

February 27, 2009

The Honourable David Caplan
 Minister of Health and Long-Term Care
 Ministry of Health and Long-Term Care
 56 Wellesley Street West, 12th Floor
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via email: regulatoryprojects.moh@ontario.ca

Dear Minister Caplan:

The Ontario Pharmacists' Association (OPA) welcomes the opportunity to offer its comments on the final report by the Health Professions Regulatory Advisory Council (HPRAC), entitled *Critical Links: Transforming and Supporting Patient Care* ("Final Report").

OPA commends the efforts of HPRAC in creating a broad consultative approach and we are pleased with the Final Report recommendations regarding pharmacists' professional services. The report recommends bringing Ontario a step closer to utilizing pharmacists to the best of their abilities; recognizing their role as healthcare professionals with accountability and responsibility not only for the procurement and dispensing of medications, but also for their safe and effective use by patients in the prevention of disease and the promotion of health and wellness. Recognizing the value of the services pharmacists provide to their patients will also improve the long-term sustainability of the profession in Ontario.

OPA advocates for the profession of pharmacy in Ontario, where more than 11,000 pharmacists practice in community retail stores, family health teams, long-term care facilities, hospital clinical settings, education, business and government.

Consistent with the core objectives of inspiring the profession and its practices, advocating for the wellness of the patients we serve, and the daily experiences of more than 7,200 member pharmacists practicing in more than 3,000 clinical settings, we are pleased to provide the following comments for your consideration as you review HPRAC's recommendations.

PRACTICE ISSUES

OPA is pleased with the recommendations regarding an enhanced role for pharmacists in Ontario's healthcare system, and there is strong support by the profession to bring these recommendations into practice by working in collaboration with the Ministry, the Ontario College of Pharmacists (OCP) and other healthcare professions. As part of our presentation to HPRAC through submissions and discussions, we proposed that under an expanded scope of practice, legislation and regulations would enable pharmacists to:



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1. Authorize further extension of a prescription, where there are no existing refills, for continuity of care,
2. Adapt an existing prescription to facilitate patient adherence,
3. Adjust dosage of existing medication in response to monitoring of laboratory tests or other tests,
4. Order relevant laboratory tests for the purpose of monitoring and managing a patient's medications,
5. Initiate Schedule I, II, and III drugs pursuant to a Minor Ailments Program, subject to defined protocols,
6. Initiate Schedule I drugs for the purposes of smoking cessation therapy,
7. Perform a procedure on tissue below the dermis with limits and conditions,
8. Administer a substance by injection or inhalation for the purposes of education and demonstration, with limits and conditions,
9. Administer routine injections when it is in the patient's best interest, appropriate in the pharmacist's professional judgment, and subject to defined protocols and certification,
10. Initiate Schedule I drugs for purposes of travel prophylaxis, subject to additional training,
11. Provide Schedule II and III drugs on prescription when required for reimbursement under drug plans.

In its reports, HPRAC endorsed the first four activities of our proposal (prescription extension, adaptation, adjustment, and monitoring through laboratory testing) under the umbrella of "Medication Therapy Management" (MTM). As an extension of MTM, the enabling of pharmacists to pierce the dermis (skin pricking) and to administer drugs by injection and inhalation will greatly facilitate their monitoring and management roles for chronic diseases, such as diabetes and asthma. Through the implementation of MTM, pharmacists will ensure that continuity of care is available to each patient while contributing to a reduction in therapeutic failures and decreased congestion in physicians' offices and emergency rooms. HPRAC has also recommended that a Minor Ailments Program, similar to the one in the United Kingdom, be implemented in Ontario, which will enable patients suffering from ailments such as athlete's foot or cold sores to be assessed by a pharmacist for triage and treatment. In addition to minor ailments, patients interested in smoking cessation can continue to consult their pharmacist; under an expanded scope, the pharmacist will be able to initiate the most appropriate therapeutic option, including Schedule I products, while continuing to provide ongoing monitoring and support that will increase the patient's chances of success.

While we are pleased with the recommendations for pharmacy put forth by HPRAC, there are a number of proposals advanced in our submissions that were not included in the Final Report. Notwithstanding the rationale cited by HPRAC, we would like to introduce additional information in support of these proposals for Ministerial reconsideration.

