Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2023

Explanatory notes for SL 2023 No. 170

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2023

Authorising law

Section 240 of the *Medicines and Poisons Act 2019.*

Policy objectives and the reasons for them

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) regulates medicines and complements the *Medicines and Poisons Act 2019* (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 medicines; and
- providing flexible requirements for several 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.

Section 232 of the Act enables the chief executive or their delegate to make extended practice authorities that:

- state the places or circumstances in which an approved person may deal with a regulated substance;
- impose conditions on dealing with a regulated substance; or
- require an approved person to hold particular qualifications or training to deal with a regulated substance.

Schedule 1, part 1 of the Medicines Regulation lists the approved Extended Practice Authorities by name and version number. When a new version of an Extended Practice Authority is made

by the chief executive or their delegate, the Medicines Regulation must be amended to reflect the new version so it can take effect.

Schedules 3 to 15 of the Medicines Regulation provide authorisations for certain classes of persons to deal with certain medicines. Extended practice authorities provide additional authorisations for a specific class of person to deal with certain medicines beyond the authorisations in the Medicines Regulation.

The *Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2023* (Amendment Regulation) amends the Medicines Regulation to:

- facilitate implementation of the Queensland Community Pharmacy Scope of Practice Pilot (Pharmacy Pilot) and provide for a new extended practice authority;
- clarify that enrolled nurses and anaesthetic technicians may possess a schedule 4 (S4) or schedule 8 (S8) medicine, if the medicine is possessed under the supervision of a registered nurse, midwife, dentist or medical practitioner;
- update references to reflect the revised Commonwealth Poisons Standard;
- remove all references to, and authorisations for, restricted ivermectin to reflect the updated Therapeutic Goods Administration guidelines; and
- update references to a new version of the Queensland Ambulance Service (QAS) Extended Practice Authority.

Pharmacy Pilot

In 2020, the Queensland Government committed to work with the Pharmaceutical Society of Australia (Queensland Branch), the Pharmacy Guild of Australia (Queensland Branch) and other stakeholders to design and implement a pilot of pharmacists working to their full scope of practice. The Pharmacy Pilot delivers on this commitment and supports access to high-quality, integrated and cost-effective primary health care services for Queenslanders.

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 medication management services that may include clinical services related to quality use of medicines or functions related to the dispensing and supply of medicines. Pharmacists are trained to administer vaccinations as part of their clinical training and are required to maintain competency as part of their ongoing registration.

Enabling pharmacists, among other health professionals, 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. A number of programs have been undertaken in Australia to expand the scope of pharmacy practice, including the Queensland Pharmacist Immunisation Program, the Queensland Urinary Tract Infection Pharmacy Pilot, four pharmacy prescribing trials in Queensland public health services and facilities, and collaborative prescribing trials in Victoria and New South Wales.

The Pharmacy Pilot will commence in March 2024, with the supporting extended practice authority commencing 1 February 2024. The Pharmacy Pilot extended practice authority must be in place prior to the pilot commencing to allow sufficient time for the appropriate on-boarding of pharmacies and pharmacists prior to services commencing.

The Pharmacy Pilot enables participating pharmacists to undertake additional medicine management and prescribing activities. The services in the Pharmacy Pilot include:

- medication management, including therapeutic adaptation, therapeutic substitution and continued dispensing;
- autonomous prescribing for specified acute common conditions and health wellbeing, such as:
  - gastro-oesophageal reflux and gastro-oesophageal reflux disease;
  - acute nausea and vomiting;
  - allergic and nonallergic rhinitis;
  - mild to moderate atopic dermatitis;
  - impetigo;
  - herpes zoster (shingles);
  - acute exacerbations of mild plaque psoriasis;
  - mild to moderate acne;
  - acute minor wound management;
  - acute diffuse otitis externa;
  - acute otitis media;
  - acute mild musculoskeletal pain and inflammation;
  - smoking cessation;
  - hormonal contraception;
  - oral health screening and fluoride application;
  - travel health including relevant travel vaccinations; and
  - management of overweight and obesity.
- structured prescribing as part of a chronic disease management program including:
  - cardiovascular disease risk reduction program including management of type 2 diabetes, hypertension and dyslipidaema;
  - improved Asthma Symptom (and Exercise Induced Bronchoconstriction) Program; and
  - Chronic Obstructive Pulmonary Disease (COPD) Monitoring Program.

