Medicines and Poisons (Medicines) Amendment Regulation 2024

Explanatory notes for SL 2024 No. 44

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation 2024

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 public harm;
- 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 requires updating to keep up with changes to Queensland Health policies and practices and the evolving needs of health care in 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 reflects the current needs of health consumers in Queensland.

The *Medicines and Poisons (Medicines) Amendment Regulation 2024* (Amendment Regulation) amends the Medicines Regulation to:

- exempt relevant practitioners from the requirement to check QScript (the monitored medicines database) in specified low-risk circumstances;
- give effect to a new version of the Monitored Medicines Departmental Standard (Monitored Medicines Standard) which reduces the scope of the standard so that it only applies minimum requirements to monitored medicine treatment provided to current Queensland Opioid Treatment Program patients;

- give effect to new versions of the extended practice authorities to:
  - authorise a broad workforce to administer respiratory syncytial virus (RSV) preventative therapies;
  - 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.

Exempting relevant practitioners from the requirement to check QScript in specified low-risk circumstances

The Amendment Regulation amends the Medicines Regulation to exempt relevant practitioners from the requirement to check QScript (the monitored medicines database) in specified low-risk circumstances. QScript is a real-time prescription monitoring system that collects real-time information about prescribing and dispensing of monitored medicines.

Monitored medicines are specified in schedule 2, part 4 of the Medicines Regulation and are strictly monitored due to evidence of harm, including death, associated with their use in the Australian community. Section 224 of the Act requires the chief executive to keep an electronic database (the 'monitored medicines database') to record information about the prescription and supply of monitored medicines. The database—named 'QScript'—is a real-time prescription monitoring system that collects monitored medicine prescription information from prescribing and dispensing software systems. This information can be viewed by authorised prescribers and pharmacists to support their clinical decision-making.

Section 41 of the Act requires 'relevant practitioners' to check QScript before prescribing, dispensing or giving a treatment dose of a monitored medicine for a person. 'Relevant practitioners' are specified in schedule 18, part 1 of the Medicines Regulation.

Section 41(3) of the Act provides that QScript look-up requirements do not apply if the practitioner has a reasonable excuse, or if the circumstance is exempt from the requirements by regulation. There are currently no exemptions prescribed in the Medicines Regulation that exempt a relevant practitioner from QScript look-up requirements. Queensland is the only Australian jurisdiction that mandates look-up of its real-time prescription monitoring system without exemptions.

Health practitioners have reported that the mandatory QScript look-up requirements are impractical and unreasonably burdensome when applied in certain healthcare settings such as residential aged care facilities and busy hospitals, particularly in emergency departments and surgical settings. Practitioners reported that the current look-up requirements have resulted in adverse impacts on patients, including practitioners limiting or avoiding writing monitored medicine prescriptions, patients experiencing inadequate pain management and significant treatment delays in the immediate-term (e.g. waiting longer in waiting rooms) and mid-to-long-term (e.g. fewer patients seen on surgical lists) and compromised patient safety as a result of practitioners diverting attention away from patients to check QScript. Importantly, it has been identified that in certain situations, mandatory checking of QScript does not provide clinical or safety benefits and is not necessary, particularly in low-risk circumstances.

Amendments to the Medicines Regulation to exempt relevant practitioners from the requirement to check QScript in specified low-risk circumstances will benefit all sectors and reduce unnecessary regulatory burden and inefficiencies reported by health practitioners and stakeholders. Sectors to gain benefit from the exemption include private and public hospital patients and healthcare providers, residential aged care facility patients and healthcare providers, patients and practitioners in correctional facilities, watchhouses and other residential healthcare settings and end-of-life care and voluntary-assisted-dying treatment providers and patients.

Mandatory requirement to comply with the Monitored Medicines Standard

The Amendment Regulation amends the Medicines Regulation to give effect to a new version of the Monitored Medicines Standard, which reduces the scope of the standard so that it only applies minimum requirements to monitored medicine treatment provided to current Queensland Opioid Treatment Program patients.

The Monitored Medicines Standard is an approved departmental standard prescribed in schedule 1, part 2 of the Medicines Regulation. The Monitored Medicines Standard is a legal instrument which outlines the minimum requirements prescribers and dispensers must comply with to demonstrate the steps they have taken to ensure the prescribing and dispensing of monitored medicines for patients is clinically justified, safe and appropriate. Sections 93 and 126 of the Medicines Regulation require prescribers and dispensers to comply with the Monitored Medicines Standard when prescribing a monitored medicine for dispensing or for giving a treatment dose and when dispensing a monitored medicine for a person.

Health practitioners have reported that applying the Monitored Medicines Standard requirements in practice has caused unintended adverse consequences, such as increased burden on health practitioners, increased inefficiency in health care settings and misapplication of the Monitored Medicines Standard. Practitioners also reported that most of the minimum requirements outlined in the Monitored Medicines Standard, other than the minimum requirements relating to the Queensland Opioid Treatment Program, are duplicative of existing professional practice requirements.

