptions would follow. The pharmacy would fill the prescription relying on the regular prescription. The pharmacy developed a practice of maintaining a list of the missing TPP prescriptions and then would fax the list to Dr. Visconti's office. At the start Dr. Visconti would forward the missing TPP prescriptions in a timely manner - usually in a week or so. However, this changed.

In the summer of 2017 Mr. Abu Zahra was away on vacation overseas. He came back in August 2017 and learned from the team at the pharmacy that Dr. Visconti was very behind in sending the TPP prescriptions. In the Fall of 2017, he began to try to find a solution. He went to Dr. Visconti's office a couple of times. Dr. Visconti claimed that the CPSA was behind in sending him TPP prescription pads but that by early the next year the problem should be solved. Mr. Abu Zahra believed Dr. Visconti when he said that the CPSA was behind.

With respect to the fax to Dr. Visconti concerning the Health Canada inspection, Health Canada did inspect the Boyle McCauley Pharmacy, but they had not identified any issue with Dr. Visconti's TPP prescriptions. However, Mr. Abu Zahra used the inspection as a way to put pressure on Dr. Visconti to address the problem. On cross-examination, Mr. Abu Zahra said he didn't remember if Health Canada took copies of Dr. Visconti's prescriptions or whether they were going to contact the CPSA.

When matters did not improve in 2018, he began contacting the CPSA. He phoned at least 3 times and at some point, he discussed the issue with Dr. Wickland-Weller. He said that they were short a very large number of TPP prescriptions from Dr. Visconti and asked her what advice she would give him. She said that she could not disclose information to him about Dr. Visconti. Mr. Abu Zahra believes this conversation was before the public announcement of Dr. Visconti's suspension. He thinks he may have also spoken to Dr. Wickland-Weller after

Dr. Visconti's suspension. He believes that the CPSA told him there was nothing they could do. Given that Dr. Visconti was suspended, the CPSA was not going to give him more TPP prescription pads.

With respect to the investigation, Mr. Abu Zahra accepts that in the time period of January 1, 2018 to May 3, 2018 there are about 1,395 missing TPP prescriptions. He does believe that the prescriptions he filled for Dr. Visconti were all current, authentic and complete.

On cross-examination, Mr. Abu Zahra acknowledged that he was familiar with the TPP and understood he was expected to comply with it. He tried to comply. He understood that a TPP was only valid for 72 hours. With respect to the obligation in the TPP of having patients sign the TPP prescription, Mr. Abu Zahra explained that he would have the patient sign the regular prescription. Then when the TPP arrived a few weeks later, they would attach the TPP with the regular prescription. When Dr. Visconti completed the TPP prescription after the fact, he would back-date the TPP to the date he wrote the regular prescription. Mr. Abu Zahra acknowledged that by 2017 the regular practice at the pharmacy was to get a regular prescription for TPP medication, dispense the medication relying on the regular prescription and get the TPP prescription at some point later.

On cross-examination Mr. Abu Zahra was also asked about pharmacists being allowed to fill TPP medication using a regular prescription form in "emergencies." He considered that he was acting within the rules because he knew that Dr. Visconti would fill out the TPP later. He says he called the ACP office and was told that pharmacists can use their professional judgment to dispense using a regular prescription but need to ensure that the physician sends the completed TPP later. He also considered the prescriptions to be accurate and complete because the pharmacists were checking for the right drug, the right patient, and the right dose.

With respect to the period of time when pharmacists were required to submit the TPP prescriptions to the CPSA, the pharmacy would submit only the TPP once received. They would not submit the original regular prescription. Mr. Abu Zahra was not aware of the requirement in the TPP document to submit both the regular and the TPP prescription.

V. SUBMISSIONS

On behalf of the Complaints Director, David Jardine made a number of submissions summarized briefly below:

- He reviewed the TPP Document arguing that Mr. Abu Zahra was clearly not compliant. The document states that pharmacists as per ACP standards of practice must ensure that the prescription is current, authentic, complete and appropriate. Prescriptions issued on TPP forms are only valid for 72 hours. If

the TPP prescription is not received until after 72 hours how can the prescription be considered complete?

