Regulatory Impact Statement: Designated Prescribing Authority for Podiatrists

Coversheet

Purpose of Document	
Decision sought:	Analysis produced for the purpose of Cabinet decision making on prescribing authority to podiatrists
Advising agencies:	Ministry of Health | Manatū Hauora (the Ministry)
Proposing Ministers:	Hon Dr Shane Reti
Date finalised:	*ie, date the RIS was signed out*

Problem Definition

There is significant burden on people and the health system caused by the inefficiency of accessing and receiving prescription medications for podiatric care. This burden includes poorer health outcomes, increased cost to people and the health system, and impacts quality of life for New Zealanders.

Executive Summary

It is proposed that podiatrists are extended designated prescribing authority under the Medicines Act 1981. This will allow podiatrists who complete the additional training to prescribe a specified range of medicines relevant to podiatric practice.

The rationale for extending prescribing authority to podiatrists is to increase quality and efficiency of care, reduce burden on the health system, reduce barriers to accessing podiatric care, and improve health outcomes.

Limitations and Constraints on Analysis

The main limitation on the analysis is the inability to infer the exact costs and savings to podiatrists, the health system, and persons seeking podiatric care. We have described likely cost savings based on the current cost of podiatric care to the health system, however this does not reflect exact costs and savings.

Responsible Manager(s) (completed by relevant manager)

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12 June 2024

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10 June 2024

Quality Assurance (completed by QA panel)	
Reviewing Agency:	Ministry of Health
Panel Assessment & Comment:	The Ministry of Health's Papers and Regulatory Committee has reviewed the attached RIS and considers it meets the QA criteria.

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

Podiatrists current scope of practice

1. Podiatrists are currently unable to prescribe medicines. If they were, podiatrists could play a key role in the reduction of challenges faced by the health system and contribute to more efficient services for patients and reduced burden on the health system.

2. A podiatrist is a health practitioner who uses medical, physical, palliative, and surgical means to provide diagnostic, preventative, and rehabilitative treatment of conditions affecting the feet and lower limbs. Podiatrists play an important role in the treatment and prevention of lower limb complications as a result of conditions such as diabetes.

3. Currently there are 471 registered podiatrists spread across the country and working in a mixture of private clinics and community settings, including marae-based clinics in rural communities.

4. Podiatrists in New Zealand are regulated as a health profession under the Health Practitioners Competency Assurance Act 2003 (the HPCA Act). The HPCA Act imposes set requirements to maintain a regulated health profession.

5. To become registered, podiatrists must have completed a Bachelor of Health Science in podiatry. This course includes a pharmacology paper to be completed in the second year of study. The learning outcomes of the paper are:
    1. Critique the professional, sociocultural, and politico-legal context of medicines' management.
    2. Demonstrate understanding of pharmacokinetics.
    3. Demonstrate understanding of pharmacodynamics.
    4. Demonstrate understanding of pharmacotherapeutics.

6. The Podiatrists Board (the board) have developed a podiatrist prescriber course should designated prescribing authority be granted. This course will initially be a standalone qualification, available to all podiatrists who hold a current annual practising certificate. In the long-term it is proposed that the course will be included in the undergraduate programme for podiatrists entering the profession.

Prescribing under the Medicines Act 1981

7. The Medicines Act 1981 (the Medicines Act) provides that prescription medicines can only be sold on receipt of a prescription from someone authorised to prescribe. The authorised prescribers are medical practitioners, midwives, dentists, optometrists, nurse practitioners, or any other group of health practitioners who are authorised to prescribe by regulations made under the Medicines Act.

8. The Medicines Act allows the making of regulations to extend prescribing authority to designated groups of health practitioners (known as designated prescribers). The policy objective was to achieve more timely and effective treatment; improved flexibility in the delivery of health and disability services; and make better use of the skills of New Zealand's health practitioner workforce. Current professions with designated prescribing authority include nurses, dieticians, and pharmacists. The

extension of designated prescribing authority to these professions has allowed for more direct access to health care and savings for people and the health system.

