Medicines and Poisons (Medicines) Regulation 2021

Explanatory notes for SL 2021 No. 140

made under the

Animal Care and Protection Act 2001
Electoral Act 1992
Environmental Protection Act 1994
Medicines and Poisons Act 2019
Planning Act 2016
Police Powers and Responsibilities Act 2000
Prostitution Act 1999
State Penalties Enforcement Act 1999
Veterinary Surgeons Act 1936
Waste Reduction and Recycling Act 2011

General Outline

Short title

Medicines and Poisons (Medicines) Regulation 2021

Authorising law

Section 217 of the *Animal Care and Protection Act 2001*
Section 392 of the *Electoral Act 1992*
Section 580 of the *Environmental Protection Act 1994*
Section 240 of the *Medicines and Poisons Act 2019*
Section 284 of the *Planning Act 2016*
Section 809 of the *Police Powers and Responsibilities Act 2000*
Section 140 of the *Prostitution Act 1999*
Section 165 of the *State Penalties Enforcement Act 1999*
Section 37 of the *Veterinary Surgeons Act 1936*
Section 271 of the *Waste Reduction and Recycling Act 2011*

Policy objectives and the reasons for them

Medicines, poisons and therapeutic goods are currently regulated in Queensland under the *Health Act 1937*, *Health (Drugs and Poisons) Regulation 1996* and *Health Regulation 1996*. The use of pesticides for pest management activities is regulated under the *Pest Management Act 2001* and *Pest Management Regulation 2003* (Pest Management Regulation).

Following a review of the existing legislation, it was determined that the Health Act, Pest Management Act, Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation would be repealed and replaced with a suite of legislation comprising the:

- *Medicines and Poisons Act 2019* (Act);
- *Therapeutic Goods Act 2019*;
- *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation);
- *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*;
- *Medicines and Poisons (Pest Management Activities) Regulation 2021*; and
- *Therapeutic Goods Regulation 2021*.

The Act and Therapeutic Goods Act were passed by the Legislative Assembly on 17 September 2019 and received Royal Assent on 26 September 2019.

On 13 August 2020, a postponement regulation (SL 2020 No. 150) was made under section 15DA of the *Acts Interpretation Act 1954*, postponing the automatic commencement of the Act by one year, until the end of the day on 26 September 2021. The scheme was originally planned to commence in mid-2020 but was delayed due to the impact of COVID-19.

The Act and Therapeutic Goods Act automatically commence on 27 September 2021. Their supporting regulations will also commence on 27 September 2021. At this time, the Health Act, Pest Management Act, Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation will be repealed.

Medicines and poisons are scheduled by the Therapeutic Goods Administration in the Commonwealth *Standard for the Uniform Scheduling of Medicines and Poisons* (Poisons Standard). Chemicals used for pest management activities, are registered or permitted for use as pesticides or fumigants by the Australian Pesticides and Veterinary Medicines Authority. Also, many pesticides and fumigants are scheduled poisons and listed in the Poisons Standard.

A key objective of the Act is to ensure substances, including medicines, poisons, pesticides and fumigants are used safely and effectively and do not cause harm to human health. The Act and Regulations cover activities that involve substances scheduled by the Therapeutic Goods Administration and substances registered or permitted by the Australian Pesticides and Veterinary Medicines Authority. Collectively, these substances will be referred to as ‘regulated substances’.

The Medicines Regulation regulates medicines and complements the Act by authorising activities that would otherwise be unlawful, and defining the outcomes required of lawful actions. Key objectives of the Medicines Regulation include:

- supporting the objectives of the Act to ensure regulated substances are used safely and effectively and to reduce public harm;
- the use of 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;
- improved clarity for authorised activities and approved persons, previously known as particular endorsements, to reduce reliance on approvals;
- more 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; and
- better facilitation of the prescribing, manufacturing, delivery and administration of medicated feed for use by primary producers.

Achievement of policy objectives

New categories of medicines

The Medicines Regulation includes new categories of medicines that were previously identified in the Health (Drugs and Poisons) Regulation as controlled drugs, regulated controlled drugs, regulated restricted drugs or restricted drugs of dependence and Schedule 2 (S2) or Schedule 3 (S3) poisons.

Although the rules and restrictions of these medicines remain largely unchanged, the new terminology for categories of medicine denotes the type of risk associated with these medicines and the controls of use to safeguard public health. The new terminology for each category of medicines is outlined below.

Restricted medicines are Schedule 4 (S4) and Schedule 8 (S8) medicines identified as having specific health risks that may be mitigated by restricting availability through specialist medical practitioners. Schedule 2, part 1 of the Medicines Regulation lists the restricted medicines, which can only be prescribed by a certain class of specialist medical practitioner or an individual who holds a prescribing approval. Restricted medicines include medicines whose use may cause birth defects (such as thalidomide), medicines with a higher risk of serious side effects (such as the antipsychotic medicine clozapine), or medicines that meet both these criteria (such as isotretinoin as treatment for severe skin conditions).

High-risk medicines are all Schedule 8 (S8) medicines and some specified Schedule 4 (S4) medicines, which have a higher potential for harm, impairment, misuse, abuse or dependence and are prescribed for recognised therapeutic purposes. Schedule 2, part 2 of the Medicines Regulation lists the high-risk medicines. High-risk medicines include pharmaceutical opioid medicines like oxycodone, codeine or morphine, amfetamines and antianxiety or sedative drugs such as diazepam (Valium™) or zolpidem.

Diversion-risk medicines are medicines that may have value as an illicit substance, such as anabolic steroids, peptides or pseudoephedrine products. All dependence-forming medicines that are considered high-risk medicines are also categorised as diversion-risk medicines. Schedule 2, part 3 of the Medicines Regulation lists the diversion-risk medicines.

Monitored medicines are medicines identified as potentially presenting a high risk of harm to patients as a result of misuse, abuse, diversion, substance use disorder or overdose. Monitored medicines are all Schedule 8 (S8) medicines and some Schedule 4 (S4) medicines. Schedule 2, part 4 of the Medicines Regulation lists the monitored medicines including pharmaceutical opioid medicines, amfetamines and antianxiety or sedative drugs such as diazepam (Valium™) or zolpidem.

Schedule 2, parts 2 and 4 currently include the same list of medicines in both the high-risk medicines and monitored medicines categories. However, as the medicines in these categories may change over time, the lists have been separated to future-proof the Medicines Regulation.

Approved persons

The Medicines Regulation provides for particular classes of persons to be authorised to carry out regulated activities with regulated substances that are medicines because of their profession or occupation, or because of the position they hold. These persons are known as 'approved persons'.

Approved persons are not required to apply for a licence or general approval under the Medicines and Poisons Act to carry out specific regulated activities. The majority of these authorities are conferred on individuals to facilitate the provision of health and veterinary services in various settings, including community settings such as schools. Schedules 3 to 15 of the Medicines Regulation specify the authorisations for each class of person or persons at a specified place.

The different types of endorsements provided under the Health (Drugs and Poisons) Regulation have been streamlined and classified by each category of approved person. The amendments achieve the policy objectives by ensuring the broad model provided in the Health (Drugs and Poisons) Regulation is retained, while being streamlined and improved.

Extended Practice Authorities

The Medicines and Poisons Act enables the chief executive to make Extended Practice Authorities that state the places or contexts an approved person may deal with a regulated substance, imposing conditions on dealing with the substance, or requiring a person to hold particular qualifications or training.

Similar to Drug Therapy Protocols in the Health (Drugs and Poisons) Regulation, the Medicines Regulation authorises specified classes of approved persons in stated circumstances to deal with regulated substances without a prescription under an extended practice authority approved by the chief executive. The Medicines Regulation states the class of health professional who is authorised under a specific extended practice authority.

The Medicines Regulation provides a set of criteria the chief executive must consider when deciding to approve an extended practice authority, such as whether people carrying out regulated activities with medicines have the necessary competencies, that health and safety risks are appropriately managed, the types of medicines to be dealt with and the service that needs to be met by the authority.

Schedule 1, part 1 (Approved extended practice authorities) of the Medicines Regulation lists the name of each extended practice authority made by the chief executive and the version number. The Medicines Regulation will be amended to reflect the name and version number of an extended practice authority each time a new version is made. A copy of the updated extended practice authority will be tabled in Parliament as extrinsic material each time the regulation is amended, to reflect the revised document. The extended practice authorities made under the Medicines Regulation are for the following classes of persons:

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

Departmental standards

The Medicines Regulation is more outcomes-focused, with many of the prescriptive requirements contained in the Health (Drugs and Poisons) Regulation being repealed. Where possible, the Medicines Regulation prescribes particular outcomes that must be met in order to achieve compliance and will refer to departmental standards for acceptable methods by which to achieve prescribed outcomes.

The Act empowers the chief executive to make departmental standards relevant to the objectives and administration of the new regulatory framework. The standards will be outcomes-focused and set minimum safety and accountability criteria that must be met in relation to particular activities. Persons who deal with regulated substances will be required to comply with the departmental standards applicable to the activity they are performing.

Schedule 1, part 2 (Approved departmental standards) of the Medicines Regulation lists the name each departmental standard made by the chief executive and the version number. The Medicines Regulation will be amended to reflect the updated name and version number each time a new version of a standard is made. A copy of the updated standard will be tabled in Parliament as extrinsic material each time the regulation is amended, to reflect the revised standard. The Act provides that the standard does not take effect until it is approved by the regulation and, if a later day is stated in the standard, on the later day. All departmental standards will be published on the Queensland Health website.

The departmental standards which support the Medicines Regulation are:

- Compounding;
- Monitored medicines;
- Pseudoephedrine recording;
- Requirements for an electronic prescription management system;
- Secure storage of S8 medicines; and
- Substance management plans for medicines.

Substance management plans

The Act contains a new requirement for responsible persons at particular places to develop substance management plans. A substance management plan allows these responsible persons at particular places such as hospitals or community pharmacies the flexibility to identify and manage the risks with medicines relevant to them. It recognises that there are many options for how risks be managed rather than the current prescriptive approach. The plan must also document accountabilities and responsibilities of persons employed or engaged by the entity or undertaking dealings with medicines at a place for which a substance management plan is required. Where a substance management plan applies to a person, the person must comply with the plan to carry out the regulated activity in the authorised way.

A substance management plan must demonstrate that a responsible person has considered risks involving regulated substances and taken steps to ensure these are adequately mitigated or managed in the particular context of the practice and work environment the place the plan relates to. In developing and implementing a plan, there must be compliance with any relevant standards, such as the 'Secure storage of S8 medicines' departmental standard.

Schedule 17 of the Medicines Regulation prescribes the regulated places that must have a substance management plan and who is the responsible person for making the plan at that place. For example, for an aged care facility, the responsible person is the nurse manager of the aged care facility or for an ambulance station the responsible person is the ambulance officer in charge of the station.

The substance management plan needs to be reviewed at least every five years. Reviews must also occur after a significant event such as an identified risk occurring, an audit identifying gaps in the management of risks with medicines, the entity changing or renovating premises, or a change in organisational restructure or ownership.

Entities will have one year after the Act commences to comply with the substance management plan requirements, to give entities sufficient time to make their plan, so that their activities will not be interrupted.

Adoption of parts 2 and 4 and appendices H, K and L of the Poisons Standard

The Poisons Standard provides for the uniform scheduling of substances classified from Schedule 2 (S2) to Schedule 10 (S10). All States and Territories refer to the Poisons Standard when regulating possession, access and use of scheduled substances.

The Medicines Regulation will achieve the policy objectives by adopting, by reference, parts 2 and 4 and appendices H, K and L of the Poisons Standard, subject to the modifications made by the Medicines Regulation.

Part 2 of the Poisons Standard includes model provisions about packaging and labelling and other controls for the management of medicines and poisons risks. The matters predominantly apply to sale and supply. The Medicines Regulation also includes additional requirements about these controls, for example the requirement to label an S3 medicine with the name of the person for whom it is supplied (as is required under the Health (Drugs and Poisons) Regulation).

Part 4 of the Poisons Standard classifies medicines and poisons into Schedules:

- Schedule 2 – pharmacy medicine (S2);
- Schedule 3 – pharmacist only medicine (S3);
- Schedule 4 – prescription only medicine or prescription animal remedy (S4);
- Schedule 5 – low harm poison (S5);
- Schedule 6 – moderate harm poison (S6);
- Schedule 7 – dangerous poison (S7);
- Schedule 8 – controlled medicine (S8);
- Schedule 9 – prohibited substance, should only be available for medical or scientific research, or for analytical, teaching or training purposes (S9); and
- Schedule 10 – prohibited substance, known for their dangerous properties (S10).

Appendix H lists the S3 substances permitted to be advertised directly to consumers. Appendix K lists the drugs required to be labelled with a sedation warning. Appendix L details the requirements for dispensing labels for human and veterinary medicines.

To achieve the policy objectives, the Medicines Regulation:

- includes provisions that require that substances are only supplied when labelled and in a container that complies with part 2 of the Poisons Standard;
- places additional controls on certain dealings with medicines listed in Appendix D of the Poisons Standard. Appendix D of the Poison Standard lists Schedule 4 and Schedule 8 substances that require additional controls on possession and supply; and
- places controls on the advertising of medicines.

Real-time prescription monitoring

The Act provides a head of power to implement a real-time prescription monitoring system, referred to in the Medicines Regulation as the monitored medicines database (database). Establishing real-time prescription monitoring will meet a recommendation of the Health Ombudsman's 2016 report, '*Undoing the knots constraining medicine regulation in Queensland*'.

The Health (Drugs and Poisons) Regulation contains existing requirements relating to treating drug-dependent persons with certain prescription medicines. Prescribers must obtain an approval from Queensland Health before treating a drug-dependent person with S8 medicines and certain S4 medicines. This approval process often takes place during a patient's consultation and prescribers can only obtain S8 prescription information for Queensland patients through Queensland Health's telephone enquiry service. Approvals can only be granted during business hours, Monday to Friday.

The introduction of a real-time prescription monitoring system means prescribers will be able to access real-time prescription information for their patients at the point of care, allowing them to make informed decisions about clinical treatment. As prescribers will be able to directly review this information themselves, there is no longer a need for them to contact the telephone enquiry service to obtain this information from Queensland Health, or to obtain an approval to treat a drug-dependent person with S8 or S4 medicines. It is expected the requirement to check the database will be more efficient than the current telephone procedure, which is time consuming for practitioners and patients.

The database will contain real-time prescription and dispensing information and will monitor prescribing and dispensing of certain medicines, such as pharmaceutical opioids and other prescription only medicines. These medicines have a recognised therapeutic use but may also present a high risk of physical, mental and social harms. The database will help doctors, other prescribers and pharmacists with their clinical decision-making by providing them with access to real-time prescription information before they prescribe, dispense or give a treatment dose of certain medicines and will provide lifesaving benefits to patients by promoting early identification of monitored medicine-related risks.

The greatest risk for patients suffering harm from pharmaceutical opioids and other prescription only medicines happens in the community sector outside of hospitals, and this is where the vast majority of prescribing activity occurs. A number of recent coronial findings have noted the lack of prescription information by community doctors and pharmacists has been a contributing factor in the deaths of patients. Coroners have repeatedly recommended that a real-time prescription monitoring system is established to address this issue. Accordingly, the most pressing priority for real-time prescription monitoring is in establishing access to this system for community prescribers and pharmacists.

It is recognised that hospitals also need access to real-time prescription monitoring to manage patients being admitted for care, managing emergency presentations and improving appropriateness of supply of monitored medicines on discharge and to outpatients. Queensland Health also recognises the need to capture dispensed monitored medicines prescription information from hospital pharmacies for complete information about a person's prescription history.

The Medicines Regulation enables the capture of this information from public sector hospital pharmacies, but does not currently compel this information to be recorded as at this time there are technical limitations that prevent the capture of these records as public sector hospital dispensing software in not yet able to send records to the database in the way required under national arrangements. It is intended that the database will capture dispensing records generated in public sector hospital pharmacies once technical barriers have been addressed.

On commencement of the Medicines and Poisons Act and Medicines Regulation, health practitioners will be able to access the monitored medicines database via the internet, through any mobile, tablet or desktop device. This will provide prescribers and dispensers of monitored medicines working in all healthcare environments (including hospitals and residential aged care facilities) with access to the monitored medicines database to inform their clinical decision-making.

Queensland Health recognises the importance of protecting privacy and confidentiality of medical records and information. Access to the monitored medicines database will be limited to only those practitioners who are providing (or are proposing to provide) therapeutic monitored medicines treatment to a patient and relevant health regulators, such as the Queensland Health Ombudsman and the Australian Health Practitioner Regulation Agency.

Access to the database will be subject to regular review and targeted auditing by Queensland Health, and penalties will apply for inappropriate access and use of information. Two-factor authentication to ensure only authorised users gain access to the database will be required to meet Queensland Health and national cybersecurity standards.

On 1 May 2020, the *Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020* commenced. This regulation commenced certain provisions of the Act to facilitate the establishment and testing of the monitored medicines database using information given and recorded under the Health Act. The regulation will be repealed on commencement of the Medicines and Poisons Act and Medicines Regulation.

Offences

The Act introduces a simplified and consistent regime of general offences, to replace the numerous offences in the Health (Drugs and Poisons) Regulation, Health Regulation and Pest Management Regulation.

The Act provides that no offence is committed if a person holds the necessary authority, licence or approval to perform the activity in question and the activity is performed in the way specified under the Act, Regulations, a Standard and, if applicable, a substance management plan for a place.

The Act provides for substance authorities to have conditions prescribed in a regulation or to be set out in the authority instrument. Failure to comply with a condition of an authority will constitute an offence under the Act.

Although the Act broadly addresses offences associated with authorities or performing regulated activities with regulated substances, the Medicines Regulation provides for some additional offences that are not covered by the Act.

The Medicines Regulation inserts offence provisions for non-compliance with requirements for electronic prescription management systems, medicine storage systems, medicine registers, tracking deliveries of stock of medicines, the recording and keeping of information, reporting particular matters such as lost or stolen medicines or fraudulent prescriptions, advertising, and a prohibition on sale of scheduled medicines from a vending machine.

Licensing

The new regulatory regime rationalises the licensing requirements for medicines and poisons and streamlines and simplifies the licensing process.

Under the Medicines Regulation licences may be required for:

- manufacturing of medicines;
- the sale of medicines by wholesale; and
- the retail sale of S2 medicines.

The Medicines Regulation will achieve the policy objectives by streamlining the current licensing regime in the following ways:

- Under the Health (Drugs and Poisons) Regulation, holders of a Commonwealth manufacturing licence from the Therapeutic Goods Administration or Australian Pesticides and Veterinary Medicines Authority must also hold a Queensland manufacturing licence. Under the new medicines and poisons regulatory framework, Commonwealth manufacturing licences will be recognised as authorising the holder to manufacture medicines. Consequently, the holders of these licences will not be required to hold a separate Queensland manufacturing licence.

- The Medicines Regulation authorises entities holding a manufacturing licence issued under a law of the Commonwealth to sell the medicines they manufacture by wholesale under the Commonwealth licence.
- A licence holder that manufactures or supplies medicines at more than one location in Queensland may apply to consolidate their licences into one licence that will cover all locations.
- Representatives of medicines manufacturers and wholesalers who supply sample packs of medicines to prescribers and pharmacists required a licence under the Health (Drugs and Poisons) Regulation. Under the Medicines Regulation, this activity is now authorised by an approved person authority.

Some standard conditions have been included in the Medicines Regulation, with additional conditions able to be included on the authority instrument depending on the substance involved, the purpose of use, and any other relevant criteria.

Medicine wholesalers are required to comply with the *Australian Code of Good Wholesaling Practice for medicines in Schedules 2, 3, 4 and 8*, which together with possible licence conditions, will ensure traceability of substances of high illicit value and allow for the recall of substances that do not meet product specifications or other compliance requirements.

Licences granted under the Health (Drugs and Poisons) Regulation will continue until the current licence ends, is suspended or cancelled or a new substance authority is granted under the Act, at which point the licence will be issued under the new scheme. An exception to this applies to holders of manufacturing licences issued under the Health (Drugs and Poisons) Regulation that also hold a Commonwealth licence, permit or approval to manufacture, as a substance authority under the Act will not be required. These persons or entities will be required to undertake activities with substances authorised to the extent specified within the Commonwealth licence, permit or approval to manufacture.

General approvals

A general approval will authorise the holder of the approval to undertake a regulated activity with the regulated substance stated, and under the conditions stated in the approval. General approvals may be granted to any legal entity for a range of regulated activities, including possession and administration of medicines for particular purposes. The Medicines Regulation prescribes different classes of general approvals and prescribes standard conditions for those different classes of general approval (acute health conditions at isolated sites, emergency first aid and emergency management of animals). Standard conditions include that an authorised prescriber (for example, a doctor, nurse practitioner or veterinary surgeon) is employed and is available to oversee the dealings under the general approval. Additional conditions may be prescribed on the authority instrument depending on the substance involved, the purpose of use and any other relevant criteria.

Approvals granted under the Health (Drugs and Poisons) Regulation will continue until the current approval ends, is suspended or cancelled or a new substance authority is granted under the Act, at which point the approval will be issued under the new scheme.

Fees

A fee is payable for all licences granted under the Act. The new fee structure under the medicines and poisons regulatory framework reflects the changes to licences outlined above.

In conjunction with the revised licence structure simplification, the revised fee structure will not introduce new fees or charges for licences and approvals. The streamlining and simplification of fees is achieved through a number of measures.

Under the medicines and poisons framework, there will be no changes to the fee amount for a licence payable under the Health (Drugs and Poisons) Regulation other than a general increase due to indexation. No fees will continue to be payable for general approvals.

Wholesale representatives who previously required a licence under the Health (Drugs and Poisons) Regulation and who are authorised under the Medicines Regulation by an approved person authority will no longer pay a licence fee.

Commonwealth manufacturing licence holders are no longer required to hold a separate Queensland manufacturing licence. This means they will no longer pay a licence fee to manufacture and wholesale medicines that they produce.

In line with the Health (Drugs and Poisons) Regulation, Queensland licences authorising the manufacture and wholesale of medicines will attract a specific fee if the licence authorises the manufacture or wholesaling of S8 medicines in addition to S2, S3 or S4 medicines. Where only S8 medicines are manufactured or sold, only the specific S8 fee would apply. For example:

- manufacture of an S2, S3 or S4 medicine – one licence, one fee;
- manufacture of an S8 medicine – one licence, one fee; or
- manufacture of an S2, S3 or S4 medicine and manufacture of an S8 medicine – one licence, two fees.

Manufacturing, wholesale or retail licence holders with multiple sites may apply to consolidate their licences so that they may hold a single licence that covers each site. They will be required to pay a separate licence fee for each site operating under the licence. To reduce the administrative and regulatory burden for paying fees for multiple sites, the new medicines and poisons regulatory framework allows for pro-rata fees to be paid for periods other than a whole number of years. This will allow licence holders to pay for a number of months when adding a new site or consolidating sites under the one licence, so that the fees for all sites under the licence fall due at the same time. The scheme allows for refund of partial fees if a different term is granted to the one applied for.

For procedural fairness, the new medicines and poisons regulatory framework also provides for refunds to be issued for withdrawn or rejected applications and authorities surrendered before the end of their term. A processing fee, equivalent to the difference between a new application and a renewal application, is to be withheld when determining the refund amount.

In a small number of cases, an existing licence holder with one licence will need two licences under the Act to continue to perform the same activities as they were permitted under the Health (Drugs and Poisons) Regulation. For example, the wholesaler of both S4 medicated feed and S7 agricultural poison only requires a restricted drug wholesaler licence under the Health (Drugs and Poisons) Regulation, but due to the separation of requirements between the Medicines Regulation and *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*, the wholesaler will require both a medicines wholesale licence and an S7 poisons wholesale licence under the medicines and poisons regulatory framework. To ensure licensees are not disadvantaged by this change, the new framework will require that although two licences are to be issued, only a single fee will be payable, in situations where only one

licence was required under the Health (Drugs and Poisons) Regulation. This will apply to both existing licence holders and new industry entrants.
Advantages of the revised fee structure compared to the fees charged under the Health (Drugs and Poisons) Regulation include:

- reduced administrative burden for holders of multiple licences who choose to consolidate to a single licence;
- no fees or licensing requirement for wholesale representatives;
- no fees or licensing requirement for holders of relevant Commonwealth licences; and
- greater clarity over when and how refunds may be issued.

Particular medicines

The Medicines Regulation updates the terminology used to describe categories of medicines associated with certain risks. In the Health (Drugs and Poisons) Regulation, these medicines were called controlled drugs, regulated controlled drugs, regulated restricted drugs or restricted drugs of dependence and S2 or S3 poisons. Although the rules and restrictions for the use of these medicines remains largely unchanged, the Medicines Regulation achieves the policy objectives of the Act by introducing new terminology that is more meaningful, indicating the reason why the medicine is deemed to have risks to public health that require control of use. The new terminology is as follows:

- *Diversion-risk medicine* – refers to medicines that may have an illicit value, such as S8 medicines, S4 drugs of dependence, anabolic steroids, peptides or pseudoephedrine products. There are significant penalties for improperly purchasing or supplying these medicines.
- *High-risk medicines* – refers to prescription medicines that are S8 medicines and some specified S4 medicines that have a recognised therapeutic need but also have a higher potential for harm, impairment, misuse, abuse and dependence. There are specific offences for self-prescribing and self-administration of these medicines.
- *Monitored medicines* – refers to those medicines to be included in the real-time prescription monitoring database. The Medicines Regulation specifies the S4 and S8 medicines to be included in the monitored medicines database. The Act specifies that relevant practitioners must review the database prior to prescribing, dispensing or giving a treatment dose of these medicines.
- *Restricted medicines* – refers to S4 and S8 medicines identified as having specific health risks that may be mitigated by restricting availability through specialist medical practitioners and includes those medicines listed in Appendix D of the Poisons Standard, as requiring prescribing by a specialist.

