Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2025

Explanatory notes for SL 2025 No. 60

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2025.

Authorising law

Sections 54 and 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

The main purposes of the *Medicines and Poisons Act 2019* (Act) include ensuring particular substances are made, sold, used and disposed of in an appropriate, effective and safe way and ensuring that health risks arising from the use of these substances are appropriately managed.

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) regulates medicines and complements the Act by:

- ensuring regulated substances are used safely and effectively to reduce harm;
- setting out the 'authorised way' for a person to perform regulated activities with certain regulated substances (medicines); and
- providing flexible requirements for authorised activities, such as storage and disposal, that are commensurate with the approved person's qualifications and activities, and the public health and safety risk of the medicines.

The Medicines Regulation requires updating to keep up with changes to Queensland Health policies and practices and to improve access to high-quality health services throughout Queensland. The changes to the Medicines Regulation aim to address practical and operational issues that have been identified by stakeholders and operational areas within Queensland Health. The changes will ensure the Medicines Regulation remains fit for purpose and allows health practitioners to practice to their full scope, enabling greater access to health services across all parts of Queensland.

The objective of the *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2025* (Amendment Regulation) is to amend the Medicines Regulation to:

- transition to business-as-usual (BAU) the authorisations for pharmacists to deal with medicines for the acute common condition services, the health and wellbeing services and the medicines management services from the Community Pharmacy Scope of Practice Pilot (Pharmacy Pilot) and the hormonal contraception service from the Community Pharmacy Hormonal Contraception Pilot (Contraception Pilot);
- make an administrative amendment to amend the circumstances and conditions and list of medicines for the Urinary Tract Infection Community Pharmacy Service to align it with clinical best practice and the transitioning pilot services;
- authorise dental assistants who are suitably trained and employed by a Hospital and Health Service (HHS) to possess and administer fluoride varnish under the supervision of a dental practitioner; and
- authorise intern pharmacists acting under the supervision of a pharmacist and trainee pharmacists acting under the direct supervision of a pharmacist to deal with additional medicines to the extent authorised for a pharmacist.

Transitioning Pharmacist Authorisations to Business-as-usual

Pharmacists are a nationally regulated profession under the Health Practitioner Regulation National Law. A pharmacist must be registered with the Pharmacy Board of Australia and meet the Board's Registration Standards to practice in Australia. Pharmacists work in public and private health settings across Queensland. They provide medicines management services that may include clinical services related to quality use of medicines or functions related to the dispensing and supply of medicines.

Enabling pharmacists to work to their full scope of practice provides an efficient and effective way to improve access to healthcare delivery and lessen the impacts of workforce shortages and distribution problems, particularly in regional and rural communities.

The Medicines Regulation is being amended to transition the authorisations for pharmacists to deal with medicines for the acute common condition services, health and wellbeing services and medicines management services under the Pharmacy Pilot and the hormonal contraception service under the Contraception Pilot to BAU.

Chronic condition management services from the Pharmacy Pilot will continue to be delivered under a pilot framework, which will be renamed as the Community Pharmacy Chronic Conditions Management Pilot and will continue until the originally planned end date of 30 June 2026. Recognising the greater complexity involved in chronic conditions management and the significantly low number of these services delivered through the pilot to date, continuation of the chronic condition management services ensures that these services remain available to consumers while further evaluation assesses their longer-term value and effectiveness within the broader healthcare system.

The Amendment Regulation also amends the Medicines Regulation to give effect to the updated version of the Extended Practice Authority – Pharmacists (EPA-Pharmacists), inserts a reference to the new Extended Practice Authority – Community Pharmacy Chronic Conditions Management Pilot (EPA-Chronic Conditions Management Pilot) and removes a reference to the Extended Practice Authority – Community Pharmacy Scope of Practice Pilot (EPA-Pharmacy Pilot).

An administrative amendment is also being made to the EPA-Pharmacists to amend the circumstances and conditions and list of medicines that can be sold under the Urinary Tract Infection Community Pharmacy Service.

Transition to business-as-usual

On 21 March 2025, the Honourable Tim Nicholls MP, Minister for Health and Ambulance Services announced amendments that lock in easier access to health services at the pharmacy, by allowing community pharmacists to prescribe some medicines for a range of common conditions. This announcement committed to make the Pharmacy Pilot acute conditions and health and wellbeing services and the hormonal contraception service permanent by 1 July 2025.

The oral health risk assessment and fluoride application service that is currently provided through the Pharmacy Pilot will transition to BAU. However, to ensure consistency of the training requirements for the application of topical fluoride with those required for other professions, it will be addressed as a separate authority under the EPA-Pharmacists.

As a result of stakeholder feedback, the Pharmacy Pilot's medicines management services will also transition to BAU and apply to all pharmacists. The medicines management services enable the following dealings with an S4 medicine, other than a restricted medicine or diversion risk medicine:

- sell, other than on prescription, to enable continued dispensing[1];
- amend a prescription, without the agreement of the prescriber who made the prescription ; and
- dispense an equivalent medicine[2] on an amended prescription as a substitute to the medicine stated on the original prescription.

