SUBMISSION TO THE GOVERNMENT ADMINISTRATION SELECT COMMITTEE - THERAPEUTIC PRODUCTS AND MEDICINES BILL

7 FEBRUARY 2007

Submission to:
Clerk of the Committee
Government Administration Select Committee

Contact for this submission:
Helen Snell, Nurse Practitioner, MN, MPhil (Nursing), FCNA(NZ)
Chair NPNZ
Diabetes Lifestyle Centre
MidCentral Health
Gate 13, Ruahine Street
Palmerston North
Ph: 06 3508114
Fax: 06 3508128
Mobile: 027 2500115
email: helen.snell@midcentral.co.nz

I do wish to appear before the Select Committee to support this submission.

1. EXECUTIVE SUMMARY

The Government Administration Committee is seeking submissions on the Therapeutic Products and Medicines Bill.

This submission has been prepared by Nurse Practitioners New Zealand (NPNZ) which is a division of the College of Nurses (Aotearoa).

NPNZ agrees with the need to update the Medicines Act 1981 and supporting regulations. NPNZ welcomes the opportunity to respond to the call for submissions on the Therapeutic Products and Medicines Bill as it considers that there are some components of the Bill that require amendment in order to better meet the health care needs of New Zealand's population while ensuring practitioners are fully able to practice as intended.

NPNZ recommends that nurse practitioner prescribers be recognised as *authorised prescribers*, rather than *designated prescribers*; that nurse practitioners as authorised prescribers would therefore be able to issue standing orders; and that registered nurses who in future may be approved to practice in a collaborative arrangement are included in the proposed bill as designated prescribers.

NPNZ wishes to appear before the Select Committee to support its submission. The following members will appear:

- Helen Snell (Chair)
- Deborah Harris
- Jenny Carryer.

2. RECOMMENDATIONS

NPNZ recommends that:

- Under the Therapeutic Products and Medicines Bill, nurse practitioners be classed under section 6 as *authorised prescribers* (part 6, clause 339, page 211).
- As authorised prescribers under the proposed bill, nurse practitioners would therefore be able to issue standing orders and authorise changes to standing orders.
- Registered nurses approved to work in a collaborative prescribing arrangement are classed under the Therapeutic Products and Medicines Bill as *designated prescribers*.

3. BACKGROUND

3.1 Nurse Practitioners New Zealand (NPNZ)

NPNZ is a forum for New Zealand registered Nurse Practitioners to contribute to individual and national advancement of the NP role. Membership is open to New Zealand registered nurse practitioners.

More specifically, the purpose of NPNZ is to:

- provide a professional formal network for registered Nurse Practitioners
- provide a forum where practice direction is debated and formulated on a national level
- provide a forum to guide and integrate the strategic directions into the context of Nurse Practitioner clinical practice
- work with and co-ordinate effort with the Nurse Practitioners Advisory Committee of New Zealand
- provide a forum to contribute the ongoing development of nursing as a discipline
- act as a source of mentoring and support for all registered Nurse Practitioners in New Zealand
- link with equivalent Nurse Practitioner forums internationally
- provide a contact point for key stakeholders.

The Therapeutic Products and Medicines Bill is an omnibus bill whose purpose is twofold:

1. it aims to establish a new joint trans-Tasman regulatory scheme for the regulation of therapeutic products
2. it aims to repeal the Medicines Act 1981 with updated legislation for controls on medicines.

NPNZ has comments in three specific areas in relation to this Bill:

1. the role of nurse practitioners
2. standing orders
3. registered nurses prescribing at the collaborative level.

4. SUBMISSION

While NPNZ supports the proposed Therapeutic Products and Medicines Bill, it considers that several changes are required in order that the Bill better meets the health care needs of the New Zealand population and is aligned with changes that have occurred in the health delivery arena.

