

Kim A. Ruthig, BSc(Pharm), RPh

August 21, 2008

By E-Mail Attachment

Annie Schiefer, Project Manager
Health Professions Regulatory Advisory Council
55 St. Clair Avenue West
Suite 806, Box 18
Toronto, Ontario, Canada M4V 2Y7

Dear Ms. Schiefer:

RE: Ontario College of Pharmacists (OCP) Submission to HPRAC re "Scope of Practice" (Pharmacy)

I have practised pharmacy in Ontario for 28 years, of which at least half were in the capacity of inspectional duties with both Health Canada and the OCP (Senior Investigator). I am presently employed as Director of Regulatory Compliance with three pharmacies. I am consulted by law enforcement agencies on practice-related issues, and I have attended numerous clinics concerning pharmaceutical fraud. I have, over the years, investigated a plethora of practice-related issues. As such, I feel qualified to address certain areas within the OCP submission to HPRAC, concerning pharmacy's "Scope of Practice."

I shall address my concerns in two ways: first, to the "Executive Summary" (ES) submitted by OCP; and secondly, by number within the detailed response provided to HPRAC's questions (per that numbering).

I concur, at the outset, with my colleagues' submissions and comments wherein they identify that pharmacist resources have been grossly under-utilized by government, as well as by other professions. My position is that pharmacy must be collaborative with other health care professionals (HCPs) and in doing so, cannot expect to be permitted to perform controlled acts which are the purview of other **properly educated** health professionals. In this regard, I fully endorse the concerns expressed by the Ontario College of Family Physicians.

Having said this, should **full consultation** with all involved parties (including pharmacists in a format more than an occasional district meeting) be undertaken, after which dialogue results in a general consensus permitting expansion of practice scope into other areas (whether "prescribing" or "extended dispensing" or whatever they may ultimately term it), then the public interest will not have been compromised. Such dialogue, especially with members, needs to outline the specifics of what such new "powers" will entail: not a "give us the means and trust that we'll figure it out" format. Giving such broad powers to any individual or organization can be dangerous, and Ontario pharmacists will be acutely aware of this with recent actions taken by the Ontario Drug Programs Branch.

OCP EXECUTIVE SUMMARY

I support the view, on page (ii) of the ES, that certain controlled acts (such as piercing of the dermis, administering insulin for demonstration purposes, and administering a substance by inhalation for educational purposes) should be permitted by pharmacists. I do, however, have a problem if it is suggested that actually performing such acts is the only way to properly educate the patient. Historically, placebo inhalers have been available for demonstration purposes, and showing how a lancet works can be done without having to actually pierce the patient's finger. In most of these cases, the patient will have

received instructions from a diabetic or asthma clinic, upon being diagnosed. And as has been mentioned in other submissions, there is "coverage" for occasional need to perform these actions, within s.29(1)(e) of the *Regulated Health Professions Act* (RHPA).

Page (ii) of the ES addresses proposed wording for the scope of practice:

"The practice of pharmacy is the promotion of health, ... through medication and non-medication therapy; ..."

Would this not create conflict with other health care practitioners who use non-medication therapy in their practice, being deemed to be "practising pharmacy?" One example is massage therapists. Given the proposed definition, they would be practising pharmacy. Perhaps, an exclusionary clause would correct this (e.g.: inserting in brackets after "non-medication therapy" the words: "(non-inclusive of other regulated health professions practising within their scope of practice", or putting such a statement at the end).

Reference to RHPA s.29(1)(e) "never [intending]...to circumvent the controlled acts model" suggests, by its very wording, that colleges will try to find ways around restrictive legislation. Ethically, this is completely inappropriate, as is allowing this to transpire pending regulatory change.