Chronic condition management services are to remain part of the Pharmacy Pilot, which will be renamed the Community Pharmacy Chronic Conditions Management Pilot, and will continue to 30 June 2026 as originally planned, allowing for further evaluation and consultation.

[1] Continued dispensing is the supply of a medicine to a person by a pharmacist, where there is an immediate and ongoing need for the medicine but where it is not practicable to obtain a valid prescription to maintain treatment.
[2] Equivalent medicine, means a medicine that is listed on the register under the *Therapeutic Goods Act 1989* (Cth) for the same indication as the original medicine, is able to be dispensed in a dose and for a duration that is intended to have a therapeutic effect equivalent to the therapeutic effect of the original medicine and has the same or similar chemical composition or pharmacological means of action as the original medicine.

Pharmacy Pilot

On 1 February 2024, the *Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2023* commenced, facilitating the implementation of the Pharmacy Pilot. The pilot enables pharmacists, who have completed additional training and been authorised to participate in the Pharmacy Pilot by Queensland Health, to undertake additional medicines management and prescribing activities as provided for in the EPA-Pharmacy Pilot.

The Pharmacy Pilot allows participating pharmacists to work to an expanded scope to provide consumers greater access to primary healthcare services and to help address the impacts of workforce shortages, particularly in regional and rural communities. It is a nation-first pharmacy pilot, increasing Queenslanders' access to high-quality and cost-effective primary health care. The Pharmacy Pilot supplements, not replaces, existing primary care services, giving consumers more choice.

To be authorised to participate in the Pharmacy Pilot, a pharmacist must meet all participation requirements, including holding general registration with the Pharmacy Board of Australia with no limitations to practice, completion of education and training programs, holding appropriate professional indemnity insurance and being authorised by Queensland Health to participate.

The services in the Pharmacy Pilot include:

- medicines management, including continued dispensing and therapeutic adaptation and substitution[3];
- autonomous prescribing for specified acute conditions and health and wellbeing services such as:
    - acute exacerbations of mild plaque psoriasis;
    - acute minor wound management;
    - acute nausea and vomiting;
    - acute otitis externa;
    - acute otitis media;
    - allergic and nonallergic rhinitis;
    - gastro-oesophageal reflux and gastro-oesophageal reflux disease;
    - herpes zoster (shingles);
    - impetigo;
    - management for overweight and obesity;
    - mild, acute musculoskeletal pain;
    - mild to moderate acne;
    - mild to moderate atopic dermatitis;
    - oral health risk assessment and fluoride application;

[3] Therapeutic adaptation and substitution is terminology used in the Pharmacy Pilot that will now be captured by the new provisions for dispensing an equivalent medicine on a prescription that has been amended by the pharmacist.

  - smoking cessation; and
  - travel health.
- structured prescribing as part of a chronic condition management service including:
  - cardiovascular disease risk reduction program including management of type 2 diabetes, hypertension and dyslipidaemia;
  - improved Asthma (and Exercise Induced Bronchoconstriction) Symptom Program; and
  - Chronic Obstructive Pulmonary Disease (COPD) Monitoring Program.

Contraception Pilot

On 1 July 2024, the *Medicines and Poisons (Medicines) Amendment Regulation (No. 2) 2024* commenced, facilitating the implementation of the Contraception Pilot. This authorised community pharmacists who have completed appropriate training to prescribe a range of hormonal contraceptives to women and girls over the age of 16 as provided for in the EPA-Pharmacists.

Pressures on the health system in Queensland from increased demand and workforce shortages meant it was challenging for many women and girls to access contraceptive medicines. The Contraception Pilot reduced time and geographical barriers to accessing hormonal contraception for Queensland women and girls, particularly those in regional, rural and remote areas.

Transitioning the hormonal contraception service to BAU will enable Queensland women and girls to access a range of contraception options from a local pharmacist, including the combined oral contraceptive pill (excluding those with a high estrogen dose), the progesterone-only pill, injected medicine (depot medroxyprogesterone acetate) and the combined hormonal contraceptive vaginal ring.

Extended practice authority amendments

The EPA-Pharmacists has been amended to transition the acute common condition services, health and wellbeing services and medicines management services from the Pharmacy Pilot and the hormonal contraception service from the Contraceptive Pilot to BAU. The EPA-Pharmacy Pilot has been replaced by the EPA-Chronic Conditions Management Pilot which provides for all remaining Pharmacy Pilot services – that is, prescribing for the chronic condition management services.

An EPA states the places or circumstances in which an approved person may deal with a regulated substance. It may also impose conditions on the dealing with a regulated substance or require an approved person to hold particular qualifications or training to deal with a regulated substance.

Section 232 of the Act enables the Director-General of Queensland Health (or their delegate) to make an EPA. Schedules 3 to 15 of the Medicines Regulation provide ‘as-of-right’ authorisations for certain classes of person to deal with certain medicines. EPAs provide additional authorisations beyond those stated in the Medicines Regulation.

Schedule 1, part 1 of the Medicines Regulation lists the approved EPAs by name and version number. When new versions of an EPA are made by the chief executive or their delegate, the Medicines Regulation requires an amendment to reflect the new version so it can take effect.