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OPA Proposal #9 - Administration of Drugs – Immunization:

OPA agrees with HPRAC's assessment regarding administering drugs by injection that "it is in the public interest to ensure that pharmacists have the core competencies to undertake these activities when needed for emergencies". However, the development and ongoing maintenance of these core competencies is at risk without a change to pharmacists' scope of practice. Without enabling pharmacists to provide routine immunizations, there will be no incentive for the development of structured, Ontario-approved, training programs to provide even the basic core competencies. Furthermore, with administration of drugs by injection restricted to education, demonstration and emergency, there are fewer opportunities that will allow pharmacists to become proficient in the training they might receive. In times of emergency, there will be no time or opportunity for pharmacists to undergo "refresher" courses. Proficiency in this technical task only comes with routine performance.

Finally, and as mentioned in our original submission, we suggest that through routine provision of immunizations by pharmacists, adherence rates for vaccines requiring multiple injections over several months will be increased as patients will have improved access to a trained healthcare professional for their administration. Attached as Appendix 1 to this correspondence is a copy of a letter addressed to HPRAC on December 2, 2008 from pharmacists Dr. Régis Vaillancourt, Preveshen Naidoo, and Carmen Ma and pharmacy student Joshua Brady. These authors provide additional support to OPA's position on the provision of routine immunizations by pharmacists.

OPA Recommendation: Based on the supplementary information provided, Ontarians will best be served by enabling pharmacists to provide routine immunizations. Therefore, OPA recommends that pharmacists be permitted to routinely administer drugs by injection, including for purposes of education, demonstration, and emergency subject to training and certification.

OPA Proposal #10 - Prescribing Schedule I Products for Travel Prophylaxis:

Since our original and supplemental submissions, we have heard from an increasing number of pharmacists who stress that access to travel information and clinics is limited outside of major urban centres. To determine the frequency of requests, we sought to assess the number of pharmacists who are contacted by physicians to provide advice on travel prophylaxis. In order to quantify this number, a surrogate marker was measured, examining the number of questions relating to travel prophylaxis submitted to OPA's Drug Information and Research Centre (DIRC) from January 1, 2008 to December 10, 2008. DIRC is a drug information subscription service for healthcare professionals staffed by pharmacists, which provides timely responses to drug information queries.

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In 2008, DIRC logged approximately 1.5 calls per business day pertaining to disease prevention for patients travelling abroad. While DIRC's policy is that questions regarding travel prophylaxis be referred to travel clinics, often the situation involves the provision of care for patients without timely access to a travel clinic. In these circumstances, the primary care provider may prescribe the required medication at an additional cost (OHIP does not cover travel consultations and immunizations) regardless of whether DIRC provides advice on therapy or not. In these instances, to ensure patient care, DIRC pharmacists provide therapeutic alternatives based on the best available evidence.

It is common for DIRC pharmacists to field calls regarding the most appropriate Schedule I drug, dosage and frequency for malaria prophylaxis, vaccines, antibiotics in case of traveller's diarrhea, diuretics for high altitude, etc. Every call, including the outcome and references used, is logged.

Aside from calls logged by DIRC, there are pharmacists in the province who provide this information to patients and physicians on a daily basis. The need across Ontario for this service is greater than may have been originally thought. In terms of training, pharmacists are expected to be able to demonstrate competency on topics such as traveller's diarrhea as part of the current Pharmacy Examining Board of Canada qualifying exam¹. Thus, additional protocols and certification would serve to augment the current baseline knowledge.

OPA Recommendation: Based on the supplementary information provided, OPA believes that there is sufficient need, particularly in under-served areas of Ontario, to enable pharmacists to initiate therapy for Schedule I, II and III products for purposes of travel prophylaxis, subject to defined protocols and provider certification.

OPA Proposal #11 - Initiation of Therapy for Schedule II, III and Unscheduled Products:

In our original submission to HPRAC, OPA proposed for the ability of pharmacists to initiate therapy for OTC products for patients with public or private drug plan coverage. Upon review of the interim report, we recognize that our recommendation requires clarification. Our proposal should reflect that there are many non-prescription products, critical for chronic disease management and ongoing monitoring of therapy that pharmacists should initiate and that should be recognized by payors as part of the scope of practice.