Prescribing and Prescriptions

The Medicines Regulation regulates prescribing and prescriptions to facilitate the safe supply and administration of medicines by authorising only certain people to issue a prescription and provides the rules that must be followed when issuing prescriptions.

This achieves the policy objective of ensuring regulated substances are used safely and effectively and reduces the risk of causing harm to the public.

The Medicines Regulation achieves the policy objectives in the following ways:

- a prescriber whose authorisation to prescribe is given under a prescribing approval must include the prescriber's prescribing approval number on the prescription;
- computer generated paper prescriptions for S8 medicines will no longer be required to have their components reproduced in handwriting on the prescription by the prescriber;
- a prescription authorising administration of a medicine in a person's medication chart must contain the same elements as a prescription to supply, with the exception of the prescriber's address, qualification or quantity of medicine to be supplied;
- a prescription that authorises administration will be valid for the same duration as a prescription to supply, 12 months from the date it is written for a S2, S3 and S4 medicine and 6 months for S8 medicines;
- a medical practitioner or nurse practitioner can make a standing order for the treatment of patients in an institution, an indigenous health service and at other places subject to approval and a veterinary practitioner may make a standing order under a particular class of general approval. A standing order is a document that authorises a medicine to be administered or given as a treatment dose to or for a person or animal at the place, provided certain conditions are met. Since standing orders allow approved persons who are not authorised prescribers to make decisions to administer or supply a medicine to a patient or animal in the circumstances of the standing order, sufficient governance capability is required for a place in which standing orders are used;
- supports the use of electronic prescribing by establishing the rules for the system and its operation; and
- permits authorised prescribers to direct the administration and supply of opioid replacement medicines using a prescription for a patient in an opioid treatment program.

Destruction and disposal of S8 and other diversion-risk medicines

To provide greater flexibility, more timely destruction of S8 medicines, reduce the risk of waste being stolen during transport for destruction and reduce the burden on specific authorised persons, the Medicines Regulation extends the authority to destroy medicines to a broader range of people, including pharmacists, medical practitioners, nurse practitioners, eligible midwives, dentists and veterinary surgeons.

To achieve the policy objectives, the Medicines Regulation includes provisions to:

- permit specified persons to destroy S8 medicines in the presence of an authorised witness;
- require that each time an S8 medicine is destroyed, there must be a record made in an S8 medicines register that includes the date, item and quantity destroyed and the name of the person who witnessed the destruction;
- allow the destruction of a previously sterile container, unused portion of a tablet or a lozenge containing an S8 medicine that is not required for administration to a patient, to be destroyed by a person who is authorised under the Act to administer the medicine, without requiring a witness;
- allow the Royal Flying Doctor Service (RFDS) to monitor disposal of diversion-risk medicines in RFDS medical chests by excluding waste from medical chests from the provisions; and
- require other diversion-risk medicines to be disposed of in a way that prevents public access to the waste.

Supply to patients

The Medicines Regulation provides arrangements for the safe and secure supply of medicines. Medicines may only be supplied to patients by authorised persons in defined circumstances, if there is an identified therapeutic need for the medicine, and in packaging that is labelled to facilitate and ensure the safe administration of the medicine. In addition, a record of the supply to a patient is required to be kept for most medicines to ensure continuity of care and facilitate recall of a supplied medicine if required.

In line with the Health (Drugs and Poisons) Regulation, the controls on who may supply medicines to patients vary according to the risk to the public of the medicine and the location of the patient. The schedule of the medicines specified in the Poisons Standard categorises medicines on the basis of the risks associated with the medicine. Where possible, supply of medicines to patients or animals should be via a pharmacist (in accordance with a prescription if the medicine is a S4 or S8 medicine) or by a person authorised to prescribe the medicine. However, the Medicines Regulation also authorises other approved persons to supply medicines to patients, including registered nurses, ship's masters, corrective services officers, and the holder of a retail S2 licence in certain defined circumstances. Pharmacists are authorised to sell S2 and S3 medicines to a patient without a prescription and, in limited circumstances, S4 medicines.

Storage

The Medicines Regulation establishes consistent standards for storing medicines across a range of industries and settings which are proportionate to the relative risks of storing the medicines. In recognition of advances in technology, such as dispensing robots and electronic storage and supply units, the Medicines Regulation introduces regulatory controls to ensure medicines being stored in these machines will not be compromised. The level of security for storing S8 medicines in dispensing robots and electronic supply units, and in other storage receptacles, has been defined in the *Secure Storage of S8 Medicines* departmental standard, made under the Act. The standard will be able to be updated to reflect changes in technology and industry best practice.

Recording and reconciliation of S8 medicines

The Medicines Regulation requires the keeping of records for each entry and removal of S8 medicine stock from secure storage and reconciliation of records against the stock of S8 medicines held. The Medicines Regulation achieves this by specifying the information that must be recorded, the form in which these records must be kept and by requiring a register of S8 medicines is reconciled frequently enough to detect any discrepancy. The frequency of reconciliation may be different depending on the size and nature of an entity. However, at a minimum, reconciliation must be performed once a month.

Selling stock of medicines

The Medicines Regulation sets consistent standards for the sale of stock of medicines including the requirements for purchase orders, transport and delivery and record-keeping. Generally, medicines may only be sold by wholesale by the holder of a manufacturing licence or wholesale licence.

The Medicines Regulation inserts provisions authorising pharmacists to sell medicines by wholesale without a wholesale licence where the activity could be considered part of normal pharmacy business. This would include:

- sale of small quantities of stock of medicines (that are not for resale), to an aged care facility;
- supplying a medical practitioner or other authorised prescriber with medicines, for example, supply for a doctor's bag; or
- selling S3 medicines, such as asthma relievers or adrenaline (epinephrine) to a school or authorised first aid provider.

In addition, the Medicines Regulation includes a provision allowing a pharmacist to supply or loan stock to another pharmacist to fulfil a purchase order for an immediate customer request.

The Medicines Regulation places the onus on a seller supplying stock (medicine that is non-dispensed or not for a named patient) to ensure that they are selling to a person that is authorised to issue a purchase order for the medicine stock.

The Medicines Regulation achieves the policy objectives of the Act by providing that a person who sells stock can only sell to someone who is authorised to purchase stock. This includes:

- an approved person as per their authority, including Commonwealth and interstate licensees;
- a person or entity authorised under a substance authority (a substance authority holder); or
- an approved person working for a substance authority holder and authorised by the substance authority holder to purchase stock—the substance authority holder's management plan will articulate who is authorised to buy stock for that substance authority holder. The substance authority holder will need to provide that information to the supplier.

Procurement and purchasing certain medicines

The Act places controls on the supply of all regulated substances. The Medicines Regulation supports this objective by prescribing who may issue a purchase order. These include:

- holders of manufacturing or wholesale licences who may purchase regulated substances as permitted by their licence;
- holders of general approvals, who can purchase regulated substances as permitted by their approval;
- other persons in particular places specifically authorised by the Regulation. They include certain persons at aged care facilities, education and child care facilities, ships, detention centres, prisons, and watch-houses; and
- approved persons where the Regulation allows for this under the approved person's authority.

The Medicines Regulation achieves its objectives by providing more flexible approaches for certain authorised persons such as principals at a school or first aid providers to purchase certain medicines. For example, the Regulation clarifies that for classes of first aid providers, it is reasonable for a pharmacist to sell the first aid provider the necessary medicines, for example, adrenaline (epinephrine) in an auto-injector, without requiring that the supply is for a specific and known patient.

Standing orders

A standing order is a type of direction that has been written in advance that allows certain authorised persons to administer or supply a medicine without a patient specific direction. A lack of specificity about standing orders in the Health (Drugs and Poisons) Regulation means that they are sometimes used in circumstances in which patient-specific directions would be safer and more appropriate. The new framework inserts provisions that more formally recognise the use of standing orders as a type of instruction and also puts conditions on their use.

The Medicines Regulation achieves its objectives by allowing timely access for the public to safe and effective treatment with medicines while ensuring that sufficient governance is in place to safeguard the use of standing orders. Appropriate governance arrangements are important because a standing order may allow approved persons who are not authorised prescribers to make decisions to administer or supply a medicine to a patient in the circumstances of the standing order.

Compounding of medicines

To ensure patients are able to access required medicines, the Medicines Regulation continues the authority in the Health (Drugs and Poisons) Regulation for pharmacists to compound medicines for the treatment of a specific patient. To ensure that the compounded medicines are fit for their intended use and free from contamination, the Medicines Regulation requires an approved person who compounds a medicine to comply with the Compounding Standard made by the chief executive. The Compounding Standard replaces the provisions about compounding that were previously included in the Health Regulation.

Medicated feed

The Medicines Regulation regulates the way veterinary surgeons prescribe and order medicated feed for animals under their care. The obligations under the Health (Drugs and Poisons) Regulation, which required manufactured feed to be delivered to the ordering vet for subsequent sale to the primary producer, did not align with industry practices, particularly as a prescribing veterinary surgeon may be based in a different state to the animals and tonnes of medicated feed may be prescribed with weekly preparation and delivery.

Restricting the prescribing of medicated feed to veterinary surgeons is required, as prescribing medicines for animals is an act of veterinary surgery that may only be performed by a registered veterinary surgeon under the *Veterinary Surgeons Act 1936*. The provisions requiring a prescription to authorise supply and administration are justified as the medicines prescribed are predominantly antibiotics and the judicious use of antibiotics is pivotal in managing antimicrobial resistance.

The Medicines Regulation achieves the policy objectives of reducing the regulatory burden and costs placed on primary producers by authorising the holder of a manufacturing licence to sell medicated feed, that they have manufactured according to a prescription issued by a veterinary surgeon, directly to the end-user.

The provisions are compatible with and do not duplicate the obligations on veterinary surgeons and primary producers under the *Biosecurity Act 2014* and the *Chemical Usage (Agricultural and Veterinary) Control Act 1988*.

The requirements for prescriptions in the Health (Drugs and Poisons) Regulation do not specify the detail necessary to controls the use of medicated feed. The Medicines Regulation includes a provision requiring a veterinary surgeon to give a prescription, in writing and containing specified details, to the farmer (which includes the owner or custodian of a group of animals whether or not the animals are food-producing animals), authorising them to administer the prescribed medicated feed to their animals. The Medicines Regulation also authorises a holder of a manufacturing licence to sell feed to a person to whom a medicated feed prescription has been issued. The veterinary surgeon is required to keep a record of all issued prescriptions, and the manufacturer is required to keep a record of all supplies made on a prescription, and to give a copy of this record to the prescribing veterinary surgeon if requested. This will assist in both controlling and tracking supplies of medicated feed.

Penalty infringement notices

The Medicines Regulation amends the *State Penalties Enforcement Regulation 2014* to prescribe that penalty infringement notices (PINs) may be issued for particular offences. The offences for which a PIN may be issued are the following provisions of the Act:

- Section 41(2) – This provision requires a person to check the monitored medicines database before prescribing, dispensing or giving a treatment dose of a monitored medicine. The maximum penalty for the offence is 20 penalty units and the PIN is 2 penalty units ($275.70).
- Section 71 – This provision requires a person to whom a substance authority applies to comply with the conditions of the authority unless the person has a reasonable excuse. The maximum penalty for the offence is 200 penalty units and the PIN is 5 penalty units for an individual ($689.25) and 25 penalty units for a corporation ($3,446.25).
- Section 93(1) – This provision requires the responsible person for a regulated place to make a substance management plan for the place that complies with section 93(2) before any dealing with a regulated substance happens at the place, unless the person has a reasonable excuse. The maximum penalty for this offence is 250 penalty units. The PIN only applies if the substance management plan does not comply with section 93(2)(a) of the Act, which requires the plan to state the day the plan starts, the location of the place for the plan, the dealings and regulated substances to which the plan applies and the persons the plan applies to. The PIN is 6 penalty units for an individual ($827.10) and 30 penalty units for a corporation ($4,135.50).
- Section 137 – This provision requires an inspector to return their identity card within 21 days after they cease being an inspector unless they have a reasonable excuse. The maximum penalty for the offence is 20 penalty units and the PIN is 1 penalty unit ($137.85).
- Section 226(1) – This provision requires information providers specified in schedule 18 part 2 of the Medicines Regulation to give the chief executive the information specified in schedule 18 part 2 for the provider at the time and in the way specified in the Medicines Regulation unless the information provider has a reasonable excuse. The maximum penalty for the offence is 100 penalty units and the PIN is 10 penalty units ($1,378.50).

These offences have been identified as being suitable for a PIN at the commencement of the medicines and poisons scheme. Additional offences may be added as PINs in future.

These PINs may be issued by an inspector appointed under section 131 of the Act.

Transitional provisions

Prescribed day when monitored medicines database is fully operational

The Medicines Regulation prescribes the monitored medicines database as being fully operational from 27 October 2021. Section 281 (Procedure until monitored medicines database operational) of the Act sets out transitional arrangements to deal with the application of the monitored medicines database provisions until the monitored medicines database is operational.

During the transition period, that is, between commencement of the transitional provision and 27 October 2021:

- a person will not be subject to relevant offence provisions (sections 41 and 226 of the Act); and
- sections 84(2)-(10), 84A(3) and (4), 120, 122, 213 and 213A of the Health (Drugs and Poisons) Regulation, which provide for approvals for the treatment of drug dependent persons, which will continue to apply as they did immediately before commencement of the legislative framework.

Section 281 of the Act does not prevent a person complying with the Act to the extent practicable during the transition period. This will allow prescribers and dispensers to begin familiarising themselves with the system during the transition period. Relevant offences for misusing the database will apply during the transition period.

Sending and keeping particular prescriptions during special arrangement period

If a prescriber gives a digital copy of a paper prescription for an S4 medicine, other than a diversion-risk medicine, to a dispenser during the special arrangement period, the prescriber is temporarily exempt from the legal requirement to send the original prescription to the dispenser. The special arrangement period ends at the end of the day the special arrangement (*National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (Cwlth)) is repealed or expires.

As required for the special arrangement, the prescriber must retain the original paper prescription for a period of two years (whether for a Pharmaceutical Benefits Scheme/Repatriation Pharmaceutical Benefits Scheme or private prescription) after giving the dispenser a digital copy of the paper prescription.

Continuation of certified way of packaging

If the chief executive certified a container for packing a medicine under section 10(3) of the Health (Drugs and Poisons) Regulation and the certification was in effect immediately before the commencement of the Medicines Regulation, the certification is taken to be an alternative way for packaging the medicine approved under clause 237 of the Medicines Regulation. The certification expires on the stated day in the certification or no later than one year after the commencement of the Medicines Regulation.

Continuation of certified way of labelling

If the chief executive certified an alternative way of labelling a package for a medicine under section 11(3) of the Health (Drugs and Poisons) Regulation and the certification was in effect immediately before the commencement of the Medicines Regulation, the certification is taken to be an alternative way of labelling a package for the medicine approved under clause 237 of the Medicines Regulation. The certification expires on the stated day in the certification or no later than one year after the commencement of the Medicines Regulation. For example, when COVID-19 vaccines were urgently imported from overseas, an alternative way of labelling a COVID-19 vaccine was certified under section 11(3) of the Health (Drugs and Poisons) Regulation. This alternative label is taken to be an alternative way of labelling the medicine under the transitional provisions of the Medicines Regulation.

Controlled drugs registers

A controlled drugs register is taken to be a medicine register for S8 medicines if, immediately before the commencement of the Medicines Regulation, a person kept a controlled drugs register under section 50 of the Health (Drugs and Poisons) Regulation.

Clinical protocols

A clinical protocol made under the Health (Drugs and Poisons) Regulation that was in effect before the commencement of the Medicines Regulation is taken to be a clinical protocol for the person practising the profession at the place until the day the existing protocol is revoked or the day stated to be the expiry date in the protocol made under the Health (Drugs and Poisons) Regulation.

Orthoptist protocols

A health management protocol, made under the orthoptist drug therapy protocol, that was in effect immediately before the commencement of the Medicines Regulation is taken to be a clinical protocol for a person practising orthoptics until the day the existing protocol is revoked or the day stated to be the expiry date in the protocol.

The orthoptist drug therapy protocol, which is made under sections 170(A)(1) and 256AA(1) of the Health (Drugs and Poisons) Regulation, states the circumstances and conditions under which an orthoptist is authorised to administer a restricted drug or scheduled poison. The drug therapy protocol details the minimum requirements and the content required to be included in the health management protocol.

Practice plans

A practice plan for an Aboriginal and Torres Strait Islander health practitioner or a practice plan for a physician's assistant made under the Health (Drugs and Poisons) Regulation that was in effect immediately before the commencement of the Medicines Regulation is taken to be a practice plan for a practitioner who is an Aboriginal and Torres Strait Islander health practitioner or a practice plan for practitioner who is a physician assistant under the Medicines Regulation.

Chief executive's approvals or certifications for bodies and facilities

An approval or certification by the chief executive for a professional body, a facilities accreditation body, a laboratory or another facility, which was in effect under the Health (Drugs and Poisons) Regulation immediately before the commencement of the Medicines Regulation, continues in effect under Medicines Regulation to the extent the chief executive's approval is required for the same purpose that the body or facility was approved or certified for.

Consistency with policy objectives of authorising law

The Regulation is consistent with the policy objectives of the 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 regulation is the only effective means of achieving the policy objectives.

Benefits and costs of implementation

The cost of implementing the new regulatory framework will be met within existing budget allocations, and the resources used to manage the existing regulatory framework will continue to be used to administer the new framework.

There are no new or increased fees under the proposed legislation. The Queensland Treasury Principles for Fees and Charges (January 2018) require agencies to set fees and charges to accurately reflect the full cost of providing their services. Agencies are also required to have processes in place to ensure the fees and charges maintain their value over time. Therefore, the proposed fees will continue to be subject to annual indexation in line with the Government indexation policy as advised by Queensland Treasury.

The new regime will represent less duplication of some licence categories (for example, Commonwealth and State manufacturing licences for medicines) and the removal of the need for wholesale representative licences, and some revenue may be lost as a result. This will be offset by a reduction in administration and monitoring costs under the Medicines and Poisons framework, resulting in a more revenue-neutral outcome.

Queensland Health has developed an education and communication strategy for real-time prescription monitoring to enable:

- all stakeholders to be well-informed about the database and how to use it; and
- users to have access to educational opportunities and resources so they can understand the information displayed in the database and work within the new medicines and poisons regulatory framework with confidence.

Education and training will cover a wide range of topics including:

- an overview of health practitioners' legislative requirements in relation to QScript;
- how to access and navigate the monitored medicines database; and
- clinical information and advice on each monitored medicine and related practice issues.

As part of the education and training delivered by Queensland Health, prescribers and dispensers will be provided guidance on how to manage difficult conversations and deal with difficult clinical scenarios.

To support the implementation of substance management plans by stakeholders and industry, templates, guidelines and other tools will be provided. As many of the entities required to implement a substance management plan will already have Workplace Health and Safety Management Plan or comply with accreditation schemes, guidelines developed by Queensland Health will describe how these materials may also be used to fulfil the requirements for substance management plans. Queensland Health will provide ongoing support and information to stakeholders leading up to commencement of the scheme and during the one-year transition period for existing entities, to assist entities to develop and implement a plan. Support information will also be provided on an ongoing basis for affected stakeholders, businesses, health practitioners and industry.

Consistency with fundamental legislative principles

The Medicines Regulation is generally consistent with fundamental legislative principles. Potential breaches of fundamental legislative principles are addressed below.

Rights and liberties of individuals

Does the legislation make rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review?

Section 4(3)(a) of the *Legislative Standards Act 1992* states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation makes rights and liberties, or obligations, dependent on administrative power only if the power is sufficiently defined and subject to appropriate review.

Section 93 (Requirements for substance management plan) of the Act imposes obligations on the responsible person for a regulated place to make a substance management plan for the place before any dealing happens in relation to a regulated substance and that the plan is to be reviewed at the time prescribed by regulation. A substance management plan is a document setting out known and foreseeable risks associated with dealing with a regulated substance at a regulated place. Clause 174 (Review of plan—Act, s 93) of the Medicines Regulation provides that a substance management plan must be reviewed as soon as practicable after a review incident happens and at least every five years after the day the substance management plan starts, or the plan is reviewed following a review incident. A review incident is defined as an incident requiring review of a substance management plan in the departmental standard called *Substance management plans for medicines*.

It is accepted industry practice that similar types of plans for risk management and accreditation against quality schemes are reviewed at least every five years, or in response to a significant incident. The entity is best placed to review their plan as they have the knowledge and expertise based on their operating procedures and industry practices. The timeframe of five years reflects workplace health and safety practice. Section 274 of the *Work Health and Safety Act 2011* provides that a code of practice expires five years after it is approved. The accreditation intervals for the community pharmacy accreditation scheme (the Quality Care Pharmacy Program) and general practice accreditation are two and three years respectively while the accreditation interval for the National Safety and Quality in Healthcare Standards may be up to four years.

Examples of incidents which would require a review of the substance management plan might include commencement of a new compounding service in a pharmacy, or a residential aged care facility discovering repeated losses of S8 medicines over time. The occurrence of these incidents would indicate to the entity that the risk management measures in place to mitigate or prevent these risks need to be updated or are inadequate. For incidents where S8 medicines are lost for example, the substance management plan would require a review about the activity of 'possessing' but should be extended to 'administering', 'supplying' and 'disposing of waste' to ensure there are no other gaps in risk mitigation measures to improve traceability of medicines and reduce the opportunity for theft.

Does the legislation allow the delegation of administrative power only in appropriate cases and to appropriate persons?

Section 4(3)(c) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation allows for the delegation of administrative power only in appropriate cases and to appropriate persons.

Schedule 5, clause 1 (Class of person) provides that a person who is the commissioner of the Queensland Ambulance Service under the *Ambulance Service Act 1991* or is exercising a power under that Act as the commissioner's delegate, may give a purchase order, possess or dispose of waste from stock of an S4 or S8 medicine for the Queensland Ambulance Service. Delegation of these responsibilities from the Commissioner to a delegate of the Commissioner is critical to enable the continuation of services by the Queensland Ambulance Service. It would not be practical for the Queensland Ambulance Service to function without this delegation and the Commissioner is the appropriate person to determine such delegation. The Queensland Ambulance Service has policies and procedures in place to ensure only appropriate persons can undertake certain activities, as well as appropriate reporting and accountability requirements for staff.

Schedule 13, clause 8 (Class of person) provides that the principal of a school or the principal's delegate, may administer or possess stock of a specified medicine when dispensed for a child attending the school. The principal may need to delegate the administration and possession of these emergency medicines to allow for situations where the principal is absent, and medicines need to be administered in an emergency. Also, it may not always be practical for the principal to be consulted about administration of medicines, particularly for larger schools with hundreds of students or multiple campuses or buildings.

Schedule 13, clause 13 (Class of person) provides that the head of a child care facility or the head's delegate, may administer or possess stock of a specified medicine when dispensed for a child attending the childcare facility. The head of the childcare facility may need to delegate the administration and possession of these emergency medicines to allow for situations where the head is absent and medicines need to be administered in an emergency.

Institution of Parliament

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

Section 4(5)(e) of the Legislative Standards Act states that whether legislation has sufficient regard to the institution of Parliament depends on whether the subordinate legislation allows the subdelegation of a power delegated by an Act, only in appropriate cases and to appropriate persons, and if authorised by an Act.

Under the Medicines Regulation, the chief executive has a range of administrative powers, including:

- Clause 104 (Making other standing orders) provides that a prescriber must not make a standing order, that is not for a relevant institution, unless the order relates to:
  - a place used to provide an Aboriginal or Torres Strait Islander heath service; or
  - a place or circumstance authorised under a general approval (emergency first aid) or a general approval (emergency management of animals); or
  - a place or circumstance otherwise approved by the chief executive.
- A standing order for a medicine means a document authorising the medicine stated in the document to be administered or given as a treatment dose at a stated place or in stated circumstances. Since standing orders allow approved persons who are not authorised prescribers to make decisions to administer or supply a medicine to a patient in the circumstances of the standing order, sufficient governance capability is required for a place in which standing orders are used. Standing orders are most commonly, and most appropriately, used at relevant institutions (being aged care facilities, public hospitals, private health facilities, prisons and detention centres), given the governance that is in place in these facilities. However, there is a need to allow other places to use standing orders, for example in a privately operated in-home palliative care service remote area health service. Given the importance of governance to safeguard patient care, It is necessary to allow the chief executive to approve the use of standing orders at places that can demonstrate sufficient clinical governance to assure Queensland Health that the use of standing orders presents no, or minimal, increased risk to public health and safety.
- Clause 237 (Chief executive may approve alternative ways of labelling or packaging medicines) provides the chief executive may approve an alternative way of labelling or packaging a medicine that is different to the Poisons Standard. The chief executive may approve the alternative way only if the chief executive is satisfied it is unlikely to adversely affect public safety, having regard to the nature of the medicine and the purpose for which it is to be used. The chief executive must publish, on the department's website the requirements of the alternative way, the day it takes effect and the period for which it has effect. The provision allows products to be labelled or packaged in the alternative way in temporary circumstances such as when a medicine is re-scheduled or when a medicine with labelling or packaging from another country is used in Australia to meet a temporary shortage or an urgent need (for example, to address an infectious disease outbreak). Without the ability to approve suitable alternative labelling or packaging, supply of such products would be unlawful and patients would be denied timely access to the medicine.

