Prescriptive Authority for Pharmacists

Frequently Asked Questions for Pharmacists

Disclaimer: When in doubt, the text of the official bylaws should be consulted. They are available at:

http://napra.ca/Content_Files/Files/Saskatchewan/ProposedPrescribingBylawsAwaitingtheMinisterofHealth.pdf

In this document:

“CPSS” means the College of Physicians and Surgeons of Saskatchewan

“practitioner” means a physician or medical specialist and prescribers of drugs other than pharmacists such as nurse practitioners, dentists, optometrists and midwives.

“PAR” means the Pharmacist Assessment Record

“PIP” means the Pharmaceutical Information Program

“SMA” means the Saskatchewan Medical Association

1) What is Level I prescribing?
Level I can be characterized as the basic level that leverages your existing skill and reflects conventional interdisciplinary collaboration. In other words, lawfully allowing you to perform many of the functions and tasks currently being performed with the confidence of knowing that the patient’s physician would support you.

The bylaws divide pharmacists as prescribers into two levels, I and II. The bylaws authorize you to have Level I prescribing when a “collaborative practice environment” exists. It is defined in the bylaws and exists when a practitioner can reasonably rely upon your basic skills to prescribe in best interests of your patient. You also communicate such decisions to the practitioner (either to prescribe a drug, and if not, a referral if justified). The environment is presumed to exist when you prescribe according to the requirements of the bylaws. Basically the bylaws specify some limits and expect you to prescribe only when having met the competency, assessment, documentation, communication and transparency requirements.

Finally, the environment does NOT exist when a practitioner communicates otherwise. For example, where you receive a communication from the patient’s physician that s/he does not want you to prescribe to a patient or class of patients, then the environment does not exist and prescribing is not permitted in that circumstance.

2) What happens to the collaborative practice environment if a physician leaves or ceases to practice for reasons such as retirement, relocation or death?
The bylaws are silent on the specific issue of what happens to the collaborative practice environment when a physician leaves practice. Therefore, the bylaws are subject to interpretation. We have had a
long standing agreement with the CPSS that there should be an active patient-physician-pharmacist relationship for drug therapy to be valid. However, we recognize that judgment is needed to deal with situations where the physician leaves practice. In the interests of the patient, we often advise members not to deny reasonable patient access to needed medication, but to provide it and work with the patient to restore a relationship with another physician as soon as possible. We take this same position respecting the status of the collaborative practice environment.

3) What is Level II prescribing?
Level II, characterized as advanced, leverages advanced skills of some of you and/or is likely more applicable to more highly functioning or more sophisticated interdisciplinary collaboration or teams. For example, you may have advanced training in managing disease states that would allow an expanded role for you to prescribe drugs for those disease states. Or you may have very close working relationships with a physician or a group of physicians that would support more advanced prescribing. Currently, the bylaws authorize this prescribing only pursuant to “collaborative practice agreements”. Please refer to the resource section for more information on the framework and template found at:

http://napra.ca/Content_Files/Files/Saskatchewan/collaborativepracticeagreementframeworkfinal.pdf

4) Do physicians support this legislation?
The CPSS and SMA have been involved from the beginning with the Interdisciplinary Advisory Working Group and supported almost all of the policies and framework that guides the legislation that was approved by Council. Because the legislation is consistent with those policies and framework, both organizations have confirmed their support except for minor ailments prescribing. SCP has established another interdisciplinary advisory committee. While the CPSS has not expressed support for minor ailments prescribing, they have confirmed that they will continue to work with us on this committee. The SMA has given qualified support for minor ailments prescribing by agreeing to some of the selected conditions and asking that the others be reviewed or reconsidered. Resolution of these concerns will be a priority for this committee. However, it is possible that some individual physicians may not support this legislation. What it means is we have the support as described above of the organizations they belong to.

5) Will there be communication and education to the public to help them understand the new role of pharmacists as prescribers in Saskatchewan?
Yes, but in two parts.

