

**Enabling the Therapeutic
Products and Medicines Bill
to Allow for the Development
of Collaborative Prescribing**
Consultation Document

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Introduction

In late 2006, the Ministry identified, through consultation on the Medicines (Standing Orders) Regulations 2002, the need for the development of a class of collaborative prescriber. Collaborative prescribing would allow a non-prescribing health practitioner, after authorisation from their registration authority, to prescribe under the supervision of an authorised prescriber.

However, to allow such a policy to be given effect to, the Medicines Act 1981 (the Act) will need to be amended to provide a mechanism to allow for this class of prescriber.

Currently the Act is being reviewed and updated through the Therapeutic Products and Medicines Bill (the Bill) which is, at present, under consideration by Parliament's Government Administration Committee. The Ministry recognises the opportunity to enable collaborative prescribing through this process but notes the tight timeframe for doing so.

The Ministry is looking to consult on the proposal to enable the Medicines Act to allow for collaborative prescribing, through a Supplementary Order Paper (SOP) on the bill to be put to the House during the Committee of the Whole House stage of the bill. The SOP would include provisions in the Bill to allow the making of regulations by the Governor-General, on the recommendation of the Minister of Health, to permit collaborative prescribing. If it is not possible to implement this change through the Bill now, it may be several years before legislative amendment can be undertaken in order to allow for collaborative prescribing to proceed. The Ministry believes this would be a great loss to New Zealand's ability to develop innovative practice and consumers' ability to access safe, timely and appropriate services.

The **closing date for consultation will be 13 April 2007**. Recognising the short consultation period and the need to ensure all interested and affected parties have the opportunity to be heard, the Ministry is open to meeting, in person, with any groups who may wish to discuss the proposal.

Please forward your comments to Ryan McLean or contact Ryan if you would like to meet to discuss the proposal. Ryan's contact details are:

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The following information provides context for discussion and poses questions to help guide your comments.

Context

Currently a practitioner may only access medicines under standing orders¹ or after attaining independent prescribing rights².

In late 2006, the Ministry consulted on the operation of the Medicines (Standing Orders) Regulations 2002 (the Regulations); specifically the requirement that all interventions undertaken by a practitioner working under a standing order must be counter-signed by a medical practitioner within the period of time specified in the order.

Submissions on this consultation identified a gap between the ability to independently prescribe and the need to work under standing orders. The responses to consultation clearly indicated the need for practitioners to be able to access medicines under a more flexible policy. This policy would ensure patient safety while acknowledging the individual non-prescribing practitioner's competence and relationship with independently prescribing colleagues. The policy would match this with a level of supervision that reflected that competence and relationship.

What is Collaborative Prescribing?

It is proposed that collaborative prescribing be broadly defined as follows:

Collaborative prescribing is where a non-prescribing health practitioner, after authorisation from their registration authority, may prescribe under the supervision of an authorised prescriber.

Several questions are posed in **Appendix 1** to help guide your responses when considering the potential for collaborative prescribing. Several case studies are attached as **Appendix 2**. These provide examples of environments in which collaborative prescribing may be beneficial.

Potential benefits of collaborative prescribing

Collaborative prescribing may be broadly beneficial in the following ways.

More timely, safe and appropriate services for patients

More flexibility in the way in which prescription medicines can be accessed will be very helpful in allowing new ways of delivering services. This is especially important in community and rural settings and in meeting the growing demands of chronic disease

¹ A standing order is a written instruction issued by a medical practitioner or dentist, in accordance with the regulations, authorising any specified class of persons engaged in the delivery of health services to supply and administer any specified class or description of prescription medicines or controlled drugs to any specified class of persons, in circumstances specified in the instruction, without a prescription.

² Currently medical practitioners, dentists, midwives and some nurse practitioners and optometrists may prescribe without supervision.

(eg, diabetes care, etc). Getting the kind of flexibility that is needed is proving extremely difficult. It is placing strain on health resources, particularly in rural communities and specific service environments (eg, diabetes care, cardiac care, sexual and reproductive health).

