



COLLEGE OF NATUROPATHIC PHYSICIANS OF BRITISH COLUMBIA

Prescriptive Authority for Naturopathic Physicians:
Objectives, Rationale and a Framework for
Regulation

**A proposal for
The British Columbia Ministry of Health**

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Prescriptive Authority for Naturopathic Physicians: Objectives, Rationale and Framework for Regulation

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SUMMARY

Naturopathic physicians are highly skilled primary health care providers who provide a complementary approach within our health care system. Demand for naturopathic medical services continues to rise as patients seek valid, science-based alternatives emphasizing disease prevention and overall wellness along with disease management. Concurrently, naturopathic physicians are denied access to many traditional medicaments for which they have been trained to use and prescribe. This restriction limits the effective delivery of health care.

This paper documents the rationale and regulatory framework for granting naturopathic physicians (NDs) prescriptive authority in British Columbia. Presented in this paper are what ongoing regulatory and policy reviews support the implementation of prescriptive authority for NDs, and how other jurisdictions regulate prescriptive authority for NDs. Discussion also includes an outline of NDs' education, training and current practices and how prescriptive authority will be regulated by the College of Naturopathic Physicians of British Columbia (CNPBC). In conclusion, this paper demonstrates how such a move is a safe, natural transition based on current practice and training.

INTRODUCTION

Naturopathic medicine is a system of primary health care: the science, philosophy, the art and practice of diagnosing, treatment of illness, and promotion of wellness by encouraging the natural healing processes, through individualized care, diagnostic techniques, and prescribing and/or administering preparations and medicines.

The salient difference between the approaches of naturopathic and allopathic physicians is not derived from a divergence in medical knowledge, but rather in treatment protocols. The MD places a medical emphasis on treating or managing the effects of pathological processes using medications, surgery and/or

some physical treatments. The ND, however, emphasizes preventing and correcting the root cause of pathological processes, combining a wider variety of therapeutic modalities, including medications, in a broad, patient-centred approach. Both disciplines are guided by scientific, evidence-based approaches to treatment and intervention. In addition, both disciplines evolve with advances and changes in science and technology.

Naturopathic physicians are regarded and valued as primary health care (PHC) practitioners by the public and by many MDs, pharmacists and other health professionals. "A shared vision for primary health care, guided by strong principles and values and supported by effective infrastructure and funding, will deliver the kind of health care Canadians have in mind. Interdisciplinary collaboration must be a part of that vision." (*EICP-ACIS: The Principles and Framework for Interdisciplinary Collaboration in Primary Health Care.*) Naturopathic medicine is well equipped to play a greater role in addressing some of the critical issues facing the health care system. NDs can support a better public health care system by: creating better access to and alleviating practitioner shortages; increasing inter-professional collaboration; emphasizing disease prevention and self-care by patients; and minimizing adverse drug events and their consequences by integrating judicious use of pharmacotherapies along with other effective treatments.

Naturopathic physicians are also valued as complementary health care practitioners, integrating their services with other health professions to positively contribute to health care delivery in BC. The breadth of naturopathic medical training ensures the appropriate treatment of disease as well as the referral to other health care providers as deemed medically necessary. In addition to disease management, naturopathic philosophy greatly complements and encourages the promotion of wellness. NDs emphasize disease prevention through unique individualized assessments and treatments that focus on addressing the root cause of a patient's symptom or condition.

In short, the public values NDs' contribution as privately funded primary and complementary

health care practitioners. The medical care delivered by NDs positively impacts our health care system as is evidenced by the ever-increasing demand for such services in British Columbia.

Despite this, over the past decade, NDs in British Columbia have seen their scope of practice narrowed through re-definition of scopes of practice along with increasing regulatory restrictions on natural health products. The CNPBC now seeks legislative action to restore prescriptive authority to NDs' scope of practice. This authority will enable NDs to, once again, provide the pharmacotherapies their patients may need as part of their overall care plan. It will also eliminate the costly and time-consuming process of referrals to an allopathic physician for basic prescription medications.

In support of such action, this document:

- Summarizes the issues and concerns with respect to prescriptive authority;
- Summarizes NDs' relevant education, clinical training and credentialing requirements;
- Presents the key objectives and a rationale for re-incorporating prescriptive authority into NDs' scope of practice;
- Recommends regulatory steps to be taken by the Ministry of Health and the CNPBC to grant and regulate prescriptive authority for qualified NDs;
- Proposes a transition process whereby current practitioners will be able to demonstrate current competence to safely and effectively prescribe scheduled medications;
- Describes mechanisms to continue to monitor and enhance safe and effective pharmacotherapeutic practices.