The College has been working with Tap Communications from Saskatoon to build a communication and education strategy for the public. The strategy builds on the role of the pharmacist and what the role of the pharmacist means with respect to prescriptive authority. Tap communications has developed a more focused campaign on prescriptive authority. “Partners in Prescribing: My Pharmacist Knows” is the theme of this campaign. We will provide bag stuffers, with resources referring to the www.mypharmacistknows.com website including downloadable “Frequently Asked Questions” for prescribers and patients that you can provide to these groups. There have also been communications of similar messages to all other healthcare professional stakeholders. Print and Radio ads will be launched on March 4, 2011 and will run for duration of 2 weeks.

6) How would existing collaborative agreements be integrated with the new legislation?
The legislation authorizing prescribing under collaborative practice agreements is based on existing models currently used in the province and recognizes Regional Health Authority policy. It should be relatively easy to adapt the present arrangements by converting them into formal written agreements following the framework and template provided by the SCP, and then having these agreements executed by the current pharmacists and physicians involved, or according to RHA policy as the case may be.
7) How would a physician advise that he or she does not approve of Level 1 prescribing by pharmacists?

The bylaws are constructed so that the ‘collaborative practice environment” is deemed to exist if the bylaws are followed. A practitioner must communicate formally to you either verbally or in writing that they have opted out of the environment, which means that they do not want you to prescribe for their patient or group of patients. Out of courtesy, this communication should also give reasons. If a physician notifies a pharmacy that they wish to opt out then it applies to all pharmacists practicing in that pharmacy.

8) Does the physician have the option to make a blanket statement in not allowing level 1 prescriptive authority?

No, other than as indicated above. We have good working relationships with both the CPSS and SMA. If the opting out is due to interprofessional scope of practice conflicts, we can rely on their organizations to assist. To opt out they will need to demonstrate that their relationship with the pharmacist is not a collaborative one.

9) Does the prescriptive authority apply to other health professionals, such as nurse practitioners, dentists and midwives that have authority to prescribe as well?

Yes. If you have a working collaborative relationship with any of those practitioners the prescriptive authority bylaws will apply to that relationship.

10) Is the collaborative practice environment only between Saskatchewan pharmacists and physicians?

No. The collaborative environment can exist with physicians, dentists, optometrists and midwives from other provinces because we recognize their prescribing privileges and accept their prescriptions. This does not apply to out of province nurse practitioners. Only nurse practitioners registered with the Saskatchewan Registered Nurses Association can prescribe in Saskatchewan as their privileges are governed by the bylaws of the SRNA.

11) Can a Pharmacist prescribe for Non – Saskatchewan residents?

Yes. The bylaws provide an exception for you from reviewing the profile and recording the prescription in PIP under these circumstances. You may prescribe for patients that are not Saskatchewan residents in accordance with the remainder of the bylaws. In this case they require you to perform a reasonable inquiry into the patient’s medication history before prescribing. This could include interviewing the patient, or obtaining their history from their pharmacy. You are still required to complete a PAR and provide it to the patient’s primary practitioner. This can be done manually for out of province patients using the model form found in your training materials or refer to the template found at: http://napra.ca/Content_Files/Files/Saskatchewan/PharmacistAssessmentRecordTemplate.pdf

12) What happens when a you prescribe refills while a doctor is away?

Upon the physician’s return you should provide them with a list of refills and corresponding documentation which were issued during his/her absence.

13) What happens when the patient does not have a primary care physician?

The best thing to do is to communicate with the patient’s last prescriber to meet the needs of the bylaws.

14) Do I need to communicate with more than one practitioner?

Depending on the clinical situation, you may decide to communicate with more physicians, or other practitioners involved in their care. The bylaws do not prevent you from providing the PAR to more than one practitioner.
15) **What kind of documentation is required by community pharmacists when prescribing?**

Documentation is intended for complete records and to notify other members of the health care team what actions you have taken and the reasoning behind your actions. You are expected to record the following in the Pharmacist Assessment Record (PAR) for each drug prescribed:

(i) the date of the prescription
(ii) the name and address of the patient
(iii) brand or generic name of the prescribed drug and the quantity
(iv) the drug’s strength
(v) the dosage
(vi) the amount prescribed
(vii) relevant patient information including drug related problems, action plans and instructions for patient use of medication.
(viii) pharmacists name
(ix) rationale of the pharmacist’s for prescribing the drug

The PAR must then be sent to the patient’s primary practitioner immediately, if required or as soon as possible. The prescription(s) must also be recorded in the prescribing application within PIP according to its capabilities. The Level I training sessions have shown you how to use the PIP application to generate your PAR.

