# Regulatory Impact Statement

**Amending the Medicines (Standing Order) Regulations 2002**

## Agency Disclosure Statement

The Ministry of Health has prepared this Regulatory Impact Statement.

It provides an analysis of the proposed regulatory change to allow nurse practitioners and prescribing optometrists, those optometrists with Therapeutic Product Authorisation, to issue standing orders. Overall the change is expected to improve timeliness and ease of access to medicines for particular people and enable more efficient service delivery in health care teams.

The proposal does not:

* Impose additional costs on businesses
* Impair private property rights, market competition, or the incentives on businesses to innovate and invest, or
* Override common law principles

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## Executive summary

1. The Medicines (Standing Order) Regulations 2002 (Regulations) currently allow only medical practitioners and dentists to issue standing orders.
2. The proposed amendment to the Regulations so that nurse practitioners and prescribing optometrists can issue standing orders has two objectives:
	1. to improve people’s access to appropriate and effective treatment;
	2. to enable nurse practitioners and prescribing optometrists to work more efficiently with appropriately trained staff in health care teams.
3. The Ministry considers that the objectives can only be fully met by amending the Regulations.
4. The proposed amendment is relatively minor.
5. The Ministry has consulted on amending the Regulations to include nurse practitioners and prescribing optometrists as issuers of standing orders. The proposal is well supported by stakeholders.
6. The Ministry analysed whether amendment of the Regulations should proceed now or in conjunction with the implementation of the new therapeutic products regime. The Ministry concluded that amending the Regulations in advance of the wider review of therapeutic products legislation will provide immediate gains for patient care and will not compromise the wider review.

## Status quo and problem definition

1. Standing orders are a well-established mechanism, widely used to enable the supply and administration of medicines without a prescription in priority health care settings such as aged care, rural health, primary care, sexual health and family planning.
2. The Medicines Amendment Act 2013 made nurse practitioners and prescribing optometrists authorised prescribers and amended the definition of a standing order so that nurse practitioners, prescribing optometrists and midwives could issue standing orders under regulations[[1]](#footnote-1).
3. The Regulations currently only allow practitioners, defined as medical practitioners and dentists, to issue standing orders.
4. In some clinical settings this leads to:
	1. people being unable to receive timely treatment, when prescribers are not immediately available;
	2. nurse practitioners and prescribing optometrists being inhibited from working to the full extent allowed by the primary legislation and their scopes of practice;
	3. inefficient use of medical practitioners’ time.

## Objectives

1. The proposed amendment to the Regulations so that nurse practitioners and prescribing optometrists can issue standing orders has three objectives:
	1. to improve people’s access to appropriate and effective treatment;
	2. to enable nurse practitioners and prescribing optometrists to work more efficiently with appropriately trained staff in health care teams;
	3. to give effect to the potential of the Medicine Amendment Act 2013 which enabled nurse practitioners and prescribing optometrists to issue standing orders in accordance with any applicable regulations.

## Options and Impact analysis

1. In its analysis of the options the Ministry considered whether an amendment, to include nurse practitioners and prescribing optometrists as issuers of standing orders in the Regulations, should happen immediately or in conjunction with the implementation of the regulatory regime for new therapeutic products expected in 2018.

### Option 1: Amend the Regulations as part of the implementation of the new therapeutic products regime

1. The Ministry of Health is undertaking a review of the regulatory regime for therapeutic products. The therapeutic products review aims to develop a more flexible regulatory regime.
2. The new legislation is expected to come into force in 2017, with regulations likely to be enacted in 2018.
3. Prescribing frameworks and the role of standing orders, including whether they are fit for purpose, are part of the review policy work. The review will consider if changes are needed to the current regime for monitoring and audit of standing orders.
4. Early indications are there will be little change to the arrangements for standing orders under the new Act. Practitioners authorised to prescribe are likely to be able to continue to issue standing orders.
5. If there are unforeseen delays in the implementation of the new therapeutic products regime, the current barriers to making the best use of the workforce to improve health outcomes will remain.