NPNZ proposes three changes to the proposed Therapeutic Products and Medicines Bill, each of which is detailed further in this submission:

- Nurse practitioner prescribers are classed as *authorised prescribers* instead of *designated prescribers*
- This change would therefore allow nurse practitioners to both issue standing orders and authorise changes made under standing orders
- Registered nurses approved in future to work in a collaborative prescribing arrangement are classed as *designated prescribers*.

4.1 Authorised and designated prescribing

Currently the mechanism for nurse prescribing in New Zealand is via the role of nurse practitioners. Nurse practitioners are expert nurses who work within a specific area of practice incorporating advanced knowledge and skills. They are extensively prepared before being assessed and registered by the Nursing Council of New Zealand as nurse practitioners.

Under the proposed Therapeutic Products and Medicines Bill there are two classes of prescribers – *designated prescribers*, and *authorised prescribers*. Under the Bill, there is a pathway for nurse practitioner prescribing as *designated prescribers* (explanatory note p15, s 519, 545).

Designated prescribers are essentially subject to extensive requirements in relation to qualifications, training and competence.

Prescribing notices are a new feature, are mandatory (s373, 374, 375) and only apply to *designated prescribers*. The prescribing authority must review these notices after 6 months and publish a list of all prescription medicines. Only medicines that relate directly to the scope of practice of the designated prescriber are permitted to be included in a prescribing notice (373(3)(a)).

Authorised prescribers, however, are defined under the proposed Bill as a dentist; medical practitioner; midwife; or health practitioners of a registered class named as authorised prescribers by regulations made under section 502. Prescribing notices do not apply to authorised prescribers.

NPNZ is aware that designated prescribers can become authorised prescribers under regulations (s502). There is discussion of this in the explanatory note on p 16 describing it as a way, over time, if designated prescribers demonstrate their competence to prescribe safely and appropriately, they could become authorised prescribers. However, NPNZ considers that nurse practitioners should be classed as *authorised prescribers* under the proposed bill instead of as *designated prescribers*. There are several reasons NPNZ has come to this conclusion.

First, nurse practitioners have already demonstrated their competency in order to become authorised prescribers. Internationally there is a forty year history of safe nurse practitioner independent prescribing (where NPs have equivalent preparation to NZ – Goolsby 2005; Latter, Maben et al. 2005) and now since 2003 a number of New Zealand nurse practitioners have also prescribed without incident. Ongoing competency assessment is obligatory, and includes that the nurse practitioner provide evidence of ongoing multidisciplinary peer review of their prescribing practice (Renouf, 2005).

Nurse practitioners provide improved access to health services and have safely and proactively met the needs of many consumers who have been traditionally hard to reach, impoverished, and who have become responsive to the nurse practitioner approach to care (Perry, Thurston et al. 2005).

Second, NPNZ argues that nurse practitioners have educational equivalency to be included in the authorised prescriber category alongside doctors, midwives and dentists. The qualifications and experience required by a registered nurse in order to become registered by the Nursing Council as a nurse practitioner are extensive and include:

a. Registration with the Nursing Council of New Zealand in the Registered Nurse Scope of Practice, AND
b. A minimum of four years of experience in a specific area of practice, AND
c. Successful completion of a clinically focused Masters Degree programme approved by the Nursing Council of New Zealand, or equivalent qualification, AND
d. A pass in a Nursing Council assessment of Nurse Practitioner competencies and criteria. Nurse Practitioners seeking registration with prescribing rights are required to have an additional qualification:
e. Successful completion of an approved prescribing component of the clinically-focused Masters' programme relevant to their specific area of practice (Nursing Council of New Zealand, 2006).

Nurse practitioners receive an extensive postgraduate clinical education within the required Master's degree. This includes:

a. Pharmacology and pharmacotherapeutics which is developed in conjunction with New Zealand's pharmacy schools and experienced practitioners
b. Diagnostic reasoning and specialty practice courses
c. Evidence-based practice, research, and practicums culminating in a prescribing practicum being signed off/passed by experienced practitioners including often medical practitioners where appropriate.

