Medicines and Poisons (Medicines) Amendment Regulation 2025

Explanatory notes for SL 2025 No. 19

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation 2025

Authorising law

Sections 7, 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:

- 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 *Medicines and Poisons (Medicines) Amendment Regulation 2025* (Amendment Regulation) amends the Medicines Regulation to:

- provide a low-risk exemption for the transfer of immunisation medicines between registered Immunisation Service Providers from generic wholesaling and licensing requirements, such as buying, supplying or possessing stock of immunisation medicines;
- authorise registered nurses to deal with scheduled medicines (possess, repackage, or give a treatment dose), for persons-in-custody of a custodial facility;
- authorise pharmacists employed at a public sector health service facility or private health facility to prescribe medicines collaboratively with a medical practitioner or nurse practitioner in accordance with a collaborative prescribing protocol; and
- give effect to new versions of extended practice authorities (EPAs) to:
  - allow registered nurses to administer or give a treatment dose of certain first responder medicines when undertaking hospital-based ambulance activities;
  - allow first-contact emergency physiotherapy practitioners to prescribe and administer medicines in urgent care facilities, in addition to hospital emergency departments;
  - reflect the revised list of medicines in the updated Primary Clinical Care Manual;
  - allow health professionals to administer additional immunisation medicines; and
  - make other minor administrative amendments.

Low-risk exemption for the transfer of immunisation medicines

The Medicines Regulation is being amended to establish a low-risk exemption from wholesaling and licensing requirements for the transfer of immunisation medicines between registered Immunisation Service Providers (ISPs).

ISPs are solely responsible for the delivery of the federal National Immunisation Program and state-funded immunisation programs in Queensland. There are over 2,700 Queensland Health Immunisation Program registered ISPs in Queensland of varying types including entities such as general practitioner clinics, pharmacies, Aboriginal and Torres Strait Islander Community Controlled Health Organisations, Hospital and Health Services (HHSs), some local government authorities and other private providers.

Under schedule 13, part 7 of the Medicines Regulation, a health department employee is authorised to supply stock of an immunisation medicine if the stock is supplied to a registered ISP. While this authorisation enables ISPs to receive immunisation medicines from the Department of Health, it does not enable further transfer between ISPs. Consequently, if an ISP needs to transfer an immunisation medicine to another ISP — for example, to redistribute immunisations to communities where they are needed — wholesaling requirements apply.[1] These include the requirement to possess a wholesaling licence and to ensure a compliant purchase order is received to supply the immunisation medicine stock. ISPs are also required to provide invoices to the buyer, ensure record-keeping of relevant documentation, and meet other obligations under the Medicines Regulation.

[1] A limited exception to the wholesaling and licensing requirements exists where a pharmacist is transferring immunisation medicines within the pharmacist's authorised dealings under the Medicines Regulation. Specifically, schedule 9, part 1, division 1 authorises pharmacists to supply stock to another pharmacist to urgently fill a shortage of stock held by the other pharmacist, to prevent the stock expiring, to satisfy an order made by a client of the other pharmacist, or supply stock from a pharmacy to an approved person, other than a pharmacist, who is authorised under the Medicines Regulation to give a purchase order for the medicine (for example, a community pharmacy to another ISP such as a general practitioner clinic).

Continuing to subject ISPs to generic wholesaling and licensing requirements does not represent a pragmatic and efficient approach to the transfer of immunisation medicines between ISPs: The purpose of the wholesaling and licensing requirements is to ensure the safe, regulated distribution and handling of regulated substances. But registered ISPs are already subject to regulatory controls that achieve the same purpose, as discussed below.

Removing these requirements will:

- reduce the risk of disruption to immunisation services, which may impact timeliness of immunisation and potentially increase the risk of transmission of immunisation-preventable diseases;
- reduce wastage of Government funded immunisation medicines; and
- reduce the significant regulatory and administrative burden on Queensland's constrained primary care sector with a process that is of little practical value in the absence of a financial transaction.

The exemption for the transfer of immunisation medicines between ISPs is made under section 7 of the Act, which enables a regulation to exempt low-risk activities from the Act's regulatory controls. An exemption can only be made if the Minister is satisfied the activity being undertaken with the regulated substance could reasonably be expected to pose no or a negligible health risk to any person.

The Minister is satisfied the transfer of immunisation medicines between ISPs poses little or no health risk for the following reasons:

- The exemption only applies to registered ISPs. ISPs are registered with Queensland Health after completion of an Immunisation Management Protocol, which demonstrates they have robust cold chain management processes and emergency management plans in place. Audits of ISPs occur on a three yearly basis to ensure these processes are maintained in accordance with Queensland Health protocols.
- The exemption only applies to the transfer of immunisation medicines from one registered ISP to another registered ISP, that is, to an entity that is also required to have and maintain an Immunisation Management Protocol.
- The exemption only applies to immunisation medicines provided to ISPs by Queensland Health, that is, medicines provided to ISPs for no financial consideration. The medicines themselves are considered to have negligible risk of diversion or misuse.
- The transfer of immunisation medicines will remain monitored by Queensland Health as ISPs will be required to notify the department as soon as practicable after a transfer has occurred.