- The TPP program provides that pharmacists should not fill prescriptions for TPP medications issued on regular prescription forms. The program description says that “occasionally” there are legitimate circumstances where the prescriber can use a regular prescription as a temporary substitute. The ACP website indicates that it can be done in an “emergency” situation. Dr. Lee testified about the practice being justified on rare occasions. Instead of dealing with the possibility of filling TPP medications occasionally or in emergency situations without a TPP prescription, Mr. Abu Zahra established this process as a regular and routine practice.
- Patients would not sign the actual TPP prescription even when Dr. Visconti submitted them later.
- There was systematic avoidance of the TPP requirements with 1,395 missing TPP prescriptions in a short period of time. No TPP prescriptions were ever received for January and February prescriptions.
- Even after Mr. Abu Zahra sent the fax to Dr. Visconti about the Health Canada inspection, the pharmacy continued to fill Dr. Visconti’s prescriptions with no TPP prescriptions. This continued right up until Dr. Visconti’s suspension.
- The TPP program is mandatory. Mr. Abu Zahra admitted that he was aware of the program and that he was supposed to comply. While the TPP program is not addressed in the standards of practice or the code of ethics, regulatory obligations go beyond that. The program was adopted by the ACP more than 33 years ago. It has been part of practice since 1986. The obligations are addressed in the jurisprudence examination. Dr. Lee testified that compliance is not optional. The Standard of Practice for pharmacies requires not only compliance with the law but also the spirit of the law. The spirit of the TPP program is to control and monitor dangerous narcotics. There are many programs adopted by the ACP that may not be specifically set out in a standard of practice. Not every expectation for practice has to be formalized in a standard of practice.
- Section 6 of the Standard of Practice for pharmacists requires that they must determine that the prescription is current, authentic, and complete. Prescriptions for TPP medications where the TPP prescription form is never received cannot be considered “complete” in any way.
- The actions of Mr. Abu Zahra undermined the integrity of the profession. The ACP entered into the TPP with other professions and the program depends on the compliance by professionals. The conduct shows a lack of skill and judgment. The actions are also misconduct as a licensee since Mr. Abu Zahra was responsible for the pharmacy and he supported a system designed to

circumvent the TPP which was established to protect the public. The actions of Mr. Abu Zahra undermined the best interests of the public.

On behalf of the Mr. Abu Zahra, Simon Renouf made a number of submissions summarized briefly below:

- The TPP does not have the force of law and if it does not have the force of law, then Mr. Abu Zahra cannot be found to have engaged in unprofessional conduct as a pharmacist and he cannot be found to have breached his obligations as a licensee.
- The whole area of drugs is highly regulated and highly codified and yet the TPP is not mentioned in the *Health Professions Act*, the regulations under the HPA, the Schedule in the HPA for the pharmacy profession, *the Pharmacy and Drug Act*, the ACP's standards of practice, the ACP's code of ethics, or in federal legislation concerning drugs and narcotics.
- There is uncertainty about what exactly happened back in 1986 with respect to the adoption of the program. No proof was presented by the ACP that the February 2012 version of the TPP was formally adopted by the ACP.
- Mr. Abu Zahra believed he was complying with the program. The medication was dispensed within 72 hours of receiving the regular prescription with the understanding that Dr. Visconti would send in the TPP prescription. Obviously, the dates on the two needed to match. Also, the TPP provides that pharmacists can accept faxed prescriptions, and in some cases, it is preferable to fax a prescription rather than provide the prescription directly to a patient.
- The TPP contemplates that in certain cases the pharmacist can dispense TPP medications relying on the regular prescription. The TPP is clear that it is the responsibility of the physician to ensure that the TPP prescription is subsequently sent. Nothing obligates the pharmacist to follow-up. The ACP gives no guidance on what a pharmacist should do if the physician does not follow-up as required.
- Even though the obligation to follow-up rests on the physician, Mr. Abu Zahra did what he could. He contacted Dr. Visconti directly and contacted the CPSA.
- Mr. Abu Zahra complied with all obligations that have the force of law and as a result there should be no findings against him.

VI. FINDINGS

Background

The Hearing Tribunal carefully considered the evidence presented during the hearing, including the testimony provided by the Complaints Director for the ACP, Mr. James

Krempien; the Director of Professional Practice for the ACP, Dr. Shao Lee; and, the investigated person, Mr. Rajeh Abu Zahra.

