

Regulatory Impact Statement:

Medicines (Designated Prescriber) Regulations

Agency Disclosure Statement

This Regulatory Impact Statement has been prepared by the Ministry of Health (the Ministry).

This assessment considers the analysis of options to improve patient access to 230 prescription medicines. The analysis includes the status quo, as well as two regulatory options to allow registered nurses working in primary health and specialty teams to have improved access to prescription medicines for patients. There are no non-regulatory options to extend access to prescription medicines by registered nurses working in primary health and specialty teams or to allow prescribing access to the medicines being considered in this impact statement.

Neither of the regulatory options covered in this assessment imposes additional known costs on the health sector; impairs private property rights, market competition, or the incentives on businesses to innovate and invest; or overrides fundamental common law principles.

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Executive Summary

1. One of Government's priorities is to improve patient access to healthcare services in New Zealand. Making best use of the potential of health practitioners, including registered nurses working to their full capacity would reduce the number of steps required for patients to access medicines and is one way to achieve this priority.
2. It is recognised that patient access to medicines should be timely and convenient, particularly in order to manage workloads in some settings and where there are issues with access to services (such as rural areas). Patients with multiple health conditions which may include common conditions such as hypertension, respiratory diseases, common skin conditions and infections could be managed by a registered nurse with designated prescribing authority who works as part of a multi-disciplinary team within a primary health or specialty team.
3. The Medicines Act 1981 allows the making of regulations to extend prescribing authority to designated classes of health professionals, such as registered nurses. Designated registered nurse prescribers working in diabetes health are already able to prescribe medicines in New Zealand under these regulations.
4. An evaluation of diabetes nurse prescribing in New Zealand has found that it is safe, of good quality and clinically appropriate. Diabetes physicians had fewer interruptions to their work due to nurses initiating prescriptions. Patients were satisfied with the change as it was convenient, saved time and led to fewer delays. Moreover the clinical interventions are safe and appropriate.
5. Internationally, the benefits of nurse prescribing have been found to include improved patient access to treatment, enhanced patient care, more effective use of medical staff time and greater professional satisfaction for nurses. In addition, inter-professional working practices have been strengthened.
6. Designated registered nurse prescribers will practise in primary health and specialty teams, work with patients with long term and common conditions and prescribe from a limited list of commonly used medicines. Employment arrangements would be expected to provide mentoring and support. In addition, designated registered nurse prescribers will be required to meet, and continue to meet, specific educational and competence standards managed by the Nursing Council of New Zealand (the Nursing Council) in accordance with the Nursing Council's statutory role under the Health Practitioners Competence Assurance Act 2003.
7. This proposal seeks to make:
 - a regulation to extend prescribing authority for designated registered nurse prescribers within primary health and specialist teams under the Medicines Act 1981.
 - amendments to the Misuse of Drugs Regulations 1977 to extend the length of supply of specific controlled drugs from three days to seven days.
8. The proposal will not lead to a significant increase in costs for medicines. Registered nurses already supply and administer many medicines through the use of standing orders. Further, much of the prescribing undertaken by designated registered nurse prescribers, including repeat prescriptions, is expected to replace the current need for medical or nurse practitioner prescribing.

