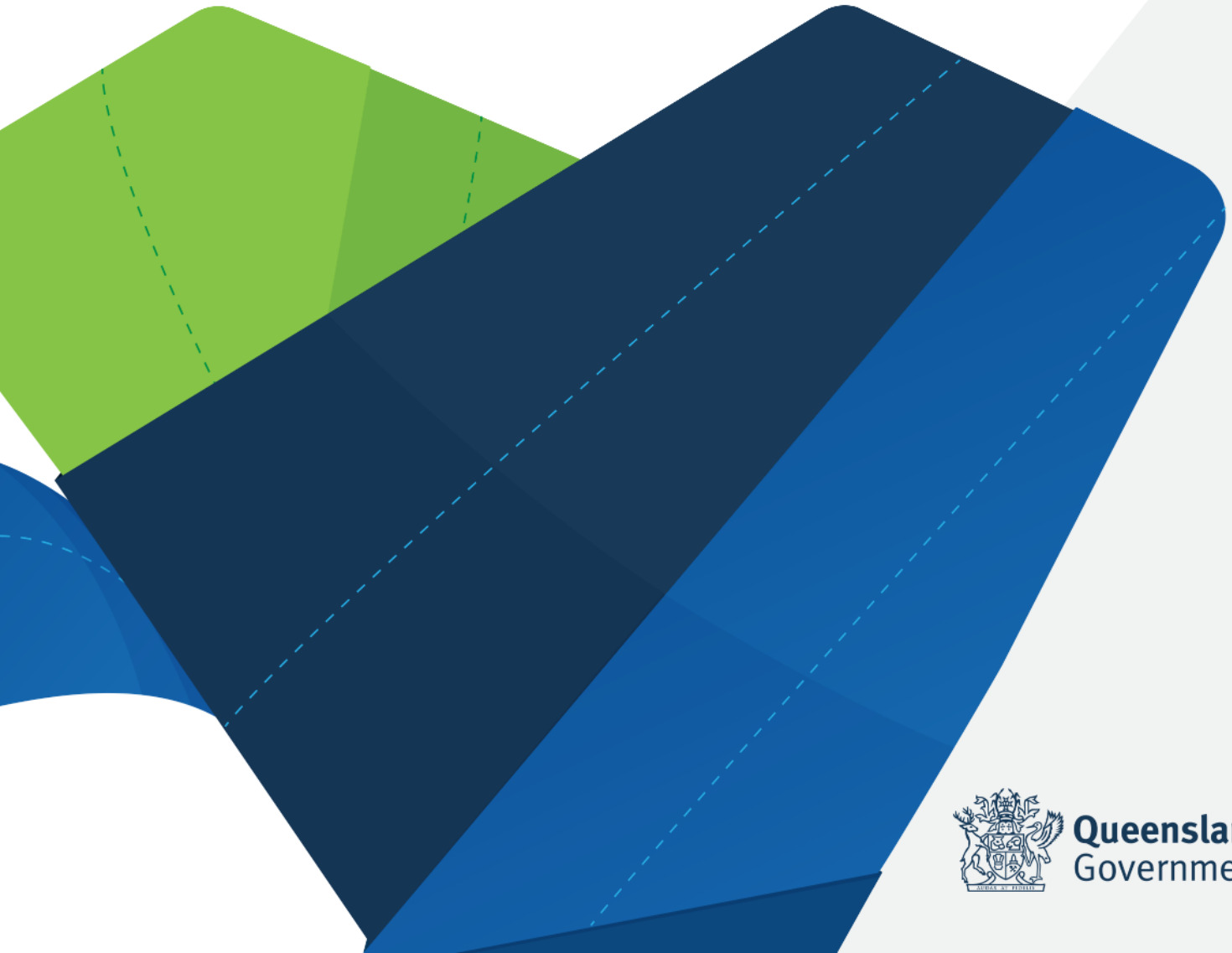
Queensland Health

Medicines and Poisons (Medicines) Amendment Regulation 2024

Consultation Paper

February 2024



Queensland Government

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Purpose

The purpose of this consultation paper is to seek stakeholder feedback on amendments proposed for inclusion in the draft *Medicines and Poisons (Medicines) Amendment Regulation 2024* (Amendment Regulation).

Queensland Health acknowledges and thanks those stakeholders who have previously provided feedback on the proposed amendments. This feedback has been taken into consideration during the further development of the proposed amendments.

The consultation paper is for **consultation purposes only** and does not represent Queensland Government policy.

Your views are valuable and may be referred to in material provided to Government in considering this proposal. If legislative amendments are progressed, your feedback may be referred to in public documents, for example, as part of the Explanatory Notes.

Please provide any feedback on the proposed amendments by email to legislationconsultation@health.qld.gov.au by **5pm, 1 March 2024**.

If you have any questions or require further information about possible changes, please email your queries to the email address above before the closing date and an officer from Queensland Health will contact you.