Amendments to the Monitored Medicines Standard retain the requirement for a health practitioner to comply with the standard when prescribing a monitored medicine for dispensing, when giving a treatment dose or when dispensing a monitored medicine for a person. However, the minimum requirements of the amended Monitored Medicines Standard will only apply to monitored medicine treatment provided to patients currently registered on the Queensland Opioid Treatment Program. This will relieve the burden on health practitioners. The amendment will also remove the regulatory burden for Queensland Health as it reduces the requirement to monitor compliance with the Monitored Medicines Standard.

Extended Practice Authorities

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 certain 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 new versions of an extended practice authority 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. 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 Amendment Regulation amends the Medicines Regulation to give effect to new versions of the extended practice authorities to:

- authorise a broad workforce to administer RSV preventative therapies;
- 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.

Respiratory syncytial virus

RSV is one of the leading potentially preventable causes of mortality in children with acute lower respiratory tract infection during their initial five years of life. RSV is of significant public health concern, causing significant mortality and morbidity, particularly in young children, the elderly population, and those with pre-existing conditions. RSV remains one of a few major causes of childhood acute lower respiratory infection and is the most common cause of hospitalisation in infants and young children in Australia. As a single RSV infection does not result in long-lasting protective immunity, symptomatic illness tends to occur repetitively in children.

Older children, adolescents and adults can still develop RSV disease, but it is less common for these groups to develop severe illness. Those at greatest risk of serious RSV disease include:

- infants aged 12 months and under, especially those aged six months and under;
- young children aged two years and under with medical conditions such as chronic lung disease or congenital heart disease;
- infants and young children aged two years and under who were born pre-term or with a low birth weight; and
- Aboriginal and Torres Strait Islander infants and young children.

Severe RSV lower respiratory tract infection in early childhood can be prevented either by directly administering monoclonal antibody products to infants and young children, or by administering the RSV vaccine during pregnancy.

Nirsevimab is a monoclonal antibody that was approved for use by the TGA in November 2023 and listed on the Australian Register of Therapeutic Goods for prevention of RSV lower respiratory tract disease in infants born during or entering their first RSV season, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. A monoclonal antibody against RSV is made using recombinant technology and is given to help the body fight off an infection. Monoclonal antibodies start working soon after administration, while vaccines generally take 1–3 weeks to 'teach' the immune system to develop its own antibodies. Nirsevimab looks similar to and is administered in the same way as a vaccine. It is administered by intramuscular injection. Clinical trials of RSV monoclonal antibodies in infants showed that local and generalised adverse reactions were uncommon and included pain, redness and swelling at the injection site, and rash. Globally, there have been no observed signals for significant adverse effects related to the administration of nirsevimab.

Nirsevimab reduces the risk of hospitalisation from RSV in infants by almost 80% and has an efficacy in preventing RSV-associated lower respiratory tract infection with admission to an intensive care unit (ICU) of 90%. One dose of nirsevimab protects infants for at least 5 months. As nirsevimab does not activate the immune system, protection is most effective in the weeks directly after nirsevimab is given and gradually reduces over time. Nirsevimab does not provide long-term protection against RSV disease, but it does protect infants when they are most at risk of getting very sick from RSV. As children get older, their risk of severe disease with RSV infection reduces.

Amendments to the midwives, registered nurses, Aboriginal and Torres Strait Islander health practitioner and Indigenous health worker extended practice authorities will authorise these workforces to administer nirsevimab independently.

While there is limited data on the RSV disease burden in adults in Australia, between 2006 and 2015 the hospitalisation rate in adults aged 65 years and older was estimated at 20 per 100,000 population. Since RSV disease was historically regarded as a disease that affects infants and children, testing for the virus in adults was previously uncommon. The reported rate of RSV hospitalisations in older adults has been increasing with the growing awareness of RSV disease and more frequent laboratory testing in this age cohort.

The risk of severe RSV disease is also higher among adults with chronic medical conditions and older adults (with the risk increasing with age). For non-First Nations adults, the risk is greater from age 75. For First Nations adults and adults with chronic medical conditions the risk is greater from age 60.

The Australian Technical Advisory Group on Immunisation (ATAGI) clinical statement provides advice on the use of RSV vaccines for the prevention of RSV disease in older adults in Australia. This statement recommends a single dose for all adults aged 75 years and older and Aboriginal and/or Torres Strait Islander peoples aged 60 to 74 years, who have the highest burden of RSV hospitalisation and are likely to have the greatest benefit from vaccination.

Amendments to the midwives, registered nurses, Aboriginal and Torres Strait Islander health practitioners, Indigenous health workers and pharmacists extended practice authorities will enable these workforces to administer RSV vaccines independently.