Custodial nurses

The amendments to the Medicines Regulation will authorise registered nurses to deal with scheduled medicines (possess, repackage, or give a treatment dose) for persons-in-custody at any custodial facility. The objective of these amendments is to reduce administrative burden and ensure there is consistency for registered nurses dealing with scheduled medicines across the different types of custodial facilities.

All registered nurses, regardless of work location, have certain authorisations to deal with schedule 2 (S2), schedule 3 (S3), schedule 4 (S4) and schedule 8 (S8) medicines under schedule 7, part 3, division 2 of the Medicines Regulation. The scope of dealings for

registered nurses under this division allows for medicines to be administered to prison patients when they are located within a prison.

Prison nurses (that is, registered nurses who work in prisons only) have an additional authority to possess, repackage and give a treatment dose of S2, S3 or S4 medicines prescribed for a prison patient, to take when they are not physically at the prison, such as when they are attending court hearings, being transferred to another prison, or being released under schedule 7, part 3, division 5 of the Medicines Regulation.

While the Medicines Regulation authorises prison nurses to possess, repackage and give a treatment dose in the above circumstances, authorisations for registered nurses working in other custodial facilities (that is, corrective service facilities, youth detention centres and watch-houses) are not provisioned. As such, registered nurses who work in custodial facilities other than prisons are not authorised to possess, repackage and give a treatment dose of medicines for persons-in-custody.

Collaborative Pharmacist Medication Prescribing

The Medicines Regulation is being amended to enable the implementation of a Collaborative Pharmacist Medication Prescribing (CPMP) model of care for pharmacists employed at a public sector health service facility or a private health facility. This will allow pharmacists to prescribe medicines in collaboration with a medical practitioner or nurse practitioner, optimising the efficiency and safety of pharmacist charting services.

Pharmacists employed at a public sector health service facility or a private health facility are not authorised to prescribe any medicines under the Medicines Regulation and therefore are not authorised to chart medicines for administration or supply by another person, such as a registered nurse. A medication chart is a form of prescription used to direct the supply and administration of medicines or record medicines used in the treatment of patients.

Under current pharmacist medication charting services in Queensland, each individual medicine order charted by a pharmacist must be co-signed by a medical practitioner to validate it as a legal prescription made by the medical practitioner. This requirement interrupts medical practitioner workflow, reduces efficiency of pharmacist medication charting, and may cause delays or omissions to medicine administration.

Collaborative prescribing is within the existing scope of practice of a pharmacist, with the Pharmacy Board of Australia issuing a position statement to this effect.[2] The amendments provide that pharmacist prescribing may only occur under a collaborative prescribing protocol, which must meet legislated minimum standards. The requirements include that the protocol is made available for inspection and pharmacist prescribing only occurs in collaboration with a medical practitioner or nurse practitioner. This will allow the authorised pharmacist to prescribe medicines in line with the collaborative prescribing protocol without the need for another authorised prescriber's co-signature on each individual medicine prescription. This includes charting the medicines for administration or supply by an authorised person and directing the supply to patients on discharge or in an outpatient setting.

[2] Pharmacy Board of Australia - Pharmacist prescribing - Position statement - 15 October 2019. Available at: www.pharmacyboard.gov.au/News/Professional-Practice-Issues/Pharmacist-Prescribing-Position-Statement.aspx (last accessed 9 January 2025).

The CPMP model of care addresses service demands through the sustainable and collaborative optimisation of workforce scope of practice. The likely benefits of the CPMP model include early optimisation of medicines, reduced medication errors, improved patient flow through hospital services, and timely administration of medicines.

Extended practice authority amendments

Section 232 of the Act enables the chief executive or their delegate to make EPAs 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 certain qualifications or training to deal with a regulated substance.

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.

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

The Amendment Regulation amends the Medicines Regulation to give effect to new versions of the EPAs to:

- allow registered nurses to administer or give a treatment dose of certain first-responder medicines when undertaking hospital-based ambulance activities;
- allow first-contact emergency physiotherapy practitioners to prescribe and administer medicines in urgent care facilities, in addition to hospital emergency departments;
- reflect the revised list of medicines in the updated Primary Clinical Care Manual;
- allow health professionals to administer additional immunisation medicines; and
- make other minor administrative amendments.

<u>Hospital-based ambulances</u>

The Registered Nurses EPA is being amended to allow registered nurses to administer or give a treatment dose of certain first-responder medicines when undertaking hospital-based ambulance (HBA) activities.