An amendment is being made to the EPA-Pharmacist for the oral health risk assessment and fluoride application service to ensure consistency of the training requirements for the application of topical fluoride with those required for other professions.

An administrative amendment is also being made to the EPA-Pharmacists for the Urinary Tract Infection Community Pharmacy Service to amend the circumstances and conditions and list of medicines that can be sold under this service. Part 2 of the EPA-Pharmacists has been amended to include reference to the current online version of the relevant section of Therapeutic Guidelines for the provision of this service, with the list of medicines in Appendix 4 being updated to reflect this. These amendments align this service with the circumstances and conditions and list of medicines for the new and updated parts of the EPA for BAU acute common condition services and health and wellbeing services and BAU hormonal contraception service, ensuring consistency and transparency. Aligning these parts of the EPA-Pharmacists ensures that pharmacists are working in accordance with best practice clinical guidelines.

Dental Assistants

The amendments to the Medicines Regulation will authorise dental assistants who are suitably trained and employed by a HHS to possess and administer fluoride varnish under the supervision of a dental practitioner, which includes a dentist, dental hygienist, dental therapist or oral health therapist.

Skilled dental assistants are essential members of HHS oral health teams. In Queensland a dental assistant employed by a HHS is required to have obtained a Certificate III in Dental Assisting with effective supervisory frameworks in place.

Under the Commonwealth Poisons Standard[4], fluoride varnish, which is used to reduce dental decay and assist in the prevention of root caries, is an unscheduled medicine when it is supplied to registered dental practitioners or to persons with an appropriate authority. In all other circumstances, fluoride varnish is regulated as a schedule 4 (S4) medicine.

As dental assistants are not registered dental practitioners, any dealings with fluoride varnish are as an S4 medicine. In Queensland, dental assistants do not have any specific authorisations to deal with medicines under the Medicines Regulation. Dental assistants are covered by a general provision under schedule 15, part 2 of the Medicines Regulation that authorises health practitioner assistants to possess an S4 medicine under the direct supervision of a health practitioner for the purposes of stock management at their place of employment.

[4] *Therapeutic Goods (Poisons Standard – February 2025) Instrument 2025*.

Suitably trained dental assistants can apply for a general approval to enable them to possess and administer fluoride varnish under section 75 of the Act. Under section 76 of the Act, the chief executive (or their delegate) may consider several matters when determining whether to grant a general approval. For example, the safety and efficacy of the substance, the proposed activity with the substance, the suitableness of the proposed location for the activity, and the appropriateness of the person.

Currently, for a general approval to be granted to administer fluoride varnish, a dental assistant's application must be supported by evidence of appropriate training and competency in the use of fluoride varnish, which can be demonstrated by the completion of relevant modules through a registered training organisation. These applications are considered on a case-by-case basis.

The application process for general approvals may present a barrier to enabling dental assistants in HHSs to utilise their additional training to apply fluoride varnish and limits access to preventive dental services, particularly in high-risk communities.

To improve access to preventative dental services, the Amendment Regulation will amend the Medicines Regulation to provide for dental assistants employed by a HHS as a new class of person, with authorisation to administer fluoride varnish under the supervision of a dental practitioner. This will remove the need for these practitioners to apply for and maintain a general approval.

Restricting the authorisation to those employed by a HHS ensures dental assistants have the requisite level of training and qualifications and are working in environments with appropriate safeguards and protocols, which may not be mandated or in place at a private facility.

Intern and Trainee Pharmacists

The Medicines Regulation is being amended to authorise intern pharmacists and trainee pharmacists to deal with medicines, under the supervision or direct supervision of a pharmacist, to the full extent authorised for pharmacists employed at a community pharmacy or private health facility or a pharmacist who is a health service employee.

In October 2023, the Medicines Regulation was amended by the *Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2023* (2023 Pharmacist Amendment Regulation) to insert a new division 1A in schedule 9, part 1, which enables pharmacists employed at a community pharmacy or private health facility, or employed by a health service to:

- administer a schedule 2 (S2) or schedule (S3) medicine;
- administer any medicine, if the medicine is administered on a standing order;
- administer an S4 or schedule 8 (S8) medicine, if the medicine is administered on a prescription or in accordance with the medicine's approved label; and
- possess an S4 or S8 medicine if the medicine is possessed for the purposes listed above.

The 2023 Pharmacist Amendment Regulation extended the scope of dealings authorised for pharmacists beyond the general authorisations for pharmacists to deal with medicines in schedule 9, part 1, division 1 of the Medicines Regulation. The 2023 Pharmacist Amendment Regulation did not capture intern and trainee pharmacists.

Intern pharmacists are registered under the Health Practitioner Regulation National Law (National Law) to practise in the pharmacy profession with provisional registration and are employed as an intern undertaking supervised practice as provided in schedule 9, part 1, division 3 of the Medicines Regulation. Currently, intern pharmacists are authorised to deal with medicines in the same manner as a fully qualified pharmacist, provided it is under the supervision of a pharmacist in accordance with the general authorisations for pharmacists in schedule 9, part 1, division 1 of the Medicines Regulation.