COVID-19 Vaccination Training Program

The Commonwealth Department of Health and Aged Care was responsible for delivering 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 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.

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 requirements. By removing the CVTP requirements from the extended practice authorities, this barrier will be removed, and all immunisers who have completed standard immunisation training will be authorised to administer the COVID-19 vaccine.

Immunisations - registered nurses and midwives

Over the past two years Queensland has experienced a decline in vaccination coverage rates of children and adults and there has been reduced uptake of adolescent vaccination through school immunisation programs. Vaccine hesitancy and vaccine fatigue are thought to be a contributing factor to this trend, as well as access to timely and convenient immunisation services.

Registered nurses and midwives in Queensland have a demonstrated track record of providing safe and effective vaccination services in a variety of settings for decades.

The Registered Nurses Extended Practice Authority (EPA-RN) and the Midwives Extended Practice Authority (EPA-Midwives) lists vaccines on the *National Immunisation Program* (NIP), as well as 'higher risk' vaccines (e.g., live vaccines, vaccines with more complex clinical considerations, and/or interventions prior to administration). As such, the professional scope of the registered nurse and midwife and current immunisation training requirements provide the regulatory framework to enable registered nurses and midwives to offer Queenslanders timely and safe access to a broader range of vaccines without a prescription in accordance with the *Australian Immunisation Handbook*, which is the national clinical guideline.

The amendments to the EPA-RN expand the list of vaccines registered nurses can administer to include:

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

In addition, the amendment to the EPA-RN expands 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; or
- an Aboriginal and Torres Strait Islander Health Service.

The amendments to the EPA-Midwives 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;
- Pneumococcal;
- Poliovirus;
- Rotavirus;
- Tetanus;
- Varicella (chickenpox); and
- Zoster (herpes zoster).

Further reforms to the EPA-Midwives implement changes 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 not regulatory in nature and best sourced from the recommended best practice guidance in the *Australian Immunisation Handbook* and *Immunisation Schedule Queensland*. The amendments ensure that a midwife acts in accordance with the current online version of the *Australian Immunisation Handbook*, or the current recommendations provided by the ATAGI or by the *Immunisation Schedule Queensland* or the product information approved by the TGA. They 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 EPAs, and the range of immunisation program service locations that a registered nurse working under Part D of the EPA-RN can administer vaccines from, help to address low vaccination coverage rates in Queensland, address vaccine hesitancy and vaccine fatigue and increase the wellbeing of mothers and children.

<u>Enabling registered nurses and midwives to administer hormonal intrauterine devices</u>

There is a high unmet need for effective contraception in Australia. The barriers to accessing contraceptives include high costs, misinformation among women and health practitioners and limited health practitioners who can insert and remove long-acting reversible contraceptives. Long wait times to access general practitioners, particularly in rural and remote regions and First Nations communities, remain problematic, especially for people seeking contraception access.

Working within interdisciplinary teams, registered nurses and midwives provide an indispensable sexual and reproductive health service to Queenslanders. 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, which extends to sexual and reproductive 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 are authorised to provide varied contraception to consumers. Since March 2023, registered nurses working under part C of the EPA-RN in a sexual and reproductive health service, and midwives working under the EPA-Midwives who have completed appropriate training and education, are authorised to administer subdermal etonogestrel implants (e.g., Implanon®) without a prescription from an authorised prescriber.

An amendment to the EPA-RN and EPA-Midwives to include the levonorgestrel intrauterine device (e.g., Mirena®, Kyleena®) will increase the list of long-acting reversible contraceptives that registered nurses working in a sexual and reproductive health service and midwives may administer. By adding hormonal intrauterine devices into the EPA-RN and the EPA-Midwives, it is expected that 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 practitioners, obstetricians, gynaecologists, nurse practitioners and sexual health physicians to provide this service.

Providing an additional study option of a rural and isolated practice area program of study

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.

Due to these changes, newly 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 part B of 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.

Part B of the EPA-RN authorises registered nurses working in rural and isolated practice areas to give a treatment dose or administer medicines when providing emergency and acute care. To meet the requirements to work under part B of the EPA-RN, a registered nurse must be practising in an isolated practice area or at a rural hospital and have completed a program of study relevant to the use of medicines in providing emergency and acute care in a rural and isolated practice area. The program of study, which was recognised by the Nursing and Midwifery Board of Australia, enabled 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' under the *Health Practitioner Regulation National Law (Queensland).*

The current education requirements for registered nurses to work under part B of the EPA-RN also limit registered nurses who have obtained a similar qualification in another state or territory from working to their full scope of practice in Queensland. This is particularly important considering current and projected workforce shortages where skilled migration is important for workforce sustainability.

The EPA-RN requires amendment to provide for an additional study option of a rural and isolated practice area program of study that is approved by the relevant employing health service, or non-government organisation and encompasses, as a minimum, knowledge of the appropriate use of medicines relevant to registered nurses working in services in rural and isolated practice areas.