A model form can be found in your training materials or refer to the template found at: [http://napra.ca/Content_Files/Files/Saskatchewan/PharmacistAssessmentRecordTemplate.pdf](http://napra.ca/Content_Files/Files/Saskatchewan/PharmacistAssessmentRecordTemplate.pdf)

16) **What kind of documentation is required by hospital pharmacists with Level I prescribing?**

Until hospital systems are integrated with PIP, documentation according to RHA policy is acceptable. However, the patient’s medication history in PIP should be consulted.

17) **When a pharmacist with Level I Prescribing Authority is prescribing refills the Bylaws state,**

“The additional quantity not to exceed the lesser of :

a) the quantity equivalent to the amount last dispensed to the patient by a licensed pharmacist; or

b) one hundred (100) days supply of the drug, at the frequency and dosage level last dispensed by the licensed pharmacist “

**What does this mean?**

This means that if the quantity last dispensed was for 34 days, the interim extension would be for up to 34 days. If the quantity last dispensed was for 100 days, the bylaws allow the interim extension to be for up to 100 days at the frequency and dosage level last dispensed. This does **not** mean that you are able to extend the prescription for 100 days for a 34 day drug by dispensing for 34 days and giving two refills.

18) **Is there a time period between when the prescription was written and when the pharmacists can extend refills on that prescription?**

If you are practicing under a collaborative agreement there is no specified time period between the time when the prescription was written and when you can extend refills. It is up to you to decide what is appropriate for each patient. Conversely, if you prescribe in an emergency situation, the prescription must have been issued or dispensed to the patient under authority of a prescription made by a practitioner within the previous 6 months.
19) The bylaws state that, “No Licensed Pharmacist may prescribe a drug where the most previous prescription for that drug, or therapeutic substitution for a drug was issued by a Licensed Pharmacist;” What does this mean?
If another pharmacist extends a refill, that same pharmacist or another pharmacist is not able to prescribe again, meaning for example extending that refill a second time, as a pharmacist initiated the first extension. At that point the patient must return to their practitioner. However, other bylaws allow you to dispense prescriptions issued by other pharmacists.

20) Will prescriptive authority replace the current practice of having to fax refill requests and waiting for authorization before filling?
Yes. If you have Level I prescriptive authority and are within a collaborative practice environment, it will. Instead of faxing the practitioner for authority to refill, you will be faxing your Pharmacist Assessment Record (PAR) to notify the practitioner of your action and rationale.

21) What happens if I do not have Level I authority because I have not taken the training, or am not within a collaborative practice environment?
You will not be allowed to perform the activities that are legal under the bylaws. You will be required to obtain authorization for the prescription from the practitioner before dispensing it.

22) Am I able to prescribe drugs under the Controlled Drugs and Substances Act?
Not presently. You will not be able to prescribe controlled substances until pharmacists are recognized as a prescriber under new regulations that recognize new classes of practitioners (i.e. prescribers) under the federal Controlled Drugs and Substances Act. There is a federal process under these regulations before pharmacists are formally recognized. In particular, the onus is on the profession in conjunction with their provincial ministries of health to demonstrate that prescribing of these substances is within the profession’s scope of practice and that this scope is common to most, if not all, provinces. Thus, as prescriptive authority for pharmacists evolves across Canada, it will take some time, at least a few years, before this federal recognition occurs.

23) What is the status of zopiclone?
In spite of its relationship to benzodiazepines, it is not federally scheduled as a Targeted Substance. It is thus considered to be a Schedule F drug meaning that you can prescribe it.

24) I understand Level I or II prescribing does not include prescribing Narcotics and other Controlled Substances. I practice in a collaborative environment in a methadone clinic. Physicians need to apply for an exemption to prescribe methadone for the clinic prescriptions. Is it possible to investigate the possibility of Level II prescribing of methadone by pharmacists within a collaborative practice agreement?
At this time, this would be part of the process of applying for recognition under the new federal regulations as described above. However, there may be opportunities to explore interpretations of federal laws, but this has yet to occur.