BACKGROUND

Until the late 1990s, naturopathic physicians' scope of practice included prescribing, compounding and dispensing of natural substances and their derivatives, and nearly all of the other reserved acts, as did that of allopathic physicians.

During the 1990s, the British Columbia government mandated the Health Professions Council (HPC) to review the scopes of practice of each regulated health profession. The Council issued its preliminary report outlining Naturopathic Physicians' Scope of Practice in December 1998 followed by an update in March 2001. In its preliminary report, the HPC included naturopathic physicians' long-standing practice of prescribing Schedule I drugs in their scope of practice. In response, the College of Pharmacists of British Columbia (CPBC) recognized the longstanding skills and expertise of NDs and supported granting NDs prescriptive rights. In the post-hearing update, the HPC, with little evidence, reversed its support and did not recommend the granting of this reserved act to NDs, based on questions about the adequacy of ND's clinical training in the use of Schedule I substances. Most of these questions arose from objections raised by other professions that appeared to indicate a lack of understanding of contemporary naturopathic medical practice. The HPC also referenced the federal initiative to create a category of natural health products, or NHPs. The outcome of the NHP regulatory framework was to be monitored to "ensure that provincially regulated health care practitioners, like naturopathic physicians, maintain access to natural health products which are essential to their practice."

On January 23, 2003, Dr. Penny Ballem, then Deputy Minister of Health Planning, indicated that the Ministry would recommend that the recommendations of the HPC, excluding prescriptive authority for NDs, be adopted to guide the changes to the Naturopathic Physicians Regulation.

Meanwhile, in May 2003, the CPBC reiterated its support for including in NDs' regulations the authority to prescribe certain Schedule I drugs. Linda Lytle, then CPBC Registrar, explained that "we support the concept that each regulatory college should be allowed to implement, set standards and monitor appropriate activities for its registrants, provided that the necessary knowledge, skills and competencies can be identified and ensured by the college." This stance was also taken by the College of Registered Nurses of British Columbia (CRNBC) and supported by the Ministry in developing the

legislation, scope of practice and regulatory framework for nurse practitioners.

It is noteworthy that ten of the fourteen regulated jurisdictions in the US also permit NDs to prescribe drugs.

Gap Analysis

In 2003, the Ministry of Health Services supported an independent review by health care consultant Richard Ritter of the issues separating the positions of the profession and the Ministry. In his report, Mr. Ritter observed that:

- A number of procedures not recommended by the HPC for use by NDs have been performed as part of NDs' traditional scope of practice;
- Some of the procedures not recommended for NDs by the HPC because of concerns in respect to training are covered as core competencies within the ND education program and licensing requirements;
- In spite of HPC concerns over the safety of some procedures performed by NDs, the profession has an exemplary safety record both in BC and elsewhere in North America, as substantiated by low numbers of complaints to regulatory boards and infrequency of litigation against NDs. Furthermore, the training of NDs in a variety of treatment modalities allows them to choose treatments that minimize the risk to patients and
- A narrow approach to naturopathic scope of practice would be regressive and not in the interest of patients."

Mr. Ritter found no rational basis for the disparity between the two HPC reports. He recommended implementing a progressive scope of practice for naturopathic physicians, including prescribing, compounding and dispensing or administering Schedule I and II substances, according to a schedule of preparations and medicines for use by NDs.

Federal Drug Schedules

Drug schedules, now harmonized across Canada, are determined by the federal government, which modifies the status of drugs

from time to time. Some natural medicines that have long been used safely and effectively by NDs have been shifted from nonprescription to prescription status. Parallel to this, the federal NHP initiative applies only to over the counter (OTC) items. Thus, nearly all of the same natural health products listed in Schedules I and II remain in these schedules—inaccessible to naturopathic physicians.

The HPC's proposed scope, as well as the federal "rescheduling" of some medicines is doubly negative for NDs. Limits are placed on medications traditionally used by NDs as well as constraints on providing basic primary care.

Health System Reform

Parallel with these initiatives, the federal and provincial governments have sought to reform the health system to ensure that human, technical and financial resources are deployed optimally in providing safe and effective health care and that patients have choices to help them maintain and improve their own health and well-being. In January 2005, the Health Council of Canada called on all stakeholders to speed up the pace of renewal, identifying four key areas for improving and sustaining Canada's health system, including: strengthening health human resources management; accelerating the development of multidisciplinary teams as the basis of primary health care reform; broadening the use of information technology for patient health records and reducing health disparities, particularly in Aboriginal communities. This Council and the Enhancing Interdisciplinary Collaboration in Primary Health Care Initiative, which is currently ongoing, recognize that maximizing the skill sets and competencies of all health professionals will benefit both individual patients/clients and the health system at large.