Twenty-two rural and remote locations provide pre-hospital emergency first response services through HBAs in lieu of a Queensland Ambulance Service presence. The HBAs are operated by registered nurses or Patient Support Officers instead of paramedics.

Under the Registered Nurses EPA, a registered nurse can be credentialed to administer or give a treatment dose of medicines if the registered nurse is working for an HHS that uses a credentialing process meeting the requirements of the current Health Service Directive. However, the current version of the Registered Nurses EPA does not allow registered nurses to administer or give a treatment dose of a number of first-responder medicines to patients.

Additional S4 medicines are being added to the Registered Nurses EPA to allow suitably qualified and authorised registered nurses to administer or give a treatment dose of first-responder medicines in HBA services to deliver essential healthcare to Queenslanders in regional, rural and remote practice settings during time-critical acute events. Registered Nurses already have as-of-right authorisations to administer S2 and S3 medicines under the Medicines Regulation.

First-contact emergency physiotherapy practitioner prescribing

The Physiotherapists EPA is being amended to enable first-contact emergency physiotherapy practitioners to prescribe and administer medicines in urgent care facilities, in addition to hospital emergency departments.

First-contact emergency physiotherapy practitioner roles are a long-established model of care within HHSs. First-contact emergency physiotherapy practitioners are credentialed by their employing HHS to autonomously manage a wide variety of lower acuity, non-complex neuromusculoskeletal injuries, including limb fractures and dislocations, sprains and strains. This is within a collaborative and multidisciplinary care setting with local clinical and professional governance structures in place.

The Physiotherapists EPA authorises appropriately trained and credentialed physiotherapists to prescribe and administer specified approved medicines in a public sector hospital emergency department, including analgesics, local anaesthetics, antispasmodics, specific medicines for the management of neuropathic pain, and specific medicines for the relief of nausea and gastro-oesophageal reflux associated with prescribed analgesics.

A public sector hospital emergency department is defined in the Physiotherapists EPA as a service that meets the descriptors outlined in the *Clinical Skills Capability Framework: Emergency Services* for a level 4 service or above. This definition excludes urgent care clinics and minor injury and illness facilities at the seven new satellite hospitals, and Queensland Health emergency departments that are Clinical Skills Capability Framework level 3 and below (135 emergency department services out of a total of 155), despite the model of care, workload, and patient presentations being the same.

This limitation negatively impacts on the efficiency and efficacy of urgent care and minor injury and illness services that were established to manage lower acuity and non-complex conditions such as musculoskeletal presentations currently managed within the emergency physiotherapy practitioner first-contact model of care, to reduce the pressure on public emergency departments.

Primary Clinical Care Manual

The Office of Rural and Remote Health, Queensland Health, in partnership with the Queensland Royal Flying Doctor Service, is due to publish the 12th edition of the Primary Clinical Care Manual (PCCM) in June 2025. The following EPAs are being updated to align with the medicines contained in the revised edition of the PCCM. This will enable suitably qualified rural and remote members of the health workforce to deal with medicines as specified in the EPAs for:

- Midwives;
- Registered nurses;
- Queensland Ambulance Service – Isolated practice area paramedics;

- Aboriginal and Torres Strait Islander health practitioners; and
- Indigenous health workers.

The PCCM is the principal health management protocol for clinicians working in rural and isolated practice areas. The PCCM is reflective of contemporary evidence adapted to the rural and remote context and ensures Queensland residents living in rural and remote areas have safe and timely access to medicines.

Administration of immunisation medicines

The following EPAs are being amended to authorise the relevant health professionals to administer additional immunisation medicines, thereby reducing barriers to access critical immunisations:

- Pharmacists — provide authorisation to administer mpox (formerly known as monkeypox) and rabies vaccination (for pre-exposure prophylaxis) and add an age restriction (2 years or over) to the RSV immunisation medicine to clarify the policy intent;
- Registered nurses — provide authorisation to administer mpox vaccination, remove the occupation specific restrictions for administration of meningococcal, diphtheria, tetanus and pertussis (whooping cough) vaccines, and authorise an immunisation nurse to give a treatment dose of paracetamol when administering the meningococcal B (menB) vaccine for a child under two years of age;
- Aboriginal and Torres Strait Islander health practitioners — provide authorisation to administer mpox vaccination on prescription;
- Indigenous health workers — provide authorisation to administer mpox vaccination on prescription;
- Aboriginal and Torres Strait Islander health workers — provide authorisation to administer mpox, measles, mumps, rubella, respiratory syncytial virus (RSV), varicella (chickenpox) and zoster (shingles) immunisations on prescription; and
- Midwives — provide authorisation for midwives to administer COVID-19, influenza, RSV, diphtheria, tetanus, and pertussis immunisations without the requirement to complete an immunisation training course.