25) Will malpractice liability insurance change now that we are accountable for the decisions made under both Level I and II prescriptive authority?
Yes. Council has approved an increase in the minimum liability insurance requirement for licensure from $1 million to $2 million based on the advice from insurance experts that the new minimum level is adequate for the circumstances. If you acquire your insurance through PAS, they will automatically provide you with the $2 million coverage as part of your membership. Information received from other insurance providers indicates they will also provide you with the basic $2 million level as well.
26) What is the College doing to ensure that pharmacists have access to various laboratory diagnostic test values to ensure proper prescribing when doses need to be adjusted. After successful implementation of prescriptive authority, we plan to pursue this next with the Ministry of Health and relevant authorities. We also anticipate that pharmacists will be able to access this information as it becomes integrated within the Electronic Health Record in Saskatchewan.

27) Scenario when a prescription requires a pharmacist to "increase the suitability of a drug": It is a medication that the patient is already or will be on long term (e.g. anticonvulsant) and the patient would prefer a liquid instead of a tablet. The prescriptions has 6 refills Does the pharmacist "prescribe" all the refills too? Or can they only prescribe one month (or three in this case) and then have to contact the doctor to amend the other refills? The answer relies upon the interpretation of the definition of a prescription. Under federal law, the number of refills is not technically part of the body of the prescription as the Food and Drug Regulations allow the prescriber to specify the number of times a prescription for a Schedule F drug may be refilled. Hence, using this interpretation, the pharmacist will only change the dosage form in the body of the prescription and that would apply to all refills. There would be no need to contact the doctor to obtain authorization to amend the other refills. Also, the physician's intent is clear.

28) Under the "insufficient information" section of the bylaws can a pharmacist prescribe if the prescription is missing a doctor's signature? If so, are all the refills "prescribed" by the pharmacist as well? Yes to both questions if you are satisfied that the original practitioner's intent is clear. This includes honoring the refills as authorized by this practitioner using the same rationale explained in question 27.

29) Can pharmacists prescribe under Level I or Level II for schedule 2, 3 or unscheduled drugs? Yes, theoretically, because this is not specifically authorized or prohibited for all circumstances in the bylaws. What is clear is that when you prescribe these drugs you are expected to meet the same standards as for Schedule I drugs.

Note:
Schedule I – Prescription drugs
Schedule II – No-public access non-prescription drugs
Schedule III – Non-prescription drugs restricted to sale from pharmacies and available to the public from the self-selection area
Unscheduled – Non-prescription drugs available in any retail outlet

SPECIAL HOSPITAL PHARMACY ISSUES
1) The bylaws require that your prescription decision has been consented to by the patient or patient’s legal representative. How does that work in the hospital setting? Generally, consent for treatment is determined by RHA policy. This includes pharmacist prescribing, but for greater certainty, the RHA consent policies should specify these services.

2) Because a Director of Pharmacy may have legal authority to bind the licensed pharmacists who are employees of the RHA, he or she can execute a collaborative practice agreement on your behalf authorizing your Level II prescribing. However, the Medical Director may not have the authority to bind the practitioners who have privileges with the RHA. Then, how can collaborative practice agreements between pharmacists and physicians be executed within the RHA’s.

The bylaws include special provisions for RHAs. Such agreements can be made in accordance with RHA policy.

3) Some of the following practices fall under Level II prescriptive authority. However, certain requirements of the collaborative prescribing agreement would be difficult to enact (i.e. a specific training program) and define for all pharmacists and all physicians:
1. Step down therapy. Hospitals that use established step down therapy criteria to change intravenous therapy to oral therapy. These are usually policy and procedure driven and give pharmacists the ability to change the route of administration according to defined criteria. How should this be managed?

2. Physician orders that currently are written for a specific patient "as per pharmacy". Examples include an order for a particular antibiotic, or CADD Dilaudid "as per pharmacy". Can these continue as individual specific orders without a formal collaborative prescribing agreement? It would be difficult to enact formal collaborative prescribing agreements for these individual specific occasions.

3. Current protocols that exist as established practice; ie physician orders as vancomycin or gentamicin as per protocol (the protocol directs gentamicin or vancomycin interval or dosage adjustment, based on lab results). This situation is common and fits under the Level II prescriptive authority.