Background

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 and to reduce public harm;
- using modern electronic medication management systems (for example, electronic prescription management systems and electronic medicine registers) to better support public health outcomes;
- improving terminology for medicines that are associated with increased risks of diversion or harm by providing access to real-time prescription information at the point of care, providing more clarity for restrictions of use and reporting obligations;
- setting out the 'authorised way' for a person to perform regulated activities with certain 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 regularly requires updating to keep up with changes to Queensland Health policies and practices and the evolving needs of health care in Queensland.

The proposed 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 reflects the current needs of health consumers in Queensland.

Overview of the Medicines and Poisons (Medicines) Amendment Regulation 2024

Proposed amendments

The Amendment Regulation will amend the Medicines Regulation to:

- provide a low-risk exemption for buying and supplying medicine stock held in, or obtained from, the National Medical Stockpile;
- give effect to new versions of the extended practice authorities to:
  - remove references to the mandatory COVID-19 vaccination training program requirements;
  - increase the number of vaccinations registered nurses and midwives can administer, broaden the locations where registered nurses can administer vaccines and remove restrictions/conditions imposed on midwives for some of the current vaccines;
  - enable registered nurses and midwives to administer hormonal intrauterine devices; and
  - provide for an additional study option of a rural and isolated practice area program of study.

Details about the proposed amendments are provided below.

Additional amendments

Queensland Health has consulted separately on the following proposed amendments, which will also be included in the Amendment Regulation. These amendments will:

- exempt relevant practitioners from the requirement to check QScript in specified low-risk circumstances, such as:
  - a patient being prescribed a monitored medicine for administration;
  - a patient receiving treatment in a hospital, unless the patient is prescribed, dispensed or given a treatment dose of a monitored medicine on discharge;
  - a resident being treated in a residential aged care facility;
  - a patient being treated in a prison, detention centre or watchhouse, unless the patient is prescribed, dispensed or given a treatment dose of a monitored medicine on release from the prison, detention centre or watchhouse;
  - a person being provided end-of-life care;
  - a person who, under the Voluntary Assisted Dying Act 2021, has been assessed by a consulting practitioner to be eligible for access to voluntary assisted dying; and

  - a patient being provided emergency treatment for a serious or life-threatening illness or injury.

- give effect to a new version of the Monitored Medicines Departmental Standard, which reduces the scope of the Standard so that it only applies minimum requirements to current Queensland Opioid Treatment Program patients.

To access further information or to provide feedback on the additional proposals please click on this link. Consultation closes on 23 February 2024.

Description of proposed amendments

Exempting the National Medical Stockpile from the operation of the Act

The National Medical Stockpile is a strategic reserve of medicines and other supplies, such as vaccines, antidotes and personal protective equipment, for use in national health emergencies. The National Medical Stockpile is managed by the Commonwealth Department of Health.

The Queensland *Emergency Order – National Medical Stockpile* (Emergency Order), which authorised bespoke arrangements for the supply and distribution of COVID-19 vaccines and antiviral medicines in Queensland, expired on 29 October 2023. Without an emergency order or an exemption under the Medicines Regulation, there is limited ability to rapidly deploy or flexibly distribute National Medical Stockpile medicine stock to where it is needed or to be able to undertake regulated activities, such as buying and supplying stock held in or obtained from the National Medical Stockpile. The proposed amendment will transition the arrangements that were in place under the Emergency Order to business as usual.

Section 7 of the Act provides that the Minister must not recommend to the Governor in Council the making of a regulation to exempt an activity with a substance from the operation of the Act, unless the Minister is satisfied the substance could reasonably be expected to pose no or a negligible health risk to any person. Queensland Health considers an exemption for the National Medical Stockpile poses little or no health risk. The exemption would only apply to authorised approved persons, prescribed in the Medicines Regulation, to access stocks of medicine from the National Medical Stockpile, distribute those medicines between relevant institutions for the treatment of patients and return unused stock of medicines to the stockpile.

Proposed amendments to extended practice authorities

COVID-19 Vaccination Training Program

The Commonwealth Department of Health and Aged Care delivered the COVID-19 Vaccination Training Program (CVTP) and mandated completion of the CVTP for all authorised COVID-19 vaccination providers.

On 1 October 2023, the Commonwealth ceased the CVTP. Completion of the training is no longer mandatory under the transition to business-as-usual arrangements in the post-pandemic environment. There will be no separate training required for COVID-19 vaccines other than standard immunisation training under the National Immunisation Education Framework for Health Professionals.

The requirement to undertake the mandatory CVTP has been included in the following extended practice authorities:

- Aboriginal and Torres Strait Islander health practitioners;
- Aboriginal and Torres Strait Islander health workers;
- Indigenous Health Workers;

- Midwives; and
- Registered nurses.

This means that from 1 October 2023, new immunisers cannot be authorised through their respective extended practice authority to initiate the administration of COVID-19 vaccines as they cannot complete the CVTP.

It is proposed to amend the extended practice authorities listed above to remove the CVTP requirements. These changes will result in new versions of the extended practice authorities being made.

Immunisations

The Registered Nurses Extended Practice Authority (EPA-RN) and the Midwives Extended Practice Authority (EPA-Midwives) set out which vaccines registered nurses and midwives are authorised to administer without a prescription. In addition, registered nurses working under Part D of the EPA-RN can only provide immunisation services in specified approved locations, such as Hospital and Health Services and local government immunisation services.