- Schedule 3 (Aboriginal and Torres Strait Islander health professions), clause 4 (Definitions for part) provides that the chief executive can approve, for an Indigenous health worker, an alternative course of training to the North Queensland Rural Health Training Unit Isolated Practice Course. This allows for a more flexible, responsive workforce, as there may be instances where the course is unavailable, or additional Indigenous health workers are needed with limited notice, in which case alternative courses, including those offered interstate, can be recognised. As the alternative courses offered are not controlled by Queensland Health and subject to change, it is not possible to state these courses in the Medicines Regulation. Allowing these courses to be approved by the chief executive provide the necessary adaptability and flexibility to respond to emergent needs.
- Schedule 7 (Nursing and midwifery professions), clause 9 (Definitions for part) refers to a document made by the chief executive titled *Repackaging medicines into a dose administration aid: Guidelines for registered nurses, version 1*. The regulation will be updated to reflect the name and version number of the guideline each time a new version is made. A copy of the updated guideline will be tabled as extrinsic material each time the regulation is amended, to reflect the updated document. The guideline is monitored and updated when necessary, aligns with clinical best practice and is published on the Queensland Health website.
- A rural and isolated hospital nurse and a prison nurse can repackage any medicine, if the medicine is repackaged for giving a treatment dose for a patient on a prescription and if repackaged in a dose administration aid under the dose administration aid repackaging guidelines. The guideline for the packaging of medicines into dose administration aids requires assessment of the suitability of the device for safe use, stability of the medicines to be included in the dose administration aid and processes to minimise and detect errors. It is considered that due to the technical nature of the document, which is periodically updated to reflect best clinical practice, the need to sub-delegate by referring to an external document in the Medicines Regulation is justified to ensure Queenslanders receive safe and timely health care, particularly in these specified settings.
- Schedule 12 (Other health practitioners), clause 3 (Class of persons), clause 9 (Class of persons) and clause 12 (Class of persons) provides that the chief executive can approve a professional body to accredit or certify a person to work as a clinical perfusionist, respiratory scientist or speech pathologist. The criteria the chief executive considers when deciding whether to recognise the professional body is whether the individual would be eligible for employment as a clinical perfusionist, respiratory scientist or speech pathologist under the first limb of the provisions, for example, whether the individual's qualifications and experience are consistent with the role requirements of a clinical perfusionist, respiratory scientist or speech pathologist employed by a Hospital and Health Service, private health facility or approved health facility. The majority of clinical perfusionists, respiratory scientists and speech pathologists are employed at facilities that fall within the first limb of the definition. The second limb ensures those persons who do not work in those facilities can also be recognised appropriately for their qualifications and experience. The chief executive relies on the experience of the professional body to accredit or certify a person to work as a clinical perfusionist, respiratory scientist or speech pathologist to determine whether to recognise them. The professional body must be approved by the chief executive and the chief executive must be satisfied the professional body is a reputable and appropriate organisation to recognise a person's qualifications and experience.

- Schedule 13 (Workers at institutions and facilities), clause 30 (Definitions for part) and clause 31 (Class of person) provides that the chief executive can approve an entity to carry out an immunisation program and approve a person to deal with vaccines for an immunisation program. These entities are primarily those that provide vaccines under the tax payer funded National Immunisation Program and so it is necessary for the chief executive to be assured that the vaccine service provider is able to manage the cold chain for vaccines to avoid wastage and to deliver the service in a way that is consistent with the Australian Immunisation Handbook. The chief executive must coordinate with the Commonwealth to approve these entities and limit the persons in the Health Department who can buy, possess and supply these vaccines to these registered providers.
- Schedule 16 (Classes of general approvals), clause 5 (Definitions for part) provides that the chief executive can approve a training course about the safe administration of medicines to animals. As the persons who will administer medicines to animals under these general approvals granted by the chief executive are primarily volunteer wildlife carers, it is appropriate for the chief executive to approve training courses as this requires expertise in workplace training and assessment, including knowledge of required competencies and clinical application to ensure effective use of the medicines and to avoid accidental poisoning of the volunteer or other people.

Extended practice authorities

Section 232 (Making extended practice authorities) of the Act empowers the chief executive 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. Section 232(3) provides that a regulation may prescribe matters the chief executive must consider before making an extended practice authority.

The following provisions refer to extended practice authorities:

- Schedule 3, clause 3 (Dealing authorised) provides that an Aboriginal and Torres Strait Islander health practitioner can give a treat dose of, repackage, administer and give a purchase order for a medicine mentioned in the *Aboriginal and Torres Strait Islander health practitioner* extended practice authority.
- Schedule 3, clause 6 (Dealing authorised) provides that Indigenous health workers in remote areas can give a treat dose of, repackage and administer a medicine mentioned in the *Indigenous health workers* extended practice authority.
- Schedule 5, clause 4 (Dealing authorised) provides that a person who is an ambulance officer under the *Ambulance Service Act 1991* can give a treatment dose of, administer and possess a medicine mentioned in the *Queensland Ambulance Service* extended practice authority.
- Schedule 7, clause 6 (Dealing authorised) provides that a midwife can give a treatment dose of, administer and give a purchase order for a medicine mentioned in the *Midwives* extended practice authority.
- Schedule 7, clause 11 (Dealing authorised) provides that a registered nurse can give a treatment dose of, administer and give a purchase order for a medicine mentioned in the *Registered nurses* extended practice authority.

- Schedule 9, clause 2 (Dealing authorised) provides that a pharmacist can sell, other than on a prescription, and administer a medicine mentioned in the *Pharmacist* extended practice authority.
- Schedule 12, clause 8 (Dealing authorised) provides that a physiotherapist can prescribe and administer a medicine to a patient stated in the *Physiotherapists* extended practice authority.

Extended practice authorities are not a new concept and are known as Drug Therapy Protocols (DTPs) under the Health (Drugs and Poisons) Regulation. DTPs state the circumstances and conditions under which certain authorised persons are able to do certain activities defined by the regulations and scope of the protocol.

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act. An extended practice authority is a document certified by the chief executive of Queensland Health that sets out matters of technical detail for how an approved person can carry out a regulated activity with a regulated substance. The extended practice authorities will 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 will be 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 higher levels of care specific to 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 will be updated to reflect the name and version number of an extended practice authority each time a new version is made. A copy of the updated extended practice authority will be 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 approved person.

By including a list of extended practice authorities in the schedule it creates certainty for professionals and the public about the status of extended practice authorities published on the Queensland Health website and the date when they took effect.

It is considered that the rigour surrounding the development of the 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 departmental standard titled *Secure storage of S8 medicines* provides alternative security measures for ensuring S8 medicines are stored securely.

The following provisions refer to particular standards:

- Clause 47 (Compounding for patients under departmental standard) provides that if an authorised person compounding a medicine for a patient must compound the medicine in accordance with the *Compounding* departmental standard.
- Clause 93 (Compliance with monitored medicines standard) provides that if a prescriber prescribes a monitored medicine, whether orally or by written prescription, the prescriber must prescribe the medicine in accordance with the *Monitored Medicines* departmental standard.
- Clause 126 (Compliance with monitored medicines standard) provides that if the medicine being dispensed is a monitored medicine, the dispenser may dispense the medicine only in accordance with the *Monitored Medicines* departmental standard.
- Clause 162 (Record keeping for pseudoephedrine) provides that if the medicine is an S3 medicine containing pseudoephedrine, then as soon as practicable after selling the medicine, the pharmacist must keep a record electronically in a way that complies with the *Pseudoephedrine recording* departmental standard.
- Clause 173 (Matters for plan—Act, s 93) provides that for section 93 of the Act, the matters to be addressed for a substance management plan relating to medicines are mentioned in the *Substance management plans for medicines* departmental standard.
- Clause 174 (Review of plan—Act, s 93) provides that a substance management plan for a regulated place relating to medicines must be reviewed as soon as practicable after a review incident happens in relation to the place and at least every five years after the day the substance management plan starts, or the plan is reviewed. A review incident means an incident identified in the *Substance management plans for medicines* departmental standard as an incident in which a substance management plan must be reviewed.
- Clause 186 (System must comply with departmental standard) provides it is an offence if the system manager of an entity's electronic prescription management system fails to take all reasonable steps to ensure the system complies with the *Requirements for an electronic prescription management system* departmental standard. The offence carries a maximum penalty of 80 penalty units.
- Clause 197 (S8 safe must comply with standard) provides it is an offence if an S8 safe establisher for a place fails to establish an S8 safe for S8 medicines at the place in a way that complies with the *Secure storage of S8 medicines* departmental standard. The offence carries a maximum penalty of 40 penalty units.

- Clause 200 (S8 safe establisher giving access to S8 safe) provides that if an S8 safe establisher gives a person a device or electronic way to open a safe, it is an offence if the S8 safe establisher fails to give the device or electronic way to the authorised user in accordance with the Secure storage of S8 medicines departmental standard. The offence carries a maximum penalty of 40 penalty units.

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, changes to clinical treatment with medicines, for example monitored medicines, and changes at a national level in relation to the monitored medicine database systems. 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.

<u>Poisons Standard</u>

In accordance with the National Scheduling Policy Framework for Medicines and Chemicals, Queensland will continue to adopt the classification system for medicines and poisons under the current version of the Poisons Standard made under section 52D of the *Therapeutic Goods Act 1989* (Cwlth).

Clause 6 (Exemption for national blood supply arrangements—Act, s 7) provides that the listed blood products, when dispensed or given as a treatment dose on a prescription made in the national blood tracking system, must be labelled in accordance with Appendix L of the Poisons Standard or labelled in accordance with any labelling requirements imposed by the appropriate authority, if the product has been granted a labelling exemption under section 1.5.5 of the Poisons Standard.

Clause 73 (Labels and containers must comply with Poisons Standard or approved alternatives) provides that a supplier may supply stock of a medicine to a buyer unless the labelling on the medicine in accordance with the labelling requirements in part 2, section 1 of the Poisons

Standard or the container of medicine complies with the requirements for containers for the medicine stated in part 2, section 2 of the Poisons Standard.

Clause 118 (Labelling dispensed medicine) provides that the dispenser must not dispense the medicine unless the labelling on the medicine complies with the labelling requirements for the medicines under Appendix L and if applicable to the medicine, Appendix K of the Poisons Standard.

Clause 134 (Labelling treatment dose of medicine) provides that the authorised person must not give a treatment dose of the medicine unless the labelling on the medicine complies with the labelling requirements for the medicines under Appendix L and if applicable to the medicine, Appendix K of the Poisons Standard.

Clause 154 (Labelling sold medicine) provides that the pharmacist must not sell the medicine unless the labelling on the medicine complies with the labelling requirements for the medicines under Appendix L and if applicable to the medicine, Appendix K of the Poisons Standard.

Clause 234 (Unlawful advertising of medicines) provides that it is an offence for a person to advertise or cause someone else to advertise and S3, S4 or S8 medicine unless the medicine is an S3 medicine listed in Appendix H of the Poisons Standard.

These provisions may be seen to breach the principle that subordinate legislation should allow the subdelegation of a power delegated by an Act only in appropriate cases and to appropriate persons and if authorised by an Act (section 4(5)(e) of the Legislative Standards Act). Applying sections of part 2 and relevant appendices of the current version of the Poisons Standard will ensure key regulatory controls governing the packaging and labelling necessary for safe use and advertising of medicines in Queensland will continue to be consistent with those in the other states and territories.

Reference to the Poisons Standard provides national consistency. There are representatives from each State on the scheduling committee to ensure the Poisons Standard is applicable in all jurisdictions. Additionally, the committee meets three times each year to discuss updates to be made to the Poisons Standard.

By referencing the Poisons Standard, as opposed to stating requirements directly in the Regulation, ensures the Regulation will always be consistent with the Poisons Standard and relevant to national requirements. It is also necessary to refer to the Poisons Standard in the Regulation rather than to duplicate it in the Medicines and Poisons scheme, as it is technical and detailed in nature.

External Standards and Guidelines

In some cases, it is necessary to adopt or specify standards that have been developed by relevant industry bodies, for example, the Optometry Board of Australia and the Podiatry Board of Australia.

Schedule 8, clause 3 (Dealing authorised) provides that an optometrist may administer a topical S2, S3 or S4 medicine mentioned in appendix A of the *Guidelines for use of scheduled medicines* made by the Optometry Board, if the optometrist administers the medicine under the guidelines.

Schedule 8, clause 5 (Dealing authorised) provides that an endorsed optometrist may prescribe, give a treatment dose of and administer an S2, S3 or S4 medicine mentioned in appendix B and appendix C of the *Guidelines for use of scheduled medicines* made by the Optometry Board and the endorsed optometrist prescribes, gives a treatment dose of or administers the medicine under the guidelines.

Schedule 10, clause 5 (Dealing authorised) provides that an endorsed podiatrist may prescribe, administer or give a treatment dose of a medicine mentioned in attachment A of the document called the *Registration standard: endorsement for scheduled medicines* made by the Podiatry Board, if the endorsed podiatrist prescribes, administers, or gives a treatment dose of, the medicine under the standard.

The inclusion of references to the *Guidelines for use of scheduled medicines* and the *Registration standard: endorsement for scheduled medicines* may give rise to a potential breach of fundamental legislative principles. The Medicines Regulation refers to the scheduled list of medicines published by the relevant National Board. Relying on an external document that is not subject to parliamentary scrutiny may be seen to breach section 4(5)(e) of the Legislative Standards Act, which provides that the subdelegation of a power delegated by an Act should only occur in appropriate cases and to appropriate persons, and if authorised by an Act.

The Podiatry Board of Australia and the Optometry Board of Australia publish lists of classes of scheduled medicines, which are updated from time to time. To ensure the Medicines Regulation is kept up to date, it will be updated to reflect the date of the new version each time a new version is made. A copy of the updated guidelines and standard will be tabled as extrinsic material each time the regulation is amended, to reflect the changed standard or guideline.

There is a rigorous process that National Registration Boards must follow to amend registration standards and guidelines. The process is governed by the Health Council (formerly known as the COAG Health Council) and any amendments must be approved by the Minister for Health from each jurisdiction. The Ministerial Council may, at any time, ask a National Board to review an approved or proposed registration standard for the health profession for which the National Board is established. The registration standards and guidelines are published online under the relevant sections on the respective Board's website.

- Optometry Board of Australia – https://www.optometryboard.gov.au.
- Podiatry Board of Australia – https://www.podiatryboard.gov.au.

This potential breach of the fundamental legislative principle is considered justified as it will support national consistency in the authorised scope of medicines dealings for optometrists and podiatrists and makes it clear which version of the guidelines and standards these practitioners are authorised to use.

Fundamental legislative principles not contained in Legislative Standards Act 1992

Offences

The offences and penalty amounts contained in the Medicines Regulation are generally consistent with similar offences and penalty amounts contained in the Health (Drugs and Poisons) Regulation and Health Regulation, with the exception of the new clauses and subsequent offences in relation to electronic prescription management systems.

The high penalty levels are justifiable given the level of potential harm to people and the environment that can be caused by mistakes with, or misuse of, medicines. The remaining offence provisions and corresponding maximum penalties have been reviewed and the penalties are proportionate to the seriousness of the offences.

Electronic prescription management systems

Unlike a paper prescription prepared and signed in handwriting by a prescriber, the making of an electronic prescription is not solely in control of the prescriber. Electronic prescription management systems are software systems used to prepare, record, transmit electronic prescriptions and to dispense and record the dispensing of electronic prescription as well as the people who operate and use the software.

To ensure only authorised person prescribe or dispense electronic prescriptions, that the prescription is unaltered and that the integrity and retrievability of the records is maintained, it is necessary to purchase a software system with the required functionality (as defined by nationally agreed conformance requirements) and to implement it in a way that gives effect to that functionality.

An individual prescriber or dispenser is not always the person responsible for purchasing and implementing the system, nor is the day-to-day administration of the system, such as granting system access to new users or removing access when users leave, performed by an individual prescriber or dispenser yet these functions are critical for information security and to ensure the integrity of the electronic prescription. It is also necessary maintain the information security and record integrity for the system by implementing software updates, security patches and backup procedures for record.

There are a number of offences which relate to the electronic prescription management system, including:

- Clause 185(1) (Appointments for managing system) provides it is an offence if the head of an entity fails to appoint, in writing, an appropriately qualified person (a *system manager*) to be responsible for establishment and operation of the entity's electronic prescription management system, unless the head has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.
- Clause 185(2) (Appointments for managing system) provides it is an offence if the system manager of an entity's electronic prescription management system fails to appoint, in writing, one or mor appropriately qualified persons (each a *system administrator*) to be responsible for the administration and technical maintenance of the system, unless the manager has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.
- Clause 185(3) (Appointments for managing system) provides it is an offence if the system manager fails to record and keep the name and contact information for each person appointed under subsection (2). The offence carries a maximum penalty of 80 penalty units.
- Clause 185(4) (Appointments for managing system) provides it is an offence if the person in charge of the entity fails to take all reasonable steps to ensure each person appointed under subsection (1) or (2) is advised, in writing, or the provisions applying to the person under this part. The offence carries a maximum penalty of 80 penalty units.

- Clause 186 (System must comply with departmental standard) provides it is an offence if the system manager of an entity's electronic prescription management system fails to take all reasonable steps to ensure the system complies with the *Requirements for an electronic prescription management system* departmental standard. This standard specifies the national conformance requirements. The offence carries a maximum penalty of 80 penalty units.
- Clause 187 (Security measures required for system) provides it is an offence if the system manager of an entity's electronic prescription management system fails to take all reasonable steps to ensure security measures are embedded in the system to prevent a person who is not approved to use the system from accessing or using the system, monitor any breaches of the system or impacts on the integrity of the system and keep entries made in the system for at least two years after each entry is created. The offence carries a maximum penalty of 80 penalty units.
- Clause 188(1) (Giving access to the system) provides it is an offence if a system administrator of an entity's electronic prescription management system gives access to the system unless the administrator reasonably believes the access is necessary for the person to perform the person's role or function for the entity and the person has appropriate authorisation under the Medicines and Poisons Act to use the system to perform the person's role or function for the entity. The offence carries a maximum penalty of 80 penalty units.
- Clause 188(3) (Giving access to the system) provides it is an offence if the system administrator gives each approved user more than one secure system identifier for the electronic prescription management system. The offence carries a maximum penalty of 80 penalty units.
- Clause 189(2) (Cancelling access to the system) provides it is an offence if a system administrator of an entity's electronic prescription management system becomes aware that an approved user of the system has stopped performing the role of function for the entity for which the user was given access and the system administrator fails to cancel the approved user's access to the electronic prescription management system, unless the administrator has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.
- Clause 190(2) (Making and keeping records of users) provides it is an offence if a system administrator fails to make and keep a record of any information used to give or cancel a person's access to the electronic prescription management system, including the name of the person and the person's secure system identifier, the date on which the person was given access and the date on which the person's access was cancelled, if applicable, unless the system administrator has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.
- Clause 191 (Maintaining system) provides it is an offence if each system administrator for an entity's electronic prescription management system fails to take all reasonable steps to maintain the security of the system and all the records kept in the system. The offence carries a maximum penalty of 40 penalty units.
- Clause 192(2) (Reporting system breaches for monitored medicines) provides it is an offence if the system manager, or system administrator, of an entity's electronic prescription management system, fails to give notice to the chief executive within five business days after the incident, if they become aware that the system may have been unlawfully accessed or used to obtain a monitored medicine, unless the manager or administrator has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

- Clause 193 (Protecting secure system identifiers) provides it is an offence if an approved user of an entity's electronic prescription management system fails to take all reasonable steps to keep a secure system identifier given to the user secure from access by another person. The offence carries a maximum penalty of 20 penalty units. Examples of reasonable steps include, using a strong password for the person's secure system identifier or locking a device that can be used to access an electronic prescription management system.

These penalties are justified due to the seriousness of ensuring the security of the electronic prescription management system is maintained. Establishing and controlling the system correctly is crucial for information security and privacy and reduces the risks to public health and safety of unauthorised persons accessing the system to create false prescription or to tamper with prescriptions or records made by an authorised prescriber. Electronic prescription management systems allow for authorised health practitioners to prescribe electronically, should this system be established or controlled incorrectly, it could allow for an unauthorised person to fraudulently prescribe regulated substances for themselves or others. The offences apply to the persons managing and administering the systems rather that placing an obligation on a prescriber or dispenser for matters beyond their control as is the case for offences with similar penalties related to electronic prescriptions under the Health (Drugs and Poisons) Regulation.

The penalties are further justified due to the serious consequences if the system does not comply with the listed requirements. For example, the system manager may be responsible for how the system works securely across a health practice where a number of doctors can have access to the system. The system manager will need to be aware of how the system is being used by the doctors and ensure that all doctors using the system are adequately informed of the policies. They will also need to add or remove doctors from the system as required.

Reporting any breaches of the electronic medication management system is necessary so that Queensland Health can take the necessary compliance measures, alert the Australian Digital Health Agency of breaches to the systems used by prescribers across Australia or release statements of warning if required to prevent risks to the community.

<u>Establishing stores and S8 safes, managing S8 safes and using stores and S8 safes</u>

The high illicit value of S8 medicines means that the risk of diversion is significant, requiring sound and comprehensive security arrangements for their storage and records accounting for the movement and use of these medicines, The necessary security arrangements involve implementing a range of measures, including: controls on the physical site, the infrastructure, the people who may deal with the S8 medicines, the procedures for granting access and record-keeping, which together seek to deter, delay and allow timely detection of unauthorised removal of, or interference with, stored S8 medicines.

All medicines can degrade or become unfit for their intended use if not stored appropriately. Therefore, a medicine store, including an S8 safe, must also be set up in a way that ensures that medicines are being stored according to the manufacturer's recommendations. Further, the harm associated with unintentional poisoning with a medicine can be severe so all medicines must be stored out of reach of the public.

There are a number of offences which relate to the establishment of stores and S8 safes, managing S8 safes and using stores and S8 safes, including:

- Clause 196(2) (Appointing establishers and managers) provides it is an offence if the person in charge of the shared clinic fails to appoint, in writing, an appropriately qualified person to be responsible for establishing and maintaining an S8 safe for stock of any S8 medicines kept at the place and a medicine store for stock of any other medicines kept at the clinic. The offence carries a maximum penalty of 40 penalty units.
- Clause 196(3) (Appointing establishers and managers) provides it is an offence if the person in charge of a shared clinic fails to appoint, in writing, an appropriately qualified person to be a manager of the S8 safe or medicine store at the clinic. The offence carries a maximum penalty of 40 penalty units.
- Clause 196(4) (Appointing establishers and managers) provides it is an offence if the person in charge of the shared clinic fails to take all reasonable steps to ensure that each person appointed under subsection (2) or (3) is advised, in writing, of the provisions applying to the person in this part. The offence carries a maximum penalty of 40 penalty units.
- Clause 197(1) (S8 safe must comply with standard) provides it is an offence if an S8 safe establisher for a place fails to establish an S8 safe for S8 medicines in a way that complies with the *Secure storage of S8 medicines* departmental standard. The offence carries a maximum penalty of 40 penalty units.
- Clause 197(2) (S8 safe must comply with standard) provides it is an offence if the S8 safe establisher fails to take all reasonable steps to ensure the S8 safe is established and maintained in a way that keeps the medicines in the safe in accordance with the manufacturer's conditions for the medicines. The offence carries a maximum penalty of 40 penalty units.
- Clause 198(1) (Storage for safety and quality of medicines) provides it is an offence if a medicine store establisher for a place fails to establish and maintain a medicine store for storing S2, S3 and S4 medicines at the place. The offence carries a maximum penalty of 40 penalty units.
- Clause 198(2) (Storage for safety and quality of medicines) provides that it is an offence if the medicine store establisher fails to take all reasonable steps to ensure the medicine store is established and maintained in a way that keeps the medicines in the store in accordance with the manufacturer's conditions for the medicines. The offence carries a maximum penalty of 40 penalty units.
- Clause 198(3) (Storage for safety and quality of medicines) provides it is an offence if the place has stock of pentobarbital, and the medicine store establisher fails to ensure the medicine stored for the pentobarbital is lockable. The offence carries a maximum penalty of 40 penalty units.
- Clause 199(1) (Preventing unauthorised access to medicines) provides it is an offence if a medicine store establisher for a place fails to put each medicine store for a place in an area where the establisher reasonably believes a member of the public could not access the store without being seen by a worker at the place. The offence carries a maximum penalty of 40 penalty units.
- Clause 199(2) (Preventing unauthorised access to medicines) provides it is an offence if pseudoephedrine is possessed at the place and the medicine store is kept in an area that can be seen by members of the public. The offence carries a maximum penalty of 40 penalty units.