4. Automatic substitution policies are well developed in a number of Saskatchewan hospitals and cover a wide range of situations. For example, the ability to change an order for 500mg acetaminophen to 650mg acetaminophen (the RHA stocks 325mg tablets). This would not be permitted under Level 1 prescribing authority however how would we cover this with a collaborative prescribing agreement? Does this support the position that automatic substitution policies will still be needed and considered valid?

5. A second example of a generalized Level II situation, dosage adjustments required in renal impairment in the geriatric population. What would a collaborative practice agreement look like and what type / evidence of training would be required?

Generally, the bylaws do not prevent incorporating Level I prescribing within a collaborative practice agreement. Level II prescribing can only occur under the authority of such agreements. The bylaws state, in part:

“(4) Level II Prescribing Authority  
(a) a Licensed Pharmacist has Level II Prescribing Authority as provided for in a Collaborative Practice Agreement;  
(b) a Collaborative Practice Agreement must:  
(i) be in writing and:

(1) in the case of a bylaw or policy of Public Health Care Institution, or agreement between one or more Licensed Pharmacists and a Public Health Care Institution, be made or entered into by such institution in accordance with the applicable authority for making bylaws, policies or agreements, as the case may be; and

(2) in all other cases…………………….”

Therefore in hospitals, the practices described above can occur according to the policies of the RHA addressing such agreements.

To assist, SCP has developed a framework and template for these agreements. It is acceptable to incorporate or refer to the RHA protocols or policies within the agreement if the framework and template are followed. For example, if the agreement lists the prescribing pharmacists and their credentials, and both are linked to the services provided by the policies or protocols integrated into or referred within the agreement, this is acceptable.

**Scenarios:**

Adapted from an exchange of e-mails with an RHA pharmacy director:
Q: One thing that has come up from my colleagues is a question about how those of them that work for a health authority in an ambulatory setting will be able to prescribe (e.g. renal units, warfarin-dosing programs, etc). As these will be Level II activities and we have time to address the issue - but they are not associated with a community pharmacy.

Right now, usually the pharmacist makes recommendations and physicians either write the prescription or in some instances just sign the prescription as completed by the pharmacist. In our warfarin clinics, the physician will write a broad prescription something like "Warfarin 1mg tablets x 1 year - dosed as per warfarin clinic".

A: The operative bylaw states that the licensed pharmacist must:

"(ii) except as provided in paragraph (d) of sub-section (10) (sic: exemption for out of province patients), within the limitations of the Pharmaceutical Information Program, record, or cause to be recorded, the prescription(s) in the Pharmaceutical Information Program, as soon as reasonably possible. “

Therefore, in an RHA ambulatory clinic situation, recording the prescription in PIP is required on the face of the bylaw if this is not limited by the PIP system. One of the reasons is that it is conceivable that the prescription could be filled in a community pharmacy.

However, prescribing within the RHA is governed by RHA policy to the extent that it is consistent with the intent of the bylaws. We interpret this as meaning that if all of the elements of the service are within the RHA (i.e. prescribing and dispensing), then recording in PIP is not needed. This logic follows through with this prescribing being within Level II. The bylaws authorize Level II prescribing under Collaborative Practice Agreements sponsored by the RHA within the jurisdiction and resources of the RHA. Otherwise, when for example the prescription will be filled outside of the RHA the logic and the bylaws require recording the prescription in PIP.

Besides all of this, what is important to keep in mind is the presence of a collaborative practice environment. Key principles supporting this environment are transparency and accountability through communication. We are assured this will occur through RHA policy and thus by its nature will occur only within those facilities and services under the jurisdiction of the RHA. Otherwise, tools such as recording the prescription in PIP and providing the primary physician with the Pharmacist Assessment Record are required by the bylaws consistent with these principles.

The reverse is not true. Nothing in our bylaws prevents the recording of prescriptions in PIP within the jurisdiction of the RHA even when they may be dispensed within the RHA as long as the PIP system allows. The complication here is that the patient’s profile in PIP will show the prescription but not the dispense because presumably the dispense is not submitted to the Drug Plan’s ADAPT system for capture or adjudication that ultimately populates the patient’s profile in PIP. This is an acknowledged gap in the system for which we are uncertain as to how to guide members.

In short, if the RHA ambulatory clinic prescription is released and filled in the community, record the prescription in PIP as long as PIP allows. If it is not and is filled within the RHA, you may use your discretion according to RHA policy and the limitations of PIP.