Trainee pharmacists are registered under the National Law to practise in the pharmacy profession as a student or for training purposes, as provided by schedule 9, part 1, division 4 of the Medicines Regulation. Trainee pharmacists have a more limited scope of dealings authorised than intern pharmacists. Their authorised dealings include selling by retail, administering, compounding and possessing medicines provided for in the general authorisations for pharmacists in schedule 9, part 1, division 1 of the Medicines Regulation when under the direct supervision of a pharmacist.

Entry-level education and training for pharmacists cover pharmacology principles, including the pharmacokinetics and pharmacodynamics of medicines, safe and effective medicine use in patient care, proper administration routes, dosing principles, and drug interactions.

The current dealings authorised under the Medicines Regulation for intern and trainee pharmacists have the effect of authorising intern and trainee pharmacists to administer certain S4 and S8 medicines, such as methadone and buprenorphine for the treatment of opioid dependence on a prescription when under a form of supervision. For an intern pharmacist, this must be under the supervision of a pharmacist, and for a trainee pharmacist, under the direct supervision of a pharmacist.

As the 2023 Pharmacist Amendment Regulation amendments do not currently apply to intern and trainee pharmacists, they are unable to administer or possess the medicines provided for by these amendments, such as administering an S4 medicine in accordance with the medicine's approved label. As a result, intern and trainee pharmacists do not currently have experience in administering the full range of medicines they will be authorised to administer upon registration as a pharmacist.

Both intern and trainee pharmacists are required to practice to the extent of a registered pharmacist, under supervision or direct supervision, so that upon registration they are competent and have experience in all facets of pharmacy practice.

The Amendment Regulation amends the Medicines Regulation to authorise intern pharmacists and trainee pharmacists to deal with medicines, under the supervision or direct supervision of a pharmacist, to the full extent authorised for pharmacists.

Achievement of policy objectives

The Amendment Regulation commences on 1 July 2025.

Transitioning Pharmacist Authorisations to Business-as-usual

Prescribing medicines

The Amendment Regulation transitions to BAU the authorised dealings for pharmacists to autonomously prescribe an S4 medicine, other than a restricted medicine or diversion-risk medicine, for a range of acute common conditions, health and wellbeing services and the hormonal contraception service. Pharmacists that have completed additional training and meet the requirements under the EPA-Pharmacists will be able to autonomously prescribe medicines to manage the following conditions and services:

- acute exacerbations of mild plaque psoriasis;
- acute minor wound management;
- acute nausea and vomiting;
- acute otitis externa;
- acute otitis media;
- allergic and nonallergic rhinitis;
- gastro-oesophageal reflux and gastro-oesophageal reflux disease;
- herpes zoster (shingles);
- hormonal contraception
- impetigo;
- management for overweight and obesity;
- mild, acute musculoskeletal pain;
- mild to moderate acne;
- mild to moderate atopic dermatitis;
- smoking cessation; and
- travel health.

As noted earlier, the oral health risk assessment and fluoride application service currently provided through the Pharmacy Pilot will also transition to BAU. However, to ensure consistency of the training requirements for the application of topical fluoride with those required for other professions, it will be addressed as a separate authority under the EPA-Pharmacists.

Selling, without a prescription

The Amendment Regulation enables pharmacists to sell, without a prescription, an S4 medicine, other than a restricted medicine or diversion-risk medicine, for the purposes of continued dispensing. Making the continued dispensing arrangements BAU will improve pharmacists' ability to provide an emergency supply of a medicine which supports patient adherence to their prescribed medicines. Transitioning the continued dispensing arrangements from the Pharmacy Pilot extends the existing authorisations for continued dispensing under the Medicines Regulation, and will enable consumers to receive the smallest available size of a manufacturer's pack of their S4 medicine, rather than three days' supply. This affords patients greater flexibility to have a follow up appointment with a prescriber, such as a general practitioner.

The Amendment Regulation replaces sections 158 and 159 of the Medicines Regulation with new sections 158 and 159 and amends sections 153, 155, 156, 157 and 160 to enable a pharmacist to sell, other than on prescription, for continued dispensing. Transitioning the continued dispensing provisions from the Pharmacy Pilot required a restructure of these sections to combine the existing authorisations with those from the pilot transitioning to BAU.

New section 158 deals specifically with selling S4 restricted medicines, rather than having the requirements detailed across a number of provisions in chapter 5, part 2, division 3, subdivision 3 of the Medicines Regulation. There are no changes to the conditions in which a pharmacist can sell an S4 restricted medicine for the purposes of continued dispensing or the quantity that can be sold.