### Option 2: Amend the Regulations prior to the implementation of the new therapeutic products regime (preferred option)

1. The Ministry considers that a relatively minor amendment of the Regulations, in advance of the wider review of therapeutic products legislation, will provide immediate gains for patient care, and will not compromise the wider review. More people could receive more timely and effective treatment earlier and barriers to the most effective use of the workforce will be removed.
2. Targeted consultation in Oct 2015 and Feb 2016 undertaken by the Ministry indicates that there is general agreement that nurse practitioners and prescribing optometrists should be able to issue standing orders. Stakeholders overall agreed that the amendment will improve access, improve efficiency and make best use of NPs and prescribing optometrists.
3. The proposed amendment aligns with other recent activity to remove legislative barriers to innovation and making the best use for the health workforce:
	1. The omnibus Health Practitioners (Replacement of Statutory References to Medical Practitioners) Bill will be presented to the House for its second reading in 2016. Seven acts are amended so that suitably qualified health practitioners can undertake certain statutory functions currently limited to doctors.
	2. Regulations were made in 2013 to allow Pharmacists to prescribe medicines as designated prescribers and Cabinet agreed in 2015 to the making of regulations for designated registered nurse prescribing which will be enacted before the end of 2016.

### Risks and Mitigating factors of amending the Regulations

1. The table below outlines the potential risks of amending the Regulations to authorise nurse practitioners and prescribing optometrists to issue standing orders.

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| **Potential Risk** | **Mitigating factors** |
| Nurse practitioners (NPs) and prescribing optometrists do not have sufficient diagnostic, prescribing or pharmacology knowledge to safely issue standing orders. | * NPs have been prescribing since 2004. Prescribing optometrists have been prescribing since 2005.
* The Nursing Council and the Optometrists and Dispensing Opticians Board are the responsible authorities under the Health Practitioners Competence Assurance Act 2003 and assure safe practice, including prescribing, for NPs and prescribing optometrists.
* NPs and prescribing optometrists work under the Health Practitioners Competence Assurance Act 2003. They are professionally responsible to undertake activities and bound by scopes of practice. They must also be competent to practice with an annual declaration they are keeping up-to-date.
* NPs have a minimum of 4 years nursing experience in their area of practice and a clinical master’s degree that includes education in advanced assessment, pharmacology and a prescribing practicum.
* Prescribing optometrists pass a university programme in ocular therapeutics approved by the Prescribing optometrist and Dispensing Optician Board.
* Responsible Authorities report that NPs and prescribing optometrists are safe prescribers with no adverse prescribing events requiring disciplinary action or competence reviews.
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| NPs and prescribing optometrists issuing standing orders for administration by registered nurses (RNs) and non-prescribing prescribing optometrists or unregulated health care staff will pose a greater risk than the current authorised prescribers. | * All authorised prescribers are legally accountable for their practice under the Health Practitioners Competence Assurance Act 2003.
* NPs and prescribing optometrists are known (anecdotally and through research evidence) to be safe and cautious prescribers.
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| Standing orders are used widely, and may in some cases be inappropriately used; allowing nurse practitioners and prescribing optometrists to issue standing orders could increase the unsafe use of standing orders.  | * NPs and prescribing optometrists would have the same legal accountability as medical practitioners and dentists to comply with the regulatory requirements for monitoring and audit of the standing orders they issue.
* To ensure the accountability, consistency and legality of standing orders, the Regulations set minimum requirements for the content, review, audit and use of standing orders. This includes the accountability of health practitioners issuing the standing orders and defines the responsibilities of those administering or supplying medicines under the standing order.
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### Impacts of amending the Regulations

1. There are unlikely to be any additional fiscal impacts from the amendment. It is likely that any costs incurred through the administration or supply of medicines under standing orders issued by nurse practitioners or prescribing optometrists will be off-set by a decrease in the administration or supply of medicines under standing orders issued by a medical practitioner.
2. Positive health impacts are expected:
	1. improved access to appropriate and effective treatment;
	2. improved efficiency in health care teams.