It is proposed to amend the EPA-RN to expand the list of vaccines registered nurses can administer to include:

- Cholera;
- Rabies – pre-exposure only; and
- Typhoid.

It is also proposed to amend the EPA-RN to broaden the locations where registered nurses can administer vaccines under part D of the EPA-RN. The expansion of immunisation program service sites will assist in increasing vaccination coverage rates. These sites include:

- an aged care facility;
- a general practice;
- a community pharmacy;
- a facility operated by a relevant health service, being a Hospital and Health Service or Aboriginal or Torres Strait Islander Health Service; or
- a facility where a general approval has been granted under the Act to provide an immunisation program.

It is proposed to amend the EPA-Midwives to expand the list of vaccines midwives can administer to include:

- *Haemophilus influenzae* type B;
- Hepatitis A;
- Human Papillomavirus;
- Japanese encephalitis;

- Meningococcal (ACWY);
- Meningococcal B;
- Meningococcal C;
- Poliovirus;
- Rotavirus;
- Tetanus;
- Varicella (chickenpox); and
- Zoster (herpes zoster).

It is also proposed to amend the EPA-Midwives to remove some of the restrictions or conditions imposed against some of the current vaccines. Some of the restrictions or conditions contain clinical information that is best sourced from the recommended best practice guidance in the *Australian Immunisation Handbook* and *Immunisation Schedule Queensland*. The proposed amendments will ensure that a midwife is able to follow contemporary recommendations in the online version of the *Australian Immunisation Handbook* and the *Immunisation Schedule Queensland*. They will also enable the midwifery workforce to be responsive to family needs and provide opportunistic vaccination to the family unit.

Expanding the list of vaccines registered nurses and midwives can give under the respective EPA, and the range of immunisation program service locations that a Registered Nurse working under Part D of the EPA-RN can administer vaccines from, will help address low vaccination coverage rates in Queensland, address vaccine hesitancy and vaccine fatigue and increase the wellbeing of mothers and children.

Long-acting reversible contraception (hormonal intrauterine devices)

Long-acting reversible contraception is used for purposes including contraception and in the management of irregular menstrual bleeding. There is a high unmet need for effective contraception in Australia. A number of barriers exist to accessing contraceptives, including high costs, misinformation among women and health practitioners and limited health practitioners who can insert and remove long-acting reversible contraceptives.

Midwives are autonomous practitioners who are specialists in pregnancy, childbirth and postpartum care. They operate under the EPA-Midwives to provide essential services to women throughout Queensland, including preventative health care. Registered nurses working under the EPA-RN Part C, provide essential services to women all over Queensland for sexual and reproductive health matters, including preventative health care.

Registered nurses and midwives working under their respective EPAs are currently able to administer subdermal Etonogestrel implants without a prescription from an authorised prescriber.

It is proposed to amend the EPA-RN and EPA-Midwives to increase the list of long-acting reversible contraceptives that registered nurses working in a sexual and reproductive health service and midwives may administer, to include the hormonal intrauterine device (e.g., Mirena®, Kyleena®).

By adding hormonal intrauterine devices into the EPA-RN and the EPA-Midwives, it is expected consumer choice will be enhanced, the uptake of long-acting reversible contraceptives will improve, unintended pregnancies will decrease, and an easing of demand will occur on general practice, obstetricians, gynaecologists, nurse practitioners and sexual health physicians to provide this service.

Recognised study for rural and isolated registered nurses

The EPA-RN Part B applies to nurses working in services in rural and isolated practice areas. One of the requirements for a registered nurse may only administer or give a treatment dose of medicines under Part B of this EPA if the registered nurse:

- is practising in an isolated practice area or at a rural hospital;
- has completed a program of study relevant to the use of medicines in providing emergency and acute care in rural and isolated practice; and
- the program of study was previously recognised by the Nursing and Midwifery Board of Australia to enable the registration of the registered nurse to be endorsed as 'qualified to obtain, supply and administer Schedule 2, 3, 4 and 8 medicines for nursing practice in a rural and isolated practice area' 3 under the *Health Practitioner Regulation National Law (Queensland).*

The relevant programs of study that were previously recognised by the Nursing and Midwifery Board of Australia have undergone revision to reflect contemporary practice. The current versions of these courses no longer represent the previously endorsed programs. New registered nurses who have completed the revised programs of study and who are working in a rural and isolated practice area cannot apply to work under the EPA-RN. This impacts the pipeline of registered nurses authorised and trained to deliver essential emergency and acute care in rural and isolated practice areas.

The current education requirements also limit registered nurses who may have obtained a similar qualification in another state or territory, preventing them from working to their full scope of practice. This is particularly important considering current and projected workforce shortages where skilled migration is important for workforce sustainability.

It is proposed to amend the EPA-RN to provide for an additional study option of a rural and isolated practice area program of study:

- approved by the employing relevant health service, or non-government organisation; and
- that encompasses, as a minimum, knowledge of the appropriate use of medicines relevant to registered nurses working in services in remote or isolated practice areas.