At the forefront of this potential list of products are diabetic supplies. It is well-established that ongoing self-care monitoring is crucial for optimal management of diabetes within the circle of care. Patients, physicians, nurses, pharmacists,

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dietitians, and caregivers rely on the regular provision of diabetic supplies such as test strips, lancets, swabs, and meters to ensure optimal outcomes are achieved and maintained. Similarly, many cardiac patients are prescribed low-dose aspirin as preventative therapy against negative health outcomes. In many instances, drug plan coverage (or lack thereof) will influence adherence to costly prescription and non-prescription therapies. Attached, as Appendix 2 to this correspondence, is a letter written by Dr. Régis Vaillancourt that provides evidence supporting the impact of pharmacists' prescribing of Schedule II, III and Unscheduled products. The study cited in this letter suggests improved adherence rates to therapy and a relief of stressors on other elements of the healthcare system (emergency rooms, walk-in clinics, etc.) for continuity of care and optimal health outcomes. In collaboration with all relevant stakeholders, OPA will assist in the identification of those OTC products that can aid in chronic disease management and monitoring of pharmacotherapy.

OPA Recommendation: Based upon the above clarification, pharmacists should be enabled to initiate therapy with Schedule II, III and Unscheduled products for purposes of chronic disease management and monitoring of therapy.

REGULATORY ISSUES

HPRAC has proposed significant changes to the current regulatory structure which would have a great impact on regulatory colleges including an effect on human resource allocation. OPA supports the view of the OCP that an oversight agency, such as the Council on Health Professions Regulatory Excellence (CHPRE), is not required to ensure that health professions are working collaboratively.

Definition of Dispensing:

OPA is pleased that HPRAC has decided to define the term "dispensing" to ensure clarity for all healthcare professionals. However, upon examination of the proposed definition (page 82), OPA is of the opinion that additional language is necessary to ensure that appropriate value is placed on the cognitive component, which truly makes dispensing a professional activity. While there may be some degree of overlap, OPA recognizes that the cognitive component of dispensing is not equivalent to the cognitive component of prescribing; OPA believes that not all prescribers should necessarily dispense and, similarly, not all dispensers should prescribe. As the proposed definition currently stands, any professional authorized by law to prescribe would be allowed to dispense; in spite of this, HPRAC did not recommend dispensing privileges to optometrists or midwives, both professions which can prescribe.

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OPA Recommendation: OPA recommends that the following changes be made to the proposed definition of “dispensing” for purposes of the Regulation Health Professions Act:

*The provision of prescription drugs to a patient by a professional ~~authorized by law to prescribe drugs or a professional acting~~ pursuant to a prescription **and as authorized by law** after the professional:*

- a) *Records, selects, measures, reconstitutes, inspects, packages and labels the drug; and*
- b) *Uses professional judgment **and all relevant patient-specific information available** to confirm the appropriateness of supplying the drug in the particular situation.*

Safeguards for Dispensing, Compounding and Selling Drugs:

OPA is in agreement with HPRAC that dispensing not only needs to be defined, but also that standards of practice be developed, circulated and enforced for all professionals authorized to dispense drugs. We also believe the same should hold true for compounding and selling medications. However, OPA respectfully submits that the standards to be developed, circulated and enforced are equivalent to those in place for pharmacists, rather than physicians, to ensure that these controlled acts are performed to the most exacting standards. OPA is in strong agreement with the OCP in its position that “all healthcare professionals who are authorized to compound, dispense or sell drugs to their patients be held to the same high practice standards and accountability required of pharmacists. To do less would, in our view, erode the controls which exist in the current drug distribution system in Ontario, a system which has shown itself to be safe and effective”².

OPA Recommendation: Standards for dispensing, compounding and selling drugs should be developed, circulated and enforced for all professionals authorized to perform these acts. These policies should be based on the high practice standards required of pharmacists.

Dispensing, Compounding and Selling Drugs by Health Care Professionals:

HPRAC has recommended that in addition to pharmacists, physicians and dentists, several healthcare professionals be authorized to dispense, compound or sell drugs to patients. While the OPA is not in a position to comment on the training and education associated with each of the professions, we do feel that notwithstanding HPRAC’s recommendations, some health professionals may not

² Ontario College of Pharmacists Letter to Minister Caplan, February 11, 2009 regarding HPRAC’s Final Report.