The schedules of the Medicines Regulation authorise certain health professions to deal with immunisation medicines. The Medicines Regulation further authorises specified health professions in stated circumstances to deal with medicines under an EPA. The majority of health professions that participate in immunisation programs rely on these EPA authorisations to deal with immunisation medicines.

The amendments are in line with the current immunisation authorisations for the identified health professionals. For example, pharmacists already administer a number of travel immunisation medicines similar to the rabies vaccination, and Aboriginal and Torres Strait Islander health practitioners/health workers and Indigenous health workers currently administer immunisation medicines only on prescription, with the prescription requirement maintained under the amendments. Further, the amendments to enable registered nurses to administer additional immunisation medicines will only apply to sexual or reproductive health nurses who complete specified training as a sexual health program nurse.

Immunisations play a key role in preventing serious disease and keeping Queenslanders safe. Timely and easy access is often an important factor in the decision to seek immunisation. The EPA amendments will improve and provide greater access to health services for the community.

Other minor amendments

Additional minor administrative amendments being made to the EPAs include:

- amending the route of administration for triamcinolone compound (e.g. Kenacomb®) to otic (into the ear) in the Registered Nurses EPA to clarify that the use of both ear ointment and drops is authorised;
- aligning the medicines in appendix 2 with the medicines in appendix 3 of the Registered Nurses EPA; and
- clarifying the locations where immunisation can occur under the Aboriginal and Torres Strait Islander health practitioners, Aboriginal and Torres Strait Islander health workers and Indigenous health workers EPAs to align with the Registered Nurses EPA.

Achievement of policy objectives

The Amendment Regulation commences on 7 April 2025.

Low-risk exemption for the transfer of immunisation medicines

The Amendment Regulation creates an exemption for registered ISPs to transfer immunisation medicines to other registered ISPs without complying with the usual wholesaling and licensing requirements under the Act.

The exemption will support timely and efficient use of immunisation medicines, reduce administrative burden on ISPs and Queensland Health, and promote better access to immunisation services for the Queensland public.

To ensure appropriate safeguards are in place, the exemption will only apply to registered ISPs for the transfer of immunisation medicines from one registered ISP to another registered ISP. ISPs are already required to have robust storage and transfer processes and emergency management plans in place. Further, the transfer of immunisation medicines will remain monitored by Queensland Health. To allow Queensland Health to monitor the stock levels of immunisation medicines, ISPs will be required to notify the department as soon as practicable after they have transferred an immunisation medicine to another registered ISP.

Minor amendments are also being made to replace the term ‘vaccine’ with the term ‘immunisation medicine’ throughout the Medicines Regulation. An immunisation medicine includes a vaccine, immunoglobulins, and monoclonal antibodies for prevention of infectious diseases.

Custodial nurses

The Amendment Regulation amends schedule 7, part 3, division 1 of the Medicines Regulation to include a definition for a custodial patient, being a patient:

- in custody at a custodial facility; or
- being released from a custodial facility into the custody of the court; or

- being transferred from 1 custodial facility to another custodial facility; or
- being released from a custodial facility into the community.

The Amendment Regulation amends schedule 7, part 3, division 5 of the Medicines Regulation to:

- authorise registered nurses employed at a custodial facility to give a treatment dose of:
  - an S2, S3 or S4 medicine if the medicine is given for a custodial patient on a prescription;
  - an S8 medicine, other than an amphetamine or methylphenidate or an approved opioid, if the medicine is given for a custodial patient, on a prescription, in an amount that is no more than 1 day's supply;
  - amphetamine or methylphenidate if the medicine is given for a patient in custody at, or being released from or transferred to or from a detention centre (as defined in schedule 4 (Dictionary) of the *Youth Justice Act 1992*) or prison, on a prescription in an amount that is no more than 7 days' supply;
- authorise registered nurses employed at a custodial facility to repackage any medicine, provided the medicine:
  - is repackaged for giving a treatment dose for a custodial patient on a prescription; and
  - if repackaged in a dose administration aid, is repackaged in accordance with the dose administration aid repackaging guidelines.
- authorise registered nurses employed at a custodial facility to possess an S4 or S8 medicine in the circumstances listed above.

Providing standardised authorisations for registered nurse dealings with scheduled medicines in custodial facilities will:

- support transparency and consistency in the authorised scope of registered nurses and the medicines they may deal with when working in custodial facilities across the state; and
- enable HHSs to deliver safe, flexible and efficient offender health services to persons-in-custody.

Collaborative Pharmacist Medication Prescribing

The Amendment Regulation amends schedule 9, part 1 of the Medicines Regulation to insert a new division 2B for pharmacists employed at public sector health service facilities and private health facilities. This new division outlines who can participate in and what requirements are in place for the CPMP model.