In many cases, there are highly competent practitioners who, while not competent enough to prescribe autonomously, are competent enough to prescribe in a collaborative relationship with an authorised prescriber. The fact that this is not legally possible in the current environment compromises the quality and timeliness of care in some instances.

In many cases, the potential risk to the patient is leading to practitioners breaching the law by supplying courses of prescription medicine, often with the knowledge of an authorised prescriber, but under unapproved supervisory regimes.

The formalising of a process by which these highly competent practitioners may prescribe under nationally-approved guidelines and competence requirements, in collaboration with an authorised prescriber, will be of significant benefit to the:

- patient - in ensuring timely access to medicine, in a safe environment, and continuity of care between practitioners due to the communication between the collaborative and authorised prescriber, that would be required under the proposed policy
- collaborative prescriber – in ensuring they are working within the safest environment possible with the necessary support mechanisms to facilitate their ongoing learning and practice
- authorised prescriber – in ensuring they have stronger links to non-prescribing practitioners in the community and rural settings.

Reduced need for surgery

Due to more timely and appropriate treatment, a patient's condition, particularly in rural areas, may be treated in the community. In this way fewer patients might be expected to reach the stage where their conditions require specialist attention and/or surgical intervention.

Greater collaboration within the health workforce

The necessity for a non-prescribing health practitioner to have the endorsement of an authorised prescriber in order to access medicines in the way envisaged, necessitates the need for a strong relationship between the practitioners involved. This is reflected in the implicit level of trust that would be demonstrated by both parties in entering into an arrangement for collaborative prescribing.

Under the proposed policy this relationship will be fostered by the requirement that supervision be undertaken by the authorised prescriber in the form of a review of a sample of the collaborative prescribers prescriptions on a regular basis.

Enhanced learning opportunities for all practitioners

The collaborative relationship between the authorised prescriber and collaborative prescriber and supervision requirements specified in the policy, will inherently lead to the development of not only stronger relationships between practitioners but enhanced learning and understanding of each other's role in the delivery of health services.

This arrangement will also facilitate the education of the collaborative prescriber such that they may themselves progress to designated prescriber status over time, after assessment by their registration authority.

Possible mechanisms for recognising collaborative prescribing

The Health Practitioners Competence Assurance Act 2003 (the HPCAA) establishes a number of registration authorities who are responsible for, among other activities:

- defining the boundaries around practice for given professions and
- stipulating the necessary qualifications and competencies that a person must have before they may be registered in a scope of practice.

The proposal anticipates that the registration authority would assess a practitioner against a minimum set of competencies and authorise that practitioner as a collaborative prescriber.

In addition, in order to ensure uniformity of application, the Ministry would be advocating that regulations made under the Medicines Act stipulate the minimum competencies required of a practitioner before that practitioner may prescribe in a collaborative capacity.

It may be beneficial to provide guidance to ensure that collaborative prescribing is applied uniformly to all professions. The proposed regulation-making powers under the Medicines Act could enable collaborative prescribing in respect of:

- any practitioners who are registered under the HPCAA
- practitioners who are registered in a defined scope of practice and/or
- practitioners working in defined service area(s).

Why can't collaborative prescribing be enabled under standing orders or as a class of designated prescriber?

Standing orders do not allow for "prescribing", but permit "supplying" and/or "administration" of prescription medicines.

The Ministry has considered enabling collaborative prescribing as a class of designated prescriber. However, that presents a difficulty, as "designated prescribers" are themselves a class of independent prescriber. Collaborative prescribing is not envisaged to be a form of independent prescribing but rather set in place a framework to allow for prescribing in partnership with an authorised prescriber³.

³ An authorised prescriber is a medical practitioner, dentist or midwife.

In the continuum of care, it is important that practitioners be able to access medicines in a variety of environments under varying supervisory arrangements which are reflective of the non-prescribing practitioner's competence and relationship with their independent prescribing colleagues. The Ministry does not believe it would be in the best interests of patients or practitioners to blur the lines between standing orders or designated prescribing by enabling collaborative prescribing under one or other of these existing mechanisms. Therefore, the Ministry is proposing the new class of prescriber discussed in this consultation document.

Roles and responsibilities

The need to recognise roles and responsibilities is a key aspect of ensuring the policy is able to work safely and effectively.