- Clause 200(1) (S8 safe establisher giving access to S8 safe) provides it is an offence if an S8 safe establisher fails to give a person a device or an electronic way to open an S8 safe if the person is an authorised user of the S8 medicines kept in the safe at the place and the person is permitted to open the safe under the substance management plan for the relevant institution or community pharmacy if the safe is at an institution or pharmacy. For example, giving a person a key or swipe card that opens the S8 safe or entering a person's biometric information into an electronic system that allows the person to open the safe. The offence carries a maximum penalty of 40 penalty units.
- Clause 200(2) (S8 safe establisher giving access to S8 safe) provides it is an offence if an S8 safe establisher fails to give the device or electronic way to the authorised user who is subject to any restrictions or controls required under the *Secure storage of S8 medicines* departmental standard and the substance management plan for the relevant institution or community pharmacy if the safe is at an institution or pharmacy. The offence carries a maximum penalty of 40 penalty units.
- Clause 201(2) (Requirements for authorised user accessing S8 safe) provides it is an offence if the authorised user of an S8 medicine who has been given a device or an electronic way to open an S8 safe to obtain the medicine fails to keep the device, or access information for the electronic way, secure from access by another person, fails to comply with any restrictions or controls on the device or electronic way given in writing to the user by the safe establisher and fails to close the safe using the device or way when the user is no longer using the safe. The offence carries a maximum penalty of 40 penalty units.
- Clause 202(2) (Taking medicine from S8 safe and medicine store) provides it is an offence if an authorised user of a medicine or an assistant possessing a medicine at a place fails to take the medicine from an S8 safe or a medicine store provided at the place unless the medicine is intended for supply or administration and fails to leave the medicine unattended in an area other than the S8 safe or medicine store provided at the place for the medicine. The offence carries a maximum penalty of 40 penalty units.

These penalties are justified because the provisions set consistent standards for storing medicines that are commensurate with the risks associated with the particular medicine and effectively restrict access to the medicines to people who are authorised to possess them on an as-needed basis.

The offences apply to the person responsible for establishing the store and S8 safe and managing their day-to-day operation, rather than placing obligations on the safe user for matters outside their control. The penalties for requiring an authorised user to store S8 medicines securely or to store pentobarbital in a locked store are justified in that access to medicines associated with abuse, illicit used and self-harm is deterred.

The provisions are similar in nature to the existing regulations however they have been remodelled to provide increased flexibility in storage arrangements and to accommodate advances in technology. The penalties are the same as comparable offences in the Health (Drugs and Poisons) Regulation. The requirement to store pentobarbital in a locked store or safe responds to a Coroner's recommendation.

Medicine registers

A medicine register contributes to the deterrence and timely detection of unauthorised removal of medicines from medicines stores and S8 safes.

The purpose of a medicine register is to provide an accurate record of dealings with medicines and a running tally of the stock of medicines stored at a place at a point in time. To achieve this, provisions in the Medicines Regulation specify who must maintain a medicine register, how the register must be kept and the details of transactions that must be recorded. Provisions are also included that require the regular reconciliation of a medicines register against the stock on hand, and that discrepancies be promptly investigated and reported if not resolved. A medicine register may be in electronic form provided it meets the information security requirements necessary to ensure the integrity of the records. Loss of a medicine registered must be reported as the absence of the records may allow unauthorised removal of medicines from medicines stores or S8 safes to go undetected. S8 medicines are associated with abuse, misuse and illicit use. The retention of records in a medicine register supports the monitoring of compliance with the requirements, the investigation of losses of medicines and may be evidence for enforcement action.

There are a number of offences which relate to medicines registers, including:

- Clause 206 (Manager must make and keep register with safe or store) provides it is an offence if a manager of an S8 safe or approved store fails to take all reasonable steps to make and keep a medicine register for the safe or store and fails to keep the medicine register with, or as close as practicable to, the safe or store. The offence carries a maximum penalty of 40 penalty units.
- Clause 207(1) (Layout of medicine register) provides it is an offence if a manager of an S8 safe or approved store fails to organise the information in the medicine register for the safe or store in a way that shows the stock of medicines in the safe or store at any given time, the dealings in a consecutive order based on the time the dealings occurred and a separate records for each type of medicine. The offence carries a maximum penalty of 40 penalty units.
- Clause 208(2) (Electronic register) provides it is an offence if the manager of an S8 safe or store who keeps a medicine register for the safe or store in an electronic form fails to take all reasonable steps to ensure the electronic register meets a number of specified requirements. The offence carries a maximum penalty of 40 penalty units.
- Clause 208(3) (Electronic register) provides it is an offence if the manager of an S8 safe or store gives a secure system identifier for the electronic register to a person unless the person is an authorised user of the medicines in the S8 safe or approved store or the person is given a secure system identifier that does not permit the person to make confirmed entries in the register, if the person is an assistant dealing with a medicine from the S8 safe or approved store. The offence carries a maximum penalty of 40 penalty units.
- Clause 208(4) (Electronic register) provides it is an offence if the manager of an S8 safe or store fails to make and keep a record of each person's secure system identifier for the electronic register. The offence carries a maximum penalty of 40 penalty units.
- Clause 209(2) (Paper register) provides it is an offence if the manager of an S8 safe or store fails to take all reasonable steps to ensure the medicine register has pages that cannot be removed from the register without detection and that a separate page is used for each type of S8 medicine. The offence carries a maximum penalty of 40 penalty units.
- Clause 210(2) (Replacing paper register) provides it is an offence if the manager of an S8 safe or store fails to replace the original register with a new medicine register, in the new register, record the amount of stock of each type of medicine stated in the last entry of the original register, reconcile the record with the amount of stock physically held in the S8 safe or approved store and keep the original register. The offence carries a maximum penalty of 40 penalty units.

- Clause 211(2) (Information that must be recorded in register) provides it is an offence if as soon as practicable, but no later than 24 hours after the dealing, the authorised user or assistant fails to take all reasonable steps to ensure a record is made in the medicine register of the information mentioned in sections 212 and 213 in relation to the dealing. The offence carries a maximum penalty of 40 penalty units.
- Clause 214(1) (Amending register) provides it is an offence if a person amends the medicine register, unless the person is correcting the register in accordance with subsections (2) and (3) or has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.
- Clause 215 (Keeping secure system identifier secure) provides it is an offence if a person given a secure system identifier for a medicine register kept in electronic form fails to take all reasonable steps to keep the identifier secure from access by another person. The offence carries a maximum penalty of 20 penalty units.
- Clause 216 (Making entries in paper register) provides it is an offence if a person makes an entry in a medicine register kept on paper unless the person is permitted to make the entry by the manager of the S8 safe or approved store to which the register applies, signs the entry, including any corrections to the entry and does not remove or tamper with pages in the register. The offence carries a maximum penalty of 40 penalty units.
- Clause 217(1) (Reconciling with medicines on hand) provides it is an offence if a manager of an S8 safe or approved store to which the medicine register applies fails to reconcile the register at least monthly with the amount of stock of medicines physically held in the safe or store record the date the reconciliation is done in the medicine register. The offence carries a maximum penalty of 40 penalty units.
- Clause 218 (Reporting lost, stolen or destroyed register) provides it is an offence if a medicine register is lost, stolen or destroyed (each an incident) and the manager fails to give notice in the approved form about the incident to the chief executive in the approved form as soon as practicable, but no later than the end of the next business day, after the incident. The offence carries a maximum penalty of 40 penalty units.

The penalties for failing to keep and maintain a medicines register are justified due to the important role these registers play in ensuring the secure management of medicines that are at an increased risk of diversion or misappropriation. Accurate and complete records that show the 'chain of custody' has been maintained and allow an audit to be undertaken are fundamental to the secure management of medicines. The provisions provide clear roles and responsibilities with offences that fall on the appropriate people to be accountable for carrying out activities that are within their sphere of control. The penalties are the same as comparable offences about controlled drug (S8 medicines) registers in the Health (Drugs and Poisons) Regulation.

Recording and keeping information

The requirements for written documents to authorise activities. record keeping and reporting are central to the control of access to medicines and the safe treatment of patients with medicines. Failure of a prescriber to give a written prescription to a pharmacist who has acted on an oral prescription creates an opportunity for lawful access to medicines and potentially patient harm in the event of a misunderstanding between the prescriber and pharmacist. To avoid such miscommunication, it is necessary that the writing of documents that authorise the supply of medicines must be written in English and may only include recognised professional terms so to avoid errors and patient harm.

Obligations requiring the reporting and retention of documents such as prescriptions that are suspected of being fraudulent enables action to be taken to remove the false document from circulation and to address the risk to public health and safety of persons attempting to unlawfully access medicines for illicit purposes. The reporting of lost or stolen medicines also allow action to be taken, for example to investigate diversion of medicines such as pharmaceutical opioids or pseudoephedrine to the illicit drug market or to identify situations which might result in self-harm using stolen medicines.

The retention of records also enables compliance monitoring and informs investigation of breaches of requirements under the Medicines Regulation; such requirements are specified to reduce risks to public health and safety. For example, the retention of medicines registers supports investigation of theft of S8 medicines while record of the system administrator of an electronic prescription management system would support investigation into systematic production of fraudulent electronic prescriptions. Similarly, a requirement that prescription stationery is secure reduces access to the stationery for the production of fraudulent prescriptions.

The Medicines Regulation authorises wholesale representative to provide starter packs of prescription medicines to prescribers on behalf of wholesalers or manufacturers of these medicines. The wholesale representative must keep records and report to the wholesaler or manufacturer about the started packs provided to reduce the risk of unauthorised supply of medicines, to provide for traceability of supply in the event of product recalls and to support monitoring of compliance with the requirements associated with starter packs.

There are a number of offences which relate to recording and keeping information, including:

- Clause 222(2) (Writing paper documents) provides it is an offence if a person writing on paper to comply with a requirement under the Act in relation to a dealing with a medicine, including writing a prescription or purchase order, fails to write in ink, legibly, other than the person's signature and in English or use terms or symbols, including Latin terms, used in the ordinary practice of the person's profession. The offence carries a maximum penalty of 40 penalty units.
- Clause 223(2) (Writing electronic documents) provides it is an offence if a person writing an electronic document to comply with a requirement under the Act in relation to a dealing with a medicine, including writing a prescription or purchase order, fails to write in English or use terms or symbols, including Latin terms, used in the ordinary practice of the person's profession and link or attach the other document to the electronic document, if the entry relates to another document. The offence carries a maximum penalty of 40 penalty units.
- Clause 224(3) (Period and way of keeping records) provides it is an offence if a person responsible for keeping a record to comply with a requirement under the Act in relation to a dealing with a medicine, fails to keep the record two years after the person stops being a system administrator, if the record is the details of a person appointed to be a system administrator under section 185, or two years after the policy or procedure stops having effect, if the record is a policy or procedure made under section 185 or two years after the last entry in the register is made, if the record is a medicine register or otherwise, two years after the record is made. The offence carries a maximum penalty of 40 penalty units.
- Clause 224(4) (Period and way of keeping records) provides it is an offence if for the duration of the period for keeping the record, the person fails to take all reasonable steps to ensure the record is kept in a retrievable form and is kept securely to ensure it can not be altered, obliterated, deleted or removed without detection. The offence carries a maximum penalty of 40 penalty units.

- Clause 224(5) (Period and way of keeping records) provides it is an offence if the record is kept electronically and the person fails to ensure any data stored in the record is secure and tamper-proof in accordance with acceptable industry standards and fails to backup the record regularly during the period for which the record must be kept. The offence carries a maximum penalty of 40 penalty units.
- Clause 225 (Securing prescription stationery) provides it is an offence if a prescriber fails to take all reasonable steps to keep secure any stationery used by the prescriber for prescribing. The offence carries a maximum penalty of 40 penalty units.
- Clause 226(2) (Reporting lost or stolen medicine) provides it is an offence if the person fails to give notice about the incident to the chief executive in the approved form and notify the police service about the incident, as soon as practicable, but no later than the end of the next business day after the incident. The offence carries a maximum penalty of 40 penalty units.
- Clause 227(2) (Reporting failure to give written prescription) provides it is an offence if the person fails to give notice about the prescriber's failure to comply with the relevant provision, to the relevant manager of the prescriber as soon as practicable, if the person is employed by the same entity as the prescribe, otherwise, to the chief executive in the approved form within 48 hours after the end of the period for compliance mentioned in subsection (1). The offence carries a maximum penalty of 20 penalty units.
- Clause 227(4) (Reporting failure to give written prescription) provides it is an offence if a person notifies the relevant manager of a prescriber's failure to comply, and the prescriber does not rectify the failure within 48 hours after the notification, the relevant manager must give notice about the failure to the chief executive in the approved form as soon as practicable. The offence carries a maximum penalty of 20 penalty units.
- Clause 228(2) (Reporting and preventing use of unlawful document) provides it is an offence if the person reasonably believes the document has been unlawfully obtained or made and the person fails to take the following actions:
  - record the name and address of whoever gave the person the document;
  - notify the police service as soon as practicable;
  - give notice to the chief executive in the approved form as soon as practicable, if the document is for a diversion-risk medicine;
  - keep the purchase order or a copy of the order, for a hard copy of a purchase order;
  - process the purchase order in the system in which it is kept to prevent stock of the medicine being supplied, for a purchase order given electronically;
  - keep the prescription or a copy of the prescription , for a paper prescription;
  - process the prescription in the system in which it is kept to prevent the medicine being dispensed or given, for an electronic prescription. The process used must effectively disable the prescription and any repeats to prevent the medicine from being dispensed or given, with a statement in the system that the prescription has been cancelled or not to be dispensed or given.

  The offence carries a maximum penalty of 60 penalty units.

- Clause 229(2) (Marking non-compliant paper prescription) provides it is an offence if the person fails to mark the prescription with a statement that the prescription is cancelled or not to be dispensed or given, the date of marking the prescription, the person's name or signature and the address of the place where the prescription was presented. The offence carries a maximum penalty of 60 penalty units.
- Clause 230(2) (Reporting supply on false prescription or purchase order for diversion-risk medicines) provides it is an offence if the supplier fails to give notice about the incident to the chief executive in the approved form and to the police service no later than 24 hours after becoming aware of the incident. The offence carries a maximum penalty of 60 penalty units.
- Clause 231(2) (Notification of loss or theft) provides it is an offence if the wholesaler fails to report the loss or theft of a diversion-risk medicine that was in the possession of the wholesaler immediately before the loss or theft. The offence carries a maximum penalty of 40 penalty units.
- Clause 231(3) (Notification of loss or theft) provides it is an offence if the report is not made to the police service and to the chief executive in the approved form as soon as practicable and no later than the end of the next business day, after the loss or theft. The offence carries a maximum penalty of 40 penalty units.
- Clause 232(1) (Return of transactions for wholesale representatives) provides it is an offence if a wholesale representative fails to periodically, but at least every three months, give the representative's employer a return complying with subsection (2) about the transactions carried out by the representative for the period. The offence carries a maximum penalty of 40 penalty units.
- Clause 232(3) (Return of transaction for wholesale representatives) provides it is an offence if the wholesale representative fails to keep a copy of each return sent to the representative's employer. The offence carries a maximum penalty of 40 penalty units.
- Clause 232(4) (Return of transaction for wholesale representatives) provides it is an offence if the wholesale representative's employer fails to also keep a copy of the each return received from the wholesale representative. The offence carries a maximum penalty of 40 penalty units.
- Clause 233(2) (Giving chief executive information about particular diversion-risk medicines) provides it is an offence if the pharmacist fails to give notice to the chief executive in the approved form unless the pharmacist has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.

The penalties for failing meet requirements for recording and keeping information and reporting suspected false documents or lost or stolen medicines are justified due to the seriousness of the consequences of medication errors, unauthorised access to medicines and potential harm from access to medicines associated with abuse, misuse and illicit use. The requirements are necessary to achieve the purposes of the Act to ensure health risks are managed and that people possessing, authorising supply of medicines have the competencies to perform these activities safely and are authorised to deal with the medicines. The penalties for these offences are the same as comparable offences in the Health (Drugs and Poisons) Regulation, for example, in that regulation the requirement to write a document in English carries a penalty of 40 penalty units; the penalty for the requirement to mark and cancel non-compliant prescriptions is 60 penalty units; and penalties for wholesale representative failing to report transactions are 40 penalty units.

Miscellaneous offences

The medicines regulation includes particular requirement to ensure that a medicine supplied is fit for purpose, for example, that it has not been contaminated by being supplied in a used container, and to reduces losses of stocks of medicines or unauthorised access during transit. For example, tracking systems can identify circumstances when medicines may be outside the required temperature range or where, during transit a theft may have occurred.

The regulation also includes requirements to prevent inappropriate use of medicines by patients. For example, direct to consumer advertising of prescription medicines has been shown to increase the prescribing of inappropriate treatments to patients who have seen the advertising. The selling of medicines from vending machines does not allow a person access to health professional advice when the person is buying a medicine. Access to particular levels of advice from health professional is central to risk-benefit consideration in the scheduling of medicines in the Poisons Standard.

There are a number of miscellaneous offences, including:

- Clause 219(2) (Systems for tracking stock of medicines) provides it is an offence if the carrier fails to take all reasonable steps to establish a tracking system to track stock of any medicines being delivered by the carrier. The offence carries a maximum penalty of 40 penalty units.
- Clause 220(2) (Safe delivery of stock of S2 or S3 medicines) provides it is an offence if the carrier fails to take all reasonable steps to keep the stock within any temperature limits for the stock notified to the carrier by the person who engaged the carrier to deliver it. The offence carries a maximum penalty of 40 penalty units.
- Clause 220(3) (Safe delivery of stock of S2 or S3 medicines) provides it is an offence if the carrier leaves the stock unattended, other than in a secure area. The offence carries a maximum penalty of 40 penalty units.
- Clause 220(4) (Safe delivery of stock of S2 or S3 medicines) provides it is an offence if a carrier fails to deliver the stock to the street address stated on the packaging for the stock. The offence carries a maximum penalty of 40 penalty units.
- Clause 220(5) (Safe delivery of stock of S2 or S3 medicines) provides it is an offence if the carrier leaves the stock at the street address, unless the carrier obtains a written receipt for the delivery of the stock from the person named on the package for the stock, or an adult acting, or purportedly acting, on behalf of the person at the address. The offence carries a maximum penalty of 40 penalty units.
- Clause 221 (Restriction on used containers) provides it is an offence for a person preparing a medicine for supply to use an immediate container to package the medicine if the person knows the container has previously been used. The offence carries a maximum penalty of 20 penalty units.
- Clause 234(1) (Unlawful advertising of medicines) provides it is an offence if a person advertises, or causes a person to advertise, an S3, S4 or S8 medicine. The offence carries a maximum penalty of 80 penalty units. Subsection (1) does not apply in relation to an advertisement of an S3 medicine listed in Appendix H of the Poisons Standard or an advertisement of an S3, S4 or S8 medicine in a journal, price list or other promotional material that relates only to the therapeutic use of the medicine in the practice or profession or in accordance with the *Price information code of practice*, published by the Therapeutic Goods Administration. The offence carries a maximum penalty of 80 penalty units.

- Clause 235(1) (Offence to install medicine vending machines) provides it is an offence if a person who is the owner or occupier of premises installs a medicine vending machine on the premises. The offence carries a maximum penalty of 30 penalty units.

Requiring carriers to establish tracking systems for medicines is justified due to the extent of transportation of medicines and distances over which medicines are transported, often requiring transfers between carriers. The penalty is justified due to the seriousness of the public health and safety consequences where, for example, vaccines in transit are subjected to an extended period of time outside the required temperature range or where a large quantity of S8 medicines enter the illicit drug market after the medicines are lost in transit.

The penalty for the supply of a medicine in an immediate container that has previously been used is similar to the penalty in the Health Regulation. It is justified due to risk of contamination of the medicine and the risk of poisoning.

The penalty for promoting specific prescription medicines to consumers is similar to the offence and penalty in the Health (Drugs and Poisons) Regulation where the penalty for advertising controlled drugs (S8 medicines) is 80 penalty units. The penalty is justified due to the potential for medication misadventure where a person's treatment is influenced by the advertising of a medicine to a person without the education or training to determine the veracity of the advertised claims.

The penalty for the installation of a vending machine selling medicines is similar to the penalty for the offence in the Health Act and is justified due to the risks mitigated by ensuring access to a health professional to advise on the appropriate use of medicines.

Consultation

Preliminary consultation has taken place since 2014 with stakeholders from a broad range of industries about the new legislative approach for medicines in Queensland.

In late 2018, an indicative version of the Medicines Regulation was included in stakeholder consultation on the draft Medicines and Poisons Bill. The feedback received was used to further refine the framework to meet current industry practices.

External consultation – 27 April to 26 May 2021

On 27 April 2021, an email was sent to more than 2700 stakeholders to advise them that consultation on the Medicines Regulation, Medicines and Poisons (Poisons and Prohibited) Regulation, and Medicines and Poisons (Pest Management Activities) Regulation was open. The email included a link to the Queensland Government's GetInvolved site, directing stakeholders to the consultation packages for each of the draft regulations. Each consultation package included a consultation version of the relevant regulation, a consultation paper to provide an overview, the associated departmental standards and extended practice authorities and guides, with a link to an online survey. Stakeholders were asked to provide feedback to the consultation questions for each of the regulations via an online survey or alternatively a submission. The four-week consultation process closed on 26 May 2021.

The consultation process resulted in 128 survey responses and 54 submissions on the Medicines Regulation and associated departmental standards and extended practice authorities.

Stakeholders who submitted feedback included the Alcohol and Drug Foundation (ADF); Australian College of Nurse Practitioners (ACNP); Australian Medical Association, Queensland (AMAQ); Australian Veterinary Association (AVA); Optometry – Queensland and Northern Territory; Australian Physiotherapist Association; Livestock and animal feed producers; Drug & Alcohol Nurses of Australia (DANA); MIGA Always; Orthoptics Australia; Pharmaceutical Defence Limited; Pharmaceutical Society of Australia; Pharmacy Guild of Australia, Qld Branch; Queensland Nurses & Midwives' Union and nurse practitioner branch; Queensland Farmers Federation; Royal Australian College of General Practitioners Queensland (RACGP-Q)and VIATRIS. Queensland Health also received submissions from individuals, community pharmacies, private health organisations, Statewide clinical groups and Hospital and Health Services.

In general, stakeholders were supportive of the Medicines Regulation and acknowledged the significant work undertaken by Queensland Health in developing the new medicines, poisons, and pest management activities regulatory framework. In particular, the Royal Australian College of General Practitioners (Qld) noted that the Medicines Regulation and the concept of the 'authorised way' make it clear and easy to understand how to carry out authorised activities.

Some stakeholders provided feedback on drafting matters. This feedback was incorporated in the Medicines Regulation where appropriate. Several respondents, including the Australian Veterinary Association, Anglicare Southern Queensland, Drug and Alcohol Nurses Australia, ICON Group Pharmacy Services, Queensland Nurses and Midwives' Union and health clinicians, asked for implementation resources to further clarify the new definitions, categories of medicines, terminology used and the operation of the Act together with the Medicines Regulation and departmental standards. To enable a seamless transition to new medicines legislative scheme, Queensland Health will develop resources for stakeholders to access to facilitate implementation of these changes.

Feedback included proposals to extend the authorisations specified for certain classes of persons with medicines. These matters have been noted and will be considered in future policy reviews about scope of practice for health practitioners.

Medical professional organisations

The AMAQ and RACGP-Q were generally supportive of the new legislation, in particular real-time prescription monitoring. The AMAQ supports the use of extended practice authorities being provided to nurses and noted the expansion of enrolled nurses authorisation in anaesthetic environments being equivalent to anaesthetic technicians. The AMAQ oppose the extended practice authorities for pharmacists involved in the urinary tract infection (UTI) trials and physiotherapists prescribing in emergency departments in public hospitals. The Medicines and Poisons framework translates the existing authorisations and approvals under the Health (Drugs and Poisons) Regulation.

Medicated stockfeed industry

In response to requests for focused consultation from the medicated stockfeed industry, Queensland Health established an informal consultative committee with key stakeholders from the Department of Agriculture and Fisheries and industry (including the veterinary sector and peak representative bodies for pork, chicken and egg production and feed milling). Queensland Health met with this group on a number of occasions to foster an understanding of the policy intent of the legislation, particularly in relation to medicated stockfeed, and resolving

outstanding issues. As a result of these meetings, revisions were made to several clauses of the Medicines Regulation that recognise current industry practice while ensuring that public health and safety and biosecurity objectives are met.

Nursing and Midwifery Board of Australia discontinuation of endorsement for scheduled medicines registered nurses (rural and isolated practice)

Registered nurses who currently hold the Nursing and Midwifery Board of Australia (NMBA) scheduled medicines endorsement and health services in rural and isolated practice areas raised concerns about the requirements in the consultation draft of the extended practice authority – registered nurses. The matters raised by these stakeholders were primarily about the need to include training and qualification requirements to be authorised as an authorised rural and isolated practice registered nurse (RIPRN) and the arrangements for approved health management protocols.

Queensland Health held several meetings with rural and remote clinicians and health services to foster an understanding of the policy intent of the extended practice authority – registered nurses and to resolve outstanding matters. The outcome of these meetings resulted in revisions to the extended practice authority – registered nurses to recognise the two courses currently accredited by the NMBA and include health management protocol requirements comparable to those in the current Drug Therapy Protocol under the Health (Drugs and Poisons) Regulation.

The extended practice authority registered nurses replaces and combines the existing Drug Therapy Protocols for registered nurses under the Health (Drugs and Poisons) Regulation. With the discontinuation of the NMBA scheduled medicines endorsement, the requirements of the extended practice authority registered nurses will enable appropriately qualified registered nurses to continue to supply and administer certain medicines in rural and isolated practice areas.

