

Pharmacy Council position on innovative practice

Pharmacists who are expanding practice, including developing/ delivering new and innovative services, may be looking to confirm what is allowed within existing standards and Scope of Practice.

The following statement and supporting information provide guidance to support pharmacists looking to expand their services in innovative ways.

Statement on innovative practice

The Pharmacy Council encourages pharmacists to expand and innovate to the full extent of their Scope of Practice, provided they are competent to do so, have followed a defensible process to expand their practice, and have the necessary resources and support to deliver new services safely.

We recognise that pharmacy practice evolves in response to a dynamic health care environment. The existing Scope of Practice is permissive, accommodating the breadth of pharmacy practice and allowing for broadening and innovation of practice.

All new services must demonstrate the person-centric professional practice described in the Code of Ethics and Competence Standards. This includes focussing on improving health equity and outcomes, evidence-informed practice, and upholding the integrity of the profession.

There are a range of non-regulatory solutions that pharmacists can use to support innovation. These should be developed by the profession and the health sector, to ensure new services are delivered safely. Solutions may include practice standards and guidelines, approved training, professional development options, peer support, and work-based resources and support.

Pharmacist considerations when expanding for innovative practice

Below is a list of questions to consider when looking to develop or expand a new or existing pharmacy service. Much of this information would be covered under a traditional business case or project outline.

1. What is the local community need for the service?
2. What is the evidence base that supports the proposed model / service?
3. Does the pharmacist's expanded scope and/or new service fall within the existing legislation and pharmacist and/or pharmacist prescriber scopes of practice?
 - a. Are the professional activities clearly covered within the scope of practice and supported by legislation, regulation and professional standards?
 - b. Are you able to defend the decisions made, noting that the level of diligence required increases with the level of uncertainty.
4. Is the service part of pharmacy service in other countries?
 - a. What are the safeguards in place (e.g., training requirements, legislative or regulatory changes), and what is the relevance for implementing in New Zealand?
 - b. Are you able to get support and training from overseas organisations if not available in New Zealand?
5. Is the new or expanded service in conflict with any existing contracts or agreements?
6. What are the service specifications?
 - a. Target population
 - b. Eligibility criteria/ exclusion criteria
 - c. Documentation/ reporting requirements
 - d. Risks and their mitigation
 - e. Referral pathways
 - f. Funding / fees - differential rates for different levels of eligibility,
 - g. Claiming mechanism – will this need enhanced IT?
 - h. Timeline
7. Could other service models be used to obtain the same or very similar outcomes? Are there other ways to deliver the service?

8. What are the clinical governance arrangements?
 - a. Will there be ongoing service monitoring?
 - b. What are the data collection requirements, and how will data privacy¹ and sovereignty be maintained?
 - c. How will patient and other health care practitioners' feedback be collected?
 - d. Is the service delivering what is intended?
 - e. What are the potential risks associated with the proposed service and how will these be avoided or managed?
 - f. Are the responsibilities and accountabilities for delivering the service safely clear and well understood?
9. What are the educational, training, and credentialling requirements for those directly involved in delivering the new service, and for support staff?
 - a. What new knowledge, skills, attitudes will staff need?
 - b. Who will provide the training?
 - c. What is the lead in time to gain the necessary qualification(s)?
10. What are the operational considerations?
 - a. Is there adequate space/ consulting rooms available to maintain privacy and confidentiality, if needed? Is access to toilets necessary?
 - b. Is any specialist equipment needed, including disposables? How will this equipment be validated and monitored?
 - c. What are the IT and database requirements, and the timeframe needed to achieve these?
 - d. Has a Standard Operating Procedure been developed, with all staff reading, understanding and committing to the service?
 - e. Financial viability and sustainability of the service?
11. How will the service be publicised to patients, other health care practitioners, professional indemnity and other interested parties?
 - a. Code of Ethics principle 4(l) states that pharmacists must not engage in advertising, promotion or supply of goods or services that could include misleading or unsubstantiated claims, and/or undermine public trust in the profession.

¹ Refer to the [Health Information Privacy Code 2020](#)

Purpose and background

1. This statement defines the standards expected of pharmacists who are expanding practice, including developing/ delivering² new and innovative services. The statement includes guidance to support compliance with these standards.
2. This statement supports the implicit permission for pharmacists to expand their pharmacy practice within the [Scope of Practice](#), provided they are competent to do so, have followed a defensible process to expand their practice, and have the necessary resources to deliver new services safely.
3. This statement may be used by the Pharmacy Council, Health and Disability Commissioner, the Health Practitioners Disciplinary Tribunal and the Ministry of Health as a standard by which pharmacists' competence and conduct is evaluated.