New section 159 applies to selling an S4 medicine, other than those already specified in chapter 5, part 2, division 3, subdivision 3 of the Medicines Regulation, being an S4 oral hormonal contraceptive, an S4 diversion-risk medicine, and an S4 restricted medicine. The conditions in which a pharmacist can sell an S4 medicine under this section have been extended to enable a pharmacist to sell greater than a three day's supply of a medicine in line with the provisions that have transitioned from the Pharmacy Pilot. When selling an S4 medicine under this section, a pharmacist must not sell the medicine unless the pharmacist reasonably believes the patient has not, in the year before seeking the medicine from the pharmacist, been sold the medicine without a prescription from the pharmacy at which the medicine is sought, the medicine has been lawfully supplied to the patient in the six months before being sought from the pharmacist, continuing the patient's treatment with the medicine is urgent and essential for the patient's wellbeing and it is not practicable for the patient to obtain a prescription for the medicine before needing to continue treatment with the medicine. A pharmacist must not sell an amount of the medicine that is more than the smallest available size of a manufacturer's pack of the medicine.

The Amendment Regulation also makes the following minor amendments to distinguish the different dealings with S4 medicines that are restricted medicines, diversion risk medicines, oral hormonal contraceptives, and other S4 medicines:

- section 153 – provides that for chapter 5, part 2, division 3 of the Medicines Regulation that when selling an S4 medicine without a prescription, if a Continued Dispensing Determination[5] or an extended practice authority is inconsistent with this division, the Continued Dispensing Determination or extended practice authority prevail.
- section 155 – inserts for chapter 5, part 2, division 3, subdivision 3 a definition for *pre-packed*, which for a medicine means the medicine is a pre-packed liquid, cream, ointment or aerosol. This definition was originally included in section 159 of the Medicines Regulation and due to the restructuring of provisions it now applies to the entire subdivision. Specifying a different requirement for pre-packed S4 medicines is necessary as these medicines are packaged in a way that may not allow them to be repackaged and supplied in smaller quantities. It is not always possible to supply an exact amount of a pre-packed medicine that is three day's supply, which can easily occur for other dose forms, such as tablets. There are no changes to a pharmacist being authorised to sell the smallest available size of a manufacturer's pack when selling an S4 pre-packed medicine if the conditions are met under the relevant section.
- section 156 – relocates the amount previously specified in section 159 to clarify that a pharmacist must not sell an amount of the medicine that is more than a manufacturer's pack of an S4 medicine that is an oral hormonal contraceptive for a patient.
- section 157 – relocates the amount previously specified in section 159 to clarify that for a diversion-risk medicine a pharmacist must not sell an amount of the medicine that is more than the smallest available size of a manufacturer's pack of the medicine for a pre-packed S4 medicine or for any other S4 diversion-risk medicine, no more than a three days' supply of the medicine.
- section 160 – extends the requirement for a pharmacist to record a brief description when selling an oral hormonal contraceptive or diversion-risk medicine to all S4 medicines. This amendment has been made to ensure consistency with the circumstances and conditions for selling S4 medicines that supported continued dispensing under the EPA-Pharmacy Pilot. Pharmacists who sell an S4 medicine for the purposes of continuing therapeutic treatment under the EPA-Pharmacy Pilot are required to record the reason for selling the medicine, which is considered best practice and will apply to all S4 medicines under the amendment for consistency and clarity.

Amending a prescription without the agreement of a prescriber

Under the Medicines Regulation, a written prescription may only be amended in agreement with the original prescriber, by signing and dating the handwritten amendment in a way that does not obscure the content of the original prescription. Pharmacists can amend a prescription before dispensing the medicine by adding additional information to the prescription, where clarification about the prescriber's direction is required. To do so, pharmacists are required to obtain agreement to the amendment from the prescriber who made the prescription. It is unlawful for a pharmacist to dispense a prescription that does not comply with these requirements.

[5] Continued Dispensing Determination means a legislative instrument made under the *National Health Act 1953* (Cth), section 89A(3).

The Amendment Regulation updates the Medicines Regulation to enable pharmacists to undertake additional medicines management activities including substituting an equivalent medicine for a medicine stated on the original prescription, without the agreement of the prescriber. To support these activities, the Medicines Regulation is amended to insert into chapter 4, part 8, division 1, new subdivision 2A (Amending written prescriptions) and replaces section 117 with new sections 117, 117A and 117B to enable a pharmacist to amend a written prescription for an S4 medicine.

New section 117B transitions authorisations from the Pharmacy Pilot to BAU that will enable a pharmacist to substitute an equivalent medicine for a medicine stated on the original prescription. A pharmacist may amend a prescription for a medicine, other than a restricted medicine or diversion-risk medicine, to dispense an equivalent medicine if the pharmacist assesses the amendment to be reasonably necessary for the therapeutic treatment of the patient. An equivalent medicine is a medicine that is listed on the register under the *Therapeutic Goods Act 1989* (Cth) for the same indication as the original medicine, is able to be dispensed in a dose and for a duration that is intended to have a therapeutic effect equivalent to the therapeutic effect of the original medicine and has the same or similar chemical composition or pharmacological means of action as the original medicine. The pharmacist must take all reasonable steps to advise the prescriber who made the original prescription of the details of the amendment and a brief description of why the amendment was made.