Status quo and problem definition

9. There is a need for more timely and convenient patient access to medicines. This can be achieved by making better use of registered nurses' skills and knowledge particularly in settings where there are medical and nurse practitioner shortages (for example in rural and remote areas) but also in all primary care and specialty settings.
10. Registered nurses have a broad scope of practice that covers the lifespan and most health conditions, and have a role in administering medicines and educating patients about medicines. Registered nurses are a large group with 49,769¹ practising in New Zealand. Many nurses deliver primary and specialist health care working closely with medical practitioners, nurse practitioners and other health practitioners in multidisciplinary teams.
11. Currently, registered nurses (apart from the small group of designated registered nurse prescribers working in diabetes health) are unable to prescribe medicines. Many common conditions are readily treatable by a registered nurse. However, patients have to see the doctor or nurse practitioner to get a prescription for medicine. This can lead to double handling and may delay patient access to medicines.
12. Commonly nurses supply and administer medicines under a standing order, defined in the Medicines Act as a written instruction issued by a medical practitioner, dentist registered midwife, nurse practitioner, or optometrist, under applicable regulations. A standing order authorises specified classes of persons engaged in the delivery of health services to supply and administer specified medicines or controlled drugs to specified persons without a prescription.
13. Working under standing orders may provide access to medicines only on a case-by-case basis. In addition, accountability for medicines supplied or administered under standing orders remains with the issuer. Designated registered nurse prescribers would be able to access more medicines for patients in particular areas of practice and the accountability for the prescribing practice will be more transparent.
14. The use of designated registered nurse prescribers in New Zealand has been demonstrated through introduction of designated registered nurses prescribers in diabetes health who are authorised to prescribe 26 medicines in diabetes health.
15. The 2011 evaluation of the diabetes registered nurse prescribing demonstration project undertaken by the New Zealand Society for the Study of Diabetes and Health Workforce New Zealand, found that diabetes nurse prescribing was safe, of good quality, and clinically appropriate. In addition, diabetes physicians had fewer interruptions to their work due to nurses initiating prescriptions. Patients were satisfied with the introduction of diabetes nurse prescribing as it was convenient, saved time, and led to fewer delays.
16. One option for more timely and convenient patient access to healthcare services is for patients to be seen by a designated registered nurse prescriber who can prescribe certain medicines, rather than requiring patients to see a medical practitioner or nurse practitioner who has to sign the prescription.
17. The diabetes nurse prescribing model has proven successful for people with diabetes and related conditions. Designated registered nurse prescribing for a wide range of health conditions could provide similar benefits for people with other common conditions such as hypertension, respiratory diseases, common skin conditions and infections.
18. The Nursing Council is a statutory body established as a responsible authority under the Health Practitioners Competence Assurance Act. Under legislation, the Nursing Council's

¹ The Nursing Council of New Zealand advises that as at 31 March 2015, there are 52,729 nurses in total comprising 49,769 registered nurses, 2,815 enrolled nurses and 145 nurse practitioners.

principal obligation is to assure public health and safety. The Nursing Council is responsible for establishing nursing scopes of practice, prescribing qualifications for nursing scopes of practice, setting clinical competence standards, establishing requirements for ongoing competence and ethical standards, and authorising the registration of nurses.

19. There are three scopes of practice for nurses in New Zealand: enrolled nurse, registered nurse and nurse practitioner. Nurse practitioners are authorised prescribers under the Medicines Act and are able to prescribe both prescription medicines and controlled drugs. There are 38 registered nurses currently working in diabetes health as designated prescribers. Enrolled nurses cannot prescribe medicines.
20. The Nursing Council is responsible for ensuring the safe practice of those nurses currently able to prescribe as well as those nurses who manage and administer prescription medicines, including controlled drugs. In accordance with the Nursing Council's role under the Health Practitioners Competence Assurance Act, the Nursing Council would be required to assure public safety when in the care of designated registered nurse prescribers.

Objective

21. This Regulatory Impact Statement considers options for designated prescribing authority for registered nurses working in primary health and specialist teams to meet the objectives of:
 - Improving patient access to healthcare, including access to medicines
 - Improving patient care without compromising patient safety
 - Making best use of the knowledge and skills of health practitioners in managing pharmaceuticals for positive health outcomes.

Regulatory impact analysis

Status Quo option

22. Registered nurses manage and administer prescription medicines and controlled drugs as part of their role. In many cases registered nurses' work under standing orders to supply and administer medicines. However, most nurses are unable to prescribe medicines and controlled drugs.
23. Nurses are being asked to work to the full extent of the registered nurse scope of practice to make the best use of their knowledge, skills and qualifications. In some areas, registered nurses provide nurse-led clinics for some patients and conditions. In these settings, nurses understand the medication needs of patients and are required to relay assessment information, patient history and previous medication use to a medical practitioner or nurse practitioner to enable them to issue a prescription or to supply or administer the medicine under a standing order. This can result in delays for patients and is an inefficient use of the workforce. The status quo option does not meet the policy objective of providing the most timely and convenient healthcare.

Reclassification of medicines option

24. The Ministry is responsible for administering the Medicines Act and the Medicines Regulations 1984. The regulatory framework applies to a number of inter-related controls that are intended to ensure that the therapeutic products available in New Zealand meet acceptable standards of safety, quality and efficacy or performance. Products are therefore expected to have greater benefits than risks, if used appropriately.
25. Access to medicines is controlled by a classification system that ensures that some medicines are only available through appropriately qualified health professionals.