Why this statement is necessary

4. There is some confusion about the role of the Pharmacy Council when the pharmacy profession is looking to expand and innovate.
5. Pharmacists are increasingly seeking permission from the Council for specific business expansions that may include new services. At times, the evidence of careful prior consideration is limited in areas such as defined benefits, understanding of risk and its mitigation, quality and safety, and service implementation.
6. Pharmacists have responsibilities to the public, the pharmacy profession and other health care practitioners, and the [Code of Ethics](#) reflects the values and professional expectations that are foundational and relevant to all pharmacy practice, including new or expanded services.
7. The Pharmacy Council's Statement on Innovative Practice and the supporting documentation can support the development of new services, and ensure the service is safe, by providing the framework and boundaries within which the service must operate to ensure public safety.

Definitions

8. The statement is relevant to innovative practice that may include new or expanded roles/ services/ goods delivered by pharmacists or with those whom they work alongside, that sit within their current scope of practice.
9. For any new service, pharmacists have individual or shared³ professional responsibility for its safety and effectiveness. Regardless of whether the service is established elsewhere, (e.g., prior piloting or regional delivery), pharmacists should remain open minded about the service, and when necessary, identify shortcomings in the service to contribute to its safe delivery and quality improvement.

² When relevant, includes designing a service.

³ Other pharmacists and health practitioners

Professional Regulation

10. The Pharmacy Council is responsible for setting the scope of practice and standards⁴ for pharmacist practice.
11. Pharmacy practice evolves in response to a dynamic health care environment, and regulation allows practice to develop within the boundaries set by the scope of practice description. The Scope of Practice accommodates the breadth of pharmacy practice and allows for broadening and innovation of practice.
12. The competence and ethical standards set the expectations for pharmacy practice within the prescribed Scope of Practice. These reflect established current pharmacy practice but also accommodate anticipated practice developments.
13. The scope uses broad descriptors to enable expansion beyond current implementation rather than describing all tasks and services permitted. Therefore, further safeguards beyond regulatory standards may be required to support expanded practice.
14. The Scope of Practice is a public notice describing pharmacy practice, and the public's understanding of innovative practice in relation to current pharmacy practice must be considered. In some situations, broader consultation with affected stakeholders may be required, including the public, or its advocates.
15. In exceptional situations when after due consideration the profession cannot confirm that a service is within the scope of practice, the Council will consider whether changes to the scope of practice or other measures (regulatory and non-regulatory) are needed to resolve the uncertainty.
16. Regulatory changes, such as amending scopes of practice and standards are reserved for situations when other options do not fully manage the risk to the public associated with a new practice or service.

Relevance to Practice

17. Individual pharmacists are accountable for being competent to deliver any service and must only practice in areas where they are competent, resourced and supported to do so safely. Even if legally authorised, it remains the professional responsibility of a pharmacist not to engage in activities beyond their level of competence.
18. Pharmacists may need professional support and other non-regulatory solutions, developed by the profession and the health care sector, to ensure they can deliver innovative service safely. These solutions include practice standards and guidelines, approved training, professional development options, and work-based resources and support.
19. There is a risk that without adequate oversight, pharmacists will expand their practice beyond their capability and capacity, as they are unaware and do not understand the expectations for the expanded practice.

⁴ Section 118(i) of the Health Practitioners Competence Assurance Act 2003: set standards of clinical competence, cultural competence, and ethical conduct to be observed by pharmacists.

20. New pharmacy services have generally undergone planning, development and delivery that have included a focus on identifying and addressing risks. These include, for example, training to upskill pharmacists' knowledge and competencies, before the service can be delivered.
21. Pharmacists should recognise that developing new services may require broader skills and experience than they possess and should gather the support of other pharmacists and professional organisations to progress safely.

Professional Expectations

22. The design and implementation of new services must demonstrate the patient-centric professional practice described in the Code of Ethics and Competence Standards. This includes focussing on improving health equity and outcomes, evidence-informed practice⁵, and upholding the integrity of the profession.
23. Pharmacists must determine the knowledge and skills needed to deliver the service safely and only provide the service when they are competent to do. This may include:
 - a. Seeking advice from others with expertise in identifying aspects and details of the service beyond the pharmacist's expertise or not generally associated with current pharmacy practice. This could include assessment or input by expert pharmacists and other health practitioners, health educators, informed members of the public and anyone else who can provide objective feedback on the proposal.
 - b. Testing whether the development process is defensible, by including objective expert input and feedback from health practitioners who have experience in developing innovative services and have no actual or perceived conflict of interest with the process.

The Council recommend that pharmacists seek the required support from professional associations, university staff, experienced peers and health practitioners from other professions with a history of delivering the service or similar services.