To be authorised to participate in the Pharmacy Pilot, a pharmacist must meet all participation requirements and be authorised by Queensland Health. Requirements to participate include:

- holding general registration with the Pharmacy Board of Australia with no limitations to practice;
- successful completion of all required education and training programs;

- holding appropriate professional indemnity insurance to explicitly cover the activities in the Pharmacy Pilot;
- consenting to participate in the Pharmacy Pilot in accordance with the rules and requirements of the Pilot Handbook and service evaluation for the pilot; and
- holding current first aid and CPR certification.

To participate in the Pharmacy Pilot, pharmacies must also be authorised by Queensland Health. Minimum requirements to participate include:

- accreditation with the Quality Care Pharmacy Program;
- implementation of the required clinician information system with appropriately trained staff;
- holding appropriate professional indemnity insurance to cover the pharmacy's involvement in the Pharmacy Pilot;
- consenting to participate in the Pharmacy Pilot in accordance with the rules and requirements of the Pilot Handbook and service evaluation component for the pilot; and
- ensuring only authorised pharmacists provide services as part of the Pharmacy Pilot and only at authorised sites.

Enrolled nurses and anaesthetic technicians in anaesthetic practice settings

The Medicines Regulation authorises enrolled nurses to possess an S4 or S8 medicine, if the medicine is possessed for administration under the direct supervision of a medical practitioner for an anaesthetic procedure at a hospital or under the supervision of a dentist, medical practitioner, midwife, or registered nurse in accordance with the medicine's approved label or on a prescription or a standing order. Anaesthetic technicians are authorised to possess an S4 or S8 medicine if the medicine is possessed for administration at a hospital under the direct supervision of a medical practitioner for an anaesthetic procedure.

Possess has been interpreted to be limited to the purpose of administration only and may not extend to activities such as managing medicine stock in a hospital clinical service area. For example, packing away medicines that have been ordered, cleaning up after a procedure, or returning medicines to the medicine store post procedure.

Under the repealed *Health (Drugs and Poisons) Regulation 1996* (HDPR), enrolled nurses and anaesthetic technicians (referred to as anaesthetic assistants) were authorised to possess S4 or S8 medicines at a hospital when preparing for, and during, anaesthetic procedures, under the written instruction of a doctor administering anaesthesia. The authorisations under the repealed HDPR enabled the management of medicine stock in the hospital's clinical service area, where an anaesthetic procedure was conducted.

Amendments are necessary to remove ambiguity surrounding the interpretation of authorisations for enrolled nurses and anaesthetic technicians and clarify that they can possess S4 or S8 medicines to manage medicine stock in a hospital clinical service area where an anaesthetic procedure is carried out.

Update references to the Poisons Standard

Medicines and poisons are scheduled by the Therapeutic Goods Administration in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). The Poisons Standard specifies the national uniform scheduling of substances and uniform labelling and packaging requirements which are adopted in Queensland.

On 1 February 2023, the Therapeutic Goods Administration published a revised version of the Poisons Standard, which made structural, formatting, readability and clarity improvements, without changing the content. This revision means that the Medicines Regulation no longer accurately reflects the Poisons Standard and should be updated.

Remove references and authorisations for restricted ivermectin

In October 2021, in response to the increasing public health risk from the COVID-19 pandemic, the Commonwealth Government revised Appendix D of the Poisons Standard to impose restrictions on the prescription of ivermectin.

On 3 May 2023, the Therapeutic Goods Administration announced that from 1 June 2023, ivermectin for off-label use will be removed from Appendix D of the Poisons Standard. The removal of these Commonwealth controls means that it is no longer necessary to treat ivermectin as a restricted medicine in the Medicines Regulation.

Queensland Ambulance Service Extended Practice Authority

The Medicines Regulation provides the authorisation for QAS officers to deal with a medicine mentioned in the QAS Extended Practice Authority. Under the QAS Extended Practice Authority, an ambulance officer may administer a medicine listed in Appendix 1, subject to the conditions that the medicine is administered within the scope permitted for the class of ambulance officer in accordance with a health management protocol.

To support timely patient care and prevent delays in services, it is intended that the medicines listed in the QAS Extended Practice Authority align with the revised pharmacology inventory list for Retrieval Services Queensland to enable QAS paramedics credentialed as flight paramedics to deal with the medicines. The medicines list in the QAS Extended Practice Authority will also be updated to include additional medicines to ensure the appropriate management and care of long-bone fractures and episodes of acute behavioural disturbances. An update to the QAS Extended Practice Authority is also required to recognise an alternate qualification pathway for ambulance officers to be authorised as an Isolated Practice Area Paramedic.