Pharmacy sector

Given the broad range of impacts of the new legislation on the pharmacy sector, Queensland Health engaged with as any many stakeholders from this sector as possible. To that end, notice of the consultation process was sent by email to every community pharmacy in Queensland as well as to the Pharmacy Guild of Australia, Pharmaceutical Society of Australia, Pharmaceutical Defence Ltd, private hospital pharmacy groups and Directors of Pharmacy for Queensland public hospitals. The consultation process included separate meetings with key stakeholder groups.

Overall, stakeholders commended Queensland Health on the work to modernise the scheme. There was strong support for the introduction of real-time prescription monitoring and for changes that will allow health practitioners to destroy Schedule 8 medicines, however clarification was sought regarding how these changes would be operationalised. The key issues raised by this sector were:

- expansion of the ability for pharmacists to amend/adapt prescriptions;
- enabling pharmacists to maintain continuity of treatment with a medicine by allowing supply of a full pack of a previously prescribed medicine without a prescription in emergency circumstances; and
- whether the limitations on the place of practice for a pharmacist, particularly in relation to administering vaccinations should be retained.

Refinements and improvements were made to the Medicines Regulation based on feedback received. Other changes proposed involve more significant policy shifts and the impact of these proposals on other stakeholders has not been fully considered. As a result, these proposals have not been included in the Medicines Regulation but may be considered in the future.

Substance management plans

The matters raised by stakeholders about the substance management plan (SMP) standard and guideline were to seek clarification on the expectations of Queensland Health's inspectors, if audited, and the requirements for entities with multiple sites/facilities. The primary concern raised was for resources to be available to provide advice about 'regulated places'. Positive feedback was also received on not having a prescribed format for the SMP to constrain arrangements for different types of 'regulated places'. Queensland Health will make available resources to provide context specific guidance for different types of 'regulated places' to assist them to develop their substance management plans over the 12-month transition period.

The QNMU raised a number of concerns about substance management plans. In particular, QNMU considers the requirements of the Act, Medicines Regulation and departmental standard would allow aged care workers to assist residential aged care facility residents with their medicines. The QNMU is of the view that only registered nurses and supervised enrolled nurses should be able to assist residential aged care residents with their medicines. The departmental standard is not an authorising instrument, rather it is a standard for the content of a risk management plan and specifies the required outcome for the plan that 'medicines may only be administered by persons who are competent to administer medicines in the circumstances'.

Preventing unregistered care workers from administering dispensed medicines in aged care facilities would be a significant change to current practice. This change would require extensive consultation with the aged care sector and a national approach agreed with the Commonwealth as the regulator and funder of aged care services.

Office of Best Practice Regulation

The Office of Best Practice Regulation assessed the entire medicines and poisons regulatory framework, in accordance with the *Queensland Government Guide to Better Regulation* and advised that no further regulatory impact analysis was required on the basis that the proposal is unlikely to lead to significant adverse impacts and should reduce overall regulatory requirements.

Notes on provisions

Chapter 1 Introduction

Part 1 Preliminary

Short title

Clause 1 states that the short title of the regulation is the *Medicines and Poisons (Medicines) Regulation 2021*.

Commencement

Clause 2 states that this regulation commences on 27 September 2021.

Application of regulation

Clause 3 provides that this regulation applies in relation to a regulated activity that is a dealing with a medicine.

The *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021* applies in relation to particular dealings with poisons and prohibited substances. The *Medicines and Poisons (Pest Management Activities) Regulation 2021* applies in relation to pest management activities.

Part 2 Interpretation

Definitions

Clause 4 provides that the dictionary in schedule 22 defines particular words used in this regulation.

References to registration under Health Practitioner Regulation National Law

Clause 5 provides that where a provision of this regulation refers to a person registered under the Health Practitioner Regulation National Law to practise in a profession, it also includes a person with provisional registration or limited registration for the profession, but does not include a person registered to practise in the profession only as a student or for training purposes.

Clause 5(2) provides that subsection (1) does not apply in relation to the enrolled nurses division of the nursing profession or the pharmacy profession.

Part 3 Exemptions

Exemption for national blood supply arrangements—Act, s 7

Clause 6 provides that for section 7(1) (Exemption for low-risk activities) of the *Medicines and Poisons Act 2019*, each of the following activities, with the following substances is prescribed:

- buying a listed blood product using the national blood tracking system;
- possessing a listed blood product obtained using the national blood tracking system;

- supplying, by wholesale, stock of a listed blood product using the national blood tracking system;
- dispensing a listed blood product on a prescription made in the national blood tracking system;
- giving a treatment dose of a listed blood product on a prescription made in the national blood tracking system;
- prescribing a listed blood product using the national blood tracking system;
- administering a listed blood product on a prescription made in the national blood tracking system.

Clause 6(2) provides that the activity is prescribed only to the extent:

- the activity is carried out by a person performing a function under the national blood supply arrangements; and
- for subsection (1)(d) or (1)(e), the listed blood product is labelled in compliance with:
    - the labelling requirements stated in the Poisons Standard, Appendix L; or
    - if the listed blood product has been granted a labelling exemption by an appropriate authority under the Poisons Standard, section 1.5.5, any labelling requirements imposed by the appropriate authority for the product.

Clause 6(3) provides for this section definitions of *listed blood product*, *National Blood Agreement*, *national blood supply arrangements*, *national blood tracking system* and *national product price list*.

Part 4 Approval of documents

Extended practice authorities—Act, s 232

Clause 7 provides that for section 232(4) (Making extended practice authorities) of the Medicines and Poisons Act, each extended practice authority mentioned in schedule 1, part 1, is approved. Section 232(4) of the Medicines and Poisons Act provides that an extended practice authority takes effect on the day it is approved by regulation or a later day stated in the authority. Section 54 (Authorisation of prescribed classes of persons) of the Medicines and Poisons Act provides that regulated activities with regulated substances may be prescribed for a class of person by reference to extended practice authorities.

Clause 7(2) provides that a reference in this regulation to an extended practice authority by its name is a reference to the extended practice authority mentioned in schedule 1, part 1 with that name and with the version number mentioned opposite that name. The regulation will be updated to reflect the name and version number of the extended practice authority each time a new version is made. A copy of the updated extended practice authority will be tabled in the Legislative Assembly as extrinsic material each time the regulation is remade, to reflect the changed document and to ensure appropriate Parliamentary oversight of the document.

Departmental standards—Act, s 233

Clause 8 provides that for section 233(4) (Making departmental standards) of the Medicines and Poisons Act, each departmental standard mentioned in schedule 1, part 2, is approved. Section 233(4) of the Medicines and Poisons Act provides that a departmental standard takes effect on the day it is approved by regulation, or a later day stated in the standard.

Clause 8(2) provides that a reference in this regulation to a departmental standard by its name is a reference to the standard mentioned in schedule 1, part 2 with that name and with the version number mentioned opposite that name. The regulation will be updated to reflect the name and date of the departmental standard each time a new version is made. A copy of the updated departmental standard will be tabled in the Legislative Assembly as extrinsic material each time the regulation is remade, to reflect the changed document and to ensure appropriate Parliamentary oversight of the document.

Part 5 Categories of medicines

Restricted medicines

Clause 9 provides that a medicine mentioned in schedule 2, part 1 is a ***restricted medicine***.

Restricted medicines are medicines included in a product on the Australian Register of Therapeutic Goods maintained under the *Therapeutic Goods Act 1989* (Cwlth). Restricted medicines are schedule 4 (S4) and schedule 8 (S8) medicines identified as having specific health risks that may be mitigated by restricting availability through specialist medical practitioners. Restricted medicines, which can only be prescribed by a certain class of specialist medical practitioner or an individual who holds a prescribing approval, include the following isotretinoin (oral retinoid), clozapine (psychiatric medication), amfetamines (stimulant) or methadone when used for treating opioid dependency.

High-risk medicines—Act, s 40

Clause 10 provides that for section 40(3) (Offences for self-prescribing or self-administering high-risk medicines) of the Medicines and Poisons Act, a medicine mentioned in schedule 2, part 2 is prescribed to be a ***high-risk medicine***.

High-risk medicines are all S8 medicines and some specified S4 medicines (such as codeine, tramadol and all benzodiazepines), which have a higher potential for harm, impairment, misuse, abuse and dependence and are prescribed for recognised therapeutic purposes.

Diversion-risk medicines—Act, sch 1

Clause 11 provides that for schedule 1 (Dictionary) of the Medicines and Poisons Act, a medicine mentioned in schedule 2, part 3 is prescribed to be a ***diversion-risk medicine***.

Diversion-risk medicines are medicines that may have value as an illicit substance, such as drugs of dependence, anabolic steroids, peptides or pseudoephedrine products.

Monitored medicines—Act, sch 1

Clause 12 provides for schedule 1 (Dictionary) of the Medicines and Poisons Act, a medicine mentioned in schedule 2, part 4 is prescribed to be a ***monitored medicine***.

Monitored medicines are medicines identified by Queensland Health as potentially presenting a high risk of harm to patients as a result of misuse, abuse, diversion, substance use disorder and/or overdose. Monitored medicines include all S8 medicines and some specified S4 medicines (such as codeine, tramadol and all benzodiazepines).

Chapter 2 Authorisations

Part 1 Approved persons

Approved persons—Act, s 54

Clause 13 provides that for section 54(1) (Authorisation of prescribed classes of persons) of the Medicines and Poisons Act, a class of persons stated in a relevant schedule is prescribed for the dealing with the medicine stated in the table in the schedule for the class of persons to the extent the dealing is carried out by a person acting as a member of the class of persons and within the scope of the dealing, if any.

Clause 13(2) provides for this section definitions of *relevant schedule* and *scope*.

For example, a class of person who is an Aboriginal and Torres Strait Islander health practitioner employed by a relevant health service and practicing in an isolated practice area is authorised to give a purchase order only for medicines mentioned in the *Aboriginal and Torres Strait Islander health practitioners* extended practice authority. Similarly, a pharmacy employee at a pharmacy is authorised to give a purchase order only to the extent of the scope of the dealing, that is, if the pharmacy assistant is under the direct supervision of a pharmacist and gives a purchase order for stock of medicines for the pharmacy to be delivered to the pharmacy.

Part 2 Prescribed classes of general approvals

Classes of general approvals—Act, s 68

Clause 14 provides that for section 68(2) (What is a *general approval*) of the Medicines and Poisons Act, this part prescribes classes of general approval.

Acute health conditions at isolated sites

Clause 15 provides that a ***general approval (acute health conditions at isolated sites)*** is prescribed for the classes of persons mentioned in column 1 of the table in schedule 16, section 2 for carrying out the dealings with the medicines mentioned opposite in column 2, for the purpose of treating acute health conditions.

Emergency first aid

Clause 16 provides that a ***general approval (emergency first aid)*** is prescribed for the classes of persons mentioned in column 1 of the table in schedule 16, section 4 for carrying out dealings with the medicines mentioned opposite in column 2, for the purpose of providing first aid in an emergency.

Emergency management of animals

Clause 17 provides that a ***general approval (emergency management of animals)*** is prescribed for the classes of persons mentioned in column 1 of the table in schedule 16, section 6 for carrying out dealings with the medicines mentioned opposite in column 2, for the purpose of the emergency care and treatment of sick, injured or orphaned animals.

Chapter 3 Standard conditions for substance authorities

Part 1 Preliminary

Application of chapter—Act, s 70

Clause 18 provides that for section 70(1)(a) (Conditions) of the Medicines and Poisons Act, this chapter prescribes standard conditions applying in relation to substance authorities authorising dealings with medicines.

Part 2 Manufacturing licences

Division 1 Conditions for all manufacturers

Application of division

Clause 19 provides that this division applies in relation to a manufacturing licence authorising the manufacture of a medicine.

Manufacturing must be supervised

Clause 20 provides that the holder of a manufacturing licence must appoint an appropriately qualified person to supervise manufacturing under the licence.

Clause 20 (2) provides that the holder must take all reasonable steps to ensure the medicine is manufactured under the supervision of the person mentioned in subsection (1).

Quality control

Clause 21 provides that the holder of a manufacturing licence must take all reasonable steps to ensure a medicine manufactured under the licence is fit for its intended use and free from contamination.

Clause 21(2) provides that the holder is taken to have complied with subsection (1), if the holder complies with a code, guideline, standard or quality assurance scheme that is recognised for promoting best practice in the industry for the type of manufacturing authorised under the licence. For example, the Pharmaceutical Inspection Co-operation Scheme's *Guide to good practice for the preparation of medicinal products in healthcare establishments* or the *Australian Code of Good Manufacturing Practice for the Feed Milling Industry*.

Open for inspection

Clause 22 provides that the holder of a manufacturing licence must keep an authorised place stated in the licence open for inspection during the times the place is open for carrying on business or otherwise open for entry.

Division 2 Particular conditions for manufacturers of medicated feed

Application of division

Clause 23 provides that this division applies in relation to a manufacturing licence authorising the supply of medicated feed to aa person who is a farmer of a group of animals.

Supply on prescriptions

Clause 24 provides that the holder of a manufacturing licence must not supply the medicated feed to a farmer of a group of animals unless the farmer has a written prescription for the feed from a veterinary surgeon.

Manufacturer must give and keep supply records

Clause 25 provides that when supplying medicated feed to a farmer of a group of animals, the holder of a manufacturing licence must give the farmer a document stating the following information:

- a unique identifier for the document;
- the date of the supply;
- the name and address of the farmer;
- the unique identifier on the prescription held by the farmer;
- details about the form, strength and amount of the feed supplied.

Clause 25(2) provides that if the medicated feed is to be delivered to the farmer, the address mentioned in subsection (1)(c) must be the street address for the delivery of the feed.

Clause 25(3) provides that the holder must keep a copy of the document or a record of the details contained in the document and give a copy of the document to the veterinary surgeon who prescribed the feed, if asked to do so by the veterinary surgeon.

Delivery of medicated feed

Clause 26 provides this section applies if the holder of a manufacturing licence delivers, or arranges for delivery of, medicated feed to a farmer of a group of animals.

Clause 26(2) provides that the holder must ensure a notice stating the name of the farmer and the street address for delivery is attached to the medicated feed or if it is not reasonably practicable to attach the notice to the feed, that it accompanies the medicated feed.

Part 3 Retail licences

Selling within 25km from pharmacy

Clause 27 provides that the holder of an S2 retail licence must not sell an S2 medicine under the licence within 25km in a direct route from a pharmacy.

Clause 27(2) provides that subsection (3) applies if, during the term of the S2 retail licence, a new pharmacy opens within 25km in a direct route from an authorised place stated in the licence.

Clause 27(3) provides for a period of up to six months from the day the pharmacy opens, the holder may sell any S2 medicines bought under the licence before the pharmacy opened.

Clause 27(4) provides for this section a definition of *direct route*.

Selling S2 medicines in manufacturer's pack

Clause 28 provides that the holder of an S2 retail licence must not sell an S2 medicine other than in a manufacturer's pack.

Open for inspection

Clause 29 provides that the holder of an S2 retail licence must keep an authorised place stated in the licence open for inspection during the times the place is open for carrying on business or otherwise open for entry.

Part 4 Prescribing approvals for approved opioids

Application of part

Clause 30 provides this part applies in relation to a prescribing approval authorising a dealing with an approved opioid under an opioid treatment program.

Notification when starting and stopping treatment

Clause 31 provides that if the holder of a prescribing approval starts treating a patient under an opioid treatment program, the holder must ensure notice is given to the chief executive in the approved form.

Clause 31(2) provides that the notice must given to the chief executive as soon as practicable, but no later than the end of the next business day, after the treatment starts.

Clause 31(3) provides that if the holder stops treating the patient, the holder must ensure notice is given to the chief executive in the approved form, as soon as practicable, but no later than three business days, after the treatment stops.

Part 5 General approvals

Division 1 Acute health conditions at isolated sites

Appropriately qualified practitioners

Clause 32 provides that the holder of a general approval (acute health conditions at isolated sites) must appoint a medical practitioner or nurse practitioner who is appropriately qualified to oversee the dealings authorised under the approval.

Practitioners must be contactable

Clause 33 provides that the holder of a general approval (acute health conditions at isolated sites) must take all reasonable steps to ensure a medical practitioner or nurse practitioner is available to be contacted when a dealing is carried out under the approval.

Division 2 Emergency first aid

Appropriately qualified practitioners

Clause 34 provides that the holder of a general approval (emergency first aid) must appoint a medical practitioner or nurse practitioner who is appropriately qualified to oversee the dealing authorised under the approval.

Notification about events

Clause 35 provides that the holder of a general approval (emergency first aid) must give notice to the chief executive if a registered nurse, first aid provider or paramedic intends to attend an event under the approval.

Clause 35(2) provides that the notice must be given in the approved form no less than two business days before the event happens.

Practitioners must be contactable

Clause 36 provides that the holder of the general approval (emergency first aid) must take all reasonable steps to ensure a medical practitioner or nurse practitioner is available to be contacted when a registered nurse, first aid provider or paramedic is attending an event or site under the approval.

Division 3 Emergency management of animals

Appropriately qualified veterinary surgeons

Clause 37 provides that the holder of a general approval (emergency management of animals) must appoint a veterinary surgeon who is appropriately qualified to oversee the dealing authorised under the approval.

Veterinary surgeons to be contactable

Clause 38 provides that the holder of a general approval (emergency management of animals) must ensure a veterinary surgeon is available to be contacted when a person is likely to be caring for or treating sick, injured or orphaned animals under the approval.

Part 6 All substance authorities

Application of part

Clause 39 provides that this part applies in relation to all substance authorities authorising dealings with medicines.

Keeping invoices

Clause 40 provides that the holder of a substance authority must keep any invoice received for any medicine supplied to the holder for a dealing under the authority.

Availability of records for inspection

Clause 41 provides that the holder of a substance authority must ensure any records required to be kept under the Medicines and Poisons Act in relation to an authorised place stated in the authority are available for inspection at the place.

Clause 41(2) provides that if the records are kept electronically, the holder must ensure the records for each authorised place stated in the authority are available for inspection from the primary place of business of the holder.

Notification of particular changes affecting authority

Clause 42 provides that the holder of a substance authority must give notice to the chief executive in the approved form, if any of the following changes are proposed by the holder:

- a change to an authorised place stated in the authority;
- a change to a relevant person stated in the authority;
- if the substance authority is a manufacturing licence, a change to the person who is appointed to supervise manufacturing under the licence;
- another change to the holder's circumstances that substantially affects the holder's ability to comply with a condition of the substance authority.

Clause 42(2) provides that the notice must be given as soon as practicable, but no later than five business days, after the change of circumstances happens.

Stopping dealing

Clause 43 provides that this section applies if a holder of a substance authority proposes to stop carrying out a dealing with a medicine under the substance authority.

Clause 43(2) provides that the holder of the substance authority must give the chief executive a notice in the approved form stating the following information:

- the day the dealing is proposed to stop;
- the amount of medicine that is likely to be unused on the day mentioned in paragraph (a), if any;
- how the holder proposes to deal with any unused medicine.

Chapter 4 General requirements for dealings

Part 1 Preliminary

Application of chapter—Act, s 91

Clause 44 provides that for section 91(1) (Requirements may be prescribed) of the Medicines and Poisons Act, this chapter prescribes requirements, for a person authorised under section 54(4) (Authorisation of prescribed classes of persons) or 62 (Authorisation under substance authority) of the Medicines and Poisons Act in relation to carrying out the dealing.

Clause 44(2) provides that this chapter applies to the person in addition to chapter 5, unless otherwise stated. The general requirements for dealings in this chapter do not apply to persons authorised under an emergency order.

Part 2 Manufacturing by compounding

Application of part

Clause 45 provides that this part applies to a person who is authorised to manufacture a medicine by compounding it.

Compounded medicine fit for use

Clause 46 provides that a person compounding a medicine must take all reasonable steps to ensure the medicine is fit for its intended use and free from contamination. For example, that a compounded medicine contains the required amount of the ingredients or that a medicine intended to be injected is sterile and free from microbial contamination.

Compounding for patients under departmental standard

Clause 47 provides that a person compounding a medicine for a patient must compound the medicine in accordance with the *Compounding* departmental standard.

Part 3 Buying by giving purchase orders

Application of part

Clause 48 provides that this part applies to a person (the ***buyer***) who is authorised to give a purchase order for stock of an S4 or S8 medicine.

Definitions for part

Clause 49 provides for this part definitions of *buyer* and *supplier*.

When a purchase order must be given

Clause 50 provides that a buyer must give a supplier of an S4 or S8 medicine a purchase order before or at the time of supply of the stock.

Nature of purchase order

Clause 51 provides that a buyer must make a written purchase order for stock of an S4 or S8 medicine and send it to the supplier in a way that is reasonably likely to:

- minimise fraud or tampering; and
- if sent electronically, be transmitted securely.

Clause 51(2) provides that the buyer must sign the purchase order or use the buyer's unique identifier in the purchase order.

Clause 51(3) provides that the buyer must not amend the purchase order once it is made without clearly showing the amendments in the purchase order.

Information for inclusion in purchase order

Clause 52 provides that a buyer must state the following information in a purchase order for stock of an S4 or S8 medicine:

- a unique identifier for the purchase order;
- the date the purchase order is made;
- the name and address of the buyer;
- if stock is to be delivered, the street address of the buyer, an authorised place at which the buyer is authorised to possess the stock or if the stock is to be delivered to a hospital, the name of the hospital;
- the details of the buyer's authorisation to give the purchase order;
- the name, form and strength of the stock sought;
- the amount of stock sought.

Buyer acknowledging receipt of stock of S8 medicine

Clause 53 provides that this section applies in relation to stock of an S8 medicine.

Clause 53(2) provides that on the day a buyer receives the stock, the buyer must sign the purchase order for the stock or another notice to confirm the buyer has received all of the stock, or if the stock is delivered to the buyer, ensure a signed notice is sent to the supplier to confirm the buyer has received all of the stock.

Clause 53(3) provides that if the stock is bought for a pharmacy, a pharmacist from the pharmacy must sign the purchase order or notice confirming receipt of the stock.

Clause 53(4) provides that the buyer must keep a copy of the notice sent to the supplier under subsection (2)(b). Section 224 provides details about keeping records and chapter 8, part 2, division 3 provides details about recording stock received in a medicine register.

Part 4 Supplying stock

Division 1 Preliminary

Application of part

Clause 54 provides that this part applies to a person who is authorised (a ***supplier***) to supply stock of a medicine.

Clause 54(2) provides that this part applies in relation to the supply of stock of a medicine for:

- retail on-sale; or
- use by, or in connection with, carrying on a business, industry, profession or trade.

Clause 54(3) provides that this part does not apply in relation to the supply of medicated feed to a farmer of a group of animals.

Definitions for part

Clause 55 provides for this part definitions of *buyer* and *supplier*.

Division 2 Supplying in appropriate circumstances

Supply of S4 or S8 medicine

Clause 56 provides that this section applies in relation to stock of an S4 or S8 medicine.

Clause 56(2) provides that a supplier may not supply the stock to a buyer unless:

- the supplier reasonably believes that the buyer is authorised under the Medicines and Poisons Act to give a purchase order or otherwise buy the stock or is permitted under a corresponding law or another law to obtain the stock; and
- the supplier obtains a compliant purchase order for the stock from the buyer.

Clause 56(3) provides that if the buyer is the master of a ship mentioned in schedule 13, section 19, the supplier must not supply the stock unless the purchase order is also signed by a medical practitioner.

Clause 56(4) provides that subsection (3) does not apply if the stock is required to be kept on the ship under another law.

Clause 56(5) provides for this section a definition of *compliant purchase order*.

Supply of S2 or S3 medicine for authorised facility

Clause 57 provides that this section applies in relation to stock of an S2 or S3 medicine sought by a buyer for an authorised facility.

Clause 57(2) provides that the supplier must not supply the stock to the buyer unless:

- the supplier reasonably believes the buyer is permitted by the buyer's employer to buy the stock for the authorised facility;
- the supplier reasonably believes the buyer has a reasonable need for the stock, and the amount of stock sought, for the facility;
- the supplier receives a purchase order for the stock signed by the buyer; and
- if the stock is to be delivered, the supplier obtains a street address for delivery of the stock.

Clause 57(3) provides for this section a definition of *authorised facility*.

Supply of S2 or S3 medicine for professional practice

Clause 58 provides that this section applies in relation to stock of an S2 or S3 medicine sought by a buyer for practising the buyer's profession, other than at an authorised facility under section 57.

Clause 58(2) provides that a supplier must not supply the stock to a buyer unless:

- the supplier reasonably believes the buyer is authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to administer the medicine without a prescription; and
- the supplier reasonably believes the buyer has a reasonable need for the stock, and the amount of stock sought; and
- the supplier receives a purchase order for the stock signed by the buyer; and
- if the stock is toto be delivered, the supplier obtains a street address for delivery of the stock.

Supply of S2 and S3 medicines to manufacturers, wholesalers or retailers

Clause 59 provides that this section applies in relation to stock of an S2 or S3 medicine sought by a buyer for manufacture or on-sale, other than at an authorised facility under section 57.

Clause 59(2) provides that a supplier must not supply the stock to a buyer unless:

- the supplier reasonably believes the buyer is authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to manufacture or sell the medicine;
- the supplier receives a purchase order for the stock signed by the buyer; and
- if the stock is to be delivered, the supplier obtains a street address for delivery of the stock.

When supply is not otherwise permitted

Clause 60 provides that this section applies in relation to stock of any medicine.

Clause 60(2) provides that a supplier must not supply of a medicine to a buyer if the supplier reasonably suspects the purchase order for the stock has been unlawfully obtained or made, or the purchase order for the stock has been fulfilled or cancelled.