Medicines are classified on the advice of an expert Ministerial advisory committee (the Medicines Classification Committee) which meets twice a year.

26. The Ministry of Health has considered the option of reclassifying each of the prescription medicines to non-prescription medicines or reclassifying them so that registered nurses without prescribing authority can authorise their use. For example, there are currently four medicines that have been reclassified and can be prescribed in certain situations by registered nurses in order to improve patient care.
27. The reclassification option is a regulatory approach and would require the reclassification of 230 medicines. The reclassification of the 230 medicines or the inclusion of new medicines would be time consuming and is not practicable. Reclassification of medicines is not the preferred approach of the Ministry as it is not practical or flexible.

Designated registered nurse prescribing authority option – preferred

28. The Medicines Act allows the making of regulations to enable health practitioners 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 practitioners and dependent on the practitioner's competence and scope of practice, as defined by the responsible authority.
29. Prescribing authority for specified controlled drugs for a seven-day length of supply would be enabled by amending the Misuse of Drugs Regulations 1977.
30. The Health Practitioners Competence Assurance Act assures the safety of members of the public by providing mechanisms to ensure the lifelong competence of health practitioners. The Nursing Council, as the responsible authority for nurse practitioners, registered nurses and enrolled nurses, sets standards for nursing to protect the New Zealand public. The standards are applied to all education programmes, practising nurses and overseas trained nurses working in New Zealand.
31. Nurses in New Zealand must meet these standards in order to become a nurse and are required to continue to demonstrate that they are competent and fit to practise. The new designated registered nurse prescriber role practising in primary health and specialty teams will have to meet specific educational and competence standards.
32. A nurse who fails to meet the required standards of nursing will be investigated by the Nursing Council. Depending on the nature of the issue, the Nursing Council will either assist the nurse to meet the standards or, if necessary, implement disciplinary processes as set out in the Health Practitioners Competence Assurance Act.
33. The proposal is for registered nurses practising in primary health and specialty teams to work as designated registered nurse prescribers. Designated registered nurse prescribers will be working in collaborative, multidisciplinary teams, which manage and monitor patients with conditions such as those outlined below, in outpatient clinics or general practice, or by providing home-based care.
34. Specific conditions that designated registered nurse prescribers will prescribe medicines for could include diabetes and related conditions, hypertension, respiratory diseases including asthma and chronic obstructive pulmonary disease, ophthalmological diseases, anxiety, depression, heart failure, gout, palliative care, contraception, common skin conditions and infections. They will also be able to administer vaccines.
35. Table 1 summarises the options to improve patient access to medicines.

Table 1: Options to improve patient access to medicines

Outcomes Options	Improving patient access to healthcare, including access to medicines	Improving patient care without compromising patient safety	Making best use of the knowledge and skills of health practitioners in managing pharmaceuticals for positive health outcomes
Status Quo	x	✓	x
Reclassification of medicines	✓	✓	x
Designated registered nurse prescribing	✓	✓	✓

Statement of net benefit of the proposal

36. The extension of designated prescribing authority to designated registered nurse prescribers is likely to improve patients' healthcare experience. The focus of the designated prescribing authority for registered nurse prescribers will be on prescribing for long-term and common conditions within primary health and specialist teams. Designated nurse prescribing would occur in health care settings such as general practice, specialist outpatient clinics, family planning, sexual health, public health, district and home care, and rural and remote areas.
37. The use of designated registered nurse prescribers will be cost neutral for the patient, subject to PHARMAC adding registered nurse prescribers to the Pharmaceutical Schedule for the subsidy of the proposed medicines. The cost implications of this will be considered by PHARMAC once Cabinet agrees to designated registered nurse prescribing authority.
38. In order to enable designated prescribers to access subsidies, PHARMAC will need to publically consult on and then make a decision on whether or not to amend the Schedule rules. This consultation may take several months.
39. It is expected that only a small number of registered nurses (approximately 500-1000) will seek designated prescribing authority over a 10 year period. This is based on international and New Zealand evidence.