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have the necessary clinical judgment and therapeutic knowledge required to dispense, compound and sell drugs in a safe manner. Respectfully, dispensing is not purely a technical skill whereby a drug is repackaged, labelled and provided to a patient. The drug must be checked against a prescription, be appropriate for the patient's situation, not interact with the patient's other medications, not cause an allergic reaction, and not be chosen solely because it is the product that the practitioner has available. The practitioner must apply therapeutic knowledge prior to dispensing, and this knowledge must encompass how the drug acts in the entire body, not just in one particular system. In addition, there are strict manufacturing standards that must be met prior to compounding pharmaceutical products, and there are over 3,200 pharmacies across Ontario adhering to these standards. We are pleased that OCP will be working with other colleges to ensure that identical standards are being met by all professions, and that patient safety is not compromised.

In summary, OPA would like to thank HPRAC and the Minister of Health and Long-Term Care for the opportunity to comment on the contents of *An Interim Report to the Minister of Health and Long-Term Care on Mechanisms to Facilitate and Support Interprofessional Collaboration among Health Colleges and Regulated Health Professionals, March 2008*. Enabling pharmacists to practice in an enhanced, collaborative role will reduce wait times, increase the efficiency of the Ontario health care system, and improve patient care, including the management of chronic diseases

OPA looks forward to demonstrating the value that pharmacists' professional services can bring to Ontario's healthcare system. We believe that when all healthcare professionals are permitted to practice collaboratively at their highest possible level, the system as a whole will reap the benefits. We are certain that the recommendations brought forward by HPRAC will help to ensure Ontarians have access to the best interprofessional healthcare in the country.

We look forward to continuing to participate in this process with you and your Ministry. We welcome the early opportunity to discuss OPA's recommendations in more detail. Please do not hesitate to contact the CEO's office at 416-441-0788.

Sincerely,



Tina Perlman, R.Ph., B.Sc.Pharm.
Chair of the Board



Dennis A. Darby, P. Eng.
Chief Executive Officer

Encl.

Ottawa, December 2, 2008

Ms. Annie Schiefer
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Dear Ms. Schiefer,

This letter is in response to the HPRAC proposal regarding the Review of the Scope of Practice of Pharmacy in the Interprofessional Collaboration Phase II document. We are pleased to see the recognition of the Pharmacist as an untapped resource in Canada's Health Care system, and excited about the anticipated changes in the profession moving forward.

Although we applaud HPRAC's recommendations about expanding the scope of Pharmacy practice in Ontario, we do take issue with Recommendation 7 – "That pharmacist not be authorized to perform routine immunizations". With the upcoming reopening of legislation regarding the pharmacists' scope of practice, we must make the most of this opportunity. Allowing pharmacists to administer vaccinations would be of great value to the Canadian Healthcare system. The vaccination rate in Ontario is at an inadequate level. Allowing pharmacists to administer vaccines has been shown to increase vaccination rates in the general population, but also in specific at-risk populations who are recommended to receive vaccines. Pharmacies are equipped to ensure cold-chain continuity at present, including the storage of vaccines. Pharmacists are trained to deliver drug education and ensure proper documentation. Also, if pharmacists are expected to administer vaccines in a time of emergency, they should be very familiar and well practiced at doing so. We believe that there is a compelling case to allow pharmacists to administer vaccinations, which we will present here.

Since 2000, Ontario has had the Universal Influenza Immunization Program (UIIP) in place¹, which offers free influenza vaccinations to every Ontarian aged 6 months and older. The burden that influenza places on our society and healthcare system

is understood by the government. More specifically, the UIIP stresses that those with chronic medical conditions are highly encouraged to get vaccinated ¹. In 2005, the influenza vaccination rate for Ontario was at an unsatisfactory 34% and the rate for those ages 12-49 with at least one chronic illness was 41%¹. Ontarians are not taking full advantage of the UIIP, and we must better utilize this initiative to increase these vaccination rates.