Achievement of policy objectives

Exempting relevant practitioners from the requirement to check QScript in specified low-risk circumstances

The Amendment Regulation provides for an exemption for relevant practitioners from mandatory QScript look-up requirements if the relevant practitioner is:

- prescribing or dispensing a monitored medicine for a patient being treated in a hospital, and the medicine is to be administered while the patient is at the hospital;
- prescribing, dispensing or giving a treatment dose of a monitored medicine for a patient:
  - being treated at an aged care facility;
  - being treated at a custodial facility and the medicine is taken by the patient while the patient is detained, whether or not at the custodial facility;
  - being treated urgently in an emergency;
  - assessed under the *Voluntary Assisted Dying Act 2021*, by a consulting practitioner, as eligible for access to voluntary assisted dying;
  - who has a life expectancy of less than 12 months;
  - being given palliative care; or
- prescribing a monitored medicine for administration to a patient by a person authorised to administer the medicine, for circumstances not otherwise mentioned above.

The exemptions were identified by Queensland Health and stakeholders as representing lower-risk circumstances where the regulatory burden of mandatory QScript checking typically outweighs the clinical and patient safety benefits. For example, prescribing a monitored medicine for administration to a patient presents limited patient safety risks because:

- the patient will not be in possession of the medicine;
- the medicine will be administered directly to the patient by an authorised person, for example, given to the patient for immediate consumption, injected into the patient or applied to the patient's skin; and
- the health practitioner administering the monitored medicine will be present to assist should an adverse event occur.

The amendments remove the regulatory burden of mandatory QScript look-up requirements in low-risk circumstances and decrease the inefficiencies reported by health practitioners and stakeholders. They remove the inconsistency with the look-up requirements for patients accessing voluntary assisted dying under the *Voluntary Assisted Dying Act 2021*. Importantly, they do not prevent a relevant health practitioner from checking QScript to inform their therapeutic treatment of patients, and existing controls and mechanisms will continue to support and protect patients' safety, such as professional practice obligations, local policies and procedures and Pharmaceutical Benefits Scheme requirement.

The amendments commence on 1 July 2024.

Amending the Monitored Medicines Departmental Standard

The Amendment Regulation updates the reference to the new version of the Monitored Medicines Standard, which reduces the scope of the standard to address the issues identified by health practitioners and Queensland Health, including sub-optimal patient outcomes, duplication of professional practice requirements and compliance monitoring and enforcement challenges. The amendments will mean that the Monitored Medicines Standard only applies minimum requirements to monitored medicine treatment provided to current Queensland Opioid Treatment Program patients. The minimum requirements will also be modified to reduce complexity and regulatory burden and to improve readability.

The amendments commence on 1 July 2024.

Extended practice authorities

The extended practice authority amendments commence on 1 May 2024.

Respiratory syncytial virus

The Amendment Regulation updates references to new versions of the following extended practice authorities that add nirsevimab to the list of medicines for immunisation these health workers can deal with:

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

The Amendment Regulation also updates references to new versions of the following extended practice authorities that add RSV vaccine to the list of medicines for immunisation these health workers can deal with:

- midwives;
- pharmacists;
- registered nurses;
- Aboriginal and Torres Strait Islander health practitioners; and
- Indigenous health workers.

COVID-19 Vaccination Training Program

The Amendment Regulation updates references to new versions of the following extended practice authorities to remove the CVTP requirements:

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

The Amendment Regulation removes reference to the expired CVTP training requirement from the EPAs listed above. There will be no separate training required for the COVID-19 vaccine other than standard immunisation training that meets the National Immunisation Education Framework for Health Professionals, as is required for all vaccines.

Immunisations – Registered nurses and midwives

The Amendment Regulation updates references to new versions of the EPA-RN and EPA-Midwives to expand the types of vaccinations and the range of patients that registered nurses and midwives may administer vaccines to. It also removes some of the restrictions/conditions imposed in the EPA-Midwives against some of the current vaccines. Improving access to vaccination services provided by registered nurses and midwives will assist in increasing childhood and adolescent vaccination coverage rates and help to address vaccination fatigue in Queensland.

Expanding the range of vaccination services that registered nurses and midwives can administer will promote more equitable access to healthcare for vulnerable and disadvantaged populations, including First Nations peoples and rural and remote populations, where health services are often limited. It also provides alternate options to promote better access to vaccinations and improve the accessibility of services where medicines administration is required.

Registered nurses and midwives to administer hormonal intrauterine devices

The Amendment Regulation updates references to the following extended practice authorities to:

- Part C of the EPA-RN - to increase the long-acting reversible contraceptives that registered nurses working in a sexual and reproductive health service may administer, to include levonorgestrel intrauterine device (e.g. Mirena®, Kyleena®); and
- EPA-Midwives - to increase the long-acting reversible contraceptives that midwives may administer, to include levonorgestrel intrauterine device (e.g. Mirena®, Kyleena®).