Once educational requirements have been fulfilled, they must then undergo a process of Nursing Council endorsement through portfolio, site visits, and interview by a panel which includes an experienced practitioner (often medical practitioners where appropriate) in the applicant's scope of practice (if prescribing

is to be included). Only then can NPs finally incorporate 'independent' prescribing into the range of care they offer to their patients. This takes a minimum of 8 and probably at least 10 years of combined university education and years of practice to achieve (ibid). This is well in excess of midwife's and dentist's preparation.

NPNZ would therefore argue that nurse practitioners are more academically and clinically prepared than new prescribers from other disciplines.

Third, the requirement that nurse practitioners, as designated prescribers under the proposed Bill, prescribe medication according to a specified list of medicines (which is then required to be reviewed regularly by the prescribing authority) is cumbersome and does not reflect the reality of a nurse practitioners practice. The list is not complete and if implemented, would limit nurse practitioners ability to fulfil the requirements of their role meaning they would be able to prescribe some of the required medications but leaving them dependent on working under standing orders to access other medications. The requirement that the specified list of medicines be regularly updated is unrealistic in practice. There will always be delays in such processes leaving the nurse practitioner unable to access new medications or advances in treatment.

It is a very demanding process for nurse practitioners to meet the requirements set out in section 373 regarding prescribing notices. Nurse practitioners acknowledge the need to demonstrate ongoing competence and safety, however, consider extent of requirements under this section to be unnecessarily arduous. The number of nurse practitioners within our health and disability sector is rapidly increasing. Managing specified lists of medicines for such a large group will be unworkable.

For these reasons, NPNZ recommends that nurse practitioners are classed under the proposed Therapeutic Products and Medicines Bill as *authorised prescribers* rather than as *designated prescribers*.

4.2 Standing orders

Under the proposed Therapeutic Products and Medicines Bill the requirements regarding standing orders are outlined in clause 381 and can only be issued by *authorised prescribers* (ie dentists, medical practitioners and midwives). As designated prescribers under the proposed bill, nurse practitioners would therefore be unable to issue standing orders, or authorise changes made under standing orders.

As has been outlined, nurse practitioners are expert nurses practising both independently and in collaboration with other health care professionals to promote health, prevent disease and to diagnose, assess and manage peoples' health needs. They provide a wide range of assessment and treatment

interventions, including differential diagnoses, ordering, conducting and interpreting diagnostic and laboratory tests and administering therapies for the management of potential and actual health needs. They work in partnership with individuals, families, whanau and communities across a wide range of settings. The inability for nurse practitioners to issue standing orders has affected their ability to adequately fulfil these requirements.

To illustrate the difficulties faced by nurse practitioners with regard to standing orders, a case study has been outlined below.

Standing Orders Case Study – Diabetes Nurse Practitioner

A typical specialist diabetes service operates as a multidisciplinary team, offering specialist medical, nursing, dietetic and podiatry assessment, clinical management, education, and crisis intervention to people with diabetes who are referred when the severity and complexity is beyond the scope and technical expertise of the primary health care or acute care provider.

The largest health workforce within the multidisciplinary team is the diabetes nurse educator (DNE) and/or diabetes nurse specialist (DNS) who typically have many years of experience and training within the specialty of diabetes. A major component of the practice of the DNE and DNS includes the clinical management of treatment regimens to optimise glycaemic control and improve health outcomes for people with diabetes referred to their service. DNEs and DNS's are subject to competency assessment within their respective diabetes services to ensure they are adequately prepared and safe to perform this role. In addition, these nurses operate under Standing Orders which promote safe and consistent practice however, it is not logistically possible for countersigning of every titration to a treatment regimen to occur without seriously affecting service delivery.

On an average day a DNE or DNS recommends a titration of either diabetes tablets or insulin doses according to guidelines and standing orders to, at the very least, 10 – 20 individuals. For some patients several titrations may occur within the same day, for example during crisis intervention.