### Comparison of the two options

1. The preferred option is for the regulatory change to occur prior to the implementation of the new therapeutic products regime. Immediate benefits will accrue to health consumers and best use can be made of the qualifications, skills and experience of nurse practitioners and prescribing optometrists.

### Retaining the Status quo

1. Retaining the status quo option was also considered and rejected because it does not facilitate the improvement of the public’s access to appropriate treatment. Status quo does not:
	1. remove barriers to innovation,
	2. enable best use of the available workforce to respond to health needs
	3. improve peoples’ timely access to treatment.

### Additional options considered

1. The Ministry considered (and rejected) two other options that could partially achieve the objective.
2. Develop (as part of the implementation of the new therapeutic products regime) new regulations for delegated prescribers;
3. Wait for registered nurse designated prescribing to take effect;

#### Develop (as part of the implementation of the new therapeutic products regime) new regulations for delegated prescribers

1. The Act allows delegated prescribing, but no regulations for delegated prescribers currently exist. Delegated prescribing regulations allow delegation to a health practitioner by an authorised prescriber, to prescribe specified prescription medicines.
2. The Ministry did not believe this option was viable because:
	1. There are currently no regulations for delegated prescribers. It would take considerable time to develop regulations for delegated prescribing, and to develop the education and monitoring systems needed to implement delegated prescriber roles. In the meantime access to medicines could be more quickly improved if the Regulations is amended.
	2. The Nursing Council and the wider nursing profession have not supported the development of registered nurses as delegated prescribers with the authorised prescriber taking the responsibility for the prescribing decision. It is preferred that registered nurse prescribers meet competency and education standards set by the Nursing Council to become independent prescribers, with full accountability.

#### Wait for registered nurse designated prescribing to take effect

1. It is expected that regulations to enable registered nurse to be designated prescribers will be enacted by the middle of 2016. There are approximately 48,000 registered nurses in New Zealand, and the New Zealand Nursing Council estimates there may be up to 1,000 registered nurse designated prescribers within five years.
2. The Ministry did not consider that waiting for registered nurse prescribing was a viable option because:
	1. This number of registered nurse designated prescribers is unlikely to significantly change the need for, and the current reliance on, standing orders.
	2. Even with registered nurse prescribing there would still be many circumstances and settings where standing orders would improve access to treatment.

### *Inclusion of midwives in the proposal*

1. The Ministry also considered and rejected the option of including midwives in the amendment of the Regulations.
2. Midwives are also authorised prescribers allowed to issue standing orders under the Act in accordance with regulations but are not named as issuers of standing orders in the Regulations.
3. The midwifery scope of practice is limited to the care of women in pregnancy, labour and childbirth and the post-natal period, and their babies. Midwives prescribe a limited range of medicines specific to the care of pregnant women and new-born infants.
4. Following discussion with the Midwifery Council of New Zealand and the College of Midwives the Ministry concluded midwives do not usually work in situations where the use of standing orders would improve access to medicines.