Podiatric care within the current health system

9. The current care pathway for a person accessing podiatric care who requires prescription medicines:

   General Practitioner (GP) appointment (for referral) → podiatry appointment (for diagnosis) → GP practice (for prescription) → podiatric appointment (for treatment). Some people may self-refer to a podiatrist removing initial GP appointment. This delays treatment, imposes unnecessary time and money costs on patients, and an unnecessary burden on a stretched GP workforce.

10. In New Zealand, a large number of those who access podiatric care are diagnosed with diabetes. Podiatric care plays an important role in the prevention and management of diabetes related complications. For people with diabetes, improving efficiency and access to medical intervention will have a positive impact on prevention. The estimated annual incidence of foot ulceration ranges between 1% and 4.9% of an at- risk diabetes population. Those at high risk of diabetes foot ulceration require an average of nine podiatric appointments per year.

11. The length of the current care pathway is inefficient and increases the likelihood of complications. In the case of diabetes, these can include infection and amputations. The cost a singular amputation has on the health system is approximately $50,000. This includes $10,000[1] in surgery costs and an additional $37,240[2] for a five-day hospital stay. These figures also don't account for the cost to the persons quality of life after amputation which is significant and any future impacts on mental health, ability to work, and cost for prosthetics.

12. People can access podiatric care privately at their own cost. There is also public funding through Te Whatu Ora for those with medical conditions such as diabetes and those receiving a disability allowance. The Accident Compensation Corporation (ACC) also funds podiatry care where it relates to an accidental injury.

What is the policy problem or opportunity?

13. There is an unnecessary burden on people and the health system caused by the inefficiency of accessing prescription medications when receiving podiatric care. This burden results in avoidable costs to people and the health system, and potentially poorer health outcomes.

14. The current care model introduces barriers and inefficiencies into the treatment pathway for those who require prescription medications, which can have significant negative impact on a person's life:

    - the person must make an appointment with their GP to receive the required prescription, this GP appointment, costing on average $80[3] per visit, is incurred by the patient,

[1] elective-surgery-service-schedule.pdf (acc.co.nz)

[2] cbax-model-dec2023.xlsx (live.com)

[3] Cost Resource Manual - version 3 (pharmac.govt.nz)

- the treatment timeframe may be delayed by the GP's availability, and there is typically a delay in obtaining a GP appointment time,
- the second podiatric appointment is an additional cost to the person,
- the person may not receive timely access to treatment, which may lead to complications, including widespread infections and amputations
- complications can cause significant impact on quality of life.

15. There is also burden on the health system as health professionals such as GPs are required to undertake additional work to create prescriptions. This creates unnecessary appointments and increases waiting lists. Emergency departments and hospitals are also burdened as not receiving timely access to medicines can lead to serious complications which require hospitalisation.

16. There is opportunity to align podiatric care with what is provided in other countries such as Australia. In Australia podiatrists with additional training and expertise can apply for accreditation to prescribe a range of medicines. This has been in place since 2010[4]. Other countries where podiatrists can prescribe medications include the United Kingdom, the United States, and Canada.

What objectives are sought in relation to the policy problem?

17. The objectives sought in relation to the policy problem include:
    - improved quality of podiatric service to patients/public without compromising patient safety
    - improving patient access and choice reducing duplication and inefficiencies, and streamlining service delivery,
    - easier for patients/public to get the medicines they need,
    - unnecessary appointments and waiting lists reduced,
    - benefits of fully utilising podiatrists' diverse professional skills maximised.

Section 2: Deciding upon an option to address the policy problem.

What criteria will be used to compare options to the status quo?

18. **Patient benefit,** the ability for a person to receive quality podiatric care that is accessible, reduces current risks, and removes barriers faced by people receiving podiatric care.

19. **Efficiency in the health system,** services that reduce financial burden on the health system and burden on other health professionals within the health system.

20. **Safety,** ensuring that options are safe and promote improved health outcomes for people.

21. **Implementation,** ensuring an option that is feasible, cost effective, and can be implemented easily.

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What scope will options be considered within?

22. The scope includes all regulatory powers available to the Minister and Cabinet to extend designated prescribing authority to podiatrists under the Medicines Act. This includes the development of a medicines list to be published in the New Zealand Gazette. The scope also includes the ability of the Ministers delegate to reclassify medicines in the Medicines Act.