Mr. Abu Zahra has been licensed to practice pharmacy in Alberta and has been a licensee at the Boyle McCauley Pharmacy since 2008. The Hearing Tribunal's mandate was to consider whether the allegations were factually proven and whether or not the actions by Mr. Abu Zahra rose to the level of unprofessional conduct under the *Health Professions Act* and/or misconduct under the *Pharmacy and Drugs Act*.

For reference, Type 1 Medications under the TPP are narcotics or controlled drugs that pose a particular risk to the public that includes misuse, abuse, and diversion. The TPP requires prescribers to register with TPP Alberta in order to prescribe Type 1 medications and only use secure TPP forms to prescribe them. Type 1 TPP medications include: Buprenorphine, Butalbital preparations, Butorphanol, Dextropropoxyphene, Fentanyl/Sufentanil/Alfentanil, Hydrocodone-Dihydrocodeinone, Hydromorphone-Dihydromorphinone, Ketamine, Meperidine-Pethidine, Methadone, Methylphenidate, Morphine, Normethadone, Oxycodone, Pentazocine, Tapentadol.

Is compliance with the TPP mandatory for pharmacists?

One of the central defenses presented by Mr. Abu Zahra is that compliance with the TPP is not mandatory. Mr. Renouf submits that the TPP program was designed by physicians and that there is no legislation, regulation, or standard that compels a pharmacist to comply with the Triplicate Prescription Program. Mr. Renouf argues that the TPP does not have the "force of law."

The Hearing Tribunal considered whether the Triplicate Prescription Program (TPP) in Alberta is binding on a pharmacist and a pharmacy licensee such that noncompliance would be subject to sanction. According to Dr. Lee's testimony, participation in the TPP was adopted by the council of the Alberta Pharmaceutical Association, circa 1986.

The decision of Council to adopt and participate in the TPP is consistent with the role of the ACP as set out in section 3 of the *Health Professions Act*:

3(1) A college

(a) must carry out its activities and govern its regulated members in a manner that protects and serves the public interest,

(b) must provide direction to and regulate the practice of the regulated profession by its regulated members,

(c) must establish, maintain and enforce standards for registration and of continuing competence and standards of practice of the regulated profession,

(d) must establish, maintain and enforce a code of ethics, ...

The obligation to provide direction to the regulation of the profession in section 3(1)(a) is met by the ACP in a number of ways. For example, the ACP is required to establish standards of practice and codes of ethics, but this is not the only way that the ACP provides guidance to the profession. Guidance and direction is also provided by the ACP's choice to participate in certain programs. In this case, the Council of the ACP decided to participate in the TPP program. As noted in the TPP document the program was established by the CPSA in partnership with pharmacists and dentists in 1986.

The Hearing Tribunal considered Dr. Lee's testimony relative to the inception of Pharmacy's partnership in the TPP program and the rationale behind why it is a part of accepted practice for pharmacists in Alberta. The Triplicate Prescription Program goals and operational parameters have been included as a part of the curriculum for pharmacists at the University of Alberta since adoption by the council of the Alberta Pharmaceutical Association; is included in the Structured Practical Training for pharmacists; is included in the Jurisprudence examination for licensure with the Alberta College of Pharmacy; program information is posted on the ACP website; and, any changes to the Triplicate Prescription Program operational parameters are communicated through the ACP website and through the ACP newsletter, *The Link*. Mr. Krempien also testified that compliance is mandatory, and this is understood by pharmacists. Mr. Abu Zahra testified that he understood the TPP program and that he was expected to comply with it.

The TPP Document is available to all pharmacists because all are expected to comply with the program. The document includes dispensing information for pharmacists and indicates that: "The pharmacist must ensure that the prescription is current, authentic, complete, and appropriate as per ACP standards of practice." This is a reference to the ACP Standard of Practice for Pharmacists and Pharmacy Technicians, Standard 6. The TPP Document provides that pharmacists should not fill TPP prescriptions issued on regular prescription forms unless the exception for "occasional" and "legitimate circumstances" applies. If a pharmacist routinely accepts a prescription on a regular prescription form for a TPP Type 1 medication, there can be no valid exception established and, therefore, the Hearing Tribunal does not consider that the prescription can be considered complete. This reinforces the mandatory nature of compliance with the TPP program adopted by the Council of the ACP.