## Consultation

1. The Ministry conducted targeted consultation in November 2015 on the timing of an amendment to the Regulations to allow nurse practitioners to issue standing orders. Eighteen submissions were received from nursing, medical, pharmacy and optometry stakeholders.
2. The majority of stakeholders supported making the amendment now rather than as part of the wider review of the regulatory regime for therapeutic products. No risks were identified by submitters with proceeding now.
3. The Nursing Council of New Zealand, the New Zealand Association of Optometrists and the Optometrists and Dispensing Opticians Board supported the proposed amendment to the Regulations and asked the Ministry to include prescribing optometrists in any such amendment. A further targeted consultation in February 2016 was sent to organisations that responded to the November 2015 consultation. Stakeholders were asked for feedback on the proposal to extend the amendment of the Regulations to allow prescribing optometrists to issue standing orders.
4. The New Zealand Association of Optometrists and the Optometrists and Dispensing Opticians Board strongly supported the proposal.
5. The majority of other respondents agreed that enabling prescribing optometrists to issue standing orders could improve the timeliness and efficiency of providing eye health in some settings and would make the best use of the available workforce. Submitters supported amendment now ahead of the wider review of the regulatory regime for therapeutic products.
6. The Royal New Zealand College of General Practitioners supported the amendment for nurse practitioners and more reservedly supported including prescribing optometrists in the amendment. The caution about prescribing optometrists was related to the potential risks in a commercial setting where prescribing optometrists may have less contact with people if medicines could be provided by other non-prescribing staff with the prescribing optometrist overseeing the standing order at a distance. In addition there was concern that non-prescribing optometry staff may not be encouraged to undertake further education to become prescribers if standing orders improved access to medicines in the absence of a prescriber. Analysis of the submissions from optometry stakeholders provide a reasoned case and examples to describe the situations where prescribing optometrists would issue standing orders. There is no indication that the concerns expressed by medical practitioners will impact patient safety or limit professional development for other ophthalmology staff.
7. The New Zealand Medical Association, the Royal Australian and New Zealand College of Ophthalmologists and the Pharmacy Council were in favour of deferring any amendment to be considered as part of the wider review of the regulatory regime for therapeutic products. These groups were concerned there was not a sufficient case for amending the Regulations now. These submitters were also cautious about the safety of other practitioners issuing standing orders, with the New Zealand Medical Association recommending implementation of delegated prescribing instead of extending authority through standing orders and the Royal Australian and New Zealand College of Ophthalmologists suggesting limitations through guidelines to support any regulatory change. The Regulations clearly set out the requirements for safe use of standing orders. The Ministry publication the Standing Order Guideline (2012) provides further interpretation of the regulatory requirements which apply to all issuers of standing orders.
8. We believe the risks identified by submitters opposed to the amendment apply equally to the practitioners currently permitted to issue standing orders. The Health Practitioners Competence Assurance Act 2003 and the Regulations provide sufficient protection for public safety.
9. The Ministry concludes there are benefits which outweigh any risks for both nurse practitioners and prescribing optometrists to issue standing orders. There is sufficient stakeholder agreement to support amending the Regulations now rather than as part of the wider review.

## Conclusions and recommendations

1. The Ministry recommends that the Medicine (Standing Orders) Regulations 2002 be amended now to enable nurse practitioners and prescribing optometrists to issue standing orders.

## Implementation plan

1. We will work with the responsible authorities and professional organisations for nurse practitioners and prescribing optometrists and with representatives of other professional groups and the wider health sector to communicate the change to the Regulations.
2. The Ministry will revise and republish relevant guidelines to clarify the regulatory change and provide a reference point for all practitioners working with standing orders.
3. The Nursing Council of New Zealand and the Optometrists and Dispensing Opticians Board are the responsible authorities for nurse practitioners and prescribing optometrists respectively. It will be part of the accountability of the responsible authorities to ensure that nurse practitioners and prescribing optometrists have the competence and understand their accountability to issue standing orders.

## Monitoring, evaluation and review

1. The Nursing Council of New Zealand and the Optometrists and Dispensing Opticians Board are responsible for monitoring safe practice including prescribing, and in future the use of standing orders, by nurse practitioners and prescribing optometrists. The responsible authorities must investigate and if necessary act on complaints regarding competence, health or professional misconduct of health practitioners.
2. The Regulations and Ministry of Health guidelines set out requirements for the legitimate and safe use of standing orders, including monitoring and audit.
1. A standing order is defined in the Medicines Act 1981 as “a written instruction issued by a practitioner, registered midwife, nurse practitioner or prescribing optometrist, in accordance with any applicable regulations, authorising any specified class of persons engaged in the delivery of health services to supply and administer any specified class of prescription medicines or controlled drugs to any specified class of persons, in circumstances specified in the instruction, without a prescription”. [↑](#footnote-ref-1)