Experience in Other Jurisdictions

Ontario's Health Professions Regulatory Advisory Council (HPRAC) recently recommended that the NDs be granted prescriptive authority as they become regulated. Because many natural health products now require a prescription, this is still being debated. In HPRAC New Directions, April 2006, it is stated, "HPRAC finds that optimal care cannot be offered to patients unless naturopathic doctors have access to substances

consistent with naturopathic practice. Therefore, **HPRAC recommends that naturopaths be authorized to prescribe, dispense, sell and/or compound drugs that are consistent with naturopathic practice, as prescribed in regulations.**” While recent announcements seem to indicate that this step will not be taken at this time, the regulatory process and debate is ongoing as to how NDs will gain access to drugs that are consistent with their practice.

Lagging Behind

The Health Professions Council 2001 scope of practice reports revealed differing perspectives among authors and respondents, based, to some degree, on lack of information and evidence to support granting NDs privileges to prescribe Schedule I and II medications. There were questions about the adequacy of education and training of NDs compared with that of MDs, particularly with respect to the amount of supervised clinical experience and post-graduate training required for licensure; the specificity and rigour of the examination and certification process; and the differences between them in the types of therapies typically employed in practice, thus in the ongoing experiential learning that occurs over time.

The profession takes seriously its mandate to ensure that registrants have acquired the required competencies, continue to maintain and enhance their professional competency and provide safe and effective primary care in all aspects of their various practices. Previous submissions to government have shown that NDs’ education, clinical training, credentialing and regulatory oversight processes ensure that practitioners practise within the scope of their competencies—and that the public has been well served by the profession.

It is crucial for practitioners and patients that they have access to the diagnostic, therapeutic and emergency substances critical to health care delivery. Provincial regulations have not been revised in keeping with the naturopathic profession and health reform initiatives. Both the Ministry and the profession recognize the need to work in concert to effect the necessary changes to the scope of naturopathic medical practice. The CNPBC hopes that this document

will facilitate consensus on these objectives, provide evidence to support them and expedite the necessary amendments to provincial legislation and professional regulations.

EDUCATION, CLINICAL TRAINING AND CREDENTIALING

Naturopathic physicians are educated and trained to provide primary care with all the knowledge and skills required to practice safely. They assess patients’ health status, symptoms and needs, diagnose and manage acute and chronic diseases within their realm of competence and expertise, and arrange referrals to appropriate alternate primary care providers or specialists when required. Most do not specialize in the treatment of any one body system or disease state because they treat the body as an integrated whole.

Education and Clinical Training

Naturopathic medical schools model their curricula and courses of study consistent with standard medical education. Naturopathic physicians’ academic and clinical training compares favourably with that of MDs’ training and exceeds that of all other professions to whom prescriptive authority has been granted in BC, including nurse practitioners. Academic requirements for NDs include at least four years of premedical education, followed by four years (4400 to 4600 hours) of naturopathic medical training and clinical sciences. Approximately 1500 hours are devoted to clinical training, primarily during third and fourth year of the program, providing direct patient care under the supervision of licensed NDs and MDs.

Pharmacology, diagnostic imaging and minor surgery are examples of conventional medical training that are also required in naturopathic medical schools. Because course work in natural therapeutics is added to a standard medical curriculum, naturopathic doctors receive considerably more hours of therapeutic education than the graduates of many leading medical schools, including Yale, Stanford, Johns Hopkins and Mayo Medical schools. Graduates

possess current pharmacotherapeutic knowledge and skills grounded in scientific research as well as in historical, clinical experience (as do medical graduates).

Indeed, the Oregon Office of Educational Policy and Planning, which regulates all academic degrees in the state, reviewed the education of NDs, concluding that NDs complete “a biological and biomedical education of the same breadth and depth that prepares an MD to be a primary care physician”. This report also concludes that naturopathic medicine diverges from allopathic medicine only “at the point where professionals in common possession of scientific facts conscientiously disagree on how best to use their shared knowledge in treating patients.” Thus, patient care under an ND is primary health care, based on a shared scientific foundation and body of expertise, but with a different focus. (Cited by Glenn Cassie in “The Nature of Naturopathic Medicine”.)