Achievement of policy objectives

Pharmacy Pilot

The Pharmacy Pilot is a nation-first pharmacy pilot and will increase Queenslanders' access to high-quality and cost-effective primary healthcare. Pharmacists are highly trained and regulated healthcare professionals. The Pharmacy Pilot will ensure their expertise is used to its full scope and will help address the impacts of workforce shortages and distribution problems, particularly in regional and rural communities. The Pharmacy Pilot is designed to supplement, not replace, existing primary care services and give consumers more choice.

The Amendment Regulation gives effect to the new Pharmacy Pilot Extended Practice Authority, by referencing it in schedule 1, part 1 of the Medicines Regulation. The Amendment Regulation also amends the Medicines Regulation to enable a pharmacist participating in the Pharmacy Pilot to undertake the following dealings with an S4 medicine, other than a restricted medicine or diversion-risk medicine:

- prescribe for the management of specified acute common conditions, as part of a health and wellbeing service or a chronic disease management program;
- sell, other than on prescription, to enable continued dispensing;
- amend a prescription without the agreement of the prescriber who made the prescription, to enable therapeutic adaptation and therapeutic substitution; and
- dispense for the purposes of therapeutic adaptation and substitution.

The new Pharmacy Pilot Extended Practice Authority will:

- state the restrictions and conditions under which medicines may be prescribed including the requirement that a pharmacist may prescribe a medicine for the management of:
    - a specified acute common condition or as part of a health and wellbeing service in line with the relevant Pharmacy Pilot clinical practice guideline; and
    - a condition included within a Pharmacy Pilot clinical protocol for cardiovascular disease risk reduction, improved asthma and exercise-induced bronchoconstriction symptom control and COPD monitoring in line with the relevant clinical protocol.
- state the restrictions and conditions under which participating pharmacists may conduct medication management activities including therapeutic adaptation, therapeutic substitution and continued dispensing.

<u>Prescribing medicines</u>

The Amendment Regulation expands the authorised dealings for pharmacists participating in the Pharmacy Pilot to autonomously prescribe an S4 medicine, other than a restricted medicine or diversion-risk medicine, for a range of acute common conditions and as part of health and wellbeing services that are mentioned in the Pharmacy Pilot Extended Practice Authority. Pharmacists participating within the Pharmacy Pilot will also be able to prescribe in accordance with a clinical protocol for a chronic disease management program. Autonomous and structured pharmacist prescribing will enable participating pharmacists to appropriately manage the conditions and services that are included within the approved scope of the Pilot.

The Amendment Regulation creates a new division 2A within schedule 9 of the Medicines Regulation that enables participating pharmacists to autonomously prescribe for acute common conditions, and health and wellbeing services, and prescribe as part of structured chronic disease management programs for cardiovascular disease risk reduction, asthma, and COPD.

<u>Selling, without a prescription</u>

The Amendment Regulation enables participating pharmacists to sell, without a prescription, an S4 medicine, other than a restricted medicine or diversion-risk medicine, in accordance with the Pharmacy Pilot Extended Practice Authority, for the purposes of continued dispensing.

Existing arrangements that enable pharmacists to supply a medicine in an emergency supply situation are limited to either certain pharmaceutical benefits, S4 oral hormonal contraceptives or a three-day supply of the medicine. Continued Dispensing is the supply of an eligible medicine to a person by an approved pharmacist, where there is an immediate need for the medicine but where it is not practicable to obtain a valid Pharmaceutical Benefits Scheme (PBS) prescription. Under normal Continued Dispensing arrangements, pharmacists can only supply eligible PBS listed medicines, once in a 12-month period.

Pharmacists have demonstrated the ability to provide safe and effective continuity of medicine services to patients in primary healthcare settings throughout the COVID-19 pandemic. In response to the pandemic, the Australian Government temporarily expanded the Commonwealth Continued Dispensing arrangements until 30 June 2022. These arrangements are now permanently in place and have been expanded to include some of the additional medicine groups, including medicines for chronic conditions, lung conditions, diabetes, and heart disease.

Expanding Continued Dispensing arrangements through the Pharmacy Pilot will better position community pharmacists to assist patients in emergency supply situations and improve patient adherence to prescribed medicines. Expanding the arrangements will also enable consumers to receive a standard quantity of their medicine, rather than three days' supply, reducing the need for an immediate follow up appointment with a general practitioner.

The Amendment Regulation transitions and expands the COVID-19 emergency provisions into usual business for those pharmacists and pharmacies participating in the Pharmacy Pilot, improving access to medicines under defined circumstances.

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.