Clause 60(3) provides that the supplier must not supply the stock if the date stated on the purchase order is more than one year before the day on which the stock is proposed to be supplied.

Division 3 Documentation for supply

Supplier to give invoice or other notice

Clause 61 provides that on the supply of stock of a medicine to a buyer, a supplier must give the buyer an invoice or other notice (a ***notice***) stating the following information:

- a unique identifier for the notice;
- the date of the supply;
- the name and address of the buyer;
- the place to which the stock is delivered, if the stock is to be delivered;
- the details of the buyer's authorisation or permission to buy the stock;
- the name, form and strength of the medicine supplied;
- the amount of stock of the medicine supplied.

Clause 61(2) provides that the supplier must keep a copy of the notice or a record of the details contained in the notice. Section 224 provides details about keeping records.

Completing and keeping purchase orders

Clause 62 provides that when supplying stock of a medicine, a supplier must mark the purchase order for the stock in a way that shows the order has been supplied and, if applicable, delivered and keep a copy of the marked purchase order.

Division 4 Delivery of supplied stock

Application of division

Clause 63 provides that this division applies if a supplier delivers, or arranges delivery of stock of a medicine to a buyer.

Secure packaging for all medicines

Clause 64 provides that a supplier must ensure stock of a medicine is sealed in a securely closed package that is likely to show if the package breaks or anyone tampers with it and it is clearly labelled with the name of the buyer of the medicine and the street address for delivery stated on the purchase order for the stock or otherwise obtained by the supplier.

Additional requirements for packaging S8 medicines

Clause 65 provides that this section applies in relation to stock that includes an S8 medicine.

Clause 65(2) provides that a supplier must ensure the stock is packaged for delivery in a way that does not:

- mix the S8 medicines with anything other than other S8 medicines; or
- label or mark the packaging with a statement indicating it contains an S8 medicine.

For example, delivery drivers should know which packages contain S8 medicines because it is marked on the manifest. These are the packages that the buyer must sign for.

Engaging carrier

Clause 66 provides that a supplier must not engage a carrier to deliver the stock of medicine unless the supplier reasonably considers the carrier is capable of complying with the requirements in part 5, for stock of an S4 or S8 medicine and section 220, for stock of an S2 or S3 medicine.

Clause 66(2) provides that before arranging to deliver the stock with the carrier, the supplier must notify the carrier of the temperature limits for the stock that are recommended by the manufacturer of the medicine.

Delivery to street address

Clause 67 provides that a supplier must deliver, or arrange delivery of, stock of a medicine to the street address stated on the purchase order for the stock or otherwise obtained by the supplier.

Supplier to obtain receipt for stock of S8 medicines

Clause 68 provides this section applies in relation to stock that includes an S8 medicine. Clause 68(2) provides that a supplier must obtain a signed notice acknowledging receipt of the delivery of the stock from the buyer of the stock, or from an adult acting, or purportedly acting, on behalf of the buyer at the buyer's street address.

Clause 68(3) provides that the supplier must keep the notice. Section 224 provides details about keeping records.

Supplier to notify chief executive if no receipt provided

Clause 69 provides that this section applies if a supplier has not received from a buyer a notice of the receipt mentioned in section 53 within five business days after the date of delivery of stock of a medicine.

Clause 69(2) provides that the supplier must give a notice to the chief executive in the approved form about the buyer's failure to confirm receipt.

Division 5 Other requirements

Responsibilities for employees and representatives

Clause 70 provides that a supplier must take all reasonable steps to:

- ensure stock of a medicine is handled for the supplier only by an appropriately qualified adult employed by the supplier; and
- make and keep records showing the details of any stock given to a wholesale representative of the supplier; and
- ensure each wholesale representative of the supplier is aware of requirements under the Medicine and Poisons Act applying to the supplier and representative.

Clause 70(2) provides that this section does not apply to a pharmacist or pharmacy employee dealing with stock at a pharmacy. Chapter 5, parts 2 and 3 deal with requirements that apply to pharmacists and pharmacy employees.

Compliance with code

Clause 71 provides that a supplier must comply with, and take all reasonable steps to ensure a person employed by the supplier complies with the *Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8* published by the Therapeutic Goods Administration and made on 1 April 2011 by the former Commonwealth entity knowns as the National Coordinating Committee on Therapeutic Goods.

Supplying medicines in manufacturer's packs

Clause 72 provides that a supplier must not supply stock of medicine other than in a manufacturer's pack, unless the supplier is authorised to repackage the medicine.

Labels and containers must comply with Poisons Standard or approved alternatives

Clause 73 provides that the supplier must not supply stock of a medicine to the buyer unless the labelling on the medicine complies with the labelling requirements for the medicine stated in part 2, section 1 of the Poisons Standard or if an alternative way for the medicine is approved, or taken to be approved, under section 237, the alternative way.

Clause 73(2) provides that a supplier must not supply stock of a medicine to a buyer unless the container of the medicines complies with the requirements for containers for the medicine stated in part 2, section 2 of the Poisons Standard or if an alternative way for the medicine is approved, or taken to be approved, under section 237, the alternative way.

Clause 73(3) provides that to remove any doubt, it is declared that subsections (1)(a) and (2)(a) do not apply to the supplier to the extent an exemption mentioned in the Poisons Standard applies to the labelling or packaging for the medicine.

Open for inspection

Clause 74 provides that the supplier must keep the authorised place where the stock is kept open for inspection during the times the place is open for carrying on business or otherwise open for entry.

Part 5 Possessing stock for delivery

Application of part

Clause 75 provides that this part applies to a carrier who is authorised to possess an S4 or S8 medicine for the purposes of delivery.

Clause 75(2) provides that this part applies in relation to delivery of stock of an S4 or S8 medicine other than medicated feed.

Storing stock within notified temperature limits

Clause 76 provides that a carrier must take all reasonable steps to keep stock of an S4 or S8 medicine being delivered by the carrier within any temperature limits for the stock notified to the carrier by the person who engaged the carrier to deliver the stock.

Stock not to be left unattended

Clause 77 provides that a carrier must not leave stock of an S4 or S8 medicine unattended, other than in a secure area.

Delivery to person at street address

Clause 78 provides that a carrier must deliver stock of an S4 or S8 medicine to the street address stated on the packaging for the stock.

Clause 78(2) provides that the carrier must not leave the stock at the street address unless the carrier obtains a written receipt for the delivery of the stock from the person named on the package for the stock, or an adult at the address acting, or purportedly acting, on behalf of the person mentioned in paragraph (a).

Part 6 Prescribing medicines

Division 1 Preliminary

Application of part

Clause 79 provides that this part applies to a person (a ***prescriber***) who is authorised to prescribe a medicine.

Clause 79(2) provides that this part does not apply in relation to prescribing an S4 medicine or medicated feed for administration to a group of animals by a farmer of the animals.

Definitions for part

Clause 80 provides for this part definitions of *medication chart prescription* and *national medication chart prescription*.

Division 2 Prescribing generally

Reasonable necessity for therapeutic treatment

Clause 81 provides that a prescriber must not prescribe a medicine for a patient or an animal unless the prescriber assesses the medicine to be reasonably necessary for the therapeutic treatment of the patient or animal.

Division 3 Prescribing for dispensing or giving treatment doses

Subdivision 1 Written prescriptions for patients and animals

Application of subdivision

Clause 82 provides that this subdivision applies if a prescriber makes a written prescription for dispensing or giving a treatment dose of a medicine for a patient or an animal.

Electronic prescription

Clause 83 provides that a prescriber must not an electronic prescription except by using an electronic prescription management system.

Sending prescription electronically

Clause 84 provides that the prescriber must not send a prescription for a medicine to another person using electronic communication except by using an electronic prescription management system in accordance with any requirements for using the system or by sending a digital copy of a paper prescription to a person the prescriber reasonably believes is authorised to dispense or give a treatment dose of the medicine.

Clause 84(2) provides that subsections (3) and (4) apply if the prescriber is sending a digital copy of a paper prescription for a diversion-risk medicine to a person.

Clause 84(3) provides that before sending the digital copy, the prescriber must take all reasonable steps to ensure the following details are written on the paper prescription:

- the way in which the digital copy is being sent;
- the place to which the digital copy is being sent;
- the date on which the digital copy is being sent.

Clause 84(4) provides that after sending the digital copy, the prescriber must send the paper prescription to the person as soon as practicable, but no later than:

- the end of the next business day after the digital copy was sent, if the prescription is for an S8 medicine; or
- otherwise, seven days after the electronic copy was sent.

Generation of paper prescription using computer

Clause 85 provides that this section applies if a prescriber uses a computer to generate a paper prescription.

Clause 85(2) provides that this section does not apply if a prescribing approval held by the prescriber states another way to use a computer to generate a paper prescription.

Clause 85(3) the prescriber must ensure the following things are included on the paper prescription:

- a unique identifier that allows the prescription to be matched to the prescription record for the patient or animal for which the medicine is prescribed;
- space for the prescriber to include a handwritten signature other than a signature printed by the computer;
- either the total number of medicines prescribed or scoring or hatching of any blank space below or above the prescriber's handwritten signature.

Content of written prescription

Clause 86 provides that a prescriber must state the following information on a prescription for a medicine:

- the prescriber's name, or a unique identifier for the prescriber;
- the place where the prescriber usually practices;
- the prescriber's phone number or pager number;
- the prescriber's qualifications;
- the date of the prescription;
- if the medicine is for a patient, the patient's name and address, and for a monitored medicine, the patient's date of birth;
- if the medicine is for an animal, the species of the animal, the name of the animal or another description that identifies the animal, the name and address of the owner or custodian of the animal and a statement that the medicine is for animal treatment only;

- the name of the medicine;
- the form and strength of the medicine;
- how much of the medicine may be dispensed or given, including the number of repeats for the medicine, if any;
- instructions about using the medicine;
- the date for dispensing or giving the medicine, if applicable;
- if the medicine is a restricted medicine, the details of the prescriber's authorisation to prescribe the restricted medicine or for hydroxychloroquine for treating a patient previously prescribed it by another health practitioner, the words 'continuing treatment'.

Clause 86(2) provides that subsections (1)(b), (c) and (d) do not apply if the prescription is a medication chart prescription.

Clause 86(3) provides that the prescriber is taken to comply with this section if the prescription is a national medication chart prescription.

Additional content of written prescription for S8 medicine

Clause 87 provides that this section applies, in addition to section 86, in relation to a written prescription for an S8 medicine.

Clause 87(2) provides that a prescriber must also state the following information on the prescription:

- both words and numbers to describe how much of the medicine may be dispensed or given;
- the minimum number of days, of at least one day, before the medicine may be further dispensed or given on any repeats on the prescription;
- if the S8 medicine is amfetamine, dexamfetamine, lisdexamfetamine or methylphenidate, the words 'specified condition' or words to indicate the condition being treated.

Clause 87(3) provides that the prescriber is taken to comply with subsection (2), if the prescription is a national medication chart prescription.

Clause 87(4) provides that subsection (5) applies if the prescriber is prescribing an approved opioid, other than on a medication chart prescription.

Clause 87(5) provides that the prescriber must also state the following information on the prescription:

- the identifying number of the prescribing approval if the prescriber holds a prescribing approval for prescribing the opioid;
- the name of the place where the approved opioid is to be dispensed or given;
- instructions for how one or more doses of the medicine are to be dispensed or given, including the circumstances, if any, in which the patient may be given a dose;
- the start and end dates for when one or more doses of the opioid are to be dispensed or given.

Clause 87(6) provides that the prescriber may state different forms of a particular type of S8 medicine on the prescription but must not state more than one type of S8 medicine.

Signing written prescription

Clause 88 provides that a prescriber must sign a prescription.

Using printed label on prescription

Clause 89 provides that this section applies if a prescriber uses a printed label to record any information required under section 86 or 87 on a paper prescription.

Clause 89(2) provides that the prescriber must use a printed label that is legible, attach the label to the prescription in a way that can not be easily removed, place the label in a way that clearly connects the information to the patient or animal and sign the label in a way that does not obscure the information on the printed label.

Amending written prescription

Clause 90 provides that a prescriber must not amend a prescription (the ***original prescription***) unless the prescriber made the prescription in the first place.

Clause 90(2) provides that the prescriber must sign and date the amendment handwritten on the original prescription and ensure the amendment is made in a way that does not obscure the content of the original prescription.

Clause 90(3) provides that if the original prescription was printed from a computer, the prescription must be amended on a computer and printed again.

Clause 90(4) provides that if the original prescription was contained in an electronic prescription management system, the prescription must be cancelled in the system and remade if it needs amendment.

Subdivision 2 Prescribing particular medicines for patients

Application of subdivision

Clause 91 provides that this subdivision applies if a prescriber prescribes a medicine for dispensing or giving a treatment dose for a patient.

Oral prescription for S4 or S8 medicine

Clause 92 provides that this section applies in relation to an S4 or S8 medicine.

Clause 92(2) provides that a prescriber must not give an oral prescription for the medicine except to a person whom the prescriber reasonably believes is authorised to dispense or give a treatment dose of the medicine.

Clause 92(3) provides that if the person dispenses or gives the medicine on the oral prescription, the prescriber must give the person a written prescription that confirms the oral prescription.

Clause 92(4) provides that the prescriber must give the written prescription to the person:

- seven days after the oral prescription was given, for an S4 medicine; or
- as soon as practicable, but no later than the end of the next business day, after the oral prescription was given, for an S8 medicine.

Clause 92(5) provides that this section does not apply if the medicine being prescribed is from an RFDS medicine chest kept by the Royal Flying Doctor Service of Australia.

Compliance with monitored medicines standard

Clause 93 provides that this section applies if a prescriber prescribes a monitored medicine, whether orally or by written prescription.

Clause 93(2) provides that the prescriber must prescribe the medicine in accordance with the *Monitored medicines* departmental standard.

Division 4 Prescribing for administration by authorised persons

Subdivision 1 Written prescriptions for patients and animals

Application of subdivision

Clause 94 provides that this subdivision applies if a prescriber is makes a written prescription for administration of a medicine by another person to a patient or an animal.

Content of written prescription

Clause 95 provides that the prescriber must state the following information on a prescription for a medicine:

- the prescriber's name or a unique identifier for the prescriber;
- the date of the prescription;
- if the medicine is to be administered to a patient, the patient's name and address and for a monitored medicine, the patient's date of birth;
- if the medicine is to be administered to an animal, the species of the animal, name of the animal or another description that identifies the animal and the name and address of the owner or custodian of the animal;
- the name of the medicine;
- the form and strength of the medicine;
- how much of the medicine may be administered;
- instructions about using the medicine.

Additional content of written prescription for approved opioid

Clause 96 provides that this section applies, in addition to section 95, if a prescriber is the holder of a prescribing approval and the prescriber is making a written prescription for the administration of an approved opioid, other than on a medication chart prescription.

Clause 96(2) provides that the prescriber must state the following on the prescription:

- the identifying number of the prescribing approval, if any;
- the name of the place where the approved opioid is to be administered;
- instructions for how one or more doses of the opioid are to be administered;
- the start and end dates for when one or more doses of the opioid are to be administered.

Signing written prescription

Clause 97 provides that a prescriber must sign a prescription.

Using printed label

Clause 98 provides that this section applies if a prescriber uses a printed label to record any information required under sections 95 or 96 on paper prescription.

Clause 98(2) provides that the prescriber must use a printed label that is legible, attach the label to the prescription in a way that it can not be easily removed, place the label in a way that clearly connects the information to a patient or an animal and sign the label in a way that does not obscure the information on the printed label.

Subdivision 2 Oral prescriptions for patients and animals

Application of subdivision

Clause 99 provides that this subdivision applies if a prescriber orally prescribes a medicine for administration to a patient or an animal.

Oral prescription

Clause 100 provides that a prescriber must not give an oral prescription for a medicine except to a person whom the prescriber reasonably believes is authorised to administer the medicine.

Clause 100(2) provides that if the medicine is an S8 medicine and the person administers the S8 medicine on the oral prescription, the prescriber must give the person a written prescription that confirms the oral prescription, or sign another record made by the person at the time of the administration on the oral prescription.

Clause 100(3) provides that the written prescription must be given, or the signature made, as soon as practicable, but no later than the end of the next business day, after the medicine was administered.

Clause 100(4) provides that this section does not apply if the medicine being prescribed is from an RFDS medicine chest kept by the Royal Flying Doctor Service of Australia.

Part 7 Making standing orders

Division 1 Preliminary

Meaning of *clinical protocol*

Clause 101 provides that a ***clinical protocol*** is a standing order applying in relation to an approved person performing a procedure or diagnostic test for practising any of the following professions:

- clinical perfusion;
- orthoptics;
- nuclear medicine technology;
- respiratory science;
- speech pathology.

Division 2 Standing orders

Application of division

Clause 102 provides that this division applies to a person (a ***prescriber***) who is authorised to make a standing order.

Clause 102(2) provides that this division does not apply in relation to a standing order that is a clinical protocol.

Making standing order for relevant institution

Clause 103 provides that a prescriber must not make a standing order for a relevant institution unless a medicines and therapeutics committee of the institution has approved the making of the order and the order is signed by a member of the committee who is a prescriber authorised to make standing orders.

Clause 103(2) defines a ***medicines and therapeutics committee*** of a relevant institution to mean a committee established by the institution to approve standing orders for the administration or giving of treatment doses of medicines to patients at the institution and whose members include one medical practitioner, one registered nurse and one pharmacist.

Making other standing orders

Clause 104 provides that this section applies in relation to a standing order that is not for a relevant institution.

Clause 104(2) provides that a prescriber must not make the standing order unless the order relates to:

- a place used to provide an Aboriginal or Torres Strait Islander health service; or
- a place or circumstances authorised under a general approval (emergency first aid) or a general approval (emergency management of animals); or
- a place or circumstances otherwise approved by the chief executive.

Safe circumstances for making standing order

Clause 105 provides that a prescriber must not make a standing order unless the prescriber is reasonably satisfied that the order would not allow a person to administer or give a treatment dose of a medicine in a way that exceeds the person's authorisation or training and action taken under the order would be likely to improve the timeliness of treatment and access to care by patients or animals.

Clause 105(2) provides that the prescriber must ensure the standing order does not apply in relation to more than one medicine or giving a treatment dose of a monitored medicine.

Content of standing order

Clause 106 provides that a prescriber must make a standing order in writing and sign the standing order.

Clause 106(2) provides that the prescriber must state the following on the standing order:

- the name of the prescriber;
- the date the standing order is made;
- the date, no later than two years after the standing order is made, on which the standing order expires;
- the single medicine to which the order applies;
- the class of persons who may administer or give a treatment dose of a medicine under the order;
- the medical conditions to which the order applies;
- if the order applies to administration, the way the medicine may be administered under the order;
- if the order applies to giving a treatment does, the maximum amount of the medicine that may be given under the order;
- the maximum duration for which treatment of a patient under the order is authorised;
- in what circumstances the medicine may be administered or given as a treatment dose, and the recommended dose or dose range for the circumstances;
- the circumstances in which the medicine should not be administered or given as a treatment dose;
- the reference charts for dose calculation, if required, the monitoring requirements, if required, and the type of equipment and management procedures required for management of an emergency associated with the use of the medicine; and
- the date, no later than two years after the order is made, by which the order must be reviewed.

Additional content of standing order under general approval

Clause 107 provides that this section applies if the standing order is made by the prescriber in relation to a general approval (emergency first aid) or a general approval (emergency management of animals).

Clause 107(2) provides that the prescriber must state in the standing order that a person proposing to administer, or give a treatment dose of, a medicine under the order must first attempt to contact the prescriber or another person authorised to prescribe the medicine, before administering or giving the treatment dose.

Clause 107(3) provides that the prescriber must also state in the standing order that the requirement stated in the standing order under subsection (2) does not apply in relation to administration in urgent situations requiring immediate treatment of a patient or an animal or administration of one of the following medicines:

- adrenaline (epinephrine);
- glyceryl trinitrate;
- glucagon;
- naloxone;
- nitrous oxide;
- methoxyflurane;
- salbutamol.

Standing order available for inspection

Clause 108 provides that a prescriber must take all reasonable steps to ensure a standing order made by the prescriber is available for inspection at a place to which the order relates by any person who may administer or give a treatment dose of a medicine under the order, the prescriber's employer, the chief executive, an inspector and a health ombudsman official.

Division 3 Clinical protocols

Application of division

Clause 109 provides that this division applies to a person (a ***prescriber***) who is authorised to make a clinical protocol.

Contents of clinical protocol

Clause 110 provides that a prescriber must make a clinical protocol in writing and state the following information:

- the name of the prescriber;
- the place to which it relates;
- the class of persons who may administer a medicine under the protocol;
- the circumstances to which the protocol applies;
- one or more medicines to which the protocol applies;
- the way each medicine may be administered;
- the day, no later than two years after the protocol is made, by which the protocol must be reviewed.

Protocol available for inspection

Clause 111 provides that a prescriber must take all reasonable steps to ensure a clinical protocol made by the prescriber is readily available for inspection at a place to which it relates by any person who may administer a medicine under the protocol, the chief executive, an inspector and a health ombudsman official.

Part 8 Dispensing medicines

Division 1 Patients and animals

Subdivision 1 Preliminary

Application of division

Clause 112 provides that this division applies to a person (a ***dispenser***) who is authorised to dispense a medicine on a prescription for a patient or an animal.

Subdivision 2 Prescriptions

Dispensing on compliant written prescription

Clause 113 provides that this section applies in relation to a written prescription for a medicine.

Clause 113(2) provides that a dispenser must not dispense the medicine unless the prescription contains the information mentioned in sections 86 to 88, to the extent the information is required under the sections for the medicine and if the prescription is amended by a person other than the dispenser, it is amended in a way that complies with section 90.

Dispensing on electronic prescription

Clause 114 provides that this section applies in relation to an electronic prescription for a medicine.

Clause 114(2) provides that a dispenser must use an electronic prescription management system to record the dispensing of the medicine.

Dispensing on digital copy of paper prescription

Clause 115 provides that this section applies in relation to a digital copy of a paper prescription for a medicine.

Clause 115(2) provides that a dispenser must not dispense the medicine unless the digital copy is from a prescriber or another dispenser.

Digital copy of paper prescription for diversion-risk medicine between dispensers

Clause 116 provides that this section applies in relation to a paper prescription for a diversion-risk medicine.

Clause 116(2) provides that a dispenser (a ***sender***) must not send a digital copy of the paper prescription to another person other than a person who the sender reasonably believes is another dispenser (the ***receiver***) authorised to dispense the diversion-risk medicine.

Clause 116(3) provides that before dispensing on the prescription, the receiver must make reasonable attempts to contact the sender and check whether the diversion-risk medicine has already been dispensed.

Clause 116(4) provides that subsection (5) applies if the diversion-risk medicine is also a monitored medicine.

Clause 116(5) provides that the dispenser is taken to comply with subsection (3) if the dispenser checks the monitored medicines database and information in the database indicates the medicine has not been dispensed on the same prescription or the same repeat of the prescription.

Clause 116(6) provides that the sender must give the paper prescription to the receiver, the next business day after the digital copy was sent, if the prescription is for an S8 medicine, or otherwise, seven days after the digital copy was sent.

Amending written prescription

Clause 117 provides that this section applies in relation to a written prescription for a medicine.

Clause 117(2) provides that a dispenser must not amend the prescription other than in accordance with this section or section 229.

Clause 117(3) provides that the dispenser may amend the prescription before dispensing the medicine by adding additional information to the prescription to clarify the prescriber's direction.

Clause 117(4) provides that before amending the prescription, the dispenser must obtain consent to the amendment from the person obtaining the medicine and have agreement from the prescriber who made the prescription.

Clause 117(5) provides that when amending the prescription, the dispenser must:

- if the dispenser and prescriber agree on a way to amend the prescription, amend the prescription in the way agreed; and
- sign and date the amendment in a way that does not obscure the original prescription.

Subdivision 3 Medicines

Labelling dispensed medicine

Clause 118 provides that a dispenser must not dispense a medicine unless the labelling on the medicine complies with the labelling requirements for the medicine under Appendix L and, if applicable to the medicine, Appendix K of the Poisons Standard.

Expired medicine

Clause 119 provides that a dispenser must not dispense a medicine on a day that is after the expiry date stated on the container or label of the medicine.

Subdivision 4 Dispensing in appropriate circumstances

When dispensing not otherwise permitted

Clause 120 provides that a dispenser must not dispense a medicine on a written prescription if:

- information on or with the prescription shows it has been fulfilled or cancelled; or
- for a digital copy of a paper prescription for a diversion-risk medicine, the prescription states it has been sent to another place; or
- the dispenser reasonably suspects the prescription is a document that has been unlawfully obtained or prepared, the prescription has been made by a person who is not authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to prescribe the medicine or the prescription does not otherwise comply with the Medicines and Poisons Act.

Expired written prescription

Clause 121 provides that a dispenser must not dispense a medicine on a written prescription if:

- for an S2, S3 or S4 medicine, the prescription was made more than one year before the day the medicine is to be dispensed; or
- for an S8 medicine, the prescription was made more than six months before the day the medicine is to be dispensed.

Subdivision 5 Records

Dispensing information on or with written prescription

Clause 122 provides that when dispensing a medicine on a written prescription, a dispenser must record the following information on or with the prescription:

- the date the medicine is dispensed;
- the dispensary where the medicine is dispensed;
- if the medicine is dispensed on a repeat, the number of the repeat dispensed;
- the dispenser's signature.