While more in-depth thought will be given to roles and responsibilities, during policy development, outlined in **Appendix 3** is what might be considered the minimum expectations to be placed on the parties involved in the operation of the policy in practice.

Appendix 1: Questions to Guide your Comments

1. Is there a need for collaborative prescribing in New Zealand?
2. Do you agree with the proposed way in which collaborative prescribing would work at a high level (ie, only after endorsement from the relevant registration authority and under the supervision of an authorised prescriber)?
3. What are the key elements that you feel make up the concept of “collaborative prescribing”?
4. Should collaborative prescribing be made in respect of:
 - a. all registered health practitioners,
 - b. scopes of practice (ie, only practitioners who are registered in a specific scope of practice may prescribe as a collaborative prescriber, or
 - c. service delivery environments (ie, only practitioners practising in a specific area, such as diabetes, could prescribe as a collaborative prescriber)?
5. In order to ensure uniformity of application, should minimum competencies be specified in regulations made under the Act?
6. Any other comments?

Appendix 2: Case Studies

Collaborative Prescribing and Diabetes Management

A typical specialist diabetes service operates as a multi-disciplinary 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 diabetes specialist multidisciplinary team is the proficient diabetes nurse (PDN) and/or expert diabetes nurse (EDN) who typically have many years of clinical preparation and experience within the specialty of diabetes.

A major component of the practice of the PDN and EDN includes advising on the clinical management of treatment regimens to optimise glycaemic control in order to improve health outcomes for people with diabetes referred to their service. As specialists in their field, the PDN and EDNs possess a depth of knowledge regarding diabetes pharmacological therapies that is sought by their medical and nursing colleagues on a daily basis.

PDNs and EDNs are also involved in providing direct clinical care which may involve recommendations to adjust treatment regimens, either dosage or actual medication changes. Collaborative prescribing by nurses with the appropriate level of competence will facilitate improved access to care and more timely intervention to a large number of people with diabetes.

On an average day a PDN or EDN recommends a titration of either diabetes tablets or insulin doses according to guidelines and standing orders to, at the very least, 10–20 individuals per day. For some patients several titrations may occur within the same day, for example during crisis intervention. Any concurrent illness causes an elevation in blood glucose levels due to the counter-regulatory hormone or ‘stress’ response. This can quickly develop into ketoacidosis for people with type 1 diabetes which is life threatening without prompt intervention. In this situation a collaborative prescribing arrangement would enable the nurse to immediately respond while having the support and oversight of a prescriber as required.

The PDN or EDN will assess the patient and the severity of the concurrent illness and advise the patient to seek medical assessment if their symptoms are not improving within a given time frame. The PDN/EDN will maintain 1–2 hourly face to face or telephone contact for ongoing assessment of glycaemic control, instruct the patient to give additional rapid acting insulin according to their blood glucose and urine ketone levels. The PDN/EDN may also adjust the patient’s usual (base) insulin regimen for a few days while they recover, and then change it back again once their illness has resolved. Communication with the primary health care provider is maintained throughout the episode, and consultation with the diabetes physician or nurse practitioner occurs as necessary.

Collaborative prescribing and innovative practice

Hamilton East Medical Centre has 15 general practitioners servicing 19,000 patients. It is an innovative and supportive environment. The nurse delivering this service has 23 years experience in primary health care (PHC), a Masters of Nursing (PHC) (Hons) and among other qualifications has set up and worked as a Mobile Maori Disease State Management Nurse (DSM) for four years. She is completing the last two nurse prescribing papers over the next year. During that time she will be mentored by one of the GPs but will not prescribe at all.

The Mobile Practice Nurse (MPN) service has been available to the patients of the Hamilton East Medical Centre (HEMC) for six months. This service was designed and proposed by practice staff to meet the needs of their high needs groups, specifically Maori and Pacific Islander and the elderly debilitated. It has fixed term funding through Waikato Primary Health, 20 hours per week through Services to Improve Access (SIA) and HEMC meet the other 15 hours.