Pharmacists have understood the philosophy and operational parameters of the TPP program and have participated as full partners in it for approximately 33 years. Therefore, participation in, and proper execution of, the TPP is a part of accepted pharmacist practice. The Hearing Tribunal concludes that participation in the TPP by pharmacists and licensees in Alberta is a valid expectation of the ACP, the TPP program partners, and the Public. Compliance is mandatory.

Mr. Renouf raised the issue of whether the ACP has established that the TPP was properly adopted by the ACP and indicated that there was no evidence that February 2012 was properly adopted. Dr. Lee's evidence confirmed that Council passed a resolution to participate in the program back in 1986. Both Dr. Lee and Mr. Krempien testified that the February 2012 TPP Document is the document that the ACP uses to set forth the expectations on pharmacists. There is a presumption that the TPP Document was properly adopted by the ACP. Mr. Abu Zahra has not presented any evidence to the contrary.

Specific Allegations

Having concluded that compliance with the TPP program is mandatory, our analysis with respect to the specific allegations against Mr. Abu Zahra are set out below:

Between January 1, 2018 and May 3, 2018, while you were both a licensed Alberta pharmacist and the licensee of Boyle McCauley Pharmacy & Home Health Care (ACP License #2498), you:

- 1) Knowingly dispensed or as the licensee, permitted your staff to dispense approximately 1,395 Type 1 Triplicate Prescription Program medications for one physician prior to, and without ever, receiving a Triplicate Prescription Program form from that physician for the Type 1 medications.**

The Hearing Tribunal concluded that this allegation was factually true based on the information provided in Exhibits 3 and 4, and from the testimony provided by Mr. Krempien and Mr. Abu Zahra. Mr. Zahra admitted that this allegation was factually accurate.

The Hearing Tribunal acknowledged the mandate and the operational parameters of the TPP as presented in the TPP Document, Exhibit 5, Tab 1. The TPP was designed to create a system of collaborative practice and surveillance around specific narcotics and controlled medications that pose serious health risks to the public. Pharmacists are important stewards of the drug distribution system and the public expects pharmacists to exercise professional judgement to ensure each prescription for a Type 1 TPP medication is complete, current, authentic, and appropriate for the patient. The Hearing Tribunal felt this is particularly significant in light of the current health crisis that Alberta faces with respect to the abuse, misuse, and diversion of Opioid medications.

From the testimony of Dr. Lee, the only instance where a Type 1 Medication under the TPP program would be dispensed without the requisite TPP form, would be on rare occasions when an exceptional situation occurred. The only way an exceptional situation could be declared is through collaborative assessment of the circumstances between physician and pharmacist. The pharmacist has the authority to decline to dispense the medication. However, if the pharmacist chooses to dispense the medication in this situation, a legitimate TPP form for the Type 1 medication must be provided within a “reasonable” time. According to Dr. Lee’s testimony, this would be an exceptional circumstance in regular practice, but the program allows for the pharmacist to exercise professional judgement. As noted in the TPP Document, pharmacists are not to dispense a TPP prescription issued on regular prescription forms. The TPP Program Information indicates that “occasionally” there are legitimate circumstances where the prescriber can use a regular prescription as a temporary substitute and the pharmacist can dispense; provided they are “satisfied regarding the circumstance.” The ACP website indicates that physicians are required to write triplicate prescriptions on personalized TPP pads. The website also states that if in an “emergency” situation the physician writes a triplicate on a regular prescription pad, the physician must follow up by providing the pharmacy with a TPP prescription form.

The Hearing Tribunal concluded that it is highly unlikely that an individualized legitimate assessment of exceptional circumstance could have occurred 1,395 times between January 1, 2018 and May 3, 2018 in a single pharmacy from a single physician. The public expectations of pharmacists to exercise judgment with each prescription has increased with the evolution and expansion of the scope of practice for pharmacists. Therefore, it was Mr. Abu Zahra's responsibility, and that of the pharmacists under his supervision, to make the assessment for each of these prescriptions that they would qualify as occasional exception such as an emergency. No evidence was provided that these assessments were performed. Mr. Abu Zahra testified that there may have been 1 or very few emergencies or exceptions. He also confirmed that he was fully aware of the TPP operational rules as he has been a licensed pharmacist in Alberta since 2008. It was Mr. Abu Zahra's responsibility as a pharmacist and as a licensee to exercise professional judgement and decline to dispense prescriptions issued by Dr. Visconti that were not written on legitimate TPP forms unless Mr. Abu Zahra made an individualized assessment that there was a legitimate and occasional exception due to matters such as an emergency. Instead, the number of TPP medications dispensed without TPP prescriptions reached 1,395. The testimony of Mr. Abu Zahra and Mr. Krempien and the evidence from Exhibits 3 and 4 make clear that the process for assessment for TPP prescriptions from Dr. Visconti at Boyle McCauley Pharmacy and Home Health Care was performed retrospectively and in batches. The prescriptions for the Type 1 TPP medications continued to be dispensed, many on a daily basis, without ever receiving a valid TPP form.