The amendment will allow any pharmacist, or stated class of pharmacist, who is employed at a public sector health service facility or a private health facility to prescribe medicines for the treatment of a patient where:

- the treatment is in a public sector health service facility or private health facility that has a collaborative prescribing protocol in place;
- the collaborative prescribing protocol applies to the pharmacist or their class of pharmacist;
- the treatment is provided in collaboration with a medical practitioner or nurse practitioner authorised to deal with the medicine; and
- the medicine is prescribed in the circumstances and in accordance with the process mentioned in the collaborative prescribing protocol for the facility.

A collaborative prescribing protocol for a public sector health service facility or a private health facility is defined as a document that:

- states the circumstances in which a pharmacist or class of pharmacist may prescribe a medicine;
- states the process for prescribing of the medicine, in collaboration with a medical practitioner or nurse practitioner;
- is approved by the facility's medicines and therapeutics committee (see section 103(2) Medicines Regulation) if one is established, otherwise the person responsible for the day-to-day management of the facility; and
- is available for inspection by:
  - a health practitioner providing services at the facility;
  - the chief executive of the Department of Health;
  - an inspector (under the Medicines Act); or
  - a health ombudsman official.

Extended practice authority amendments

Hospital-based ambulances

The Amendment Regulation updates schedule 1 of the Medicines Regulation to reference a new version of the Registered Nurses EPA, which enables a registered nurse authorised to participate in hospital-based ambulance activities to administer or give a treatment dose of a number of first responder medicines to consumers.

First-contact emergency physiotherapy practitioner prescribing

The Amendment Regulation updates schedule 1 of the Medicines Regulation to reference a new version of the Physiotherapists EPA, which expands the scope of operation of the EPA to enable first-contact emergency physiotherapy practitioner prescribing and administering in all public urgent care settings where the physiotherapist is appropriately credentialed by the HHS to prescribe and administer in these settings, through established governance and credentialing processes.

The amendment will enable first-contact emergency physiotherapy practitioners to prescribe and administer the same approved medicines in all public urgent care settings where the physiotherapist is credentialed by the HHS.

The amendment will allow the established model of care to be delivered in all appropriate care settings, providing improved access to comprehensive care for neuromusculoskeletal conditions for the community, delivered closer to where people live, supporting more timely, person-centred care at the right time, in the right place, and by the right person.

Primary Clinical Care Manual

The Amendment Regulation updates references to new versions of the following EPAs that update the list of medicines and routes for administration in the 12th edition of the PCCM to the list of medicines these health workers can deal with:

- Midwives;
- Registered Nurses;
- Queensland Ambulance Service – Isolated practice area paramedics;
- Aboriginal and Torres Strait Islander health practitioners; and
- Indigenous health workers.

Administration of immunisation medicines

The Amendment Regulation updates references to new versions of the following EPAs that provide for additional immunisation medicines for administration and removes certain occupation specific restrictions for administering immunisation medicines these health workers can deal with:

- Pharmacists;
- Registered nurses;
- Aboriginal and Torres Strait Islander health practitioners;
- Indigenous health workers;
- Aboriginal and Torres Strait Islander health workers; and
- Midwives.

Other minor amendments

The Amendment Regulation updates references to new versions of the following EPAs that provide for minor administrative amendments to the medicines these health workers can deal with:

- Registered nurses;
- Midwives;
- Aboriginal and Torres Strait Islander health practitioners;
- Indigenous health workers; and
- Aboriginal and Torres Strait Islander health workers.

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

Low-risk exemption for the transfer of immunisation medicines

The Act contains reasonable excuse clauses that would allow an ISP to transfer immunisation medicines in an emergency without it being an offence under the Act. For example, this may include the urgent clinical need for the transfer of the rabies vaccine for post exposure prophylaxis which is time sensitive, or in an isolated rural or remote area where immunisation service delivery would be significantly delayed without the option to transfer immunisation medicines. However, only a small proportion of transfers would be sufficiently urgent to satisfy the requirement for a reasonable excuse. Moreover, the burden of demonstrating a reasonable excuse under the Medicines Regulation would be on the ISPs involved in the transfer, who would be subject to penalties if the excuse could not be made out. It is unreasonable to place ISPs in the position of having to choose between the risk of committing an offence or refusing to participate in an urgently required transfer of immunisation medicines.

Custodial nurses

Section 76 of the Act provides for the chief executive (or their delegate) to consider applications to determine whether substance authorities (general approvals) may be granted to enable registered nurses who work in custodial facilities authority to deal with scheduled medicines prescribed for a person-in-custody.

As general approvals are tailored for each specific facility, variations exist in the authorisations, conditions and period of the approval. The general approval process creates an unnecessary regulatory and administrative burden for both applicants and the Department of Health. Rather than rely on this temporary measure, it is more appropriate to introduce a permanent solution via amendment to the Medicines Regulation.