Consultation

23. The board opened their proposal for designated prescribing authority to stakeholders for consultation. There was agreement that designated prescribing authority for podiatrists would enhance patient care and outcomes. Stakeholders consulted included relevant health professional groups, pharmacy organisations, regulatory authorities (Ministry of Health, Medsafe), funding authorities (PHARMAC), and registered podiatrists.

24. The Antimicrobial Stewardship Council and the Analgesics Stewardship Council at Te Whatu Ora Central were also consulted by the board. These stakeholders expressed support for podiatrists being extended designated prescribing authority and emphasised the importance of a carefully developed medicines list to ensure safety.

What options are being considered?

Option One – *Status Quo/counterfactual*

25. Option one is to continue with the current state which prohibits podiatrists from prescribing a range of medicines required for podiatric treatment.

26. Under the status quo, podiatrists are unable to provide efficient timely care due to the frequent requirement for additional appointments to obtain prescription medications required for podiatric treatment.

27. The status quo continues to put added pressure and burden on health practitioners such as GPs who must review referred podiatric patients to prescribe required medications. This increases the already high demand for GP appointments.

28. The need for multiple appointments between a GP and podiatrist can act as a barrier for receiving treatment and prevents equal access to health care. This specifically affects those with mobility issues who require assistance attending appointments.

29. Receiving podiatric care in the current system can be costly for a person specifically where it is not publicly funded. The need for multiple appointments at cost is unmanageable for many and may result in podiatric care becoming inaccessible.

30. The extensive cost to the health system caused by the inefficiencies of podiatric care is expected to continue and likely worsen under the status quo as the prevalence of conditions, such as diabetes, that benefit from preventative treatment by podiatrists continues to increase.

Option Two – *Developing a new scope of practice to allow registered podiatrists designated prescribing authority.*

31. Podiatrists who complete the stand-alone qualification provided by the board are extended designated prescribing authority. This would allow podiatrists, who complete the required training, the ability to prescribe a limited range of medicines relevant to podiatric practice.

32. The policy opportunity relates to the Medicines Act allowing the making of regulations to enable health practitioners, such as podiatrists, to become designated prescribers. Designated prescribers can only prescribe certain prescription medicines, as specified by the Director-General of Health by notice in the New Zealand Gazette. The prescription medicines that may be prescribed are specific to that class of health practitioner and dependent on the practitioner's competence and scope of practice, as defined by the relevant responsible authority.

33. The board have been a Responsible Authority since 1966 with long established evidence of ongoing quality assurance practices. The 2022 review of the Podiatrists Board's performance identified well established processes and systems to register applicants, issue practicing certificates, review and improve competence, respond to complaints and conduct health notifications. This performance provides assurance that the board can manage the administration of designated prescribing authority and could manage the provision of additional training for podiatrists.

34. The proposal for podiatrist prescribing supports the delivery of the provisions and principles of Te Tiriti o Waitangi, aligns with the key objectives of the Māori Health action plan 2020-2025, is consistent with the Pae Ora (Healthy Futures) Act 2022, and supports the development of mauri ora (healthy individuals), and whānau ora (healthy families).

35. The list of medicines a podiatrist can prescribe will be developed following approval of designated prescribing authority. This process is led by the Ministry and includes consultation with people or organisations affected by the change. The proposed list of medicines (once approved by the Minister) will then undergo public consultation. The final list is approved by the Director-General of Health and published in the New Zealand Gazette.

Option Three – *Reclassifying medicines used for podiatric care*

36. An additional option to address the current challenges faced by the health system in relation to podiatric care is to reclassify medicines relevant to podiatric care from prescription medicines to restricted medicines under the Medicines Act. This would allow podiatrists to refer patients to a registered pharmacist to access medicines.

37. Currently, many medications required for podiatric care are classified as prescription medicines. This means they may only be supplied by authorised or designated prescribers such as General Practitioners. Reclassifying prescription medicines to restricted medicines would mean they can be sold without prescription by a registered pharmacist.

38. Reclassifying medicines relevant to podiatric care would involve the Podiatrists Board applying to the *Ministry of Health Medicines Classification Committee* who review applications for reclassification and provide recommendations to the Minister of Health.