Examples of scenarios where a pharmacist may consider amending a prescription to dispense an equivalent medicine include:

- altering a medicine from a tablet to a liquid or dispersible form for someone having difficulty swallowing tablets;
- altering or changing the type of inhalation device for a prescribed medicine for a person who has issues with dexterity to support compliance; or
- substituting an equivalent medicine when the original medicine is subject to a shortage. For example, if a patient is prescribed 40mg of atorvastatin and there is a shortage of this medicine, the pharmacist can amend the prescription to 20mg of rosuvastatin, that is expected to have equivalent therapeutic effect to the originally prescribed medicine.

Enabling pharmacists to substitute an equivalent medicine can improve health outcomes for consumers by supporting compliance, and ensuring there is continuity of appropriate clinical care for patients, especially in situations where a prescribed medicine is not suitable for the patient or is not available due to a shortage.

Dispensing

The Amendment Regulation enables pharmacists to dispense an S4 medicine, other than a restricted medicine or diversion-risk medicine for the purposes of substituting an equivalent medicine for a medicine stated on the original prescription.

The Amendment Regulation amends section 124 of the Medicines Regulation to require a pharmacist to keep a record of the amendments made related to the substitution of an equivalent medicine for a medicine stated on the original prescription. For new section 117A, if the prescription was amended by the dispenser to clarify the prescriber's direction, the dispenser must record the details of the amendment and that there was agreement with the prescriber. For new section 117B, if the dispenser is dispensing an equivalent medicine as a substitute to the original medicine prescribed, the dispenser must record the details of the amendment and a brief description of why the dispenser made the amendment.

The amendments will provide improved access to high-quality, integrated and cost-effective primary health care services for all Queenslanders, particularly for those in areas where general practitioner availability is constrained or for consumers who do not have a usual care provider.

EPA-Pharmacists

The EPA-Pharmacists has been amended to:

- create a new part of the EPA that describes the circumstances and conditions that are required to provide acute common condition services and health and wellbeing services;
- create a new part of the EPA that describes the circumstances and conditions that are required to provide an oral health risk assessment and fluoride application service;
- change existing references to the 'Contraception Pilot' to the BAU 'hormonal contraception service' in part 3 of the EPA; and
- make an administrative amendment to update the circumstances and conditions and list of medicines that can be sold under the Urinary Tract Infection Community Pharmacy Service in part 2 of the EPA to align with clinical best practice.

EPA-Pharmacy Pilot

The EPA-Pharmacy Pilot has been replaced by the EPA-Chronic Conditions Management Pilot which provides for all remaining Pharmacy Pilot services – that is, prescribing for the chronic condition management services.

The circumstances and conditions that apply for the chronic condition management services remain largely unchanged from the current circumstances and conditions for these services. The training requirements for the Chronic Conditions Management Pilot remain unchanged from the current training requirements.

Dental Assistants

The Amendment Regulation improves access to preventative dental services by amending schedule 4 of the Medicines Regulation to insert a new part 5 (Hospital and health service dental assistants) providing for dental assistants employed by a HHS as a new class of person, provide a definition for a dental practitioner, and include the following as authorised dealings for a dental assistant:

- administer S4 fluoride that is in a preparation for human use, if the medicine is administered under the supervision of a dental practitioner; and
- possess S4 fluoride that is in a preparation for human use, if the medicine is possessed under the supervision of a dental practitioner.

A dental practitioner includes a dentist, dental hygienist, dental therapist or oral health therapist.

The Amendment Regulation will remove the need for a suitably trained dental assistant working in a HHS to apply for a general approval to apply fluoride, reducing the existing administrative burden faced by dental assistants and their supervising registered dental practitioner. Improving the utilisation of dental assistants will also help reduce the workload of dental practitioners, while improving community access to preventative dental services. This will enable a more prevention focussed oral health service, particularly in priority and high-risk communities. Dental assistants working outside of a HHS will still be able to apply for a general approval to apply fluoride.

Intern and Trainee Pharmacists

The Amendment Regulation will enable intern and trainee pharmacists to have the full breadth of work experience before becoming registered pharmacists by amending schedule 9, part 1, division 3, section 6 and division 4, section 8 of the Medicines Regulation to authorise intern pharmacists and trainee pharmacists to deal with medicines, under the supervision or direct supervision of a pharmacist (consistent with their current authorisations in schedule 9, part 1), in the way prescribed by the 2023 Pharmacist Amendment Regulation.

The Amendment Regulation will ensure intern and trainee pharmacists are competent and have experience in all facets of pharmacy practice upon registration.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the authorising Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

Transitioning Pharmacist Authorisations to Business-as-usual

Amending the Medicines Regulation to update references to the revised EPA-Pharmacists and the new EPA-Chronic Conditions Management Pilot is the only reasonable way to achieve the policy objective of transitioning certain services from the Pharmacy Pilot and the Contraception Pilot to BAU.

The authorisations relate to the extended practice of pharmacists with the relevant skills and training as provided for in the EPAs. It would not be appropriate to provide as-of-right authorisations under the Medicines Regulation for all pharmacists without condition. These amendments will deliver on an announcement made by the Minister for Health and Ambulance Services to continue the Pharmacy Pilot for chronic conditions and make the acute conditions and health and wellbeing services, including the hormonal contraception service, permanent.