The Amendment Regulation updates the Medicines Regulation to enable participating pharmacists to undertake additional medicines management activities including therapeutic adaptation and therapeutic substitution. To support these activities, amendments are required to the Medicines Regulation to enable pharmacists to amend a written prescription for an S4 medicine, other than a restricted medicine or diversion-risk medicine, without prior agreement from the original prescriber who made the prescription, in compliance with the Pharmacy Pilot Extended Practice Authority.

Therapeutic adaptation is the process of altering an existing prescribed medicine to change and adapt dosage, formulation, strength or instructions, based on a determination of clinical need and to support safety. For example, a pharmacist could alter a medicine from a tablet to a liquid or dispersible form for someone having difficulty swallowing tablets or change the type of inhalation device for a prescribed medicine for a person who has issues with dexterity to support compliance.

Enabling pharmacists to carry out therapeutic adaptation also assists with continuity of care in times of medication shortages or other disruptions to the supply of a consumer's regular medicines.

Therapeutic substitution is the supply of an alternative medicine that belongs to the same therapeutic class and/or pharmacologic class with expected dose equivalence by a pharmacist without prior approval from the prescriber. Pharmacists are limited in how they can support consumers during medicines shortages. Pharmacists can dispense substitutable medicines, replacing a prescribed medicine if there is a medicines shortage, without prior approval from a prescriber, only in circumstances where the Therapeutic Goods Administration has issued a Serious Scarcity Substitution Instrument for a specific medicine. The medicines approved for substitution and the circumstances under which a medicine can be substituted under these arrangements are limited.

Therapeutic substitution by pharmacists is at times necessary to ensure there is continuity of appropriate clinical care for patients, especially in situations where a prescribed medicine is not available or is subject to a shortage. For example, if a patient is prescribed 40mg of atorvastatin and this medicine is not locally available, they can provide the patient with 20mg of rosuvastatin instead. This will have an equivalent therapeutic effect despite being different molecules.

Enabling participating pharmacists to carry out therapeutic substitution without the requirement to contact a prescriber will improve access to medicines for consumers. Therapeutic substitution will also support ongoing compliance to a prescribed therapy during a medicine shortage to improve health outcomes for consumers.

Dispensing

The Amendment Regulation enables participating pharmacists to dispense an S4 medicine, other than a restricted medicine or diversion-risk medicine, mentioned in the Pharmacy Pilot Extended Practice Authority for the purposes of therapeutic adaptation and substitution.

Enrolled nurses and anaesthetic technicians in anaesthetic practice settings

The Amendment Regulation amends schedule 7, part 4, section 19 and schedule 12, part 1, section 2 of the Medicines Regulation to authorise enrolled nurses and anaesthetic technicians to possess an S4 or S8 medicine for the management of medicine stock in an anaesthetic practice setting under the supervision of a registered nurse, midwife, medical practitioner or dentist.

The proposed amendments will remove any ambiguity about the interpretation of *possess* for enrolled nurses and anaesthetic technicians in hospital clinical service areas where an anaesthetic procedure is carried out. The impact on industry and community will be minimal as the proposed amendments reinstate the authorisations previously prescribed under the repealed HDPR.

Update references to the Poisons Standard

The Amendment Regulation amends the Medicines Regulation to align with the revised Commonwealth Poisons Standard. The amendments are required to ensure consistency and avoid any technical misinterpretations with the revised Commonwealth Poisons Standard.

The Amendment Regulation amends the following provisions of the Medicines Regulation:

- section 6(2)(b)(ii) – replace the reference to Poisons Standard, section 1.5.5 with Poisons Standard, section 39;
- section 73(1)(a) – replace the reference to Poisons Standard, part 2, section 1 with Poisons Standard part 2, division 2;
- section 73(2)(a) – replace the reference to Poisons Standard, part 2, section 2 with Poisons Standard, part 2, division 3;
- sections 221 and 237(4) – replace the reference in the notes to Poisons Standard, part 1 with section 6; and
- schedule 22 (Dictionary) – replace the references to the Poisons Standard, part 1 with Poisons Standard, section 6 in the definition of *approved name* and *manufacturer's pack*.

Remove references to and authorisations for restricted ivermectin

The Amendment Regulation amends the Medicines Regulation to remove all references to, and authorisations for, restricted ivermectin to align with the updated Therapeutic Goods Administration guidelines.