Consultation

40. The Minister of Health received an application for designated registered nurse prescribing in October 2014 and in May 2015 directed the Ministry to develop policy papers to consider the development of Medicines (Designated Registered Nurse Prescriber) Regulations.
41. In order to inform the application to the Minister of Health, and before undertaking written consultation in 2013, the Nursing Council consulted on the extension of designated prescribing authority for registered nurses between 2012 and 2013. The Nursing Council met with relevant groups across nursing, medicine, pharmacy, and also consulted health practitioner responsible authorities, funding authorities and other interested organisations, including district health boards and primary health organisations before developing the application. The formal consultation process was completed in April 2013.
42. The consultation document generated 197 submissions that represented the views of a wide range of stakeholders including nurses, nurse practitioners, nursing organisations, medical organisations, pharmacist organisations, health practitioner responsible authorities and PHARMAC. One medical stakeholder group, the New Zealand Medical Association (the Association) submitted that they did not support the proposal for designated registered nurse prescribers.

43. The Association's preferred option for all new prescribers, including registered nurses, is for the extension of prescribing authority under a delegated model of prescribing. The Association notes concern that designated registered nurse prescribing could lead to fragmentation of care. The Association is concerned that a number of the proposed medicines are associated with potentially serious adverse events, frequent drug interactions, a high risk of dependency and/or toxicity. They also note that there is weak evidence supporting the use of nurse prescribing.
44. There is sufficient international evidence that supports the use of nurse prescribing. Nurse practitioners with prescribing authority and designated nurse prescribers are becoming increasingly common in overseas jurisdictions. An increasing number of countries allow independent nurse prescribing including Australia, Canada, Ireland, the United Kingdom, the United States, Finland, Norway and South Africa, with Spain and the Netherlands working towards it.
45. Internationally, the conditions (legal, educational, and organisational) under which nurses prescribe medicines vary between countries. In some jurisdictions, nurses prescribe independently and in other jurisdictions prescribing by nurses is only allowed under strict conditions and supervision by physicians².
46. The international evidence indicates the percentage of prescriptions written by nurses in primary care is very small in comparison to physicians and nurse prescribing is fairly cautious³. The benefits of extended nurse prescribing have been found to include improved patient access to treatment, enhanced patient care, more effective use of medical staff time and greater professional satisfaction for nurses and strengthened inter-professional working practices⁴. Trust between doctors, the nurse prescriber and nurse employer is necessary for integration; without trust, the nurse will not prescribe⁵.
47. In response to the risks identified during consultation, including those of the Association, amendments were made to the proposal for designated registered nurse prescribers. For example, the prescription medicines lists have been amended to ensure safety as outlined in the Nursing Council's Medicines: Review of the Medicines List September 2014. Full consideration has been given to the safe period for the length of supply for controlled drugs.
48. Under the Health Practitioners Competence Assurance Act, and in order to be authorised to prescribe, the Nursing Council will require that designated registered nurse prescribers have:
- a minimum of three years' experience in the area of prescribing practice
 - completed a postgraduate diploma in registered nurse prescribing for long-term and common conditions (e.g. asthma, diabetes, hypertension)
 - completed a prescribing practicum with a designated authorised prescriber (a medical or nurse practitioner) as part of the postgraduate diploma
 - a limited list of medicines from which they can prescribe within their competence and area of practice

² Kroezen, M, van Dijk, L, Groenewegen, PP, & Francke, AL. 2011. Nurse prescribing of medicines in Western European and Anglo-Saxon countries: a systematic review of the literature, *BMC Health Services Research* 11(127).

³ Buckley, T, Cashin, A, Stuart, M, Browne, G, & Dunn, SV. 2013. Nurse practitioner prescribing practices: the most frequently prescribed medications. *Journal of Clinical Nursing* 22(13-14): 2053-2063. Drennan, VM, Grant, RL & Harris, R. 2014. Trends over time in prescribing by English primary care nurses: a secondary analysis of a national prescription database. *BMC Health Services Research* 14(54). Kroezen, M, Veer, A, de, Francke, A, Groenewegen, P, van Dijk, L. 2014. Changes in nurses' views and practices concerning nurse prescribing between 2006 and 2012: results from two national surveys. *Journal of Advanced Nursing* 70(11): 2550-2561.