Amending the Medicines Regulation to transition the medicines management services to BAU is the only effective means of achieving the policy objective. The amendments set out the authorised way for a pharmacist to deal with an S4 medicine, other than a restricted medicine or diversion risk medicine when performing the following activities:

- sell, other than on prescription, to enable continued dispensing;
- amend a prescription, without the agreement of the prescriber who made the prescription; and
- dispense on an amended prescription an equivalent medicine as a substitute to the medicine stated on the original prescription.

The amendments ensure the requirements for pharmacists dealing with medicines are commensurate with their qualifications and balances the public health and safety risk of the medicines by ensuring medicines are used safely and effectively.

Dental Assistants

The current approach requires HHSs to prepare and submit individual applications for a general approval for dental assistants to apply fluoride. These applications are considered on a case-by-case basis and carry an administrative burden. This burden would remain a potential barrier to optimal utilisation of dental assistants as part of a prevention focussed oral health service.

Given the administrative burden of the current process, the skills and training of dental assistants and fluoride's minimal risk of harm, it is appropriate to provide an as-of-right authorisation under the Medicines Regulation for relevant dental assistants – that is, authorising appropriately trained dental assistants employed by a HHS to possess and administer fluoride varnish under the supervision of a dental practitioner.

Intern and Trainee Pharmacists

There are no reasonable alternatives, as in its current form the Medicines Regulation does not allow intern and trainee pharmacists to administer and possess medicines to the full extent authorised for pharmacists under the supervision or direct supervision of a pharmacist. This limits the experience a trainee or intern pharmacist is able to obtain prior to registration as a pharmacist. Amending the Medicines Regulation to allow intern and trainee pharmacists to train to their full scope of practice to the extent authorised for pharmacists is the most appropriate approach.

Benefits and costs of implementation

There are no significant financial implications associated with the proposed amendments. Any identified financial impacts for government are manageable within the existing budget allocation.

Transitioning Pharmacist Authorisations to Business-as-usual

The amendments may impose costs on persons and organisations. Consumers accessing services via a pharmacist will be required to pay for the full cost of the consultation, the medicines prescribed by the pharmacist and any other expenses associated with treatment, such as pathology and wound dressings. All medicines provided will be charged a private prescription cost and will not be subsidised under the Pharmaceutical Benefits Scheme (PBS) or count towards the PBS Safety Net. Financial consent by consumers is a key feature built into pharmacist processes, ensuring consumers are informed of the cost of the services and their options to access other services that may be more affordable. Consumers seeking to access other services may be referred to bulk-billing medical practices that can prescribe medicines under the PBS (including the PBS Closing the Gap co-payment measure). Cost may present a financial barrier for some consumers in accessing these services via a pharmacist/pharmacy.

The Amendment Regulation will improve equitable access to medicines and health services for persons living across Queensland. This will be of particular benefit to persons who have limited access to health care services in rural and remote areas. The changes will also offer consumers greater choice in accessing health services.

The amendments allow pharmacists and pharmacies to streamline the provision of acute common condition, health and wellbeing, medicines management and hormonal contraception services and maximise service availability. Enabling pharmacists to provide these services as usual pharmacy practice will help alleviate pressure on general practice and emergency departments by ensuring that patients can access appropriate care in a timely manner. Pharmacy-based services complement, rather than replace, existing models of care and are already an established component of the healthcare system internationally. These amendments align with national and global trends, where pharmacist-led care is recognised as an effective, safe, and sustainable mechanism for improving access to primary healthcare.

Dental Assistants

Enabling appropriately trained dental assistants to apply fluoride varnish will strengthen the role of dental assistants in oral health prevention, potentially improving the oral health outcomes of communities, particularly in high-risk and priority populations. These amendments will allow for greater utilisation of dental assistants in HHS oral health teams, freeing up dental practitioners to focus on more complex tasks.

There are minimal financial or resource implications associated with this proposal. The requisite systems and processes are already in place for dental assistants who have submitted applications to be authorised to apply fluoride varnish under a general approval. As the cost for the additional training required is covered by the HHS, there is a possibility of increased interest by dental assistants in completing the relevant training modules if the proposed amendments are progressed which may result in an increase in costs for HHSs. Any costs will be met within existing HHS resourcing.

Intern and Trainee Pharmacists

The proposed amendments to the Medicines Regulation enable the supervised administration and possession of medicines to be incorporated into intern and trainee pharmacist training, preparing them for this practice once they achieve general registration. Enabling intern and trainee pharmacists to deal with medicines under the supervision or direct supervision of a pharmacist may also improve access and timeliness of healthcare delivery, aid with medicine adherence, improve patient safety, and result in cost savings for the health system. There are no financial or resource implications associated with this proposal.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*; however, it may potentially impact on the fundamental principle relating to sub delegations as outlined below.

Institution of Parliament

Does the subordinate legislation allow for the sub delegation to appropriate persons or in appropriate cases?