Queensland Ambulance Service Extended Practice Authority

The Amendment Regulation updates the reference to the new version of the QAS Extended Practice Authority in schedule 1, part 1 of the Medicines Regulation. The updated extended practice authority will:

- include cefazolin and olanzapine in the list of authorised medicines in the extended practice authority to ensure the appropriate management and care of open long-bone fractures and reduce the risk of infection or complications associated with extended transportation times from injury to hospital presentation, and optimise care for patients presenting with episodes of acute behavioural disturbances where de-escalation strategies have been unsuccessful;
- align the medicines listed in the Queensland Ambulance Services Extended Practice Authority with the revised pharmacology inventory list for Retrieval Services Queensland so flight paramedics can continue to provide timely services in collaboration with Retrieval Services Queensland; and
- recognise an alternate qualification pathway for ambulance officers to be authorised as an Isolated Practice Area Paramedic, ensuring the ongoing availability of qualified Isolated Practice Area Paramedics to provide care and health services in rural and isolated practice areas across Queensland.

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

The Amendment Regulation is the only effective means of achieving the policy objective in relation to enrolled nurses, anaesthetic technicians, Commonwealth Poisons Standard, restricted ivermectin, and the QAS Extended Practice Authority.

Pharmacy Pilot

An alternative way of achieving the policy objectives would be to require all participating pharmacists to apply for a general approval. Under section 68 of the Act, the chief executive may grant a general approval to enable a person to undertake a regulated activity with a regulated substance stated in the approval. Pharmacists participating in the Pharmacy Pilot would need to apply for an individual approval to conduct regulated activities, including prescribing, as required for the Pharmacy Pilot. The applications would need to be considered on a case-by-case basis by the chief executive or their delegate.

The use of individual approvals may not provide adequate visibility and clarity for key stakeholders, consumers or members of the primary care team with respect to the extent and conditions of the authorisation. A model to enable pharmacist prescribing based on a general approval may not provide the required transparency and authority to enable the interrelated functions of prescribing.

Additionally, this option is likely to be administratively burdensome for Queensland Health. The use of a general approval may also have implications for how the professional indemnity insurance is provided to participating pharmacists, for example, the insurer may also need to issue individual letters of cover rather than amending the master policy.

Benefits and costs of implementation

The cost of implementing the amendments will be met within existing budget allocations. The amendments do not impose any new or increased fees.

Pharmacy Pilot

The proposed amendments may impose costs on persons and organisations. Consumers accessing the service will be required to pay for the full cost of the consultation, the medicines prescribed and/or dispensed by the pharmacist and any other expenses associated with treatment, such as pathology and wound dressings. All medicines provided within the Pharmacy Pilot will also be charged a private prescription cost and will not be subsidised under the PBS or count towards any PBS safety net.

Financial consent by consumers is a key feature of the Pharmacy Pilot to ensure 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

services as part of the Pharmacy Pilot. Cost and affordability of services will be a key component of the evaluation of the Pharmacy Pilot.

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.

First Nations people in Queensland continue to experience poorer health outcomes compared to non-Indigenous people. The Amendment Regulation may improve access to timely medicines and health services for First Nations people across Queensland.

The current limitations on pharmacists may adversely impact timely access to care, a pharmacist's ability to provide opportunistic and comprehensive care and may be contributing to a higher workload on other professionals who administer and prescribe medications such as medical officers and nursing professions.

Enabling pharmacists to prescribe medicines and undertake a range of medicines management activities aligns with the *HealthQ32—A vision for Queensland's health system* that identifies opportunities to strengthen the health system, in particular developing care within the community and empowering the health workforce. One of the four system outcomes of *HealthQ32* is that Queensland's health workforce is valued, respected, and empowered to lead the delivery of world-class health services, each working to the top of their scope of practice. This change in role and skill requirement for pharmacists may enable a greater shift in the provision of healthcare to primary care.

The amendments align with recommendations made within the report *Unleashing the potential: an open and equitable health system* and from the findings of the Australian Government Productivity Commission that identified the utilisation of pharmacists and other health professionals to work to their full scope of practice as a safe, efficient and effective way to improve access to healthcare.

Queensland Health has assessed the amendments in accordance with the *Queensland Government Better Regulation Policy* as being unlikely to result in significant adverse impacts. The Minister for Health, Mental Health and Ambulance Service and Minister for Women, and the Director-General of Queensland Health are satisfied that the regulatory review requirements have been met and have approved the Impact Analysis Statement for publication.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*. Potential breaches of the fundamental legislative principles are outlined below.

Institution of Parliament

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

Extended practice authorities

Section 232 (Making extended practice authorities) of the Act empowers the chief executive or their delegate to make an Extended Practice Authority, authorising an approved person to deal with a regulated substance. The Extended Practice Authority 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 Extended Practice Authority 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.