In order to be licensed as an ND in British Columbia a candidate must have graduated from an accredited school of naturopathic medicine. The Council on Naturopathic Medical Education (CNME) is the accreditation body for both Canadian and American schools. The accreditation process is similar to that of accrediting medical, pharmacy and nursing schools. According to Daniel Seitz, CNME Executive Director, “CNME requires ND programs to cover pharmacology, pharmacognosy, botanical medicine and emergency and legend (scheduled) drugs—among others. ND programs must articulate core competencies and learning objectives/outcomes, and CNME in its accreditation process seeks to determine whether these competencies and objectives are being attained. In assessing ND programs, the Council and site visitors consider whether subject areas are covered with sufficient depth and breadth. Also, since graduates of ND programs generally take the NPLEX exam (the uniform licensing exam for naturopathic medicine) programs must ensure that graduates can pass this exam.” In fact, BC and all regulatory jurisdictions require satisfactory completion of the NPLEX exam as one of the requirements for licensure.

Postgraduate residency programs have been greatly expanded in recent years, providing many opportunities for graduates. Most are offered or supervised by the schools of medicine and are certified by the Committee on Post-doctoral Medical Education (CPME, a subcommittee of CNME). Postgraduate residencies have not traditionally been a requirement for licensing, although some American jurisdictions impose a residency requirement for licensure.

In summary, the educational preparation of NDs equals or exceeds that of MDs with the exception of the postgraduate residency requirement.

Assessment and Credentialing Standards for Licensure

In order to be licensed to practice naturopathic medicine in British Columbia, candidates must meet rigorous academic and assessment standards. As indicated in the CNPBC bylaws and on the college website, candidates must:

- Complete a minimum of three years of a pre-medicine program in an accredited college or university approved by the CNPBC and a Doctor of Naturopathic Medicine (ND) degree from a CNME-approved school or college of naturopathic medicine;
- Successfully complete the required Naturopathic Physicians Licensing Examinations (NPLEX) and the CNPBC Jurisprudence and Oral Examinations and
- Be eligible to work in Canada.

The CNPBC Jurisprudence Examination focuses on regulations and standards governing naturopathic practice in British Columbia. The Oral Examination is another level of competency evaluation that requires ND’s to demonstrate verbal and practical skills before the examination committee.

The NPLEX is an internationally recognized series of examinations, the purpose of which is to ensure that the candidate for licensure as a naturopathic physician has the knowledge and clinical decision-making ability to practice safely. The NPLEX blueprint and standards are derived from a job analysis of practising NDs in both Canada and the United States. NPLEX surveyed

practitioners to determine the scope of current naturopathic medical practice in North America and the underlying knowledge that is frequently used and deemed necessary for safe practice. An examination of the blueprint reveals that all NDs in British Columbia must have demonstrated their knowledge and clinical decision-making skills in each of ten clinical domains, including pharmacology, botanical medicine and emergency medicine. In his review, Ritter cited the analysis and findings of the Oregon Office of Educational Policy and Planning as follows:

"...it would not be possible to pass all of the tests – which is necessary for licensure – without having a comprehensive foundation in the biological and medical sciences...In other words, a naturopathic medical college has no choice but to prepare NDs with a biological and medical education of the same breadth and depth that prepares an MD to be a primary care physician." (Ritter 2004)

Until 2007, a candidate who fails any of the individual domain components may retake the failed component(s), within limits, without repeating the other components. Beginning in 2007, nine of the ten examinations, including the Core Clinical Sciences and homeopathy, will be integrated into a single examination, which must be passed in its entirety.

There is one significant difference between licensing examinations of medical and naturopathic physicians. In both Canada and the United States, medical practitioners are now required to successfully complete both a national competency-based clinical knowledge assessment and a performance-based 'objective, structured clinical examination' (OSCE) in order to qualify for licensure. The addition of the OSCE provides for a highly reliable assessment in greater depth of clinical problem solving, assessment, intervention and communication skills. This assessment format has also been implemented as part of the nurse practitioner qualifying process, in order to better assess and certify these essential skills and abilities.

Recommendations:

1. The CNPBC should develop mechanisms to assess and monitor practitioners' performance in practice, to determine if this kind of assessment is needed or warranted at entry to practice once the scope of practice is updated.
2. The CNPBC and CPBC should review the Jurisprudence blueprint to ensure that the regulations and standards governing prescribing, compounding, dispensing and administration of medications are included in the assessment.