The extended scope of practice has the potential to increase the availability of effective contraception to consumers throughout the state and ease the demand on general practitioners, nurse practitioners, obstetricians, gynaecologists, and sexual health physicians to provide this service.

The program of study for registered nurses working within rural and isolated practice areas

The Amendment Regulation updates references to a new version of the EPA-RN. Amendment to part B of the EPA-RN will provide for an additional study option of a rural and isolated practice area program of study. The program of study must be approved by the employing relevant health service, or non-government organisation and encompasses, as a minimum, knowledge of the appropriate use of medicines relevant to registered nurses working in services in rural and isolated practice areas.

The amendment ensures the pipeline of registered nurses authorised and trained to deliver essential emergency and acute care in rural and isolated practice areas can continue.

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 objectives.

Benefits and costs of implementation

The cost of implementing the amendments to the Medicines Regulation will be met within existing budget allocations and the resources to manage and administer the existing regulation framework will continue to be used. The amendments do not impose any new or increased fees.

Exempting relevant practitioners from the requirement to check QScript in specified low-risk circumstances and amending the Monitored Medicines Departmental Standard

The QScript amendments are wide ranging and positively impact government, businesses, and the community. On an individual level, patients will benefit from fewer interruptions to clinical workflows, a reduced likelihood of practitioners limiting or refusing to provide monitored medicines due to regulatory burden and fewer treatment delays.

The amendments to the Monitored Medicines Standard ensure the requirements applicable to monitored medicine treatment provided to current Queensland Opioid Treatment Program patients remain, ensuring safeguards remain in place for this patient cohort who may be particularly at risk of monitored medicine-related harms due to their opioid dependence.

Health practitioners benefit from increased professional autonomy, more practical legislative requirements and reduced regulatory burden related to the impacts of mandatory QScript look-up and Monitored Medicine Standard compliance.

Queensland Health, which administers QScript and is responsible for undertaking compliance activities related to QScript use and the Monitored Medicines Standard, benefits from the amendments, as it is able to target compliance monitoring and enforcement activities in circumstances that present the highest levels of risk.

Extended practice authorities

Respiratory syncytial virus

The benefit of including the RSV monoclonal antibody and vaccine in the extended practice authorities will ensure consumers wanting RSV preventative therapies can easily access them as part of routine health care. Without the amendments, access will be limited due to the number of authorised practitioners who can administer the RSV monoclonal antibody or vaccine.

COVID-19 Vaccination Training Program

The CVTP amendments will enable registered nurses, midwives, Aboriginal and Torres Strait Islander health practitioners, Aboriginal and Torres Strait Islander health workers and Indigenous health workers to provide ongoing and timely vaccination services to protect Queenslanders against COVID-19 and continue to promote greater access to vaccination services.

Expanding the immunisation service for registered nurses and midwives and removing some of the restrictions/conditions imposed in the EPA-Midwives against some of the current vaccines

With the addition of further vaccines into the EPA-RN and EPA-Midwives, there may be additional registered nurses and midwives who are required to administer vaccines. This would have financial implications for individuals and/or organisations related to continuing professional development and training. The cost could be carried by the employer, or if employed by Queensland Health, the registered nurse or midwife may access their professional development allowance.

Broadening locations where registered nurses can administer vaccines under the EPA-RN will reduce the regulatory and administrative burden for those organisations who are currently required to apply for a general approval for immunisation services under the Act every two years.

Registered nurses and midwives to administer hormonal intrauterine devices

There is a public health benefit in making a broader range of long-acting reversible contraceptives more accessible for consumers. It is anticipated that adding hormonal intrauterine devices into the EPA-RN and the EPA-Midwives will increase the availability of health practitioners authorised, educated, and trained to administer hormonal intrauterine devices, particularly in rural and remote areas of Queensland. Consumer choice will be enhanced, the uptake of long-acting reversible intrauterine devices contraceptives will improve, unintended pregnancies will decrease, and an easing of demand will occur on general practitioners, obstetricians, gynaecologists, nurse practitioners and sexual health physicians to provide this service.

The Amendment Regulation improves the quality of life for some women who are unable to tolerate other forms of contraception. People under the care of a midwife will be able to receive reliable contraceptives in the post-natal period, rather than needing to seek contraceptive services from alternative health professionals.

With the addition of hormonal intrauterine devices into the EPA-RN and the EPA-Midwives, there may be a need for additional registered nurses and midwives to undertake education and training to insert and remove hormonal intrauterine devices under the respective EPAs. This would have financial implications for individuals and/or organisations. The cost could be carried by the employer, Queensland Health, or if employed by Queensland Health, the registered nurse or midwife may access their professional development allowance.