Mr. Renouf argues that the ACP website and the TPP Document provides that it is the physician's responsibility to follow-up with a triplicate prescription where he or she wrote a prescription on a regular prescription pad. It is the physician's responsibility to do so. However, it is also the pharmacist's responsibility to not dispense TPP medications written on regular prescription forms except "occasionally" where the pharmacist is "satisfied regarding the circumstances." One of those circumstances would be an "emergency" as set out in the ACP website. Instead of complying with these obligations, Mr. Abu Zahra developed a routine operating practice of accepting all TPP prescriptions written by Dr. Visconti on regular prescription pads regardless of the circumstances and then attempting to get Dr. Visconti to send in the TPP prescriptions later.

The Hearing Tribunal concluded that allegation 1 is factually established.

2) Failed to comply with the Triplicate Prescription Program requirement to dispense Type 1 medications pursuant to a Triplicate Prescription Program Prescription over an extended period of time.

The issues with respect to dispensing Type 1 medications on the TPP program prescribed by Dr. Visconti, were evident many months prior to January 1, 2018 (Exhibit 4 Tab 11). Through Mr. Abu Zahra's testimony, we learned that he and his pharmacy staff routinely accepted and dispensed Type 1 medications without the requisite TPP form. The pharmacy staff were able to obtain the TPP forms retrospectively for the most part by communicating with Dr. Visconti and itemizing the prescriptions that required the TPP forms. This process was not based on assessment of the prescription and the circumstance, but rather, on the convenience of Dr. Visconti. Once again, through Mr. Abu Zahra's testimony, we learned that upon return from vacation in August of 2017, the situation of receiving prescriptions for

Type 1 TPP medications without the requisite TPP form had increased dramatically. While the pharmacy was keeping a record of the Type 1 TPP prescriptions that did not have the required TPP forms, the medications continued to be dispensed. Mr. Abu Zahra did contact Dr. Visconti's office to register a concern after the Health Canada audit and did contact the College of Physicians and Surgeons of Alberta. He also created a spreadsheet of prescriptions that were deficient of the requisite TPP form that was sent to Dr. Visconti's office weekly at first, then as the problem worsened, "when they could", as the pharmacy was achieving very limited success. However, the prescriptions continued to be dispensed, again, many on a daily basis. As noted in the response to Allegation 1 above, the only circumstance where a Type 1 TPP medication could be dispensed without the requisite TPP form being provided would be on an "occasional basis" where the pharmacist was "satisfied regarding the circumstances" such as an "emergency." There is no evidence that Mr. Abu Zahra or his pharmacist staff assessed the 1,395 Type 1 medications from January 1, 2018 to May 3, 2018 and collaboratively, with Dr. Visconti, determined that the situations qualified as an "exception" under the TPP program. Yet, these prescriptions were dispensed. Mr. Abu Zahra noted in his testimony that in the future he would do the same thing but would be more proactive in getting the Triplicate prescription forms from the doctor, albeit retrospectively. The fact that Dr. Visconti was suspended and could not "cover" the missing TPP forms is irrelevant to the legitimacy of the allegation as it was the responsibility of Mr. Abu Zahra to exercise appropriate professional judgement well before this situation became as protracted as it did. This resulted in a clear failure to comply with the rules of the TPP program with respect to the 1,395 Type 1 medications dispensed between January 1, 2018 and May 3, 2018. The Hearing Tribunal has concluded that Allegation #2 is factually established.

3) Inappropriately created procedures to facilitate the ongoing dispensing of Type 1 Triplicate Prescription Program medications without requisite Triplicate Prescription Program prescriptions.