The specific services all done in the home, include the preschool check Fit for School, Outreach Immunisation Service (OIS), Diabetes Annual Diabetes Review (DAR) and care of the elderly. The service is designed to compliment existing doctors' services as the nurse acts as their eyes in the home. This pilot is based on creating a dedicated resource and seeks to identify both an efficient and an effective model of nursing care. The nurse is supplied with the appropriate assessment equipment plus a car, laptop computer and mobile phone, thus ensuring close communication with the specific general practitioner (GP) at all times.

Working with the most at risk and needy of our community in their homes, allows a holistic whanau approach to nursing. On many occasions follow-up case management is required.

For example, an elderly bedridden woman being cared for in her home by whānau, who has exacerbated asthma with a probable chest infection and urinary tract infection. The GP requested the MPN visit to assess; she will ensure the family have access to a nebuliser and correct medications, and are using them correctly. She can obtain a sputum and urine specimen and refer to the community physiotherapist. As the patient's history is available on the laptop including past laboratory results and current medications there is now an opportunity for the nurse to prescribe antibiotics while still at the home with whanau and under GP supervision. This saves the GP from doing a time consuming and expensive home visit (HV) but ensures his/her involvement through phone contact or emails.

Another example is a middle-aged Māori gentleman living in one of our rural communities, who is found while doing an ADR, to have an infected leg ulcer that he is treating with aqueous cream. The nurse will ensure a referral to District Nursing for wound management, discuss diabetes management appropriate to the lab results, take a wound swab and may prescribe antibiotics for the wound. Children with chronic ear infections could also be prescribed antibiotics, at the home.

Chronic disease management: heart, lung and diabetes are areas that nurses excel in, in the home with whānau involvement. The introduction of ACE inhibitors, beta-blockers, aspirin, statins, diuretics, biguanide, sulphonylureas and inhalers can all be discussed at greater length and in a safer way when all ears are there to listen. Under and with close GP supervision, these whanau members who would otherwise not access GP services due to travel issues or financial barriers can access medication and closer ongoing support by nurses who enter the home.

Collaborative prescribing and primary care

Note: The scenarios set out below are actual cases with names and locations removed.

ACUTE EXACERBATION OF ASTHMA

Notes as recorded by nurse following her examination.

A 25 year old active female farm worker recently moved into the area onto a dairy farm to assist with milking. The woman has a known history of seasonal asthma and hayfever. She gives her address as that of known dairy farmer just out of Ross – She has had troubles/exacerbations since childhood.

When good she says she can blow about 450 L/min on peak flow meter – has not blown for a while, not sure where her meter is. Sometimes doesn't need any reliever or preventer and gets no symptoms. Often gets flares in summer with allergies and then uses Beclazone 200 x 2 b.d. and Ventolin up to 5 or 6 times daily. Able to give good account of self – no obvious respiratory distress when sitting quietly. Had admissions to hospital x 3 as adolescent but since then has learned to get medical help earlier. Last course of steroid 2 years ago.

Is now coughing and wheezing, getting disturbed at night. Concerned that ventolin and Beclazone are getting low and thinks she has infection developing about sinuses. Examining her: peak flow 250 L/min - she goes into coughing fit. Has dirty post nasal drip. Noises all through chest with deep breaths, describes being tight/full about sinuses. Ears dull and drums retracted. Difficulty nose breathing. Obviously overgrown turbinates.

She volunteers that Amoxil and prednisone usually fix this for her and is asking for more Ventolin and Beclazone as well. Is on Depo Provera – next injection due in six weeks – enquires if nurse can give her that when she is due.

Doctor and nurse then discuss – nurse presents to doctor what she thinks:

Nurse wants to maintain regular meds – Ventolin and Beclazone adding Budesonide 100 nasal spray to be used BD back titrating over next 6 weeks to keep nose clear (she has learned that trick from GP) and Amoxycillin 500 tds for ten days (Knows that usually ten days required to get sinus infection under control) and burst of steroid – prednisone 40 mgm daily for 3 days then 20 mgm for 3 days – this lady has been coughing at night for the last 2 weeks so may need slightly longer course of steroid.