Clause 122(2) provides that if the medicine is an S8 medicine, the dispenser must record the cancellation of the prescription on or with the prescription after dispensing:

- if the prescription is for a single supply of the medicine, the single supply; or
- if the prescription is a national medication chart prescription, the last supply of the medicine; or
- otherwise, the final repeat for the medicine.

Keeping fulfilled paper prescription

Clause 123 provides that this section applies in relation to a paper prescription for a medicine.

Clause 123(2) provides that a dispenser must keep the paper prescription, or a copy of the prescription, after the dispenser has fulfilled the entire prescription for a single supply of the medicine or has dispensed the final repeat of the medicine.

Dispensing record for dispensed medicine

Clause 124 provides that a dispenser must make and keep a record of the following information as soon as practicable after dispensing a medicine:

- the name of the dispenser;
- the dispensary where the medicine was dispensed;
- the date the medicine was dispensed;
- if the medicine was dispensed for a patient, the name and address of the patient and for a monitored medicine, the date of birth of the patient;
- if the medicine was dispensed for an animal, the species of the animal, the name of the animal or another description to identify the animal and the name and address of the owner or custodian of the animal;

- the name of the medicine or other sufficient information to accurately identify the medicine;
- the form, strength and amount of the medicine;
- the name of the prescriber of the medicine;
- the date of the prescription for the medicine;
- a unique identifier given to the prescription by the dispenser;
- the instructions, for use of the medicine are stated on the prescription;
- the number of the repeat dispensed, if the medicine was dispensed on a repeat;
- the details of the amendment and the agreement with the prescriber, if the prescription was amended by the dispenser in accordance with section 117.

Clause 124(2) provides that a record made under subsection (1) is a ***dispensing record***.

Division 2 Patients only

Application of division

Clause 125 provides that this division applies to a person (a ***dispenser***) who is authorised to dispense a medicine for a patient.

Compliance with monitored medicines standard

Clause 126 provides that a dispenser must dispense a monitored medicine in accordance with the *Monitored medicines* departmental standard.

Dispensing diversion-risk medicine

Clause 127 provides that this section applies in relation to a written prescription for a diversion-risk medicine.

Clause 127(2) provides that a dispenser must take all reasonable steps to ensure the named prescriber on the prescription is genuinely the prescriber of the diversion-risk medicine.

Clause 127(3) provides that the dispenser is taken to have complied with subsection (2) if the dispenser is familiar with information on the prescription identifying the named prescriber to the dispenser or the dispenser contacts the named prescriber and confirms the prescription was made by the named prescriber.

Clause 127(4) provides that subsection (5) applies if the diversion-risk medicine is also a monitored medicine.

Clause 127(5) provides that the dispenser is taken to have complied with subsection (2) if the dispenser checks the monitored medicines database and information in the database indicates the medicine was prescribed by the named prescriber.

Clause 127(6) provides for this section a definition of *named prescriber*.

Dispensing generic medicine

Clause 128 provides that this section applies if a medicine (the ***prescribed medicine***) is prescribed for a patient using an approved name or brand name but the medicine (the ***generic medicine***) is also available under another brand name or without a brand name.

Clause 128(2) provides that a dispenser must not dispense the generic medicine for the patient instead of the prescribed medicine unless the generic medicine is, in the reasonable opinion of the dispenser, physiologically equivalent to the prescribed medicine in its clinical effect and has the same active ingredients, the prescriber of the prescribed medicine did not specifically state that only the prescribed medicine is to be dispensed, and the patient asks for, or agrees to, the dispensing of the generic medicine instead of the prescribed medicine.

Clause 128(3) provides that subsections (2)(b) and (c) do not apply if the medicine is dispensed to the patient at a public sector hospital.

Part 9 Giving treatment doses of medicines

Division 1 Preliminary

Application of part

Clause 129 provides that this part applies to a person (an ***authorised person***) who is authorised to give a treatment dose of a medicine for a patient or an animal.

Division 2 Giving treatment doses generally

Reasonable necessity for therapeutic treatment

Clause 130 provides that this section applies to an authorised person who is authorised to give a treatment dose of a medicine without a prescription for a patient or an animal.

Clause 130(2) provides that the authorised person must not give the treatment dose unless the person assesses the medicine to be reasonably necessary for the therapeutic treatment of the patient or animal.

Giving medicine in manufacturer's pack

Clause 131 provides that an authorised person must not give a treatment dose of a medicine other than in a manufacturer's pack, unless the person is authorised to repackage the medicine.

Giving diversion-risk medicine

Clause 132 provides that this section applies in relation to a diversion-risk medicine for a patient being given on a written prescription.

Clause 132(2) provides that an authorised person must take all reasonable steps to ensure the named prescriber on the prescription is genuinely the prescriber of the diversion-risk medicine.

Clause 132(3) provides that the authorised person is taken to comply with subsection (2) if the person is familiar with information on the prescription identifying the named prescriber to the person or the person contacts the named prescriber and confirms the prescription was given by the named prescriber.

Clause 132(4) provides that subsection (5) applies if the diversion-risk medicine is also a monitored medicine.

Clause 132(5) provides that the authorised person is taken to comply with subsection (2) if the person checks the monitored medicines database and the information in the database indicates the medicine was prescribed by the named prescriber.

Clause 132(6) provides for this section a definition of *named prescriber*.

When giving treatment dose is not otherwise permitted

Clause 133 provides that an authorised person must not give a treatment dose of a medicine on a written prescription if information on or with the prescription shows it has been fulfilled or cancelled or the authorised person reasonably suspects the prescription is a document that has been unlawfully prepared or obtained, the prescription has been made by a person who is not authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to prescribe the medicine, or the prescription does not otherwise comply with the Medicines and Poisons Act.

Division 3 Labelling and records

Labelling treatment dose of medicine

Clause 134 provides that an authorised person must not give a treatment dose of a medicine unless the labelling on the medicine complies with the labelling requirements for the medicine under Appendix L and, if applicable to the medicine, Appendix K of the Poisons Standard.

Clause 134(2) provides that subsection (1) does not apply in relation to an S2 or S3 medicine given in a manufacturer's pack.

Information on or with prescription

Clause 135 provides that when giving a treatment dose of a medicine on a written prescription, an authorised person must record the following information on or with the prescription:

- the date the treatment dose is given;
- the authorised person’s name and signature;
- that the prescription has been fulfilled or cancelled.

Clause 135(2) provides that if the prescription is a medication chart prescription, the authorised person must record only the following information on the prescription:

- the date the medicine is given;
- the amount of the medicine given;
- the authorised person’s signature.

Treatment dose record

Clause 136 provides that this section applies to an authorised person giving a treatment dose of a medicine that is an S3 medicine containing pseudoephedrine or an S4 or S8 medicine.

Clause 136(2) provides that as soon as practicable after giving the treatment dose, the authorised person must make and keep a record of the following information:

- the name of the authorised person;
- the date the medicine was given;
- if the medicine was given for a patient, the name and address of the patient and for a monitored medicine, the date of birth of the patient;
- if the medicine was given for an animal, the name and address of the owner or custodian of the animal;
- the name of the medicine or other sufficient information to accurately identify the medicine;
- the form, strength and amount of the medicine;
- if the treatment dose was given on a prescription, the name of the prescriber who prescribed the medicine.

Clause 136(3) provides that this section does not apply in relation to a treatment dose given on a medication chart prescription or from an RFDS medicine chest kept by the Royal Flying Doctor Service of Australia.

Division 4 Expired prescriptions and medicines

Expired written prescription

Clause 137 provides that an authorised person must not give a treatment dose of a medicine on a written prescription if:

- for an S2, S3 or S4 medicine, the prescription was made more than one year before the day the medicine is to be given; or
- for an S8 medicine, the prescription was made more than six months before the day the medicine is to be administered.

Expired medicine

Clause 138 provides that an authorised person must not give a treatment dose of a medicine on a day that is after the expiry date stated on the container or label of the medicine.

Part 10 Administering medicines

Application of part

Clause 139 provides that this part applies to a person (an ***authorised person***) who is authorised to administer a medicine to a patient or an animal.

Reasonable necessity for therapeutic treatment

Clause 140 provides that this section applies to an authorised person who is authorised to administer a medicine to a patient or an animal without a prescription.

Clause 140(2) provides that the authorised person must not administer the medicine unless the person assesses the medicine to be reasonably necessary for the therapeutic treatment of the patient or animal.

Record for administering on standing order

Clause 141 provides that this section applies to an authorised person who is authorised to administer a medicine on a standing order.

Clause 141(2) provides that as soon as practicable after administering the medicine, the authorised person must make and keep a record of the following information:

- the name of the authorised person;
- the date the medicine was administered;
- if the medicine was administered to a patient, the name and address of the patient and for a monitored medicine, the date of birth of the patient;
- if the medicine was administered to an animal, the name and address of the owner or custodian of the animal;
- the name of the medicine or other sufficient information to accurately identify the medicine;
- the form, strength and amount of the medicine;
- the name of the prescriber who made the standing order.

Expired written prescription

Clause 142 provides that an authorised person must not administer a medicine on the written prescription if:

- for an S2, S3 or S4 medicine, the prescription was made more than one year before the day the medicine is to be administered; or
- for an S8 medicine, the prescription was made more than six months before the day the medicine is to be given.

Part 11 Disposing of waste from diversion-risk medicines

Division 1 Preliminary

Application of part

Clause 143 provides that this part applies to a person (an ***approved disposer***) who is authorised to dispose of waste from a diversion-risk medicine.

Clause 143(2) provides that this part does not apply in relation to waste that is residue from a diversion-risk medicine in the form of an unused portion of a tablet, or the unused partial contents of a previously sterile ampoule of container, or a used transdermal patch, and destroyed immediately after the medicine is no longer required for administration.

Clause 143(3) provides that this part does not apply in relation to waste from a diversion-risk medicine from an RFDS medicine chest kept by the Royal Flying Doctor Service of Australia under a general approval for the service.

Division 2 S8 diversion-risk medicine waste

Application of division

Clause 144 provides that this division applies in relation to waste (***S8 waste***) from a diversion-risk medicine that is an S8 medicine.

Separation of waste

Clause 145 provides that an approved disposer must ensure S8 waste is placed in an S8 safe, separated from other medicines in the safe and clearly marked for destruction.

Transfer of waste for destruction

Clause 146 provides that an approved disposer (a ***giver***) must not transfer S8 waste for destruction other than to another person (a ***receiver***) who the disposer reasonably believes is an approved disposer authorised to destroy the S8 waste.

Clause 146(2) provides that the receiver must acknowledge receipt of the S8 waste by signing an entry for the transfer of the waste in the medicine register for the S8 safe in which the waste was kept before the transfer or signing a separate notice for the giver.

Clause 146(3) provides that the giver must keep a notice provided to the giver under subsection (2)(b).

Destruction of waste

Clause 147 provides that an approved disposer must not destroy S8 waste unless the approved disposer is:

- an ambulance officer, dentist, medical practitioner, nurse practitioner, midwife, registered nurse, enrolled nurse, pharmacist, podiatrist, podiatric surgeon or veterinary surgeon, in charge of disposal at a place; or
- specifically authorised to supervise the destruction of the waste under a substance authority.

Clause 147(2) provides that the approved disposer must not destroy the S8 waste unless the destruction is witnessed by a person not related, married to, or in a defacto relationship with, the approved disposer who is, a member of a class of persons mentioned in subsection (1) or an inspector or a police officer.

Division 3 Other diversion-risk medicine waste

Preventing public access to waste

Clause 148 provides that this section applies in relation to waste from a diversion-risk medicine other than an S8 medicine.

Clause 148(2) provides an approved disposer must not leave the waste unattended in a location unless the disposer reasonably believes a member of the public could not access the waste without being seen and the waste is likely to be taken for destruction as soon as practicable.

Chapter 5 Special requirements for dealings

Part 1 Preliminary

Application of chapter—Act, s 91

Clause 149 provides that for section 91(1) (Requirements may be prescribed) of the Medicines and Poisons Act, this chapter prescribes requirements for a person authorised under section 54(4) (Authorisation of prescribed classes of persons) of the Medicines and Poisons Act to deal with a medicine, in relation to carrying out the dealing.

Clause 149(2) provides that this part applies in addition to chapter 4, unless otherwise stated.

Part 2 Pharmacists

Division 1 Preliminary

Application of part

Clause 150 provides that this part applies to a pharmacist who is authorised to deal with a medicine, in relation to carrying out the dealing at a pharmacy.

Division 2 Supplying stock

Supply for filling another pharmacy client order

Clause 151 provides that this section applies in relation to supplying stock of a medicine to fill an order made by a client of another pharmacist.

Clause 151(2) provides that the pharmacist supplying the stock must be reasonably satisfied the request is for satisfying the client's order, supply the minimum amount of stock necessary to satisfy the client's order and obtain a signed, written request for the stock from the other pharmacist.

Records when supplying to another pharmacist

Clause 152 provides that this section applies in relation to supplying stock of a medicine for use by another pharmacist.

Clause 152(2) provides that the pharmacist supplying the stock must make and keep a record of the following information:

- the signed, written request for stock;
- the date on which the stock was supplied;
- the type of stock supplied;
- the amount of stock supplied.

Division 3 Selling medicines without prescriptions

Subdivision 1 Preliminary

Application of division

Clause 153 provides that this division applies in relation to selling a medicine without a prescription.

Subdivision 2 Labelling

Labelling sold medicine

Clause 154 provides that this section does not apply in relation to an S2 medicine in a manufacturer's pack.

Clause 154(2) provides that a pharmacist must not sell a medicine unless the labelling on the medicine complies with the labelling requirements for the medicine under Appendix L and, if applicable to the medicine, Appendix K of the Poisons Standard.

Clause 154(3) provides that if the medicine is an S3 medicine in a manufacturer's pack, the pharmacist must instead attach a label to the medicine stating the following information:

- the date the medicine is sold;
- the name of the patient;
- the name of the medicine;
- if the medicine is mentioned in Appendix K of the Poisons Standard, the warning statement mentioned in Appendix K for the medicine.

Subdivision 3 S4 medicines

Definition for division

Clause 155 provides for this subdivision a definition of *oral hormonal contraceptive*.

Selling S4 oral hormonal contraceptive

Clause 156 provides that this section applies in relation to an S4 medicine that is an oral hormonal contraceptive for a patient.

Clause 156(2) provides that a pharmacist must not sell the medicine unless the pharmacist reasonably believes:

- the patient has been treated by a prescriber with the medicine for a continuous period of a reasonable length;
- it is not practicable for the patient to obtain a prescription for the medicine before needing to continue treatment with the medicine; and
- the patient has not, in the year before seeking the medicine from the pharmacist, been sold the medicine without a prescription from the pharmacy at which the medicine is sought.

Selling S4 diversion-risk medicine

Clause 157 provides that this section applies in relation to an S4 medicine that is a diversion-risk medicine for a patient, other than a medicine sold under the Continued Dispensing Determination.

Clause 157(2) provides that a pharmacist must not sell the medicine unless the pharmacist reasonably believes the medicine has been previously prescribed to the patient, failure to sell the medicine could be life-threatening for the patient and it is not practicable for the patient to obtain a prescription before needing to continue treatment with the medicine.

Selling other S4 medicines

Clause 158 provides that this section applies in relation to an S4 medicine, other than a diversion-risk medicine or oral hormonal contraceptive, for a patient.

Clause 158(2) provides that a pharmacist must not sell the medicine unless the pharmacist reasonably believes the medicine has been previously prescribed to the patient, continuing the patient's treatment with the medicine continuing the patient's treatment with the medicine is urgent and essential for the patient's wellbeing, and it is not practicable for the patient to obtain a prescription for the medicine before needing to continue treatment with the medicine.

Amounts when selling S4 medicine

Clause 159 provides that a pharmacist must not sell an amount of an S4 medicine that is more than:

- the minimum standard pack, for an S4 medicine that is a prepacked liquid, cream, ointment or aerosol;
- a manufacturer's pack of the medicine, for an S4 that is an oral hormonal contraceptive; or
- three days' supply of the medicine, for another S4 medicine.

Record when selling S4 medicine

Clause 160 provides that as soon as practicable after selling a medicine for a patient, a pharmacist must make and keep a record of the following information:

- the name of the pharmacist;
- the date the medicine is sold;
- the name and address of the patient;
- for a monitored medicine, the date of birth of the patient;

- the name of the medicine or other sufficient information to accurately identify the medicine;
- the form, strength and amount of the medicine sold;
- the instructions given for the use of the medicine;
- the name of the prescriber who last prescribed the medicine to the person, if known;
- for an oral hormonal contraceptive or diversion-risk medicine, a brief description of why the pharmacist is selling the contraceptive or medicine.

Subdivision 4 S3 medicines

Selling S3 medicine with instructions for use

Clause 161 provides that a pharmacist must not sell an S3 medicine for a patient unless the pharmacist reasonably believes the patient has a therapeutic need for the medicine.

Clause 161(2) provides that a pharmacist must not sell an S3 medicine for an animal except to a person the pharmacist reasonably believes is the owner or custodian of the animal.

Clause 161(3) provides that the pharmacist must give instructions about the appropriate way to use the S3 medicine to the person buying the medicine.

Record keeping for pseudoephedrine

Clause 162 provides that this section in relation to an S3 medicine containing pseudoephedrine.

Clause 162(2) provides that as soon as practicable after selling the medicine, a pharmacist must make and keep a record the following information:

- the date of the sale;
- the name of the medicine;
- the amount of the medicine sold;
- the name and address of the person who bought the medicine;
- the type of document used to identify the person who bought the medicine and an identifier for the document, if applicable.

Clause 162(3) provides that the record must be kept electronically in a way that complies with the *Pseudoephedrine recording* departmental standard.

Part 3 Pharmacy employees

Application of part

Clause 163 applies to a pharmacy employee who is authorised to deal with a medicine, in relation to dealing with the medicine at a pharmacy.

Notifying pharmacist of discrepancy

Clause 164 provides that this section applies in relation to stock of S8 medicines received from a wholesale supplier for the pharmacy.

Clause 164(2) provides that a pharmacy employee in possession of the stock must immediately check the amount of stock received against the amount of stock listed on the invoice from the wholesale supplier.

Clause 164(3) provides that the pharmacy employee must notify a pharmacist at the pharmacy of any discrepancy between the invoice and stock received.

Selling S2 medicine in manufacturer's packs

Clause 165 provides a pharmacy employee must not sell an S2 medicine other than in a manufacturer's pack.

Part 4 Veterinary professions

Division 1 Veterinary surgeons prescribing S4 medicines and medicated feed

Application of division

Clause 166 provides that this division applies to a veterinary surgeon who is authorised to prescribe a medicine for an animal if the medicine is an S4 medicine or medicated feed and is to be mixed with food for administration to a group of animals by a farmer of the animals.

Instructions for administration to food producing animals

Clause 167 provides that this section applies in relation to food producing animals.

Clause 167(2) provides that a veterinary surgeon must give instructions to the farmer of the food producing animals about how to measure and combine an S4 medicine or medicated feed with food to administer to the animals and clean any residue from medicine or feed from any equipment used to administer it to the animals.

Clause 167(3) provides that this section does not apply if the veterinary surgeon has previously given the farmer the relevant instructions.

Written prescription for medicine and medicated feed

Clause 168 provides that a veterinary surgeon must make a written prescription for an S4 medicine or medicated feed for a group of animals that states the following information:

- a unique identifier for the prescription;
- the name of the veterinary surgeon;
- the address of the veterinary premises of the veterinary surgeon;
- the qualifications of the veterinary surgeon;
- the date of the prescription;

- the name and address of the farmer of the animals;
- the date, no later than six months after the date the prescription is given, when the prescription expires;
- the species of the animals;
- any other details necessary to identify the animals, including, for example, the age, breed or sex of the animals;
- a statement that the medicine or feed is for animal treatment only;
- for a medicine, the name of the medicine, the form and strength of the medicine and the final concentration of the medicine to be in the food administered to the animals;
- for medicated feed, the name of the medicine mixed, or to be mixed into the feed, the form and strength of the medicine mixed, or to be mixed into the feed, the name and address of the manufacturer to supply the feed, the final concentration of the medicine in the feed supplied by the manufacturer and how much feed may be supplied by the manufacturer;
- the instructions mentioned in section 167 for administering the medicine or feed to the animals, if any.

Clause 168(2) provides that the veterinary surgeon must sign, and keep a copy of, the written prescription.

Sending written prescription

Clause 169 provides that this section applies if a veterinary surgeon sends a written prescription for medicated feed to the holder of a manufacturing licence for the feed.

Clause 169(2) provides that the written prescription must be made and sent to the holder in a way that is reasonably likely to:

- minimise fraud or tampering;
- allow the prescription to be amended only by the veterinary surgeon; and
- if sent electronically, be transmitted securely.

Division 2 Veterinary nurses

Record for veterinary nurses administering on oral prescription

Clause 170 provides that this section applies to a veterinary nurse who is authorised to administer a medicine to an animal, if the medicine is administered on an oral prescription.

Clause 170(2) provides that the veterinary nurse must make and keep a record of:

- the oral prescription;
- the name of the veterinary surgeon who prescribed the medicine;
- the date and time the medicine is administered; and
- the amount of medicine administered.

Part 5 Wholesale representatives

Disposal of unused starter packs

Clause 171 provides that this section applies to a wholesale representative who is authorised to dispose of waste from a diversion-risk medicine.

Clause 171(2) provides that a wholesale representative must return to the representative's employer any starter pack of the diversion-risk medicine that is unwanted, expired or otherwise unused.

Clause 171(3) provides for this section a definition of *employer*.

Chapter 6 Substance management plans

Regulated places and responsible persons—Act, s 92

Clause 172 provides for the definition of a *regulated place* in section 92 (Definitions for part) of the Medicines and Poisons Act, each place stated in column 1 of the table in schedule 17, section 2 is prescribed to be a regulated place.

For the definition of *responsible person* in section 92 (Definitions for part) of the Medicines and Poisons Act, the person stated in column 2 of the table in schedule 17, section 2, is prescribed to be the responsible person for the regulated place stated opposite in column 1.

Matters for plan—Act, s 93

Clause 173 provides that for section 93(2)(b) (Requirements for substance management plan) of the Medicines and Poisons Act, matters stated in the *Substance management plans for medicines* departmental standard are prescribed.

Review of plan—Act, s 93

Clause 174 provides that for section 93(3)(b) (Requirements for substance management plan) of the Medicines and Poisons Act, the following times are prescribed for a substance management plan for a regulated place relating to medicines:

- as soon as practicable after a review incident happens in relation to the regulated place; and
- the day the plan was last reviewed, if the plan is reviewed in any five year period after the plan starts.

Clause 174(2) provides for this section a definition of *review incident*.

Chapter 7 Monitored medicines database

Part 1 Preliminary

Application to information from other States

Clause 175 provides that this chapter applies in relation to information recorded in another State to the extent the information relates to:

- a health practitioner ordinarily practising in Queensland; or

- a patient ordinarily residing in Queensland; or
- a prescription made in Queensland; or
- a medicine dispensed or given in Queensland.

Clause 175(2) provides that for applying subsection (1), a reference in this chapter to a type of information recorded under the Medicines and Poisons Act is taken to include a reference to the equivalent type of information recorded under a corresponding law, to the extent the context permits.

Definitions for chapter

Clause 176 provides for this chapter definitions of *data source entity*, *equivalent database* and *prescription exchange system.*

Queensland's real-time prescription monitoring system uses prescription exchange systems (PESs) to securely transmit prescription information between health practitioners' clinical software and the monitored medicines database. When a health practitioner prescribes or dispenses a monitored medicine using PES-integrated clinical software, a record of that medication event will be sent to the monitored medicines database via the PES in real-time.

The monitored medicines database is being established as part of a national real-time prescription monitoring solution. Each jurisdiction has committed to progressing their respective real-time prescription monitoring databases to connect to and interface with the Commonwealth's National Data Exchange (NDE). Ultimately, it is intended that certain information collected in each state and territory (e.g. prescribing and dispensing event information) will be shared between jurisdictions via the NDE to achieve a national solution.

Once the relevant technical, legal and administrative arrangements are in place to facilitate this, it is anticipated that a health practitioner using Queensland's monitored medicines database will be able to see information about relevant prescribing and dispensing events that occurred in other jurisdictions. Similarly, it is anticipated that a health practitioner in another jurisdiction viewing a patient's record in their real-time prescription monitoring database will be able to view information about relevant prescribing and dispensing events that occurred in Queensland.

Entities which may provide information for Queensland's monitored medicines database have been specified as a data source entity. This includes:

- Fred IT Group Pty Ltd (the current operator of the NDE);
- Medication Knowledge Pty Ltd (an entity which facilitates interoperability of the PESs);
- the Australian Health Practitioner Regulation Agency (which provides the database with registration details of health practitioners under the Health Practitioner Regulation National Law);
- a government entity in another State responsible for the administration of an equivalent database;
- an entity that is stated to be a data source entity under a corresponding law of another State;
- another entity that provides a PES to a health practitioner.

Additional purposes—Act, s 224

Clause 177 provides that for section 224(2)(g) (Chief executive to keep database) of the Medicines and Poisons Act, the following purposes are prescribed:

- to manage the operation of the database;
- to exercise a power, or perform another function, under the Medicines and Poisons Act relating to a monitored medicine.

Part 2 Requirement to check database

Relevant practitioners—Act, s 41

Clause 178 provides that for section 41(4) (Requirement to check database for particular dealings with monitored medicines) of the Medicines and Poisons Act, each health practitioner stated in schedule 18, part 1 is prescribed to be a ***relevant practitioner***.