With the additional responsibility to administer hormonal intrauterine devices, there may be resource implications in the form of staffing.

The program of study for registered nurses working within rural and isolated practice areas

The Amendment Regulation ensures a continued pipeline of registered nurses working under part B of the EPA-RN, and the availability of a suitably qualified and prepared workforce to provide emergency and acute care services in rural and isolated practice areas. It may result in expedited employment of interstate qualified registered nurses working in services in rural and isolated practice areas. It may also reduce the impost on scarce specialty practitioners, including medical practitioner resources to provide emergency and acute care in rural and isolated practice areas.

Registered nurses who choose to complete a program of study to enable them to work under part B of the EPA-RN will be required to self-fund the education, although the cost of the education and associated expenses may be covered and reimbursed by their employer.

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:

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 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 registered substances.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)I 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, aligns with clinical best 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 regulation is updated to reflect the name and new version number of the extended practice authority each time a new version is made. A copy of the updated extended practice authority is tabled as extrinsic material each time the regulation is amended, to reflect the updated document. 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.

By including a list of extended practice authorities in the schedule of the Medicines Regulation, it 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 when these took effect.

It is considered the rigour surrounding the development of extended practice authorities, 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.

Departmental standards

Section 233 (Making departmental standards) of the Act empowers the chief executive to make standards about carrying out regulated activities with regulated substances and other matters relating to purposes and administration of the Act.

A standard may include procedures for carrying out regulated activities, procedures for keeping, storing and managing regulated substances, training and competency requirements for persons carrying out regulated activities with regulated substances, procedures to ensure products containing regulated substances are safe and suitable for the intended use of the products and requirements for tracing the movement of a regulated substance from its manufacture to final disposal, including requirements about documentation and electronic transmission.

Schedule 1, part 2 (Approved departmental standards) of the Medicines Regulation prescribes the names of approved departmental standards and their version number. The standards are outcome focused and list options to achieve the desired outcomes, which would not be suitable for inclusion in a prescriptive requirement in a regulation. For example, the Monitored Medicines Standard describes alternative circumstances in which a prescriber may prescribe a monitored medicine to a patient currently registered on the Queensland Opioid Treatment Program.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. A departmental standard is a document certified by the chief executive of Queensland Health that is relevant to the object and administration of the new legislative regime and provides guidance, allows flexibility on activities and applies to individuals and entities. The standards are monitored and updated when necessary, align with industry best practice and are published on the Queensland Health website. When making or amending a standard, relevant individuals and organisations with expertise in, or experience of, the matters under consideration will be consulted. Consultation with stakeholders was undertaken on the proposed departmental standards at the same time as consultation was undertaken on the Medicines Regulation.

Standards are reviewed and updated regularly, with consideration given to changes in technology and changes to clinical treatment with medicines, Schedule 1, part 2 (Approved departmental standards) of the Medicines Regulation lists the name of each standard and its version number. The regulation will be updated to reflect the new name and version number of the standard each time a new version is made. A copy of the updated standard will be tabled as extrinsic material each time the regulation is amended, to reflect the new version.

The inclusion of the name of each departmental standard and its version number in the Regulation creates certainty for professionals and the public about the status of standards published on Queensland Health's website and the date they took effect.

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

Consultation

Amendments to QScript look-up requirements and the Monitored Medicines Standard

Since 2019, Queensland Health has undertaken extensive consultation with a broad range of stakeholders regarding QScript look-up requirements and the Monitored Medicines Standard.

In January 2023, Queensland Health conducted preliminary consultation seeking stakeholder views on the QScript look-up requirements and the Monitored Medicines Standard to ascertain the extent to which they were fit-for-purpose or had resulted in unintended consequences. In total, 895 submissions were received, with a majority supporting amending the look-up requirements in QScript (74 per cent). Feedback on the Monitored Medicines Standard was mixed, with some stakeholders stating the standard supports, protects and promotes patient safety and aligns with professional standards, whereas other stakeholders considered the standard to be unreasonably impractical and/or burdensome and not necessarily relevant to all clinical circumstances.

In February 2024, consultation papers on the proposed amendments to QScript look-up requirements and the Monitored Medicines Standard were published on the Queensland Health website and disseminated to key stakeholders including pharmacy, medical and nursing peak bodies and Aboriginal and Torres Strait Islander organisations.

Below is a summary of key issues raised by stakeholders.
There was strong support for all proposed QScript look-up amendments, with over 90 per cent of respondents supporting the amendments. There was also substantial support for the proposed amendments to the Monitored Medicines Standard, with over 75 per cent of respondents supporting the amendments.

Multiple stakeholders suggested additional or amended QScript look-up exemptions, for example an exemption when prescribing/dispensing to a well-known, long-standing patient, or for paediatric psychostimulant prescribing. These suggestions have been noted and will be considered in future policy reviews.