STRATEGIC OBJECTIVES

Several key objectives are inherent in the current proposal, including:

- To re-incorporate the authority to prescribe, compound, dispense and administer Schedule I and II medications into the approved scope of practice for NDs in British Columbia;
- To develop, implement and maintain regulatory processes for an expanded scope, including educational qualifications, practice standards and quality assurance mechanisms that assure the public that naturopathic medical practice in British Columbia continues to meet and regularly exceeds minimum standards for safety and effectiveness;
- To establish the principle that, federal legislation notwithstanding, primary care practitioners should not be unduly restricted from prescribing any medication that is within their scope, competency domain and regulated practice guidelines;
- Based on this principle, to gain approval for a 'formulary model' that includes:
 - all Schedule I and II drugs, excepting those prohibited by federal legislation and those that require specific expertise to be used appropriately and safely, such as chemotherapeutic agents;
 - development of formulary and prescribing regulations by the CNPBC, in consultation with the Ministry and pharmacotherapeutic experts and

- To ensure that NDs continue to meet evolving standards of pharmacotherapeutic knowledge and practice.

To achieve these objectives, it is necessary to meet key stakeholders' objectives, ensuring that:

- The public and other health professionals have a clear and positive understanding of the role of NDs in an integrated health system and their role in providing primary health care to individual clients;
- Members of the public have access to primary health care services of their choosing;
- There is an effective regulatory process based on principles of safe and effective care;
- The public has access to regulatory processes to be able to communicate their needs and solve problems when they arise.

RATIONALE AND EVIDENCE

Primary Care Access

Primary health care is the patient's first level of contact with the health system; it brings health care as close as possible to where people live, learn and work. It includes illness prevention, health promotion, diagnosis and management of health concerns. (EICP-ACIS). Primary health care agents need to have both the ability and opportunity to exercise a full range of primary care responsibilities. Naturopathic physicians have traditionally provided safe and effective primary care, within a regulatory structure that provides assurance of safe and effective practice and, thus, are increasingly being sought out by patients as primary health care agents. Withholding prescriptive authority from NDs creates a conundrum for patients (who cannot receive full service from their practitioner), for practitioners (who are being held accountable for safe and effective care and positive outcomes) and for the health care system (as patients must utilize the services of a primary care giver with prescriptive authority when

pharmacotherapies are required to alleviate symptoms or correct medical problems).

Choice of Primary Care Options

By being able to choose the nature of the primary care offered and to access various primary health care professionals, patients are able to seek care that both embraces their values and meets their physical and relational needs, thereby increasing their commitment to implementing the preventive, corrective and/or ongoing treatment strategies medically required. Increasing patient options and access is dependent on removing outdated barriers impeding safe and effective care from competent health professionals.

Removing such barriers has a ripple effect. The entire health system benefits as, e.g., managed naturopathic treatment, combining pharmacotherapy with appropriate non-drug interventions, very often affords equal or greater success in alleviating illness. As well, the naturopathic approach places heavy emphasis on health promotion and disease prevention. This focus assists and supports patients, enabling individuals to make needed changes in their lifestyle, to correct or lessen the cause of disease symptoms and prevent recurrence or delay further deterioration in their health.

Safe and Effective Evidence-based Primary Health Care

Naturopathic physicians take an extremely cautious approach to pharmacotherapies by the very nature of the way they practice and the manner in which their patients wish to be treated, thus minimizing the risk of adverse events. The practice of naturopathic medicine offers a broad range of therapeutic options. Often, other therapies can replace the need for pharmacotherapeutic intervention, further minimizing the likelihood of adverse events. Indeed, it has been shown that there have always been proportionately fewer complaints from both patients and other health care professionals to whom NDs make referrals, about either quality or outcomes of naturopathic care. There are no instances of litigation in Canada, citing naturopathic negligence or harm (Ritter 2004). NDs have a record of safety which is unsurpassed.

Along with allopathic medicine, naturopathic medicine is, increasingly, evidence-based utilizing the “gold standard” of random clinical trials. One only has to search the Internet and medical libraries to find reports of research supporting the benefits and safety of numerous naturopathic treatments, including natural pharmacotherapeutic substances, physical interventions, among others. The Cochrane Collaboration, best known for evidence-based medical research reviews, is a well-respected, reliable source of high quality systematic reviews of complementary and alternative medicine (CAM) health care therapies. (<http://www.cochrane.org/colloquia/abstracts/otawa/P-094.htm>)

Summary

In short, restoring NDs’ prescriptive authority will facilitate meeting the following three high-level health system goals:

- Greater access to primary care,
- More choice of care options and
- Evidence-based safe and effective care.

REGULATORY FRAMEWORK

Major components of a regulatory framework include:

- Delineation of *the prescribing role*, including the competencies (knowledge, skills and abilities) and *elements* required to prescribe and integrate pharmacotherapies safely and effectively into an overall care plan;
- Competency-based academic and clinical training requirements;
- Assessment and credentialing processes that assure applicants’ competency at entry to practice and at critical junctures in their practices (e.g., when resuming general naturopathic practice after a sabbatical or re-incorporating pharmacotherapy into practice);
- Clear, measurable practice quality standards and effective practice oversight;
- Regulatory tools, including legislation, regulatory structures, technologies and processes to establish, monitor and maintain

credentialing and practice quality standards and

- Quality assurance mechanisms, including transitional, continuing and remedial professional development in prescribing and integrating pharmacotherapies into an overall care plan.