Collaborative Pharmacist Medication Prescribing

There are no reasonable alternatives, as under current pharmacist medication charting services in Queensland, each individual medication order charted by a pharmacist must be co-signed by a medical practitioner to validate it as a legal prescription made by the medical practitioner. This requirement interrupts medical practitioner workflow, reduces efficiency of the pharmacist medication charting model, and may cause delays or omissions to medicine administration.

Extended practice authority amendments

<u>Hospital-based ambulances</u>

In lieu of authorisation via the Registered Nurses EPA, standing orders are used by facilities that operate HBAs. A standing order is a document that authorises a medicine to be administered or given as a treatment dose to or for a person at the designated place, provided several conditions are met. A standing order must be reviewed every two years and can only apply to a single medicine.

The current practice of utilising standing orders at local facilities increases the bureaucratic burden on individual facilities and increases patient risk due to the inconsistent use of standing orders for particular medicines across HHSs, particularly if a registered nurse is working between different HBA sites. If the medicines that have a standing order are not extensive, this limits the scope of practice for registered nurses at HBA sites and significantly impacts the quality of care provided to patients.

Given the above, it is more appropriate for additional S4 medicines to be added to the Registered Nurses EPA to allow suitably qualified and authorised registered nurses to administer or give a treatment dose of first-responder medicines in HBA services to deliver essential healthcare to Queenslanders in regional, rural and remote practice settings during time critical acute events.

First-contact emergency physiotherapy practitioner prescribing

There are no reasonable alternatives, as under the current Physiotherapists EPA only Queensland Health emergency departments that are Clinical Skills Capability Framework level 4 or above are able to prescribe and administer the specified approved medicines, despite the model of care, workload and patient presentations being the same in other urgent care facilities.

This limitation negatively impacts on the efficiency and efficacy of urgent care and minor injury and illness services that were established to manage lower acuity and non-complex conditions such as musculoskeletal presentations currently managed within the emergency physiotherapy practitioner first-contact model of care, to reduce the pressure on public emergency departments.

Primary Clinical Care Manual

There are no reasonable alternatives. It is standard practice for relevant EPAs to be updated to align with the medicines contained in revised editions of the PCCM. The PCCM is reflective of contemporary evidence which is adapted to the rural and remote context and ensures Queensland residents living in rural and remote areas have safe and timely access to medicines.

Administration of immunisation medicines

As the majority of health professions that participate in immunisation programs rely on EPA authorisations to deal with immunisation medicines, there are no reasonable alternatives to updating the identified EPAs.

Other minor amendments

There are no reasonable alternatives to updating the identified EPAs. The proposed amendments are minor and administrative in nature.

Benefits and costs of implementation

Low-risk exemption for the transfer of immunisation medicines

The amendments will support judicious and optimal use of immunisation medicines by enabling redistribution of these medicines to avoid wastage and mitigate disruption to immunisation services.

Minimising vaccine wastage is a performance benchmark in the National Partnership on Essential Vaccines Schedule.[3] The transfer of immunisation medicines is a commonly used strategy to minimise wastage.

There are no other resource implications associated with the amendments as the requisite systems are already in place for both government and the private sector.

Custodial nurses

Providing standardised authorisations for registered nurse dealings with scheduled medicines in custodial facilities:

- supports transparency and consistency in the authorised scope of registered nurses and the medicines they may deal with when working in custodial facilities across the state;
- reduces the administrative burden of applying for, considering and renewing general approvals granted; and
- enables HHSs to deliver safe, flexible and efficient offender health services to persons-in-custody.

There are no financial or resource implications associated with the proposed amendments.

Collaborative Pharmacist Medication Prescribing

Benefits of a CPMP model include pharmacists working to full scope to support medical practitioners and nurse practitioners in the efficient delivery of patient care and improved timely access to medicines for patients.

Collaborative prescribing is within the existing scope of practice of a pharmacist so no additional training is required. The Pharmacy Board of Australia has a position statement to this effect.[4]

The resource requirements for the local implementation of CPMP services will vary depending on the context in which CPMP occurs. Individual health services will need to determine pharmacist resource requirements when planning for and implementing CPMP service models. Many of the activities associated with the CPMP model are routinely undertaken by a hospital pharmacist performing usual care duties. However, there are additional activities, for example, developing any documents and following the processes required under the facilities' collaborative prescribing protocol, generating medication charts or prescriptions, that may increase the authorised pharmacist's workload.

[3] Federation Funding Agreement – Health, Essential Vaccines Schedule (2024-25 variation). Available here: www.federalfinancialrelations.gov.au/agreements/essential-vaccines.
[4] Pharmacy Board of Australia - Pharmacist prescribing - Position statement - 15 October 2019. Available here: www.pharmacyboard.gov.au/News/Professional-Practice-Issues/Pharmacist-Prescribing-Position-Statement.aspx.