This allegation is factually true and relates to Mr. Abu Zahra's capacity as a licensee of the ACP. He created the operational procedures that allowed Type 1 TPP medications to be dispensed without the requisite TPP forms. While he did create a spreadsheet that was sporadically updated and communicated to Dr. Visconti, it was abandoned altogether as the TPP discrepancies escalated. Furthermore, this practice amounted to assessing prescriptions in batches and endeavoring to collect the requisite TPP forms retrospectively. This policy clearly eliminated any requirement to assess each Type 1 TPP prescription as to whether the circumstances constituted an "exception", and actually facilitated the continuation of the process to dispense Type 1 TPP medications without a TPP form. Dr. Visconti's status with the College of Physicians and Surgeons of Alberta and subsequent inability to "cover" missing TPP forms is of no consequence to the allegation, as it was the responsibility of Mr. Abu Zahra as the licensee to create policies and procedures that were consistent with the rules of the Triplicate Prescription Program, the *Health Professions Act* and, the *Pharmacy and Drugs Act* to prevent this situation from occurring at all. Mr. Abu Zahra developed a systematic process to avoid the general obligation to only fill TPP medications if a TPP prescription form is provided. Mr. Abu Zahra failed in his responsibilities as licensee to fulfil these and the result was 1,395 Type 1 TPP medications being dispensed without the requisite TPP forms. The Hearing Tribunal finds Allegation 3 is factually well founded.

4) Failed to ensure that required pharmacy records, in particular all Triplicate Prescription Program prescriptions or prescriptions required to be filled under the Triplicate Prescription Program, received by Boyle McCauley Pharmacy & Home Health Care were properly maintained and stored.

During the hearing, it was confirmed that there was no allegation that the regular prescriptions received by the Boyle McCauley Pharmacy were not properly maintained and stored. Instead, Mr. Jardine confirmed that the substance of the allegation 4 is that Mr. Abu Zahra was required to ensure he received TPP prescriptions for TPP medications and he did not. The substance of allegation 4 is covered by allegations 1 and 2 and as a result is duplicative. Accordingly, the Hearing Tribunal does not make any finding against Mr. Abu Zahra with respect to allegation 4.

Given the factual findings set out in our analysis of allegations 1, 2 and 3, we must determine if this constitutes unprofessional conduct under the *Health Professions Act* and/or misconduct under the *Pharmacy and Drug Act*. To summarize our conclusions: Mr. Abu Zahra developed a procedure at the Boyle McCauley Pharmacy designed to systematically evade the requirements of the TPP by routinely dispensing a very large volume of TPP medications relying on regular prescription forms with an attempt to get the TPP prescription forms at some later time. Mr. Abu Zahra and his staff routinely failed to conduct an individualized assessment of the circumstances to determine whether the circumstances justified an occasional exception such as an emergency permitting them to dispense the TPP medication relying on a regular prescription form and obtain the TPP prescription soon after. Mr. Abu Zahra routinely failed to comply with the TPP.

The Hearing Tribunal finds that Mr. Abu Zahra has breached his statutory and regulatory obligations to the Alberta College of Pharmacy as a pharmacist and a pharmacy licensee by failing to comply with the Alberta Triplicate Prescription Program Guide, which at the time stated that dispensers must be presented with two copies of the Triplicate Prescription Program form for Type 1 medications. The Hearing Tribunal has concluded that this is a violation of section 1(1)(pp)(iii) of the *Health Professions Act* and this constitutes unprofessional conduct under this act. The Hearing Tribunal also concluded that this was a violation of sections 10(1)(d)(i) of the *Pharmacy and Drug Act*. Failure to obtain the requisite TPP forms for 1,395 Type 1 medications constitutes misconduct under this Act.

The Hearing Tribunal concluded that Mr. Abu Zahra has undermined the integrity of the profession of pharmacy and is, therefore, in violation of section 1(1)(pp)(xii) of the *Health Professions Act* and section 1(1)(p)(ix) of the *Pharmacy and Drug Act*. This constitutes unprofessional conduct under the *Health Professions Act* and misconduct under the *Pharmacy and Drug Act*. As a partner in the Triplicate Prescription Program for approximately 33 years, the other partners in the program (the Alberta Dental Association and College, the Alberta Veterinary Association, the College of Physicians and Surgeons of Alberta, and the Yukon Medical Council) trust in the profession of pharmacy to consistently dispense Type 1 medication according to TPP rules. This is critical to achieve the program

objectives of reducing abuse, misuse, and diversion of these medicines in order to protect the public, especially in the midst of the Opioid crisis Alberta faces. This trust is severely undermined if a pharmacist can arbitrarily decide not to follow the program rules and not exercise the professional judgment expected of a pharmacist in Alberta. The Hearing Tribunal also concludes that Mr. Abu Zahra has undermined the integrity of the profession of pharmacy in the eyes of the public. Government and the public at large expect and depend upon pharmacists to exercise professional judgement and assess each prescription to ensure that it is current, authentic, complete and appropriate. Mr. Abu Zahra has failed to meet this expectation by failing to abide by the rules of the TPP program.