Practice Elements to Ensure Safe and Effective Drug Therapy

Grainger-Rousseau and colleagues have proposed eight essential practice elements that need to be in place for a safe and effective drug therapy system, which are:

1. Prompt and accurate identification, assessment of and response to signs and symptoms;
2. Selection of safe and efficacious drug therapies;
3. Prescribing for definite objectives, to enable the practitioner and patient to assess the effectiveness of the therapy in meeting the objectives;
4. Providing patient-specific advice along with the medications, which includes advice on use of the medication, monitoring parameters, and complementary measures to both help resolve the immediate problem and prevent its recurrence or exacerbation;
5. Gaining active patient/caregiver understanding and cooperation, to implement the intended therapy successfully;
6. Monitoring for and resolving problems, such as interactions, side effects, etc.;
7. Documenting and communicating therapeutic decisions, sharing accurate and current information with other health team members using appropriate technologies;
8. A systems approach, identifying best practices, performance and outcome indicators, etc.

(N.J. MacKinnon. Drug Use Management: Prescribing Solutions. Health Policy Forum, Winter 2000)

The College of Registered Nurses of British Columbia recently developed a comprehensive definition of the prescribing role, including indicators of good practice. The College of Pharmacists of British Columbia’s *Framework of*

Professional Practice is another example of a comprehensive definition of Roles, Functions and good practice Indicators.

Recommendation:

The CNPBC should clearly define this reserved act in terms of the expected performance of NDs, including performance indicators, in order to develop appropriate practice standards and regulatory mechanisms.

Development of the CNPBC Regulatory Framework

The CNPBC has the responsibility to establish the regulatory framework, structures, technologies and processes and practice standards to support prescriptive authority, including:

- Clear regulatory objectives for independent prescribing, compounding, dispensing and administration of Schedule I and II drugs;
- Regulations, regulatory mechanisms and standards including: practice standards comparable to those of MDs and others with these privileges, including documentation in patients' records (Pharmanet), dispensing guidelines similar to those of dispensing physicians, Conflict of Interest guidelines for situations where practitioners both prescribe and dispense; plus a transition plan for increased undergraduate or post-graduate education/training in pharmacotherapy as per Arizona;
- A formulary advisory committee with representation from medicine and pharmacy;
- Regulations permitting independent prescribing and provision of Schedule I and II drugs, with specific exceptions, following the principles and developmental process of the recently adopted CRNBC formulary model and
- A new committee or new mandate for an existing committee (such as a Board of Examiners or equivalent) to establish mechanisms (beyond mandatory continuing education) to ensure that practitioners maintain current practice standards and that public safety is upheld.

Recommendations:

1. The CNPBC should determine the competencies required for effective prescribing, advocating for any increased training needs and outcome standards to be incorporated into CCNM and all other approved schools' curricula and NPLEX standards.
2. The CNPBC should consult with the Ministry of Health and the CRNBC in mandating the proposed 'formulary advisory committee' with respect to guiding principles for the development of regulations for prescribing.

Continuing Competence and Quality Assurance

Many health professions currently mandate continuing education as one means to support ongoing professional development. Currently the CNPBC requires all practitioners to complete 20 hours of continuing education annually. Other jurisdictions regulating naturopathic practice require anywhere from 15 to 37 hours annually, some of which must target pharmacotherapeutic knowledge and skills.

A growing body of research has not yet been able to show that simply mandating continuing education is an effective mechanism for ensuring that practitioners who are most 'at risk' are, in fact, maintaining a minimal level of current competence and practice quality. Thus, many health professions are turning to evidence-based continuing competency programs, requiring individuals to undertake an assessment of fundamental knowledge and skills, a practice review, or other means of demonstrating that they are practising safely and effectively, incorporating new knowledge and technologies as they become the standard of care. ("Meeting the Challenge of Continued Competence", NCSBN. 2005. "Reforming Health Care Workforce Regulation: Policy Considerations for the 21st Century", Pew 1995.)

The College of Registered Nurses of British Columbia is currently developing a practice review (assessment) process to enable the college to evaluate the performance of nurse practitioners after two years of practice and periodically thereafter. In addition, CRNBC

indicates that they will use PharmaNet data, to some extent, to monitor prescribing practices of nurse practitioners.