Some stakeholders provided feedback on drafting matters and this feedback was incorporated where appropriate. Several stakeholders sought clarification on some of the changes or requested implementation resources to ensure health practitioners and organisations clearly understand the new legislative requirements. Queensland Health will develop and publish guidance materials to assist stakeholders as part of implementation of the changes.

In some cases, respondents provided feedback on matters that were out of scope for the consultation. Commonly, this feedback related to QScript functionality and performance, suggested enhancements for QScript or healthcare workforce matters. Such feedback has been collated and recorded for further consideration by Queensland Health and other entities involved in the relevant issues.

Medical sector

The Australian Medical Association Queensland (AMAQ), Australian and New Zealand College of Anaesthetists (ANZCA), Australian Society of Anaesthetists (ASA), Royal Australian and New Zealand College of Psychiatrists—Queensland Branch of the Faculty of Addiction Psychiatry (RANZCP) and Rural Doctors Association of Queensland (RDAQ) supported all proposed QScript look-up exemptions.

ANZCA, ASA, and RDAQ supported the amended Monitored Medicines Standard. However, RANZCP opposed it, raising concerns that the reduced scope may result in further stigmatisation and difficulties in accessing healthcare for Queensland Opioid Treatment Program patients and it is not proportionate to the level of relative risk associated with prescribing monitored medicines to these patients, when compared with other common prescribing scenarios. RANZCP further noted that there is little evidence of compliance with the current Monitored Medicines Standard and recommended either removing the Monitored Medicines Standard altogether or refocussing it on the highest-risk clinical scenarios. RANZCP's submission has been collated and recorded for further consideration by Queensland Health and other entities involved in the relevant issues.

Pharmacy sector

The Pharmacy Guild of Australia—Queensland Branch (Pharmacy Guild) opposed all QScript look-up exemptions and did not believe the proposed mandatory look-up requirements are likely to support, protect and promote patient and public safety.

The Pharmacy Guild highlighted the residential aged care facility exemption as a particular concern, as these patients "are likely to be taking many medicines, and often see several prescribers. They may also receive medications from multiple community pharmacies. While it is acknowledged that these patients are unlikely to be 'prescription shopping' or diverting medicines, they are still at risk of harm due to potential misuse (intentional or not) of controlled medicines." The Pharmacy Guild also considered that the exemption may limit the opportunity for health practitioners to detect the inappropriate use of restrictive practices such as chemical restraint.

Queensland Health acknowledges the concerns raised by the Pharmacy Guild, and notes that health practitioners will retain the ability to access QScript voluntarily at any time to inform their therapeutic treatment of patients. Queensland Health also notes that the use of 'chemical restraints' in residential aged care facilities often refers to the use of antipsychotics and benzodiazepines. While benzodiazepines are specified as 'monitored medicines' in the Medicines Regulation (and monitored in QScript), most anti-psychotic medications are not monitored medicines, and not monitored in QScript (e.g. risperidone, olanzapine and haloperidol).

The Pharmacy Guild considered the voluntary assisted dying exemption to be unclear, noting that a patient may choose not to progress with the voluntary assisted dying process 'so should still have the same standard of care afforded to them as all other patients.' Queensland Health will develop guidance materials to support health practitioners and organisations understand and apply the look-up exemptions.

The Pharmacy Guild also opposed the amended Monitored Medicines Standard and did not consider that the current minimum requirements duplicate existing professional practice requirements. The Pharmacy Guild considered that the current Monitored Medicines Standard 'makes clear the minimum level of care that must have been provided to each patient,' and that the significant reduction in scope of the Monitored Medicines Standard makes it almost redundant. Queensland Health notes the Pharmacy Guild's opposition to and concerns regarding the QScript look-up exemptions and amended Monitored Medicines Standard. However, Queensland Health also notes the strong support for the changes from the rest of the pharmacy sector and broader range of stakeholders. Given this, Queensland Health has progressed the proposed amendments as described in the consultation papers and will work with the Pharmacy Guild and other stakeholders in the development of implementation resources to mitigate any risks and concerns.

Nursing and midwifery sector

The Australian College of Nurse Practitioners supported all proposed QScript exemptions. The Queensland Nurses and Midwives' Union supported all proposed QScript look-up exemptions, except the residential aged care facility exemption, which they opposed, noting concerns regarding polypharmacy and other issues related to medication management and safety in residential aged care facilities. Queensland Health acknowledges these concerns but considers that an exemption from mandatory look-up in these circumstances strikes an appropriate balance of reducing the harms associated with the current requirements while continuing to support patient safety and professional autonomy by allowing health practitioners to voluntarily check QScript to assist them in identifying and mitigating monitored medicine-related risks.

Other health organisations

The Australian Dental Association Queensland supported all proposed QScript look-up exemptions, except the exemption for prescribing a monitored medicine for administration (which they neither supported nor opposed). They queried the scope of the hospital and emergency treatment exemptions and noted that the emergency treatment exemption may be used as a 'loophole' in relation to pain medication.