According to the Medicines (Standing Order) Regulations 2002, each and every titration to a prescribed treatment regimen is required to be countersigned within a specified time frame. This means that for a specialist diabetes service over the course of one day a medical practitioner may be required to review the notes and countersign at least 60 – 120 individual treatment titrations. Over the course of three days, this accumulates to 180 – 360 individual treatment changes to be countersigned and so on. CNEs and CNS's, however, are committed to practicing lawfully but the countersigning requirement within the current Medicines (Standing Order) Regulations 2002 are unworkable and make adherence extremely difficult.

(Snell, 2006).

Nurse practitioners, as outlined, are extensively prepared with significant experience in a specific area of practice. Their practice is based on a collaborative model within a multidisciplinary team environment. Enabling nurse practitioners to be defined as authorised prescribers under the proposed bill would in turn allow them issue standing orders significantly improving their ability to fulfil the requirements of their role. This would allow nursing practitioners to share the workload with their medical colleagues who are currently subject to excessive and unnecessary requirements under standing order regulations.

4.3 Registered nurses approved to work in collaborative prescribing arrangements

As outlined, the mechanism for delivering nurse prescribing is currently via the role of the nurse practitioner. NPNZ considers that there is a need for 'future-proofing' both in terms of supporting nurse practitioners as authorised prescribers as outlined in section 4.1; and in terms of the future role of experienced registered nurses.

The role of experienced registered nurses is continually evolving and changes in nursing models of care have sometimes resulted in difficulties complying with the current legislation. This has meant that there are now increasing instances where there have been unnecessary delays providing appropriate medications to consumers. Discussion is underway about introducing collaborative prescribing arrangements between authorised prescribers (eg medical practitioners) and registered nurses with the purpose of improving access and responsiveness of care for patients.

Significant GP shortages are predicted in future, and as well our population is ageing. In order to cope with the increasing demands for health services by an ageing population, health care systems will require:

- An increasing number of practitioners
- More specialist services to deal with specific conditions associated with an ageing population
- More expertise (Ministry of Health 2004).

The need therefore for an experienced flexible registered nursing workforce that can be utilised to its full potential to work in collaboration with authorised prescribers to provide improved access to patient care will be very important.

NPNZ considers that it is critical the proposed bill recognises these impending changes without further recourse to legislation and therefore recommends that registered nurses approved to work in a collaborative prescribing arrangement

are classed under the Therapeutic Products and Medicines Bill as *designated prescribers*.

CONCLUSION

NPNZ strongly urges the Government Administration Select Committee to implement the NPNZ's proposed changes to the Therapeutic Products and Medicines Bill. These changes would significantly improve both nurse practitioners and registered nurses ability to contribute to improved population health outcomes. At the same time such changes will ensure that the Bill is aligned with the rapidly evolving models of care delivery and workforce flexibility needed for increasing levels of need in health service delivery.

REFERENCES

Goolsby, M. 2005. 2004 AANP National Nurse Practitioner Sample Survey, Part II: Nurse Practitioner Prescribing. *Journal of American Academy of Nurse Practitioners,* 17(12): 506-511.

Latter, S., Maben, J. et al. 2005. *An evaluation of extended formulary independent nurse prescribing. Executive summary of final report*. London, Department of Health.

Ministry of Health. 2004. Ageing New Zealand and Health and Disability Services 2001-2021: Background information: International responses to ageing populations. Wellington: Ministry of Health.

Nursing Council of New Zealand. 2006. *Nurse Practitioners*. Available at http://www.nursingcouncil.org.nz/nursepractitioner.html (accessed 31 January 2007).

Perry, C., Thurston, M. et al. 2005. The nurse practitioner in primary care: alleviating problems of access? *British Journal of Nursing*, 14(5):255-259.

Renouf, P. 2005. Nurse practitioner (NP) prescribing in NZ: a NP's response to the editorial by Drs Moller and Begg. *The New Zealand Medical Journal*, 118(1126): 1-4.

Snell, H. 2006. *Submission to the Ministry of Health. Amendments to the Medicines (Standing Order) Regulations*.