On page (iii) of the ES, bullet #6 (first bullet section), the "professional judgement" reference is disturbing. Historically, any situation where a pharmacist dispenses beyond an authorized, prescribed quantity is cited as "judgement" by the pharmacist, and in large part this is accepted by the OCP. In many cases, however, it's not a true "emergency". Under the PAPE agreement, it is proposed that up to a 3-month supply can be issued as "emergency" once only. But in the enforcement area, "emergency quantity" is generally taken as enough until the prescriber can next be contacted for authorization. Three months is far, far too long a supply for such circumstances (as may be the quantity "previously dispensed" as set out in the PAPE agreement). We cannot lose sight of the fact that doctors set out quantities and refills for a reason: patient care, in order to ensure that they see the patient at regular intervals. Allowing pharmacists to delay such visit up to 3 months later, is not good patient care and not in the public interest.

Further down page (iii), it reads: "Pharmacists will communicate these prescription changes to the family physician,...in a timely manner." "Timely manner" needs to be defined, and there is no reason it cannot be since a collaborative practice should include knowing when the prescriber will be available. As for the quantity allowed in the PAPE agreement, such time frame can be specific instead of vague.

The second bullet section on page (iii) is the area of most concern to me ("dispensing without further authorization"). In terms of the bullets:

Bullet #1: adapting an existing prescription (including from one dosage form to another, as well as changing a dose regimen)

I continue to be amazed by pharmacists who, as drug experts, do not see a difference in switching dosage forms and/or strengths. First, by the very Act that defines interchangeability in Ontario (DIDFA) they are not interchangeable. The pharmacist has no protection against liability by substituting a non-interchangeable drug for that prescribed. Second, rarely is consideration given to sugar/caloric content of the liquid format, or to the other flavouring ingredients.

Third, if the pharmacist switches the prescription, it becomes a new prescription, and then: who is the doctor? Certainly, the original prescriber (unless first consulted and approving the change) cannot be documented as such; her/his chart will show that the drug the patient received was as (s)he prescribed it, not as it was changed by the pharmacist. Should her/his name appear on the order and adverse events arise, the doctor could be drawn into investigation time (interviews, testimony, etc. as to what was actually prescribed) – all because her/his name appears as the prescriber.

Fourth, will drug plans accept the pharmacist as the prescriber? If not, I can almost guarantee that after one rejection, the next time such action is performed, the doctor's name will appear for the change – not the pharmacist's. And how does a regulatory agency with limited field resources even begin to "audit" such actions?

Fifth, if a drug is designed to be given every 12 hours, it is not always appropriate to tell the patient to take both daily tablets at the same time. Pharmacokinetics and bioavailability must be considered in each and every instance, and many practising pharmacists would not consider these issues in order to determine if it would be detrimental to the patient. Many factors need consideration before instituting such a proviso.

Sixth, changing a dosage form to one covered by a drug plan: I would first want to hear the positions of the *numerous* drug plans on this, before allowing it to be done. Pharmacists have been found guilty of professional misconduct in the past for putting OTC drugs “on prescription” in order to obtain coverage for the patient – and in many of these cases, it was the patient requesting it be done after seeing an advertisement for the drug. The doctor generally had no knowledge of it being taken, and denied having prescribed it. “Public interest” includes the public purse (often forgotten) and it is significant that drug plans are “cutting back” on benefits due to escalating costs, in part due to increased claims. Such actions will feed this escalation, with the result that plans won’t pay for certain drugs and will raise premiums for new members – not in the public interest.

Bullet #3: providing Schedule II and III drugs as a prescription where required for reimbursement under drug plans

Drug plans presently expect the doctor to be involved in the decision to add something to a patient’s regimen. Should the pharmacist later notify the doctor that he has “prescribed” for the patient, and the doctor says no, how do you reverse that after-the-fact? And of course: who is the prescriber in these cases? One can hardly allow the family doctor’s name to be put on the record, but this may be necessary in order to obtain drug plan coverage. There are significant liability issues to the doctor should her/his name be affiliated with legal records that did originate from her/him. The fact that these questions are not yet answered, suggests that a “rush to allow” should be halted until these facts are ascertained.