Notwithstanding it is likely the benefits associated with the CPMP model, such as a reduction in medication error and omission rates and improved liaison regarding medication supply, will result in overall improved workflow efficiencies for pharmacy and nursing staff. Additionally, the undertaking of collaborative prescribing activities by the authorised pharmacist is likely to also release medical practitioner or nurse practitioner resources.

Any financial and resource implications such as education, protocol development and record keeping, will be met within the existing resources of the relevant facilities.

Extended practice authority amendments

Hospital-based ambulances

Enabling suitably qualified registered nurses to administer or give a treatment dose of first responder medicines under the Registered Nurses EPA will:

- provide consistency across the State and within services;
- increase the availability and provision of equitable access to healthcare by enabling practitioners authorised to provide first response emergency care in HBAs;
- enhance attraction and retention of suitably qualified RNs working in services in rural and isolated practice areas through optimisation of scope of practice; and
- reduce the impost on scarce specialty practitioners, including medical practitioner resources, to provide emergency and acute care in rural and isolated practice areas.

Any financial and resource implications such as education, credentialing and record keeping, will be met within the existing resources of the relevant facilities.

First-contact emergency physiotherapy practitioner prescribing

The amendment addresses emergency service demands through the sustainable and collaborative optimisation of workforce scope of practice, innovative allied health-led models of care and the capacity of newly implemented urgent care clinics. Continued and enhanced benefits include improved patient flow through urgent care services and timely administration of appropriate medicines.

Emergency physiotherapy practitioners working outside of emergency departments in other urgent care settings already have the qualifications and credentials that would be required under the amended Physiotherapists EPA. Over previous years and financial year 2024-25, the Office of the Chief Allied Health Officer has allocated funding to support reimbursement of training course fees for eligible physiotherapists and will continue to allocate funding in financial year 2025-26 to ensure the physiotherapy workforce can sustain the emergency physiotherapy practitioner model.

HHSs already have existing well-established governance arrangements that support emergency physiotherapy practitioner prescribing and the first-contact physiotherapist model, so no additional resources are anticipated to be required.

Primary Clinical Care Manual

The amendments will ensure rural and remote Queenslanders have timely access to medicines by enabling specific health professionals to deal with medicines that have been included in the PCCM after undergoing a rigorous editorial review process.
There are no financial or resource implications associated with these amendments.

Administration of immunisation medicines

The practitioners subject to the proposed EPA changes are well-placed to administer immunisation medicines within the health system. Amending the identified EPAs will enable health practitioners to administer a wider range of immunisation medicines and has the potential to build service capacity in enabling additional professions to perform a core function related to medicine management. Extending the authorised scope of practice for these practitioners may improve access and timeliness of healthcare delivery, aid with immunisation uptake, improve patient safety and result in cost savings for the health system due to reduced disease transmission and severity of illness.

There is an established health workforce shortage particularly within underserved rural and regional areas of Queensland, where enabling health practitioners to administer additional immunisation medicines will likely build capacity within the system and increase community access. Expanding the scope of practice of Aboriginal and Torres Strait Islander health practitioners, Indigenous health workers and Aboriginal and Torres Strait Islander health workers will also improve access to culturally safe immunisation services in rural and remote areas.

Some education may be required as part of implementation. This would be undertaken within current resourcing and through collaboration with key stakeholders.

Other minor amendments

As these amendments are administrative in nature, there are no associated financial or resource implications.

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 following fundamental principles.

Rights and liberties of individuals

Is the legislation unambiguous and drafted in a sufficiently clear and precise way?

Low-risk exemption for the transfer of immunisation medicines

The low-risk exemption for the transfer of immunisation medicines from the wholesaling and licensing requirements of the Act is limited to transfers between registered ISPs. The register of ISPs is not published and is only available internally within Queensland Health. This could limit the ability for someone outside the department to identify who is a registered ISP for the purposes of the exemption.

While it is generally unnecessary for the public to know if a provider is registered with the Queensland Health Immunisation Program, individuals can contact the provider directly to inquire about the specific immunisation services offered. Certain immunisation services, such as access to the immunisation medicines under the National Immunisation Program, are exclusively available to Queensland Health Immunisation Program registered immunisation service providers.

Providers themselves will be aware of their registration status with the Queensland Health Immunisation Program. If they are uncertain about the registration status of a transferee, they will be able to confirm this with Queensland Health or their local Public Health Unit.

It is considered the above ways of confirming a provider's registration status are sufficient to ensure clarity for the community about who is in scope for the purposes of the exemption.

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 made by the chief executive 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 December 2024, a consultation paper on the proposed amendments was published on the Queensland Health website and disseminated to stakeholders across pharmacy, medical, nursing and physiotherapy peak bodies, Aboriginal and Torres Strait Islander health organisations, custodial services and Queensland Health, including Queensland Ambulance Service and Hospital and Health Services.

The Australian Medical Association Queensland (AMAQ) and Royal Australian College of General Practitioners (RACGP) were somewhat supportive of the amendments but raised concerns about expanding the scope of practice for health professionals who are not medical practitioners. 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 medical practitioners is limited.