The medical profession has a variety of checks and balances available to it for evaluation purposes, including outcome data provided by independent bodies that survey patients and others regarding the quality of care provided, mine databases of lab tests ordered, prescriptions written, specialist referrals, surgeries, complaints, out-of-court settlements, disciplinary actions, etc. In addition, hospital-based multi-disciplinary committees provide oversight of practitioners' practices in hospital settings. British Columbia physicians who are not meeting standards may be referred to a comprehensive assessment of practice knowledge, skills and abilities (including a knowledge assessment and an OSCE), developed collaboratively by UBC Faculty of Medicine, the CPSBC and the BCMA, to determine the nature of their deficiency(ies). A formal peer support process, remedial and further assessment tools are available to physicians who are not meeting standards of practice.

Recommendations:

1. The CNPBC should develop mechanisms to support, assess and monitor practitioners' pharmacotherapeutic skills in practice, to determine whether additional training, support and/or mandated quality assurance processes are needed. A mechanism that is increasingly being adopted by health professions is the use of a "learning portfolio" to assess one's practice, determine areas needing enhancement (e.g., changes in practice, patient demographics, population epidemiological data, lack of currency, etc.), identify and implement professional development opportunities, and document sustainable changes in practice that have occurred as a result of the process. A variety of models are in use by health professions in British Columbia and elsewhere.
2. As noted previously, in order to develop such quality assurance mechanisms, the CNPBC should, in collaboration with other

stakeholders (e.g., pharmacists and medical physicians), define the functions involved in prescribing natural and other medications, describe indicators of good practice, identify the requisite underlying knowledge and skill requirements, determine the minimum performance standard required for licensure purposes and determine how performance in practice is best evaluated. This will guide the development of assessment and oversight mechanisms.

TRANSITION PLAN

In Arizona, where prescriptive authority is most liberal, granting NDs authority to prescribe some narcotics and controlled substances as well as prescription-only medications, the profession created a transition plan by which qualified NDs could refresh and demonstrate their competence to prescribe and manage drug therapy. Practitioners were required to complete a series of four modules, along with supervised clinical training, within a designated timeframe in order to maintain their license that included authorization to prescribe scheduled drugs within the parameters established in formulary and practice standards. Two of the accredited naturopathic medical schools have now incorporated this material into the regular curriculum, so graduates from these programs are exempted from this requirement.

As it has been a number of years since British Columbia NDs have been able to exercise their prescribing rights and skills, it is appropriate that the CNPBC establish a similar transition process for current registrants that includes a "refresher" followed by an assessment in the relevant competencies.

Recommendations:

- 1) The CNPBC, along with pharmacotherapeutic experts, should evaluate the currency and relevancy of the Arizona professional development program as a means to support the transition to independent prescriptive authority.
- 2) The CNPBC should consider adopting or adapting the Arizona curriculum, or

equivalent, as a continuing education program, which may be supplemented by a short period of supervised prescribing, and thereby certify physicians who have graduated from schools without this curriculum component but wish to become independent prescribers.

FORMULARY MODEL

Currently in British Columbia there are three main formulary models by which prescriptive authority is regulated in different professions. The unrestricted medical model applies to medical practitioners, dentists and veterinarians. Since federal legislation is now referencing the provincial definition of practitioner the same applies to podiatrists, for the most part. Under a similar model, nurse practitioners are authorized to prescribe any drug product except narcotics, with some limitations on certain classes of drugs. Exemplifying the third, restricted model, midwives and optometrists are restricted to prescribing from a list of approved drug entities and products, consistent with their respective limited domains of practice. Under this limited formulary model, the Ministry is obliged to commit to a process for perpetual review and revision of regulations in the face of new products and information.

The limited formulary model is not without its liabilities. For example, as medical knowledge changes rapidly, concurrent with research and therapeutic advances, so do standards for clinical practice. The public expects care consistent with evolving standards, products and technologies. Therefore, the restrictions imposed on primary care practitioners by a restricted formulary would prevent practitioners from making many, often optimal, therapies available to patients who would most benefit from them. The restricted formulary is onerous to maintain and does little to promote best practices in primary care or to protect the public any more than an unrestricted model or the nurse practitioner model accompanied by effective regulation and practice standards.

Under the nurse practitioner model, specific drugs may be exempted for reasons related to the special kind of expertise required to use the

medications safely and effectively. Such drugs may be identified through expert review and consideration of the risks and benefits to patients if they were to be prescribed by primary care practitioners rather than specialists or experts in their use.