When making changes to our healthcare system, it is helpful to have information that helps quantify the decision. Luckily, information of this type is available from our American neighbours, who have been allowing pharmacists to give routine vaccinations since the mid 1990's ². According to the American Pharmacists Association (APA), Pharmacists can currently administer vaccinations of some type in 49 States ³. The beneficial effect of this is obvious when looking at the data. It has been shown that in states which allow pharmacists to administer vaccinations, there is a net increase of 10.6% (P=0.05) in influenza vaccination rates among those less than 65 years of age, who are taking indicator medications for chronic diseases for which an influenza vaccination is recommended ⁴. This is one of the population groups Ontario specifically targets for vaccinations, and it is proven that pharmacists can increase vaccination rates. Also, Pharmacists are privy to their patients' medication history. This allows pharmacists to effectively determine those patients who are on medication for a chronic disease, counsel them on the importance and value of vaccines, while at the same time offer them the convenience of vaccine administration. Furthermore, a separate study has shown that allowing pharmacists to provide vaccinations is associated with an increase in vaccination rates of 10.7% (P=<0.01) in those 65 years of age and older ⁵. It is clear that Ontario needs to improve our overall vaccination rates. Both studies prove that allowing pharmacists to provide this service has a significant, beneficial impact on vaccination rates in a wide range of patient demographics.

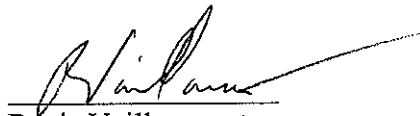
The implementation of this expansion in the pharmacists' scope of practice would not be a difficult transition. Continuing Education programs are offered by the APA to train pharmacists to administer vaccines ⁶. These programs could be adapted for Ontario, and a certification program could be set up. Vaccinations can be looked at like any other drug, and pharmacies are ideal locations for proper storage, documentation and

administration of them. The cold-chain of pharmaceutical delivery is already in place at pharmacies, and only small changes would need to occur to accommodate increased vaccine storage. Pharmacists are intimately familiar with drug documentation, and it would be an easy transition to add vaccines to their documentation systems. Also, with the push towards e-health records, it will soon be much easier to document and track vaccination records. The entire Healthcare community should be prepared for this eventuality.

Lastly, the HPRAC report recommends that in regards to administering vaccines, "it is in the public interest to ensure that pharmacists have the core competencies to undertake these activities when needed for emergencies". A time of an emergency would be the most stressful and taxing environment in which to administer a vaccine. To be properly prepared to do so, a pharmacist should be well practiced at administering vaccines. Having vaccinations as part of their everyday practice would allow pharmacists to appropriately act in an emergency situation. It is not fair to the pharmacist, or the public, to expect pharmacists to perform an unfamiliar act in a state of emergency.

Expanding the scope of pharmacy practice to include the administration of vaccines is a logical progression for the profession. This has been done for over a decade in the United States, and has proven to be an effective measure to raise vaccination rates. The Canadian Healthcare system is overburdened as it is now. We must fully utilize the Healthcare Professionals within the system, as well as focus on primary healthcare and diseases prevention, if our Healthcare system is to cope with the demographics of the aging Canadian population.

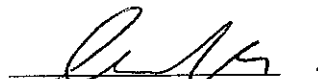
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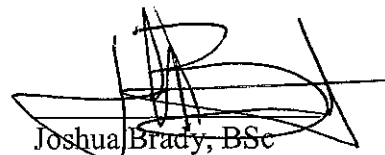
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References:

- 1) Kwong JC, Rosella LC, Johansen, H: Trends in influenza vaccination in Canada, 1996/1997 to 2005. Stats Canada Health Reports. Vol. 18, No. 4, Nov 2007.
- 2) Grabenstein JD, Josephine: Health-system pharmacists' role in immunization adults against pneumococcal disease and influenza. Am J Health-Sys Pharm. 56(17S) 3S-22S, 1999
- 3) Wendel E: Pharmacists Help Protect Patients Against Influenza. APA online publication. October 8, 2008
- 4) Grabenstein JD et al: Effect of Vaccination by community pharmacists among adult prescription recipients. Med Care. 39(4):340-348, 2001.
- 5) Steyer TE et al: The role of pharmacists in the delivery of influenza vaccinations. Vaccine. 22:1001-1006, 2004.
- 6) Pharmacy Based Immunization Delivery:
http://www.pharmacist.com/Content/NavigationMenu3/ContinuingEducation/CertificateTrainingProgram/PharmacyBasedImmunizationDelivery/Pharmacy_Based_Immun.htm. Last Accessed: November 24, 2008



December 16, 2008

Ms. Annie Schiefer
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Dear Ms. Schiefer,

This letter is in response to the HPRAC proposal regarding the Review of the Scope of Practice of Pharmacy in the Interprofessional Collaboration Phase II document. I would like to respond to Recommendation 9 – “That pharmacists not be authorized to prescribe schedule II and III drugs solely for the purpose of patient reimbursement under an insurance plan”. The HPRAC document does not provide a compelling argument to justify the rejection of the joint recommendation by the OCP and OPA regarding this topic. I believe that adding this directive into the pharmacists’ scope of practice would be both a valuable service for the people of Ontario, and economically beneficial for our healthcare system.