24. Everyone is entitled to an appropriate standard of care regardless of which health professional provides the health service.
 - a. If innovative practice includes delivering a service currently delivered by other health care practitioners, the evaluation must consider how current professional and regulatory requirements for those health care practitioners will be, at a minimum, met by pharmacists.
 - b. Pharmacists' roles may overlap and share competencies and responsibilities of other health care practitioners. Collaboration with other health care practitioners

⁵ The conscientious, explicit, and judicious use of current best evidence that considers the needs and circumstances of each individual. Evidence-informed practice is also applicable to decisions about the planning and provision of services. Evidence encompasses a range of qualitative and quantitative methodologies including indigenous methodologies and people's experiences. (As described in Competence Standards Glossary, p69):

will often be needed to minimise fragmentation of care and avoid public confusion.

25. Pharmacists are obliged under the [Health & Disability Commissioner's Code of Health and Disability Services Consumers' Rights](#) to ensure patients' and consumers' rights to be fully informed, make an informed choice, give informed consent, and receive a service of an appropriate standard.
26. The professional activities of any new or expanded practice must be covered by appropriate professional indemnity arrangements, as per Principle 5 (D) in the Pharmacy Council Code of Ethics.
27. Pharmacists who are employers or have delegated responsibility for professional services within an organisation (e.g., the responsible person on a pharmacy licence) must be able to demonstrate adequate oversight of the development, delivery and quality improvement of any new services.

Appendix 1: References and guidance

Before developing a new service or expanding existing practice, it's important to be fully aware of the various guiding documents, such as the Code of Ethics and the Competence Standards to ensure that pharmacists are competent and fit to practise. These documents express the accountability, responsibility and professional values that are fundamental to the pharmacy profession.

Code of Ethics

The Pharmacy Council [Code of Ethics](#) reflects the values and professional expectations that are foundational and relevant to all pharmacy practice, including expanding practice.

- Principles 1 to 3 place the care of patients first and recognise that pharmacists also have a role in supporting family, whānau, the wider community and public health.
- Principles 4 and 5 emphasises professional integrity.
- Principles 6 and 7 focus on professional competency and the importance of working collaboratively to deliver patient-centred care and optimal health outcomes.

Competence Standards

The domains and standards of the [Competence Standards](#) complement each other and should be considered as a whole in terms of relevance and application to the expansion of practice or new service. Some examples are listed here (not exhaustive):

Domain 2: Professionalism in Pharmacy

2.1 Practises with personal and professional integrity

2.2 Complies with ethical and legal requirements

- This standard should be considered in conjunction with the Code of Ethics and [Code of Health and Disability Services Consumers' Rights](#)
- Identify relevant legislative, regulatory and professional requirements.

2.3 Applies culturally safe practice

- Design and adapt the service to reflect the cultural diversity and needs of people that are served.

2.4 Makes effective decisions

- Describe and apply the relevant behaviours needed for a comprehensive evaluation of a new service to reach an objective and defensible decision for its delivery.

2.5 Contributes to quality improvement and knowledge advancement

- Read in conjunction with 4.1

Domain 3: Communication and Collaboration

3.2 Establishes and maintains collaborative working relationships

3.3 Problem solves and manages conflict

Domain 4: Leadership

4.1 Provides leadership

- Includes clinical governance, fostering a just and continuous quality improvement culture, and effective quality and risk management.

Domain 5: Person-centred Care and Medicines Management

- What level of pharmacotherapy knowledge and experience is reasonably expected for the expanded practice or new service?
- What is your current level of clinical knowledge and experience in applying your clinical pharmacy skills?
- Does it require further postgraduate qualifications, e.g., a postgraduate certificate or diploma in clinical pharmacy?

Domain 6: Supply and administration of medicines

- Administering medicine, including injectable medicines, is a relatively new inclusion to the pharmacist's scope of practice.
- Whilst pharmacists trained to vaccinate may also administer other injectable medicine, there needs to be a broader understanding of the skills required, given the different sites for administering injectable medicines.
- Pharmacists, when compared to some health care practitioners, may not have suitable knowledge of human anatomy to make this judgement.

7.1: Contributes to community health

Definitions

Clinical governance - A framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish (HQSC, 2024).

Service – The provision of assessment, treatment, care, support, teaching, research, promotion of independence, and other inputs provided to the consumer by the organisation (NZStandard, 2010).

Reference

HQSC. (2024). *Collaborating for quality: a framework for clinical governance* Retrieved from qsc.govt.nz/resources/resource-library/collaborating-for-quality-a-framework-for-clinical-governance/

NZStandard. (2010). *Health and Disability Services Pharmacy Standards NZS8134.7:2010.* <https://www.standards.govt.nz/shop/nzs-8134-72010>