An unrestricted model has long been the standard for primary care practitioners in Canada. All health professionals with prescribing authority are ethically bound to prescribe within their scope of competence and practice and in accordance with their profession's regulations. The responsibility for regulating health care practitioners has been entrusted by the public to the professions, who set and enforce standards that are designed to protect the health and welfare of the public. The CNPBC is focused on developing proactive interdisciplinary relationships with regulators and other health care experts in an effort to ensure excellent patient care, integrating best practices as they and other primary care givers have been amply trained to do. To move forward in this pragmatic fashion, the college requires the framework and tools necessary for providing such care—including the authority to prescribe any medications that ND's patients require for preventive, acute, chronic or emergency care.

CONCLUSIONS AND RECOMMENDATIONS

Whereas the CNPBC has provided a rationale and evidence demonstrating that NDs:

- Are an integral part of the health care system, increasingly utilized by patients who are seeking primary health care focused on disease prevention and overall wellness;
- Incorporate pharmacotherapy when required, as part of a holistic approach to care;
- Are extensively trained and examined in current pharmacotherapeutic knowledge and clinical skills in order to manage patients' pharmacotherapeutic needs;
- Are legislated to prescribe in a number of jurisdictions and have been effectively and safely prescribing in Oregon and Washington state for a number of years;

- Have consistently upheld academic, professional, clinical and ethical standards that have served the public safely and effectively for many years in British Columbia and elsewhere and
- Are currently restrained from meeting patients' health care needs for pharmacological therapy, including many natural substances that require a prescription

the CNPBC recommends that the **Ministry of Health** make regulations to include in NDs' scope of practice the reserved actions: *prescribing, compounding, dispensing or administering by any means a drug listed in Schedule I or II of the Pharmacists, Pharmacy Operations and Drug Scheduling Act* (Health Professions Council Reserved Acts List, July 2005).

To facilitate the implementation of prescriptive authority for NDs, the **CNPBC** recommends that it undertake the following regulatory initiatives, in consultation and collaboration with other stakeholders in the profession and the health system as appropriate:

1. Specify the required competencies and practice standards for prescriptive authority, in the form of a framework for all related regulations.
2. Develop regulations that will:
 - a. permit all registered NDs to prescribe Schedule I and II substances, once qualifications have been established;
 - b. specify means of determining and maintaining qualifications to prescribe Schedule I and II substances and
 - c. specify requirements for interim certification and re-certification and for ongoing registration with full prescriptive authority which may include initial and ongoing education, initial assessment and periodic reassessment and/or review of their practice in this domain (through supervised practice, on-site observation, portfolio or records review, etc.).

3. Establish a multidisciplinary advisory committee comprised of NDs, MDs and pharmacists with recognized pharmacotherapeutic expertise, to:
 - a. develop guiding principles and regulations for prescribing, formulary development and maintenance;
 - b. identify and oversee changes in practice that are needed to support prescriptive authority and
 - c. identify means for the CNPBC to ensure safe and effective prescribing practice and outcomes.
4. Work with the Ministry to gain access to PharmaNet for NDs use in reviewing patients' current medications, identifying collaborative care needs, and preventing or resolving drug related problems.
5. Work with the Canadian College of Naturopathic Medicine (CCNM), the Boucher Institute of Naturopathic Medicine (BINM) and the Arizona Board to review and, if necessary, to update the continuing education modules on advanced pharmacotherapy and clinical training and to require successful completion of this program for certification in pharmacotherapy until ND schools, accreditation standards and NPLEX have incorporated these elements into their standards/curricula.
6. Work with CCNM, BINM and the Council on Naturopathic Medical Education (CNME) to encompass the required advanced pharmacotherapy content and skill standards in academic program accreditation criteria.
7. Work with NPLEX to ensure that candidates must demonstrate mastery of these advanced pharmacotherapy and clinical skills, and thus be eligible to register with full prescriptive authority, without having to complete an additional certification process.

In Closing

As articulated by Dr. Lorne Swetlikoff, the CNPBC President, in recent communications with Ministry officials:

"We are primary health care providers, and we have been compounding, dispensing, and prescribing medicines since inception (for as long as the profession has existed). A move to greater prescriptive authority is a natural transition for registrants of this College. Unlike a newly formed college where its registrants are being granted authority to prescribe where they have never done so before, our doctors have the breadth of medical training to understand how to safely prescribe and are currently doing so.

While this process we are undertaking is essential (an evidence based case and a sound QA, regulatory structure, etc.) the above points may help interested parties better understand what it is that we bring to the health care table and help to ease training and safety concerns and may add further insight into how the regulatory structure is set up. Paramount to the College is that doctors are transitioned to prescriptive authority with the utmost competence and safety for the public."