39. The process of a podiatrist referring a person to a pharmacist for prescription medicines will not reduce the need for additional appointments to access medicines. Reducing the need for multiple appointments is important to improving accessibility which cannot be achieved through pharmacist prescriptions.

40. Pharmacists will also need to complete a consultation with the person before prescribing the medicine. This will result in a person having to repeat the discussion they previously had with the podiatrist, a significant burden for the person.

41. Reclassification of medicines will reduce the burden on other prescribing health professionals such as GPs however, the burden on the pharmacists will increase when they are already stretched and a workforce that is already under pressure.

42. Pharmacist prescribing will also allow people to bypass having a podiatric appointment and go directly to a pharmacist for consultation. This then requires the pharmacists to have a complex understanding of podiatric conditions which for podiatrists takes a minimum of three years to obtain.
43. While medicine reclassification may reduce barriers accessing podiatric care it does not produce better health outcomes, it also increases burden on pharmacists, and maintains the need for multiple appointments.

Option Four – *Authorised Prescribing for podiatrists*

44. An additional option to address the current challenges accessing podiatric care is to give podiatrists prescribing authority.

45. Prescribing authority would allow podiatrists to prescribe a full range of prescription medicines unrestricted, this would also include medicines not related to the scope of podiatric care.

46. There is no additional benefit to podiatrists having prescribing authority in comparison to designated prescribing authority. Podiatrists are only qualified to treat issues related to the field of podiatric care and therefore have no need to access medicines outside of the podiatric scope.

47. While this option addresses the burden on the health system and produce better health outcomes, it gives podiatrists the ability to act outside of their scope of practice and prescribe medicines unrelated to podiatric care.

Option Five – *Standing orders*

48. An additional option to address the current challenges to accessing podiatric care is to implement standing orders for podiatrists under the Medicines (Standing Order) Regulations 2002.

49. A standing order is a written instruction issued by a medical practitioner to allow another health professional to supply and administer specified prescription medicines.

50. While standing orders may include a range of medications the order must specify what the preferred medication is for the given purpose. Podiatrists treat a range of issues and to specify the medication for all given contexts would be difficult. This also allows very little flexibility for podiatrists to change medicines based on a patient's individual needs.

51. Health professionals prescribing under a standing order must have onsite access to the medications required. This includes the labelling, packing and storage of medicines. This is unrealistic for podiatrists who work in practices where there are no dispensing facilities.

52. While standing orders would allow podiatrists to prescribe medicines related to the area of podiatric care, the barriers a standing order creates in relation to dispensing and providing the medication mean only a small number of podiatrists will be able to prescribe medicines. Therefore, standing orders will not address the burden on the health system and improve health outcomes.

How do the options compare to the status quo/counterfactual?

	Option One – Status Quo	Option Two – Designated prescribing authority for podiatrists	Option Three – reclassification of medicines used for podiatric care	Option Four – Prescribing Authority	Option Five – Standing orders
Patient benefit	0 People experience poorer health outcomes and increased costs which can result in significant health implications and reduced quality of life.	++ Improves the quality of podiatric service and creates cost savings for people, improves health outcomes for people accessing podiatric care.	0 Reduces the cost of accessing necessary medicines, creates risk of people being misdiagnosed by pharmacists unqualified in podiatric care, therefore unlikely to improve health outcomes.	++ Improves the quality of podiatric service people can access and creates cost savings, improves health outcomes for people accessing podiatric care.	+ Provides inequitable access to podiatric care as prescriptions will be based on the ability of podiatrists to hold a standing order and dispense medications.
Efficiency in the health system,	0 There is burden on health practitioners as people wait for appointments. There is significant cost to the health system where people don't receive timely care and require more extensive treatment.	++ Podiatrists can prescribe medications and reduce the burden on prescribing practitioners and wait lists. Cost savings to the health system where more timely care reduces need for more extensive treatment.	- Burden on the health system is not reduced due to the shift in prescribing responsibility from general practitioners to pharmacists. There is significant cost to the health system where people don't receive timely care and require more extensive treatment.	++ Podiatrists can prescribe medications and reduce the burden on prescribing practitioners and wait lists. Cost savings to the health system where more timely care reduces need for more extensive treatment.	+ Provides very small reduction on health practitioners who can prescribe as the number of podiatrists able to hold standing orders is minimal due to dispensing restrictions. Provides little cost savings to the health system where timely care is received.