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

Low-risk exemption for the transfer of immunisation medicines

All stakeholders supported the amendment to establish a low-risk exemption for the transfer of immunisation medicines between registered Immunisation Service Providers to allow them to transfer these medicines without complying with the usual generic wholesaling and licensing requirements. Many of the stakeholders noted that this amendment would improve distribution of stock between Immunisation Service Providers and enhance equitable access to immunisation medicines.

Custodial nurses

All stakeholders supported the amendment to authorise registered nurses to deal with scheduled medicines (possess, repackage, or give a treatment dose), for persons-in-custody at any custodial facility. Many of the stakeholders, including nurse practitioners currently working in custodial facilities, noted that this amendment would improve management of medicines, safety, and efficiency within these facilities. It was also highlighted that this amendment would ensure consistent and transparent delivery of care. The Australian College of Nurse Practitioners and the Australian College of Nursing were among those in support.

The Queensland Nurses and Midwives' Union and Australian College of Midwives noted the amendments should extend to include midwives. Further consideration will be given to this suggestion.

Collaborative Pharmacist Medication Prescribing

The majority of stakeholders, including peak pharmacy bodies, supported the amendment to enable the implementation of a CPMP model of care for pharmacists employed at a public sector health service facility or at a private health facility, allowing pharmacists to prescribe medicines in collaboration with a medical practitioner or nurse practitioner. Feedback emphasised that the implementation of a CPMP model will foster advancements in the pharmacy sector for the benefit of patient care and Queensland's health system and assist in the management of the current demand experienced in Queensland emergency departments.

Some pharmaceutical stakeholders raised concerns about pharmacists not having Pharmaceutical Benefits Scheme authorities, meaning a discharged patient filling a script would not obtain a Pharmaceutical Benefits Scheme subsidy. A medicine prescribed by a pharmacist under the CPMP model cannot be dispensed outside of the relevant public sector health service facility or private health facility. This is because the authorised pharmacist will not have a prescriber number, meaning there is no way for the community pharmacist or regulators to recognise it as a valid script. This issue is being considered as part of implementation planning.

The Australian College of Midwives noted the amendments should extend to include pharmacist collaboration with endorsed midwives not just medical practitioners and nurse practitioners. Further consideration will be given to this suggestion.

Extended practice authority amendments

Hospital-based ambulances

The majority of stakeholders supported the amendment to the Registered Nurses EPA to allow registered nurses to administer or give a treatment dose of certain first-responder medicines when undertaking HBA activities. It was noted that the amendment aligns with the principles of timely and patient-centred care.

The Australian College of Midwives recommended the amendment be expanded to include midwives working at HBA sites. Further consideration will be given to this suggestion.

First-contact emergency physiotherapy practitioner prescribing

The majority of stakeholders supported the amendment to the Physiotherapists EPA to authorise first-contact physiotherapy practitioners to prescribe and administer medicines in urgent care facilities, in addition to hospital emergency departments. Stakeholders noted this change will enhance the effectiveness of the patient-centred service that is provided in these facilities. The Queensland Nurses and Midwives' Union, AMAQ and RACGP raised concerns about the scope of medicines included in the Physiotherapists EPA, particularly the inclusion of S8 medicines and medicines used to treat side effects of S8 medicines. No amendments are being made to the list of medicines within the existing Physiotherapists EPA. The amendments relate only to which locations the EPA applies to. It is considered the

physiotherapists the subject of the amendments have the requisite skills, training and expertise to safely carry out the activities provided for in the Physiotherapists EPA.

The Australian Physiotherapy Association emphasised that the amendment is key to ensuring continuity of care across the primary and acute care interface and will assist in alleviating the burden on emergency departments and on general practitioners by diverting non-life-threatening emergencies. They noted that prescribing by physiotherapists in emergency departments is well established in Queensland and has been demonstrated to be safe and effective in the management of non-complex neuromuscular injuries.

Primary Clinical Care Manual

All stakeholders broadly supported the amendments to the relevant EPAs to align with the medicines contained in the revised edition of the PCCM. Among this support, stakeholders noted that this alignment will ensure rural and remote clinicians can deliver contemporary and effective care.

Administration of immunisation medicines

The majority of stakeholders were supportive of the amendments and noted the benefits for community access to critical immunisations. As noted above, AMAQ and RACGP raised concerns about expanding administration of the identified immunisation medicines to other health professionals, particularly with regards to the potential fragmentation of preventative health services it may cause. All health professionals the subject of the amendments have the requisite skills, training and expertise to safely carry out the proposed activities. On balance, the potential for the amendments to improve access to immunisation services is considered to support coordinated and holistic care.

Other minor amendments

All stakeholders supported the minor administrative amendments being made to the EPAs.