Bullet #4: adjusting dosage of medication in response to monitoring (e.g. lab tests)

One aspect not touched on in the ES, is that non-compliance to therapy by the patient could be the cause of the abnormal tests. To simply note an INR is high/low and adjust the therapy as a result, only to have the patient become compliant (and toxic) would be a disaster. However, provided that compliance is first investigated, and proven to be in place, then such adjustments could occur: but again, it would have to be a new prescription since by definition, the dosage and/or strength has changed. Again: would drug plans accept the pharmacist as prescriber?

On page (iv) of the ES, it is stated that “[t]his College has not pursued the controlled act of *prescribing* for pharmacists and within the timeframe allocated for this submission, **was not able to undertake the extensive consultation with members and other stakeholders required** to change this position.” (bold added) As stated earlier, until such “extensive consultation” is performed, a hold should be placed on any such authority being granted.

PERCEIVED CONFLICT OF INTEREST

It is ironic that pharmacists express concern over doctors dispensing from their offices, stating it is a “conflict of interest” for them to be able to prescribe and dispense. Now, pharmacists want the same conflict! And it *is* “prescribing” when one considers them putting Schedule II and III drugs on prescription, where they have not been previously prescribed – semantics aside. I can see how physician perspective of such conflict arise. However, such perception of conflict would not occur in situations where it is an extension of a previously-ordered drug. It is the concept of selecting “new drugs” (whether Schedule III, or II, or I) to prescribe that creates the conflict.

Situations where pharmacists obtain a “deal” on certain drugs in some way, and then benefit by “prescribing” them to patients create yet another opportunity for conflict, or perception thereof. (Such conflict is mentioned in the submission from the College of Family Physicians).

OCP DETAILED SUBMISSION

At page 4, top: The PAPE agreement is referenced. It is noted that in the OPA submission to

HPRAC, they state (at #12) that they have no intention to include “narcotics, controlled drugs or **targeted substances**” but the PAPE agreement, item #5, only specifies narcotics and controlled drugs. With benzodiazepines (targeted substances) being a category of drugs causing psychological and physiological dependence with protracted use, and generally recommended in the professional literature for “short term use (less than one month continuously)”, permitting extensions of these drugs up to three months is not in the patient's best interests. If practitioners abuse their privilege to prescribe such substances, they can be put on notification by Health Canada (through consultation first with the licensing body), which can result in their losing their prescribing privilege for such drugs. Pharmacists would have to be put into that same category if they were to prescribe such items, and that would require regulatory changes at the federal level (*Narcotic Control Regulations*).

Page 9: I believe there is an error in the e-mail address for Mr. Veniot.

Page 18: **“The College recommends that any terms, conditions and limitations necessary to protect the public be placed in standards of practice rather than in legislation.”**

I respectfully disagree. Findings of professional misconduct at disciplinary proceedings (self-regulation) are supposed to provide deterrence, if a member survives not losing their certificate of accreditation. “Deter” is “to prevent something from happening; to persuade someone not to do something; to discourage.”

How is finding a member guilty of professional misconduct, up to four different times, showing a deterrent? If it is decided there is a lack of knowledge (such that remediation is deemed necessary, although this also fits the definition of incompetence in the RHPA), then after completing such remediation and then re-offending, how has this protected the public? The public backlash I have received, as well as from professionals, suggests it just doesn't work. If repeated breach of the Standards of Practice are not going to result in severe consequences, there is no deterrent and regulatory intervention is required in order to protect the public. Otherwise, the perception grows that the profession “protects its own” through self-regulation, rather than protecting the public. Placing the above controls into legislation eliminates “wiggle room” and creates a fair playing field for all members, as well as credibility from the public's aspect.

Page 19: It should be determined whether or not pharmacists being allowed to perform certain testing of patients cause them to fall under requirements of the *Laboratory & Specimen Collection Centre Licensing Act (Ontario)*. That Act appears to require that certain acts are required to be performed in a properly-accredited laboratory, and as such, the pharmacy would have to comply with such accreditation.