Safety	0 Safety for persons requiring medication remains low as they are more susceptible to worsening conditions due to the barriers accessing medications.	++ Person safety is improved by improving timely access to services and medications that then promote better health outcomes.	- Person safety is reduced as the expertise of the care received by pharmacists is lower than received by a podiatrist. May result in misdiagnosis.	- The lack of restriction of medicines a podiatrist may prescribe creates safety issues.	- Safety is reduced as podiatrists must dispense medications, putting them at significant risk where they work in private clinics where medications are stored on site.
Implementation	0 N/A	- There is minimal cost to implementing this option, which are covered by current budgets. The option is feasible to implement.	- - Implementation of this option is difficult as current scope and processes do not account for pharmacists taking on the role of a podiatrist. The cost of training pharmacists would also be significant.	- There is minimal cost to implementing this option, which are covered by current budgets. This option is difficult to implement as it requires legislative change.	- - There is extensive cost to implement this option associated with setting up dispensing facilities at place of practice. This is also a difficult to implement due to the need for prescribing practitioners to give standing orders.
Overall assessment	0 People continue to experience poorer health outcomes and increased costs, which may result in significant health implications and reduced quality of life.	+5 Improves access to medications and the quality of podiatric care. Also reduces burden on the health system. Keeps people safe and is feasible to implement.	-4 Ineffective at improving access to medications and improving the quality of care by podiatrists. Is difficult and costly to implement.	+2 Improves access to medications and the quality of podiatric care. Is also difficult to implement and poses safety risks to podiatrists and people.	-1 Difficult to implement and provides little benefit to access and burden on the health system. Costly to establish dispensing facilities at place of practice.

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

53. Option two (developing a new scope of practice to give designated prescribing authority to podiatrists) will address the problem, meet the policy objectives, and deliver the highest benefits by enabling timelier cost-effective access to prescription medications, while also reducing burden on the health system.

54. Podiatrists' current education and the provision of an additional training course for those who choose to extend their scope mitigates risk associated with prescribing medications. Risks associated with individual medications will be assessed and mitigated when developing a medicines list.

What are the marginal costs and benefits of the option?

55. There are significant cost savings for people accessing podiatric care who will no longer require multiple appointments with varying health practitioners to receive prescription medications related to podiatric treatment. The reduced demand for appointments by enabling prescribing is not likely to increase the cost of appointments. If podiatric fees were to increase it is very unlikely this would amount to the current cost of multiple appointments for those accessing podiatric care.

56. The marginal costs will be associated with:
    - providing additional training,
    - cost for accrediting the training courses,
    - cost for podiatrist prescribing continued professional development,
    - prescribing monitoring programme.

    These costs will be incurred by the Board in the first instance and then reflected in an increase of registration fees for podiatrists. It is not expected the additional cost to the board and registration fees for podiatrists will be reflected in an increase in fees for those accessing podiatric care. Any cost increase is likely to be modest, and spread over the approximately 500 registered podiatrists. So even if the fee for an annual practicing certificate doubled that would mean $1000 to be recovered over the course of a minimum of 2000 appointments (assuming 40-hour week and hour-long appointments) amounting to 50 cents per appointment.

57. The benefits of designated prescribing for podiatrists include:
    - improved access to prescription medications for those accessing podiatric care
    - improved quality of care for those accessing podiatric care through reduction of unnecessary appointments
    - increased accessibility for those who require assistance attending health care appointments through not needing to organise transport for multiple appointments,
    - reduced burden on prescribing health professionals
    - cost savings for the health system due to more effective and timely treatment of podiatric conditions
    - cost savings to those accessing podiatric care due to the reduction in costly appointments for prescription purpose only