Extended practice authorities 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 Extended Practice Authority is monitored and updated, when necessary, to align with best clinical practice and is published on the Queensland Health website. When making or amending an Extended Practice Authority, relevant individuals, or organisations with expertise in, or experience of, the matters under consideration are consulted.

Extended practice authorities 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 Extended Practice Authority made by the chief executive and its version number. The Medicines Regulation is updated to reflect the name and new version number of the Extended Practice Authority each time a new version is made. Queensland Health ensures a copy of the updated Extended Practice Authority is tabled as extrinsic material each time the regulation is amended. The Act provides that an Extended Practice Authority 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 extended practice authorities in the schedule of the Medicines Regulation creates certainty for the relevant professions and the public about the status of extended practice authorities published on the Queensland Health website and the date these took effect.

It is considered the rigour surrounding the development of extended practice authorities and the level of parliamentary oversight afforded by the requirement that extended practice authorities must be approved by regulation justifies the need to sub-delegate by referring to external documents in the Medicines Regulation. Queensland Health has made a commitment to table any extrinsic material referenced in legislation in the Legislative Assembly. Tabling the updated Extended Practice Authority provides the Legislative Assembly with an opportunity to consider the Extended Practice Authority and any conditions imposed under it when scrutinising the Regulation.

Consultation

Pharmacy Pilot

The Pharmacy Guild of Australia (Guild) and the Pharmaceutical Society of Australia (PSA) support the proposed amendment to the Medicines Regulation and the making of the Pharmacy Pilot Extended Practice Authority. The Guild has indicated that pharmacists working to their full scope, including prescribing, is integral to the provision of timely, consumer-centred healthcare. Pharmaceutical Defence Limited (PDL) have confirmed, subject to relevant legislative approvals being in place, support for PDL members engaged in the Pharmacy Pilot, under the cover of the PDL Master Policy.

The Australian Medical Association Queensland (AMAQ) and the Royal Australian College of General Practitioners (RACGP) do not support the Pharmacy Pilot. The AMAQ and RACGP have raised concerns regarding prescribing by pharmacists, the safety and appropriateness of services for consumers, clinical governance within the community pharmacy setting, and the potential for further fragmentation of primary health care services. The Australian College of Rural and Remote Medicine (ACRRM) does not support an expanded prescribing function for pharmacists. ACRRM submit prescribing and dispensing roles should be kept separate to prevent conflicts of interest. ACRRM supports pharmacists working within multidisciplinary general practice teams and in other team-based models of care.

The Pharmacy Pilot provides a nation-first opportunity to optimise the scope of practice for pharmacists to increase access to high quality, integrated and cost-effective primary healthcare and lessen the impact of workforce shortages and distribution problems.

The Pharmacy Pilot will commence March 2024 and is due to run until early 2026. Queensland Health has engaged Deloitte to undertake an independent service evaluation of the Pharmacy Pilot, aligned to the Australian Institute of Health and Welfare dimensions of system performance (accessibility, continuity, effectiveness, efficiency and sustainability, appropriateness, and safety). The evaluation has been co-designed with consumers and key stakeholders. In addition, consultation has taken place with consumers, industry representatives and medical representatives to design a Quality and Safety Framework to monitor and manage quality and safety indicators during the Pilot. Concerns, incidents, or feedback raised by stakeholders, clinicians or consumers will be carefully considered as part of the evaluation of the Pilot and reported as part of the Quality and Safety Framework.

Enrolled nurses and anaesthetic technicians in anaesthetic practice settings

The amendment has been developed in response to concerns raised by enrolled nurse and anaesthetic technician stakeholder groups regarding the practical barriers for handling medicines for the purposes of managing stock. Stakeholders working in Hospital and Health Services have also requested clarification from Queensland Health about whether the authorisation for possession extends to activities beyond administration of a scheduled medicine. Stakeholders are supportive of the amendments to clarify authorisations for enrolled nurses and anaesthetic technicians.

Queensland Ambulance Service Extended Practice Authority

ACRRM and the Rural Doctors Association of Queensland (RDAQ) were consulted on amendments relating to recognising alternative qualification pathways for ambulance officers to be authorised as an Isolated Practice Area Paramedic. ACRRM was supportive of the amendments and noted that they will facilitate the delivery of equitable, timely and quality patient-focussed healthcare services to Queensland's rural and remote communities. No response was received from RDAQ.

No consultation was undertaken on the remaining amendments as they are minor and technical in nature.