Following discussion GP prescribes

Ventolin 2 puffs qqh sos to relieve asthma

Beclazone 2 puffs b.d. to prevent asthma

Amoxycillin 500 mgm tds for ten days to settle infection

Prednisone 20 mgm 2 daily for 3 days then 1 daily for 3 days to settle acute inflammation

Budesonide 100 umgms 2 squirts b.d. to get and keep nose clear

The discussion also involved follow up advising patient to record peak flows which would be discussed when the nurse came back for next depo injection or before if any worries. Would discuss with patient back titrating use of preventer either before or after review.

STABLE CONTROLLED HYPERTENSIVE

Notes as recorded by nurse following her examination.

A male officer worker in local WINZ office aged 45 has been on treatment for hypertension now for 5 years. Had medications adjusted 12 months ago, saw doctor for review 3 months ago.

When reviewed by doctor 3 months ago BP 125/80. Lipids and other bloods satisfactory. Today has not had a smoke now for 5 years. Weight stable at 80 kgs. Out walking dog regularly and goes to gym 3 times a week. BP when first recorded 130/85. Later in consult when better settled 125/80. Says all is well and has no worries.

Has been on Lipitor 20 mgm nocte, Accupril 20 mgm.

Practice policy is for such patients to be reviewed at 6 monthly intervals unless concerns of patient or doctor suggest otherwise.

HYPERTENSIVE DIABETIC

A 55 year old mildly overweight diabetic on Metformin 500 b.d is seen in joint consultation with doctor and nurse. HbA1C is 7.0, lipids and creatinine are satisfactory. ACR is 5.0, BP 140/85 after several readings. Patient is on statin – Lipitor 20 with satisfactory readings.

From joint consultation doctor advises that patient should be started on aspirin 100 mgm daily and Accupril, starting with half a 5 mgm daily doubling after one fortnightly building up by 5 mgm each fortnight to 20 mgm or until BP 120/70 or lower. If not reached 120/70 when 20 mgm of accupril doctor suggests adding thiazide or perhaps calcium channel blocker – and suggest medical review or discussion at least.

Doctor provides prescription for above. Doctor and nurse agree that nurse should monitor two weekly supervising increasing dose of accupril.

Seven weeks after joint consult patient's BP 120/65 and feeling well taking accupril 5 mgm x 4 tabs. Has about run out 5 mgm tabs. Needs more tabs – nurse would want to provide **ongoing** prescription for 20 mgm daily (**prescribing one 20 mgm tab**) of accupril to cover patient until next medical review approx 3 months after last joint consultation.

COMMENT

Many nurses hold the confidence of medical practitioners to manage patient conditions such as those highlighted above. However, currently the law does not allow for nurses to manage these conditions in the most appropriate, safe, cost effective, convenient manner due to the inability of the nurse to prescribe prescription medication.

It is entirely appropriate, where a nurse holds the confidence of the medical practitioner, for the nurse to prescribe with regular review by the medical practitioner to ensure appropriate prescribing practice and ongoing patient safety.

Appendix 3: Possible minimum expectations of parties involved in the operation of collaborative prescribing

Registration authority

The collaborative prescriber's registration authority will:

- assess practitioners applying for collaborative prescribing, against the minimum competencies stipulated in regulations.
- undertake an annual audit of the reviews undertaken between the authorising prescriber and collaborative prescriber.

Authorising prescriber

The authorising prescriber will:

- ensure the Collaborative Prescribing meets the requirements of the Regulations (i.e. specifying additional competencies, medicines that may be prescribed and circumstances they may be prescribed in)
- share responsibility for adverse events occurring from any inappropriate prescribing by the collaborative prescriber where the adverse event has arisen from:
 - the collaborative prescriber not having the necessary additional competencies to prescribe within the specialist area
 - lack of support/supervision from the authorised prescriber.

Collaborative prescriber

The collaborative prescriber will:

- prescribe within the boundaries set down by the authorised prescriber
- engage with the authorised prescriber in regular meetings to review a sample of the prescriptions
- undertake any additional training identified during the review meetings
- share responsibility for adverse events occurring from any inappropriate prescribing where the adverse event has arisen from:
 - lack of adherence to the requirements specified by the authorised prescriber, and/or
 - negligence in the act of prescribing.