Consumer organisations

Chronic Pain Australia supported all proposed QScript exemptions, but opposed the amended Monitored Medicines Standard, instead recommending it be removed altogether on the basis that it replicates professional practice standards, resulting in overregulation of and additional burden on a stretched system, causing unintended harms to those seeking care.

Other government entities

The Australian Health Practitioner Regulation Agency (Ahpra) supported the QScript exemption for hospitals but did not express a definitive opinion on the remaining exemptions. Ahpra raised some concerns about the residential aged care facility exemption, noting that it may put patient safety at risk if there is a lack of knowledge about the patient/medicine or poor medication administration processes within a facility. They noted this may be compounded by an inability to identify polypharmacy and the workforce issues affecting the aged care sector. However, Ahpra further noted that the fact relevant practitioners will still be able to voluntarily check QScript did allay some of these concerns.

QScript look-up exemption—end-of-life / palliative care definition

Queensland Health received comprehensive feedback on the proposed definition of 'end-of-life care'. Multiple stakeholders noted that the end-of-life care trajectory for some patients may be longer than 12 months, and recommended the definition extend this timeframe. Other stakeholders considered that the timeframe should be reduced (e.g. to four weeks) or removed entirely from the definition.

Overall, there was general support for the exemption to encapsulate care provided to both 'end-of-life' and 'palliative care' patients. This feedback has been incorporated into the drafting of the exemption.

QScript look-up exemption—hospital discharge prescriptions

Numerous stakeholders recommended that the hospital exemption be extended to also apply to discharge prescriptions for small quantities of post-operative pain relief. Stakeholders expressed that mandatory QScript checking for these prescriptions is impractical, impedes the delivery of safe and efficient care, and rarely changes the prescribing decision. Stakeholders considered that the risk of such an exemption would be low and could be mitigated by putting conditions on the exemption. Conversely, there was strong stakeholder support for the exemption to apply as originally drafted, that is the exemption is *not* to apply to circumstances where a monitored medicine was prescribed, dispensed or given as a treatment dose to a patient on discharge.

Given this and noting that the impacts of extending the exemption to include discharge prescriptions has not been fully considered, the suggestion to extend the exemption has not been included in this amendment but may be considered in the future.

Consultation for exemption and changes to extended practice authorities

In February 2024, a consultation paper on the proposed amendments to the extended practice authorities was published on the Queensland Health website and disseminated to key stakeholders across pharmacy, medical and nursing peak bodies, women's health organisations and Aboriginal and Torres Strait Islander organisations.

Stakeholders generally indicated support for the amendments. Some stakeholders suggested changes to the policy to improve its operation or to address specific issues or concerns. A small number of stakeholders opposed the inclusion of one or more of the reforms. Some issues regarding implementation of specific reforms were identified by stakeholders, as well as potential unintended effects. All stakeholder feedback was taken into consideration when finalising the Amendment Regulation.

All stakeholders supported the following amendments to 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; and
- provide for an additional study option of a rural and isolated practice area program of study.

Registered nurses and midwives to administer hormonal intrauterine devices

There was strong support from most stakeholders in relation to increasing the long-acting reversible contraceptives that registered nurses working in a sexual and reproductive health service and midwives may administer. The change was viewed by many as an acknowledgement of national and international recommendations for sexual and reproductive health nurses to be enabled to work to full scope of practice and recognises that registered nurses and midwives are well placed and may be considered by community as preferred providers of long-acting reversible contraceptives.

The Royal Australian and New Zealand College of Obstetrics and Gynaecologists (RANZCOG) advised that further consideration should be given to enabling registered nurses and midwives to administer hormonal intrauterine devices and it considered that the actual procedure for inserting intrauterine devices should not be seen as a low-risk procedure. Queensland Health takes patient safety seriously. Appropriate clinical governance arrangements will be put in place to ensure the safe provision of care. Intrauterine device insertion will be limited to registered nurses working in sexual and reproductive health settings and midwives, who have the requisite knowledge, skills and experience to assess women's suitability for contraception. Before inserting intrauterine devices, registered nurses and midwives will be required to undertake specified education and training on the insertion and removal of intrauterine devices including patient assessment, and follow-up care and when to refer. This training will be the same training that is accessed by medical officers to perform intrauterine insertion. Registered nurses and midwives practice will be underpinned by clinical protocols and/or hospital procedures. Further, registered nurses and midwives will need to be credentialled by their employer for this activity.

Amendments not consulted on

Respiratory syncytial virus

As the TGA has only recently approved nirsevimab and the RSV vaccine to be listed for use on the Australian Register of Therapeutic Goods, consultation was not undertaken. It is imperative that the amendments are in place at the commencement of the 2024 winter virus season to ensure that these medicines can be widely administered before the peak RSV infection period.