Notes on provisions

Part 1 Preliminary

Short title

Clause 1 states the short title is the *Medicines and Poisons (Medicines) Amendment Regulation (No. 4) 2023.*

Commencement

Clause 2 provides for the commencement of parts 1 and 2 of the regulation on 1 December 2023 and part 3 of the regulation on 1 February 2024.

Regulation amended

Clause 3 provides that the regulation amends the *Medicines and Poisons (Medicines) Regulation 2021*.

Part 2 Amendments commencing on 1 December 2023

Amendment of s 6 (Exemption for national blood supply arrangements—Act, s 7)

Clause 4 amends section 6(2)(b)(ii) by omitting 'section 1.5.5' and inserting 'section 39'. This amendment reflects the revised *Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023* (Commonwealth Poisons Standard).

Amendment of s 73 (Labels and containers must comply with Poisons Standard or approved alternatives)

Clause 5 amends section 73 to reflect the revised Commonwealth Poisons Standard.

Clause 5(1) amends section 73(1)(a) by omitting 'section 1' and inserting 'division 2'.

Clause 5(2) amends section 73(2)(a) by omitting 'section 2' and inserting 'division 3'.

Amendment of s 221 (Restriction on used containers)

Clause 6 amends the note in section 221 by omitting 'part 1' and inserting 'section 6'. This amendment reflects the revised Commonwealth Poisons Standard.

Amendment of s 237 (Chief executive may approve alternative ways of labelling or packaging medicines)

Clause 7 amends the note in section 237(4) by omitting 'part 1' and inserting 'section 6'. This amendment reflects the revised Commonwealth Poisons Standard.

Amendment of sch 1 (Extended practice authorities and departmental standards)

Clause 8 amends schedule 1, part 1 by replacing the reference to version 2 for the Queensland Ambulance Service extended practice authority with new version 3.

Amendment of sch 2 (Categories of medicines)

Clause 9 omits the schedule 2, part 1, division 1, entry for ivermectin. This amendment reflects the updated Therapeutic Goods Administration guidelines and the revisions to the Commonwealth Poisons Standard to remove the mention of, and authorisation for, ivermectin.

Amendment of sch 6 (Medical practitioners and assistants)

Clause 10 amends schedule 6 to remove the mention of, and authorisation for, ivermectin to reflect the updated Therapeutic Goods Administration guidelines and the changes to the Commonwealth Poisons Standard

Clause 10(1) amends schedule 6, section 22, items 1 to 4 by omitting 'restricted ivermectin,'.

Clause 10(2) omits schedule 6, part 2, division 5A.

Clause 10(3) amends schedule 6, section 36, items 1 to 6, by omitting 'hydroxychloroquine, restricted ivermectin' and inserting 'hydroxychloroquine'.

Clause 10(4) amends schedule 6, section 47, items 1 to 6, by omitting 'hydroxychloroquine, restricted ivermectin' and inserting 'hydroxychloroquine'.

Amendment of sch 7 (Nursing and midwifery professions)

Clause 11 amends schedule 7 to clarify that an enrolled nurse may possess a schedule 4 (S4) or schedule 8 (S8) medicine, if the medicine is possessed under the supervision of a registered nurse, midwife, dentist, or medical practitioner.

Clause 11(1) amends schedule 7, section 19, item 1, column 3 by omitting 'for the safety of the patient before, or during' and inserting 'before or during'.

Clause 11(2) amends schedule 7, section 19, item 2, column 3, by omitting 'for a purpose mentioned in this column' and inserting 'under the supervision of a dentist, medical practitioner, midwife or registered nurse'.

Amendment of sch 12 (Other health practitioners)

Clause 12 amends schedule 12, section 2 to clarify that an anaesthetic technician can perform the following regulated activities:

- administer any medicine, if the medicine is administered to a patient at a hospital, under the direct supervision of a medical practitioner and the medicine is administered for the patient's anaesthetic procedure;
- possess an S4 or S8 medicine, if the medicine is possessed under the supervision of a dentist, medical practitioner, midwife or registered nurse; and
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Amendment of schedule 22 (Dictionary)

Clause 13(1) amends schedule 22 by omitting the definition *restricted ivermectin.* This amendment reflects the updated Therapeutic Goods Administration guidelines and the revisions to the Commonwealth Poisons Standard to remove the mention of, and authorisation for, ivermectin.

Clause 13(2) amends the note for schedule 22 by omitting 'part 1' and inserting 'section 6'. This amendment reflects the revised Commonwealth Poisons Standard.