⁴ Coull, A, Murray, I, Turner-Halliday, F, & Watterson, A. 2013. The expansion of nurse prescribing in Scotland: an evaluation. *British Journal of Community Nursing* 18(5): 234-242.

⁵ Bowskill, D, Timmons, S, & James, V. 2013. How do nurse prescribers integrate prescribing in practice: case studies in primary and secondary care. *Journal of Clinical Nursing* 22(13-14): 2077-2086.

- a condition included in their scope of practice to complete a further 12 months of supervised prescribing practice when they are authorised by the Nursing Council to prescribe
- ongoing competence requirements for prescribing.

49. The Ministry has discussed the content of this analysis with The Treasury, PHARMAC, the Ministry of Social Development, Ministry of Justice, Ministry of Defence, Ministry of Education, Department of Corrections, Accident Compensation Corporation, and informed Parliamentary Counsel Office and the Department of the Prime Minister and Cabinet.

Conclusions and recommendations

50. This regulatory impact analysis provides information about the benefits and, where known, the costs associated with status quo and two other options.

51. The Ministry recommends that regulations be made under the Medicines Act to extend prescribing authority to suitably qualified registered nurse prescribers. Prescribing authority for specific controlled drugs by amendment to the Misuse of Drugs Regulations 1977 is also being sought.

Implementation

52. The new regulations would replace the Medicines (Designated Prescriber—Registered Nurses Practising in Diabetes Health) Regulations 2011. Amendment to the Misuse of Drugs Regulations 1977 would also be necessary in order to change the length of supply of specified controlled drugs from three to seven days.

53. The prescribing authority option would enable designated prescribing authority for experienced registered nurses who hold a postgraduate diploma in registered nurse prescribing. Designated registered nurse prescribers would practise in primary health and specialty teams, work with patients with long term and common conditions and prescribe from a limited list of commonly used medicines.

54. Where presenting cases are beyond the registered nurse's experience and education, the nurse would seek advice or refer patients to a medical or nurse practitioner (both of whom are authorised prescribers) within the multidisciplinary team.

55. Both the prescribing authority option and the reclassification option are regulatory. Designated registered nurse prescriber is the preferred option as it will have benefits for public safety.

56. The preferred option is unlikely to lead to a significant increase in medicines costs. There will be a relatively small number of nurses who will be designated registered nurse prescribers. The pharmaceutical cost implications of nurse prescribing are likely to be similar to those associated with current levels of prescribing. It is possible that the short term costs may increase due to improved access. However, this can be balanced by the potential for longer term and better health outcomes.

57. No medicines, other than vaccines which have a cold chain requirement, have additional compliance costs. If prescribing vaccinations, the designated registered nurse prescriber will be required to have authorised vaccinator status. Some medicines are available on Practitioner Supply Order. In general, any compliance costs related to bulk supply and storage are existing costs.

58. There may be ongoing costs for registered nurses with designated prescribing authority to ensure their continued professional development and competence. District Health Boards, as employers of some designated registered nurse prescribers, may meet training costs and ongoing competence requirements for postgraduate nursing.

59. Other employers, such as primary health organisations or medical practices employing designated registered nurse prescribers, are also likely to meet the ongoing training costs for practitioners, depending on employment arrangements.
60. The Nursing Council will notify all registered nurses about the changes in prescribing authority, education and competence requirements should designated registered nurse prescribing be agreed by Cabinet.
61. As Australia already allows appropriately qualified nurses to prescribe certain scheduled medicines, there may be potential opportunities for some Australian nurses to register as designated registered nurse prescribers in New Zealand under the Trans-Tasman Mutual Recognition Arrangement. Similarly, New Zealand-qualified designated registered nurse prescribers might be able to register in Australia at an equivalent level. Regulators in both jurisdictions will need to discuss the respective activities of these nurses to determine the extent to which this will be possible.

Monitoring, evaluation and review

62. In accordance with their responsibilities under the Health Practitioners Competence Assurance Act, the Nursing Council will be responsible for monitoring the practice of designated registered nurse prescribers. The Nursing Council is exploring the monitoring systems used by the Medical Council of New Zealand and considering modifying current systems to monitor designated registered nurse prescribers.
63. The Nursing Council will evaluate the safety of registered nurse prescribing one year after implementation and thereafter at intervals yet to be determined.