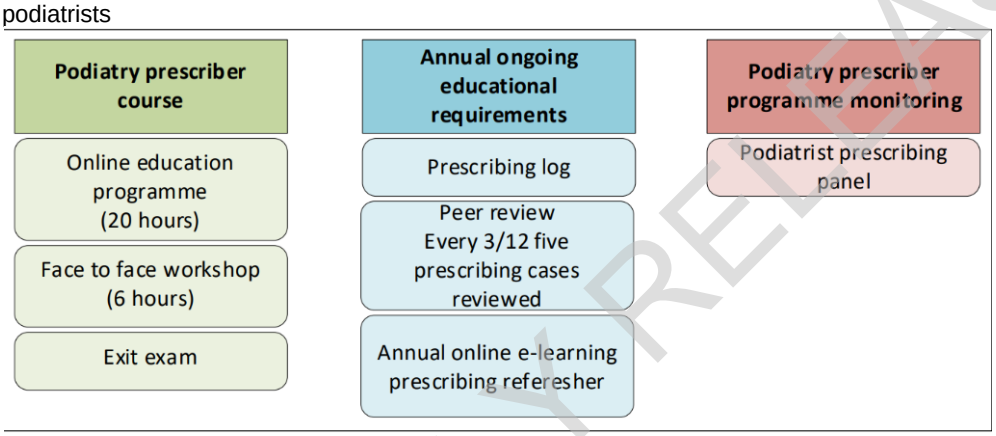
Section 3: Delivering an option.

How will the new arrangements be implemented?

58. New regulations will need to be drafted under the Medicines Act to allow podiatrists to prescribe. Once podiatrists have designated prescribing authority the list of medicines will be developed and approved by the Ministry, which includes consultation. The list will then be set by the Director-General of Health in the New Zealand Gazette.

59. The Board have developed a podiatrist prescriber course (Figure 1). This course will initially be a standalone qualification, available to all podiatrists who hold a current annual practising certificate. In the long-term it is proposed that the course will be included in the undergraduate programme for podiatrists entering the profession.

Figure 1. Overview of the proposed Podiatry Prescriber course and ongoing education requirements for New Zealand podiatrists



60. By the completion of the podiatry prescriber course the podiatrist will be able to:

1. Demonstrate an understanding of the legal and ethical obligations and considerations that pertain to prescribing of any medicines on the list of medicines as approved by the board.

2. Discuss the roles and obligations of all parties involved in the prescribing process (prescriber, dispenser, funder).

3. Write a prescription for those products that the board consider to be within a podiatrist's scope of practice that fulfils the legal requirements for a prescription. This includes checking processes, sources of information and the mechanics of writing a prescription.

4. Demonstrate an understanding of the importance of ethical behaviour and practice in a culturally sensitive and inclusive manner that works to achieve equitable outcomes for patients.

5. Demonstrate understanding of the impact that mechanisms of action, indications for use and pharmacokinetics (absorption, distribution, metabolism, excretion) of agents prescribed within the podiatrist prescriber scope of practice have on individual patients.

6. Demonstrate understanding of the potential for prescribed medicines to cause adverse reactions and of the interactions associated with these products with other medicines that may be prescribed by other health care professionals providing care to the patient.

7. Demonstrate an understanding of the importance of antimicrobial stewardship. Demonstrate an understanding of antimicrobial resistance and how to identify patients with risk factors for AMR that might necessitate a referral, change in treatment plan including a different antimicrobial choice.

8. Demonstrate clinical decision-making skills in prescribing in a range of scenarios related to current podiatric practice.

How will the new arrangements be monitored, evaluated, and reviewed?

61. The Board maintains a register of podiatrists as required under the Medicines Act (Part 6, s 138 (1), and s 149).

    a) An endorsement will be placed on podiatrist prescribers' scope of practice in the register of podiatrists.

    b) Podiatrist prescribers' practice will be monitored directly by the Board.

    c) An audit of podiatrist prescribers will also be incorporated into the existing 'continuing competence' audit for practitioners.

62. The Board also intend to establish a panel to carry out monitoring of the prescribing component of practice, course feedback, complaints, and discipline. The Board will act on recommendations and suggestions from the panel in a timely manner. This panel will be known as the podiatrist Prescribing Monitoring Panel.

63. Podiatrists are regulated under the HPCA Act and will continue to be monitored to meet the requirements as set out in the HPCA Act. The Ministry administers the HPCA Act and conducts periodic performance reviews of all responsible authorities, including the Board.