HPRAC has made most of the recommendations in its report with the intension to reduce doctor and emergency room wait times, which would allow doctors to focus their attention on more complex patients. The recommendation in question seems to follow suit exactly with this initiative. If the only way certain patients can get medications paid for is by having a prescription, then they will continue to bog down clinics and emergency rooms for this purpose. HPRAC is looking at ways optimize the role of healthcare professionals, and writing a prescription to satisfy an insurance requirement is a task that pharmacists can easily accomplish.

Imagine a mother coming into a pharmacy after the walk-in clinics have closed. She has no family doctor and has a very low income. Her 2-year-old baby has a fever, and she does not have the money to pay for the ibuprofen her baby requires. The

pharmacist must turn her away because he cannot prescribe the OTC drug, which is a requirement for ODB and other insurance plans, to obtain drug coverage. Her only remaining option is to go to a hospital and wait in the emergency room for hours to see a doctor. This does not make any sense from a humane or systems point of view. The pharmacy is the first point of care for many people. Pharmacists should be allowed to serve them properly by having the ability to prescribe OTC's in order to have them reimbursed under an insurance plan.

Looking at this issue from a purely economical standpoint, allowing pharmacists to incorporate this practice would be beneficial to our healthcare system. A pilot project run by the Canadian Forces (CF) was done to look at pharmacists providing OTC drugs to CF members who did not have access to a military base pharmacy. The essence of this project is similar to the recommendation in question. Pharmacists were "prescribing" OTC medications, from a predetermined formulary, that would be paid for by a third-party insurer only if they were "prescribed". The CF members also had the option of obtaining a prescription from a doctor, or paying out of pocket. A cost analysis showed that the financial savings of having the pharmacists prescribe the OTC medication were substantial. It was also shown that in the vast majority of cases, both positive health outcomes and a high level of patient satisfaction were achieved (See appendix for details).

Furthermore, it was shown that close to 50% of the participating CF members indicated that if this program was not in place, they would have visited a physician to treat their minor ailment. CF members have good paying, steady jobs, and yet half of them would visit a physician in order to get their OTC medication paid for. This highlights that insurance reimbursement does not only affect those in the lowest income brackets, but a wide range of the work force.

HPRAC has recommended that pharmacists should be able to prescribe drugs to treat minor ailments. I feel that allowing pharmacists to prescribe for the purpose of insurance reimbursement is linked with this. The two situations are closely related, and it is difficult to draw the line between the two. The CF pilot project emphasizes this point. The pharmacists were "prescribing" to treat a minor ailment, as well as for insurance reimbursement. If we want the public to embrace pharmacists as the healthcare

professionals who are responsible for medication therapy management, and to capitalize on pharmacists full potential, we need to give them all the tools necessary to do so. The HPRAC recommendations are a large step in the right direction, but more consideration needs to be taken regarding the issue of insurance reimbursement.

Sincerely,



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Appendix: Summary of Findings from Canadian Forces Article

Cost-Analysis

A cost-analysis of the new model included both direct and indirect costs, such as drug costs, claim processing costs, third-party adjudication costs, healthcare professional fees, and monetary values for productivity loss. It was found that the total cost per OTC for the pharmacists prescribing option was \$31.43, while the cost of the physician prescribing option was \$101.79.

Patient Outcomes

It was determined that 84% of CF members participating experienced complete resolution of their symptoms, 16% experienced either partial or no symptom resolution, and only 1% of all participants followed-up with a physician for ongoing symptoms. 96% of the CF members were either very satisfied or somewhat satisfied with the quality of service received from the pharmacists. More than 85% of the CF members said they would continue with this new drug service, if it remained available. It is believed that this is due to increased access to non-prescription drugs because of the streamlined process to just one healthcare professional (Pharmacist) as oppose to two (Doctor and Pharmacist).

See research article:

Kassam, R, Vaillancourt R, Trottier M, and Gervais, A: Evaluation of Pharmacist Managed Non-prescription Drug Benefit for Canadian Military. J Am Pharm Assoc. 2005;45:170-178.