The Hearing Tribunal concluded that Mr. Abu Zahra was in violation of sections 1(1)(p)(i) and 1(1)(p)(ii) of the *Pharmacy and Drug Act* and this constitutes misconduct under this act. The Triplicate Prescription Program has been in existence since 1986 and was designed to establish an integrated system of collaborative practice and surveillance amongst the TPP partners to ensure the safe, effective, and appropriate use of specific narcotics and controlled drugs that pose a potential health risk to the public. The integrity of this program is vital if it is to achieve these goals and maintain safeguards against abuse and misdirection of Type 1 TPP medications. Mr. Abu Zahra chose to create policies and procedures to circumvent the program rules and continue to dispense Type 1 TPP medications without first receiving valid TPP forms. He was fully aware of the problematic prescribing history of Dr. Visconti by routinely writing prescriptions for TPP medications using regular prescriptions forms. Mr. Abu Zahra chose to create policies that perpetuated this behavior and, consequently, the situation worsened dramatically until it became unmanageable. This was clearly counter to the public interest and, therefore, in violation of the sections of the *Pharmacy and Drug Act* identified above.

The Hearing Tribunal concludes that Mr. Abu Zahra failed to exercise the professional and ethical judgement expected and required of an Alberta pharmacist and a pharmacy licensee. Therefore, Mr. Abu Zahra was in violation of section 1(1)(pp)(i) of the *Health Professions Act* and this constitutes unprofessional conduct under this Act. Mr. Abu Zahra was directed by the profession of pharmacy via the ACP to comply with the rules of the Triplicate Prescription Program in order to protect the public. Instead, Mr. Abu Zahra interpreted the rules of the program to suit the needs of Dr. Visconti. While he did make efforts of attain TPP forms that were delinquent, he failed to exercise proper and timely professional judgement. Consequently, the situation escalated and became unmanageable. This is counter to the public interest. The profession, via the ACP, designed the Triplicate Prescription Program with the collaboration of partner organizations. Common goals were established to serve the public interest. Mr. Abu Zahra deferred to the needs of Dr. Visconti, rather than to serve the public interest. This is unacceptable practice, especially in consideration of the evolution of the scope of practice of pharmacists and the expectations that the public has for pharmacists.

To summarize our findings:

- We find that the conduct of Mr. Abu Zahra described above constitutes unprofessional conduct under the *Health Professions Act*: by displaying a

lack of knowledge or lack of skill or lack of judgment in the provision of professional services- s.1(1)(pp)(i); by contravening another enactment (the *Pharmacy and Drug Act*)-s.1(1)(pp)(iii); by harming the integrity of the regulated profession-s.1(1)(pp)(xii).

- We find that the conduct of Mr. Abu Zahra described above constitutes misconduct under the *Pharmacy and Drug Act*. Section 10(1)(d) requires licensees to ensure that all drugs dispensed to a patient are dispensed pursuant to a prescription. There were no proper prescriptions in 1,395 cases. We find that this contravenes the *Pharmacy and Drug Act* and constitutes misconduct –s.1(1)(p)(i). We find that the conduct is detrimental to the best interests of the public-s.1(1)(p)(ii) and is conduct that harms the integrity of the profession of pharmacists-s.1(1)(p)(ix).

VI. ORDERS

The Hearing Tribunal will hear submissions from the Complaints Director and Mr. Ab Zahra with respect to the orders that the Hearing Tribunal should make. The Hearing Tribunal asks the Hearings Director to make arrangements for those submissions by way of written submissions. The parties should attempt to agree on the timing of the submissions. If the parties cannot agree then the Hearing Tribunal will establish the deadlines for written submissions.

Signed on behalf of the hearing tribunal by the Chair on August 7, 2019.

[Rick Hackman]
Rick Hackman