Pages 19-20: **“If the optimal therapy is a Schedule II or III drug, and is a benefit under the patient's drug plan, the patient must then see an authorized prescriber for a prescription.”**

This is not entirely accurate. A patient could receive a prescription by the pharmacist collaborating with the prescriber and obtaining either a verbal or faxed prescription. The potential for *abuse*, however, is real, evidenced by past discipline cases reported publicly in Pharmacy Connection (OCP), where the patient “wants” something without any discussion with their doctor, and asks the pharmacist to put it through on their drug plan. The patient is determining what they want to “try”; there is no professional intervention by a physician. The physician is actually at “arm's length” should the patient ask them for a prescription; issuing same, if appropriate, does not result in a “sale” for the doctor. However, the pharmacist benefits from customer loyalty, and money in the bank – again, going back to the perceived conflict of interest by wearing the hat of both prescriber and dispenser.

Page 20, top: Reference is made to Alberta being favourable in action to what is proposed by Ontario. Not addressed, however, is that British Columbia only lists ONE DRUG as being “prescriptive ability” for its pharmacists. Not all provinces grant the same latitude.

Page 28, (c), last paragraph: **“Pharmacists, with their new scope of practice, can help patients by managing their minor ailments and help them with self-treatment...”**

This is presently expected of pharmacists and is being done, and prescribing is not necessary to do so. It is a standard of “pharmaceutical care” and is required of all Ontario

pharmacists by their Standards of Practice, Operational Component 1.4, which reads in part:

"If any potential or actual drug-related problems are identified, the pharmacist determines appropriate therapeutic options to solve or prevent them.

1.4.3 The pharmacist selects the most appropriate therapeutic option through consultation with the patient and/or other health care providers."

Page 33, (I): **"Physicians become frustrated when contacted by pharmacists to obtain authorization to do the above (adapting prescriptions)."**

Some may, but others are equally thankful for the options presented during collaboration, as they obtain *prior* knowledge of what is going to the patient. (This is also consistent with Standard of Practice 1.4.3).

Page 40, #18: The question asked is, are members in favour? The answer given is "yes."

That, as in the OPA submission, suggests that all members are in favour, but that is not entirely accurate and should better reflect that point by not indicating unanimity.

Table I: It is noted that New Brunswick and Nova Scotia only allow prescription extensions for up to 30 days – not potentially three months as proposed within the PAPE agreement for Ontario. It is also noted that various jurisdictions quoted by OCP require that, before a pharmacist can participate in any such actions, they must undergo further qualifications (even though the answer to question #26 suggests otherwise).

Page 61, #35: Paragraph two emphasizes "once a diagnosis is made." In essence, one could put forward the argument that there is no need for the physician to prescribe a drug AT ALL, so long as prescribers provide a diagnosis, if the pharmacist is able to "adapt" the prescription to what (s)he feels is more appropriate. This was actually a discussion undertaken in undergraduate pharmacy when I was in university: should prescribers provide the diagnosis, and leave the choice of drug to the pharmacist? While that was some 25 years ago, it never came to fruition. Should it now, if adaptive prescribing is being sought?

SUMMARY

In closing I wish to support the concept of certain "controlled acts" being permitted for pharmacists duly qualified to perform those acts.

I am also in support of "minimal extension of existing prescriptions for maintenance medications (where already filled at the pharmacy, and having been a patient for the period of time set out in the PAPE agreement); but oppose pharmacists being able to prescribe new drugs (from *whatever* drug schedule) until such time as all protocols are established that will protect the public from abuse of such a privilege.

Protocols established AFTER extensive consultation, preclude a present need for a change in this area of scope of practice until such consultation is completed. The consultation requires including all issues that could conceivably arise in practice. This requires stakeholder consultation with those having the experience to know what the nature of those issues.

Thank you for the opportunity to comment on this matter.

Yours truly,

original signed by...

K.A. Ruthig, BSc (Pharm), RPh