Clause 13(3) amends the note in the definition of *manufacturer's pack* in schedule 22, by omitting 'part 1' and inserting 'section 6'.

Part 3 Amendments commencing on 1 February 2024

Amendment of s 117 (Amending written prescription)

Clause 14 amends section 117 to enable a participating pharmacist to amend a prescription for an S4 medicine, other than a restricted medicine or diversion-risk medicine, mentioned in the Pharmacy Pilot Extended Practice Authority without the agreement of the prescriber who made the prescription, to enable therapeutic adaptation and therapeutic substitution.

Clause 14(1) amends subsection 117(4) to provide that before amending the prescription, under subsection (3), the dispenser must comply with the listed requirements.

Clause 14(2) omits subsection 117(5) and inserts new subsections 117(5), (6), (7) and (8).

New subsection 117(5) provides that subsection 117(6) applies if the dispenser:

- is a participating pharmacist practicing at a participating pharmacy who is dispensing under the Pharmacists—Community Pharmacy Scope of Practice Pilot Extended Practice Authority;
- is dispensing a medicine of an equivalent therapeutic effect to the medicine stated on the prescription (the original medicine) that:
  - is a substitute for the original medicine; or
  - is of a different form, strength or amount from the original prescription; or
  - has different instructions for use from the original medicine.

New subsection 117(6) provides that the dispenser may amend the prescription to dispense a medicine under subsection 117(5)(b) without obtaining the agreement to the amendment from the prescriber who made the prescription.

New subsection 117(7) provides that the dispenser must make an amendment under subsection 117(3) that is agreed by the prescriber or in accordance with subsection 117(6) by recording the following details on the prescription:

- the name of the dispenser;
- the place where the dispenser usually practices;
- the dispenser's phone number;
- the dispenser's qualifications;
- the details of the relevant changes made to the original medicine in accordance with subsection 117(5)(b).

New subsection 117(7) also provides that the dispenser must make an amendment by signing and dating the amendment and any amendments to the prescription are made in a way that does not obscure the information originally stated on the prescription.

New subsection 117(8) provide for this section that the definitions for *participating pharmacist* and *participating pharmacy* are in schedule 9, section 4A.

Amendment of s 124 (Dispensing record for dispensed medicine)

Clause 15 omits section 124(1)(m) and inserts new section 124(1)(m).

New section 124(1)(m) provides that as soon as practicable after dispensing a medicine, a dispenser must make and keep a record if the prescription was amended by the dispenser in accordance with section 117:

- for an amendment mentioned in section 117(3) – the details of the amendment and the agreement with the prescriber; or
- for an amendment mentioned in section 117(6) – the details of the amendment.

Amendment of s 159 (Amounts when selling S4 medicine)

Clause 16 inserts new subsection 159(ba) and renumbers the provision.

Clause 16(1) inserts new section 159(ba) provides that a pharmacist must not sell an amount of an S4 medicine under an extended practice authority that is more than the amount stated in the extended practice authority for the medicine to be sold.

Clause 16(2) renumbers subsections 159(ba) and (c) as 159(c) and (d).

Amendment of sch 1 (Extended practice authorities and departmental standards)

Clause 17 amends schedule 1, part 1 by inserting a reference to the new Pharmacists—Community Pharmacy Scope of Practice Pilot Extended Practice Authority (version 1).

Amendment of sch 9 (Pharmaceutical professions)

Clause 18 inserts new division 2A (Participating pharmacists), section 4A (Definitions for division), section 4B (Class of person) and section 4C (Dealings authorised) into schedule 9, part 1.

New section 4A provides definitions for this division for *community pharmacy scope of practice pilot*, *participating pharmacist* and *participating pharmacy*.

New section 4B provides that a participating pharmacist is a person who is practicing at a participating pharmacy.

New section 4C provides that a participating pharmacist can perform the following regulated activities:

- prescribe an S4 medicine, other than a restricted or diversion-risk medicine mentioned in the Pharmacists—Community Pharmacy Scope of Practice Pilot Extended Practice Authority, if the medicine is prescribed under the extended practice authority;
- dispense an S4 medicine, other than a restricted or diversion-risk medicine mentioned in the Pharmacists—Community Pharmacy Scope of Practice Pilot Extended Practice Authority, if the medicine is dispensed under the extended practice authority;

- sell, other than on a prescription, an S4 medicine, other than a restricted or diversion-risk medicine mentioned in the Pharmacists—Community Pharmacy Scope of Practice Pilot Extended Practice Authority, if the medicine is sold under the extended practice authority.