Extended practice authorities

Section 232 (Making extended practice authorities) of the Act empowers the chief executive or delegate to make an EPA authorising an approved person to deal with a regulated substance. The EPA may state the places or circumstances in which the approved person may deal with the regulated substance, impose conditions on dealing with the regulated substance or require the approved person to hold particular qualifications or training to deal with the regulated substances.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act.

An EPA is a document certified by the chief executive of Queensland Health (or delegate) that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance. EPAs include details such as the route of administration, the specific dose, quantity, duration and restrictions placed on substances and the circumstances in which they may be administered. The EPA is monitored and updated when necessary, to align with clinical best practice and is published on the Queensland Health website. When making or amending an EPA, relevant individuals or organisations with expertise in, or experience of, the matters under consideration are consulted.

EPAs are updated regularly, with consideration given to the healthcare needs of specific patient populations, how care can be provided in a timely and safe manner and requirements for medical advice, referral or transfer to other individuals qualified to provide higher levels of care, and the individual qualifications, skills and experience of the class of health practitioners who will act under the particular authority.

Schedule 1, part 1 (Approved extended practice authorities) of the Medicines Regulation details the name of each EPA and its version number. The Medicines Regulation is updated to reflect the name and new version number of the EPA each time a new version is made. A copy of the updated EPA is tabled as extrinsic material each time the regulation is amended. The Act provides that an EPA has effect in relation to an approved person only if a provision of a regulation states it applies to the particular class of persons, as approved persons.

Including a list of EPAs in the schedule of the Medicines Regulation creates certainty for the relevant professions and the public about the status of EPAs published on the Queensland Health website and the date when these took effect.

It is considered the rigour surrounding the development of EPAs, their use in ensuring Queenslanders receive health care based on best clinical practice and the detailed nature of the documents justifies the need to sub-delegate by referring to external documents in the Medicines Regulation.

Consultation

In March 2025, a consultation paper on the proposed amendments was published on the Queensland Health website and disseminated to stakeholders across pharmacy, medical, nursing and dental peak bodies, Aboriginal and Torres Strait Islander health organisations, custodial services and Queensland Health, including Hospital and Health Services.

The Australian Medical Association of Queensland (AMAQ) and Royal Australian College of General Practitioners (RACGP) reiterated significant concerns about expanding the scope of practice for health professionals who are not medical practitioners. AMAQ and RACGP were opposed to transitioning any of the authorisations under the Pharmacy Pilot and Community Pilot to BAU.

It is considered all health professionals the subject of the amendments, have the requisite skills, training and expertise to safely carry out the proposed activities. The amendments will ensure greater access to health services for the community, particularly those living in rural and remote locations where access to health practitioners is limited.

Further consultation feedback on each of the proposals is outlined below.

Transitioning Pharmacist Authorisations to Business-as-usual

The majority of stakeholders, including the Queensland Nurses and Midwives' Union and peak nursing and pharmacy bodies, supported the amendments to transition the acute common condition and health and wellbeing services in the Pharmacy Pilot and the hormonal contraception service in the Contraception Pilot to BAU.

AMAQ and RACGP raised concerns around the apparent lack of data and independent evaluation of the pilots. RACGP noted that they did not believe that these additional pharmacy services would reduce emergency department presentations and admissions, therefore failing to solve the issue of doctor workforce shortages.

The independent evaluation of the pilots has not yet been finalised, making it inappropriate for the data to be made publicly available; but early findings regarding consumer experience of pilot services support transition to BAU.

In a joint response, the Advanced Pharmacy Australia Queensland Branch Committee, Pharmacy Guild (Queensland Branch) and Pharmaceutical Society of Australia (Queensland Branch), expressed their strong support for the amendments to transition the acute common condition services, the health and wellbeing services and the hormonal contraception service to BAU. They also requested the transition of the medicines management services from the Pharmacy Pilot to BAU, which was not included in the March 2025 consultation paper.

It was considered that as all registered pharmacists have the necessary skills, qualifications and training to safely manage medicines to provide continued dispensing, and substitute or adapt a person's medicine, that the medicines management services would also be transitioned to BAU.

Dental Assistants

All stakeholders, including peak dental, nursing and pharmacy bodies, supported the amendments to authorise dental assistants who are suitably trained and employed by a HHS to possess and administer fluoride varnish under the supervision of a dental practitioner.

The Dental Hygienists Association of Australia Limited noted that this amendment will facilitate better oral health services, particularly preventative and early intervention oral care and will benefit vulnerable communities.

Intern and Trainee Pharmacists

The majority of stakeholders, including peak pharmacy bodies, supported the amendments to authorise intern and trainee pharmacists to deal with medicines to the extent authorised for a pharmacist, under the supervision or direct supervision of a pharmacist.

Pharmaceutical Defence Limited were supportive of the amendments however, raised concerns around the fact that the skills of a trainee or intern pharmacist occurs across a spectrum, with each trainee or intern having a different scope of practice. RACGP raised concerns around any confusion these amendments may cause to patients around the qualifications of different health professionals.

It is considered interns and trainees have the appropriate skills and training to undertake services to the full extent of pharmacists, noting at all times they will be guided by the qualified pharmacist under whom they are supervised or directly supervised.