Part 3 Information for database

Information recorded in database—Act, s 225

Clause 179 provides that for section 225(1) (Information recorded in database) of the Medicines and Poisons Act, the following information is prescribed:

- information given to the chief executive under section 226 (Giving information) of the Medicines and Poisons Act;
- information in relation to a patient's treatment stated in a prescribing approval for a monitored medicine;
- the registration details from time to time, under the Health Practitioner Regulation National Law, of a health practitioner given to, or held by, the chief executive;
- information about any other qualification of a health practitioner for treating a patient with a monitored medicine given to, or held by, the chief executive;
- personal information to identify a health practitioner for accessing or using the monitored medicines database given to, or held by, the chief executive;
- information about a health practitioner provided for the purpose of accessing or using the database.

Information providers and relevant information—Act, s 226

Clause 180 provides that for section 226(2) (Giving information) of the Medicines and Poisons Act, each entity stated in column 1 of the table in schedule 18, part 2 is prescribed to be an *information provider*.

Clause 180(2) provides that for section 226(2) (Giving information) of the Medicines and Poisons Act, the information mentioned in column 2 of the table in schedule 18, part 2 is prescribed to be the *relevant information* for the information provider mentioned opposite in column 1.

Method for data source entities giving information—Act, s 226

Clause 181 provides that this section applies in relation to an information provider that is a data source entity.

Clause 181(2) provides that for section 226(1) (Giving information) of the Medicines and Poisons Act, the way prescribed is by sending an electronic copy of the relevant information to the monitored medicines database and the time prescribed is when the relevant information is received by the information provider.

Method for dispensers giving information—Act, s 226

Clause 182 provides that this section applies in relation to an information provider who is a dispenser.

Clause 182(2) provides that for section 226(1) (Giving information) of the Medicines and Poisons Act, the way prescribed is by using a prescription exchange system and the time prescribed is when the information provider is recording the information in the system.

Part 4 Disclosure

Users—Act, s 227

Clause 183 provides that for the definition of *user* in section 227(4) (Use of information) of the Medicines and Poisons Act, each entity stated in column 1 of the table in schedule 18, part 3 is prescribed to be a user.

Clause 183(2) provides that each purpose in column 2 of the table in schedule 18, part 3 is prescribed to be a purpose for the user opposite in column 1 for in section 227(4) (Use of information) of the Medicines and Poisons Act.

Chapter 8 Offences

Part 1 Electronic prescription management systems

Division 1 Preliminary

Application of part

Clause 184 provides that this part applies in relation to an entity that establishes or uses an electronic system for making or transmitting prescriptions for dispensing medicines, or retrieving prescriptions for dispensing medicines, including recording information relating to the dispensing of the medicines.

Clause 184(2) provides that an electronic system mentioned in subsection (1) is an ***electronic prescription management system***.

Clause 184(3) provides that to remove any doubt, it is declared that the monitored medicines database is not an electronic prescription management system.

Division 2 Key appointments

Appointments for managing system

Clause 185 provides it is an offence if the person in charge of an entity to which this part applies fails to appoint, in writing, an appropriately qualified person (a ***system manager***) to be responsible for the establishment and operation of the entity's electronic prescription management system, unless the person has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

Clause 185(2) provides it is an offence if the system manager of an entity's electronic prescription management system fails to appoint, in writing, one or more appropriately qualified persons (each a ***system administrator***) to be responsible for the administration and technical maintenance of the system, unless the manager has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

Clause 185(3) provides it is an offence if the system manager fails to record and keep the name and contact details for each person appointed under subsection (2), unless the manager has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

Clause 185(4) provides it is an offence if the person in charge of the entity fails to take all reasonable steps to ensure that each person appointed under subsection (1) or (2) is advised, in writing, of the provisions applying to the person under this part. The offence carries a maximum penalty of 80 penalty units.

Division 3 System managers

System must comply with departmental standard

Clause 186 provides it is an offence if the system manager of an entity's electronic prescription management system fails to take all reasonable steps to ensure the system complies with the *Requirements for an electronic prescription management system* departmental standard. The offence carries a maximum penalty of 80 penalty units.

Security measures required for system

Clause 187 provides that the system manager of an entity's electronic prescription management system must take all reasonable steps to ensure security measures are embedded in the system to:

- prevent a person who is not approved to use the system from accessing or using the system; and
- monitor any breaches of the system or events affecting the integrity of the system; and
- keep each record made in the system for at least two years after the record is created.

The offence carries a maximum penalty of 80 penalty units.

Division 4 System administrators

Giving access to the system

Clause 188 provides it is an offence for a system administrator of an entity's electronic prescription management system to give a person access to the system unless the administrator reasonably believes the person works for the entity, the access given is limited to the extent required for the person to perform the person's role or function for the entity and the person has appropriate authorisation under the Medicines and Poisons Act to use the system to perform the person's role or function for the entity. The offence carries a maximum penalty of 80 penalty units.

Clause 188(2) provides that a person given access to an entity's electronic prescription management system under subsection (1) is an ***approved user*** of the system.

Clause 188(3) provides it is an offence if the system administrator fails to give each approved user more than one secure system identifier for the electronic prescription management system. The offence carries a maximum penalty of 80 penalty units.

Cancelling access to the system

Clause 189 provides that this section applies if a system administrator of an entity's electronic prescription management system becomes aware that an approved user of the system has stopped performing the role or function for the entity for which the user was given access.

Clause 189(2) provides it is an offence if the system administrator fails to cancel the approved user's access to the electronic prescription management system, unless the administrator has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

Making and keeping records of users

Clause 190 provides that this section applies if a system administrator of an entity's electronic prescription management system has given or cancelled a person's access to the system.

Clause 190(2) provides that unless the system administrator has a reasonable excuse, it is an offence if the administrator fails to make and keep a record of any information used in relation to giving or cancelling the access including:

- the name of the person and the person's secure system identifier; and
- the date on which the person was given access; and
- the date on which the person's access was cancelled, if applicable.

The offence carries a maximum penalty of 40 penalty units.

Maintaining system

Clause 191 provides it is an offence if each system administrator of an entity's electronic prescription management system fails to take all reasonable steps to maintain the security of the system and the records kept in the system. The offence carries a maximum penalty of 40 penalty units.

Reporting system breaches for monitored medicines

Clause 192 provides that this section applies if the system manager, or a system administrator, of an entity's electronic prescription management system becomes aware of an incident in which the system may have been unlawfully accessed or otherwise used to obtain a monitored medicine.

Clause 192(2) provides it is an offence if the system manager, or system administrator, fails to give notice to the chief executive, within five business days, about the incident in the approved form, unless the manager or administrator has a reasonable excuse. The offence carries a maximum penalty of 80 penalty units.

Division 5 Approved users

Protecting secure system identifiers

Clause 193 provides it is an offence if an approved user of an entity's electronic prescription management system fails to take reasonable steps to prevent the user's secure system identifier for the system being accessed by another person. The offence carries a maximum penalty of 20 penalty units.

Part 2 Secure storage systems

Division 1 Preliminary

Non-application of part to animal feed

Clause 194 provides that this part does not apply in relation to an S4 medicine or medicated feed to be mixed with food for administration to a group of animals or the person who is the farmer of the animals possessing the medicine or feed mentioned in paragraph (a) or administering the medicine or feed to the animals.

Definitions for part

Clause 195 provides for this part definitions of *access, assistant, authorised user, medicine store, medicine store establisher, S8 safe, S8 safe establisher* and *shared clinic*.

Division 2 Medicine stores and S8 safes

Subdivision 1 Establishing stores and S8 safes

Appointing establishers and managers

Clause 196 provides that this section applies in relation to a shared clinic.

Clause 196(2) provides it is an offence if the person in charge of the shared clinic fails to appoint, in writing, an appropriately qualified person to be responsible for establishing and maintaining an S8 safe for S8 medicines possessed at the clinic and a medicine store for any other medicines possessed at the clinic. The offence carries a maximum penalty of 40 penalty units.

Clause 196(3) provides it is an offence if the person in charge of the shared clinic fails to appoint, in writing, an appropriately qualified person to be a manager of the S8 safe or medicine store at the clinic. The offence carries a maximum penalty of 40 penalty units.

Clause 196(4) provides it is an offence if the person in charge of the shared clinic fails to take all reasonable steps to ensure that each person appointed under subsection (2) or (3) is advised, in writing, of the provisions applying to the person under this part. The offence carries a maximum penalty of 40 penalty units.

S8 safe must comply with standard

Clause 197 provides it is an offence if an S8 safe establisher for a place fails to establish an S8 safe for S8 medicines at the place in a way that complies with the *Secure storage of S8 medicines* departmental standard. The offence carries a maximum penalty of 40 penalty units.

Clause 197(2) provides it is an offence if the S8 safe establisher fails to take all reasonable steps to ensure the S8 safe is established and maintained in a way that keeps the medicines in the safe in accordance with the manufacturer's conditions for the medicines. The offence carries a maximum penalty of 40 penalty units.

Storage for safety and quality of medicines

Clause 198 provides that it is an offence if a medicine store establisher for a place fails to establish and maintain a medicine store for storing S2, S3 and S4 medicine at the place. The offence carries a maximum penalty of 40 penalty units.

Clause 198(2) provides it is an offence for the medicine store establisher fails to take all reasonable steps to ensure the medicine store is established and maintained in a way that keeps the medicines in the store in accordance with the manufacturer's conditions for the medicines. The offence carries a maximum penalty of 40 penalty units.

Clause 198(3) provides if pentobarbital is possessed at the place, it is an offence if the medicine store establisher fails to ensure the medicine store for the pentobarbital is lockable. The offence carries a maximum penalty of 40 penalty units.

Preventing unauthorised access to medicines

Clause 199 provides it is an offence if a medicine store establisher for a place fails to put each medicine store for the place in an area where the establisher reasonably believes a member of the public could not access the store without being seen. The offence carries a maximum penalty of 40 penalty units.

Clause 199(2) provides that if pseudoephedrine is possessed at the place, it is an offence for the medicine store to be kept an area that is not out of sight from members of the public. The offence carries a maximum penalty of 40 penalty units.

Subdivision 2 Managing S8 safes

S8 safe establisher giving access to S8 safe

Clause 200 provides it is an offence for an S8 safe establisher to give a person access to an S8 safe at a place if:

- the person is not an authorised user of the S8 medicines kept in the safe at the place; and
- if the safe is kept at a relevant institution or community pharmacy, the person is not permitted to open the safe under the substance management plan for the institution or pharmacy.

The offence carries a maximum penalty of 40 penalty units.

Clause 200(2) provides it is an offence for a S8 safe establisher to give the access to the authorised user without any restrictions or controls required under the *Secure storage of S8 medicines* departmental standard and if the safe is at a relevant institution or community pharmacy, under the substance management plan for the institution or pharmacy. The offence carries a maximum penalty of 40 penalty units.

Subdivision 3 Using S8 safes and stores

Requirements for authorised user accessing S8 safe

Clause 201 provides that this section applies to an authorised user of an S8 medicine who has been given access to an S8 safe to obtain the medicine.

Clause 201(2) provides it is an offence if an authorised user fails to:

- keep any device or information that allows the user to access the S8 safe secure;
- comply with any restrictions or controls on the access given in writing to the user by the safe establisher; and
- close and lock the safe when the user is no longer using it.

The offence carries a maximum penalty of 40 penalty units.

Clause 201(3) provides that subsection (4) applies if the authorised user is supervising an assistant possessing a medicine.

Clause 201(4) provides that the authorised user may give the assistant the user's device for accessing the S8 safe for the purpose for which the assistant is authorised only if the device operates solely as a key to open and close the S8 safe, without an additional code or password and the user gets the device back from the assistant immediately after the assistant uses it.

Taking medicine from S8 safe and medicine store

Clause 202 provides that this section applies to an authorised user of a medicine or an assistant possessing a medicine at a place.

Clause 202(2) provides that unless the authorised user or assistant has a reasonable excuse, it is an offence for the user or assistant to:

- take the medicine from an S8 safe or a medicine store at the place, unless the medicine is intended for supply or administration; or
- leave the medicine unattended in an area other than the S8 safe or medicine store at the place for the medicine.

The offence carries a maximum penalty of 40 penalty units.

Division 3 Medicine registers

Subdivision 1 Preliminary

Application of division

Clause 203 provides that this division applies in relation to medicines put in or taken from an S8 safe or approved store.

Clause 203(2) provides that this division does not apply in relation to an S8 medicine kept in an S8 safe that has been packed in a dose administration aid.

Clause 203(3) provides that to remove any doubt, it is declared that this division applies in relation to medicines moved or distributed at or between workplaces.

Definitions for division

Clause 204 provides for this division definitions of *approved store*, *manager* and *type*.

Subdivision 2 Managers keeping registers

Meaning of *medicine register*

Clause 205 provides that a ***medicine register***, for an S8 safe or approved store, is a document that states:

- when each type of medicine is put in, or taken from, the safe or store for a dealing; and
- the amount of the type of medicine in the safe or store at any given time.

Manager must make and keep register with safe or store

Clause 206 provides it is an offence if the manager of an S8 safe or approved store fails to take all reasonable steps to make and keep a medicine register for the safe or store and keep the medicine register with, or as close as practicable to, the safe or store.

The offence carries a maximum penalty of 40 penalty units.

Layout of medicine register

Clause 207 provides it is an offence if a manager of an S8 safe or approved store fails to organise the information in the medicine register for the safe or store in a way that shows the medicines stored in the safe or store at any given time, the dealings related to the medicines stored in the safe or store listed consecutively based on the time the dealings occurred to the extent practicable, and a separate record for each type of medicine. The offence carries a maximum penalty of 40 penalty units.

Clause 207(2) provides that despite subsection (1)(c), information about medicines disposed of by destruction may be shown in a single, combined record that is separate from a record for a particular type of medicine.

Electronic register

Clause 208 provides that this section applies to a manager of an S8 safe or approved store who keeps a medicine register for the safe or store in an electronic form (an ***electronic register***).

Clause 208(2) provides it is an offence if the manager fails to take all reasonable steps to ensure the electronic register has the following properties:

- a person can not make entries in the register unless the person has a secure system identifier;
- a secure system identifier is automatically recorded for every person making every entry in the register;
- an entry made by an assistant possessing a medicine is shown as pending in the register until an authorised user who is supervising the assistant confirms the entry or a witness confirms the entry, if the entry relates to disposal of waste from a diversion-risk medicine by destruction;
- a unique reference number is recorded with the time and date of each entry that is confirmed;
- an entry that has been confirmed cannot be deleted from the register;
- a hard copy report can be produced at any time from the register to show the balance of medicines to which the register applies at that time, or the confirmed entries in the register for any particular period of time for which the register applies.

The offence carries a maximum penalty of 40 penalty units.

Clause 208(3) provides it is an offence for the manager to give a secure system identifier for the electronic register to a person unless:

- the person is an authorised user of the medicines in the S8 safe or approved store; or
- if the person is an assistant dealing with a medicine from the S8 safe or approved store, the person is given a secure system identifier that only permits the person to make entries mentioned in subsection (2)(c) in the register.

The offence carries a maximum penalty of 40 penalty units.

Clause 208(4) provides it is an offence if the manager fails to make and keep a record of each person's secure system identifier for the electronic register. The offence carries a maximum penalty of 40 penalty units.

Paper register

Clause 209 provides that this section applies to a manager of an S8 safe or approved store who keeps a medicine register for the safe or store on paper.

Clause 209(2) provides it is an offence if the manager fails to take all reasonable steps to ensure the medicine register has the following properties:

- a page can not be removed from the register without detection;
- a separate page is used for each type of medicine.

The offence carries a maximum penalty of 40 penalty units.

Replacing paper register

Clause 210 provides that this section applies if a manager of an S8 safe or approved store who keeps a medicine register for the safe or store on paper (the ***original register****)* and the original register has no space or pages remaining to record entries.

Clause 210(2) provides that unless the manager has a reasonable excuse, it is an offence if the manager fails to:

- replace the original register with a new medicine register; and
- in the new register, record the amount of each type of medicine stated in the last entry of the original register; and
- reconcile the record with the amount of medicine physically held in the S8 safe or approved store; and
- keep the original register.

The offence carries a maximum penalty of 40 penalty units.

Subdivision 3 Users of registers

Information that must be recorded in register

Clause 211 provides that this section applies if an authorised user or assistant accesses an S8 safe or approved store for a dealing with a type of medicine.

Clause 211(2) provides it is an offence if the authorised user or assistant fails to take all reasonable steps to ensure a record is made in the medicine register of the information mentioned in sections 212 and 213 for the dealing, as soon as practicable, but no later than 24 hours after the dealing. The offence carries a maximum penalty of 40 penalty units.

General information recorded in register

Clause 212 provides that for section 211, the information for any dealing is:

- the date of the dealing; and
- the amount of the medicine; and
- the description of the dealing; and
- for an authorised user, the signature of the authorised user; and

- for an assistant, the name of the assistant and the signature of the authorised user supervising the assistant; and
- the name and signature of any other person recording the information; and
- the amount of medicine remaining after the dealing.

Specific information for particular dealings recorded in register

Clause 213 provides that for section 211, the information for each of the following particular dealings is:

- for stock of a medicine put in or taken from the S8 safe or approved store to which the register applies, the name and address of the supplier of the stock, the unique identifier of the notice mentioned in section 61(1) for the supply of the stock, the name and address of the person to whom the stock was supplied, and the unique identifier, if any, of the purchase order for the supply;
- for administration, if the administration is to a person, the name of the person, if the administration is to an animal, the name of the owner or custodian of the animal, and if the administration happens at a specified place, the time of the administration;
- for dispensing or giving a treatment dose on a prescription, the name of the prescriber and the unique identifier, if any, of the prescription, the name and address of the person, if the medicine is dispensed or given to a person, the name and address of the owner or custodian of the animal, if the medicine is dispensed or given to an animal;
- for a dealing under a general approval, the name of the person who authorised the dealing;
- for possession by distribution, the name of the person to whom the medicine was given or the place where the medicine was moved;
- for disposal of waste from a diversion-risk medicine by transfer, the name and signature of the person to whom the waste was transferred;
- for the disposal of waste from a diversion-risk medicine by destruction, the name and signature of the person who witnessed the destruction of the medicine and information stating the person's authority to witness the destruction.

Amending register

Clause 214 provides it is an offence for a person to amend the medicines register for an S8 safe or approved store unless the person is correcting the register in the way mentioned in subsections (2) and (3) or has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.

Clause 214(2) provides that the person may correct an entry in the medicines register by making a record of the following with the entry:

- the date the correction was made;
- the name and position of the person making the correction;
- the reason for the correction;
- if the correction relates to the disposal of waste from a diversion-risk medicine by destruction, the name and position of the person who witnessed the destruction of the medicine.

Clause 214(3) provides that the person must not cancel, delete or obscure an original entry when making the correction.

Keeping secure system identifier secure

Clause 215 provides it is an offence if a person given a secure system identifier for a medicine register for an S8 safe or an approved store kept in an electronic form fails to take all reasonable steps to keep the identifier secure from access by another person. The offence carries a maximum penalty of 20 penalty units.

Making entries in a paper register

Clause 216 provides it is an offence for a person to make an entry in a medicine register for an S8 safe or approved store kept on paper unless the person:

- is permitted to make the entry by a manager of the safe or store; and
- signs the entry, including any corrections to the entry; and
- does not remove or tamper with pages in the register.

The offence carries a maximum penalty of 40 penalty units.

Subdivision 4 Managers reconciling registers

Reconciling with medicines on hand

Clause 217 provides it is an offence if a manager of an S8 safe or approved store fails to reconcile the register for the safe or store at least monthly with the amount of medicines physically held in the safe or store and record the date the reconciliation is done in the medicine register. The offence carries a maximum penalty of 40 penalty units.

Clause 217(2) provides that if a substance management plan applies to the place at which the S8 safe or approved store is located, the reconciliation must be done at the times stated in the substance management plan.

Reporting lost, stolen or destroyed register

Clause 218 provides that this section applies if a medicine register for an S8 safe or approved store is lost, stolen or destroyed (each an ***incident***).

Clause 218(2) provides it is an offence if a manager of the safe or store fails to give notice about the incident to the chief executive in the approved form as soon as practicable, but no later than the end of the next business day, after the incident. The offence carries a maximum penalty of 40 penalty units.

Division 4 Carriers

Systems for tracking stock of medicines

Clause 219 provides that subsection (2) applies to a person (a ***carrier)*** who operates a business for delivering stock of medicines.

Clause 219(2) provides it is an offence if the carrier fails to take all reasonable steps to establish a tracking system to track stock of any medicines being delivered by the carrier. The offence carries a maximum penalty of 40 penalty units.

Clause 219(3) provides that subsection (4) applies to a person (an ***employee***) employed by the carrier to deliver stock of medicines.

Clause 219(4) provides that when delivering the stock, it is an offence if the employee fails to use any tracking system established by the carrier in the way advised to the employee, unless the employee has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.

Clause 219(5) provides for this section a definition of *tracking system.*

Safe delivery of stock of S2 or S3 medicines

Clause 220 provides that this section applies if a carrier is delivering stock of an S2 or S3 medicine.

Clause 220(2) provides it is an offence if the carrier fails to take all reasonable steps to keep the stock within any temperature limits for the stock notified to the carrier by the person who engaged the carrier to deliver it. The offence carries a maximum penalty of 40 penalty units.

Clause 220(3) provides it is an offence if the carrier leaves the stock unattended, other than in a secure area. The offence carries a maximum penalty of 40 penalty units.

Clause 220(4) provides it is an offence if the carrier fails to deliver the stock to the street address stated on the packaging for the stock. The offence carries a maximum penalty of 40 penalty units.

Clause 220(5) provides it is an offence if the carrier leaves the stock at the street address unless the carrier obtains a written receipt for the delivery of the stock from the person named on the package for the stock or an adult at the address acting, or purportedly acting, on behalf of the person mentioned in paragraph (a). The offence carries a maximum penalty of 40 penalty units.

Part 3 Containers

Restriction on used containers

Clause 221 provides it is an offence for a person preparing a medicine for supply to use an immediate container to package the medicine if the person knows the container has previously been used. The offence carries a maximum penalty of 20 penalty units.

Part 4 Recording and keeping information

Writing paper documents

Clause 222 provides that this section applies to a person writing on paper to comply with a requirement mentioned in this regulation, including writing a prescription or purchase order.

Clause 222(2) provides it is an offence if the person fails to write:

- in ink;
- legibly, other than the person's signature; and
- in English or use terms or symbols, including Latin terms, used in the ordinary practice of the person's profession.

The offence carries a maximum penalty of 40 penalty units.

Writing electronic documents

Clause 223 provides that this section applies to a person writing an electronic document to comply with a requirement mentioned in this regulation, including writing an electronic prescription or electronic purchase order.

Clause 223(2) provides it is an offence if a person fails to:

- write in English or use terms or symbols, including Latin terms, used in the ordinary practice of the person's profession; and
- link or attach the other document to the electronic document, if the entry relates to another document.

The offence carries a maximum penalty of 40 penalty units.

Clause 223(3) provides that this section does not apply if the person uses an electronic prescription management system to make the document.

Period and way of keeping records

Clause 224 provides that this section applies to a person if a provision of this regulation states that the person is required to keep a record.

Clause 224(2) provides that this section does not apply to a pharmacist keeping a record under section 162 or the chief executive keeping information in the monitored medicines database.

Clause 224(3) provides it is an offence if the person fails to keep the record for:

- two years after the appointment ends, if the record is the details of an appointment of a system administrator under section 185;
- two years after the last entry in the register is made, if the record is an entry in a medicine register kept on paper; or
- otherwise, two years after the record is made, otherwise.

The offence carries a maximum penalty of 40 penalty units.

Clause 224(4) provides it is an offence if during the period for which the record must be kept, the person fails to take reasonable steps to ensure the record is kept in a retrievable form and kept securely to ensure it can not be altered, obliterated, deleted or removed without detection.

The offence carries a maximum penalty of 40 penalty units.

Clause 224(5) provides if the record is kept electronically, it is an offence if the person fails to ensure any data stored in the record is secure and tamper-proof in accordance with acceptable industry standards and fails to backup the record regularly during the period for which the record must be kept.

The offence carries a maximum penalty of 40 penalty units.

Clause 224(6) provides that subsection (5) does not apply if the record is kept in an electronic prescription management system.

Clause 224(7) provides for this section a definition of *record*.

Securing prescription stationery

Clause 225 provides it is an offence if a prescriber fails to take all reasonable steps to keep secure any stationery used, or to be used, by the prescriber for prescribing. The offence carries a maximum penalty of 40 penalty units.

Part 5 Reporting particular matters

Reporting lost or stolen medicine

Clause 226 provides that this section applies to each of the following persons in the following circumstances (each an ***incident***):

- a person, in the course of acting as an approved person, reasonably suspects an S8 medicine has been lost or stolen;
- a person, in the course of acting as an approved person, reasonably suspects pentobarbital has been lost or stolen;
- a pharmacist, in the course of practicing the pharmacist's profession, reasonably suspects pseudoephedrine has been lost or stolen; or
- a person, dealing with a diversion-risk medicine under a general approval, reasonably suspects the medicine has been lost or stolen.

Clause 226(2) provides it is an offence if an authorised person fails to give notice about the incident to the chief executive in the approved form and notify the police service about the incident, as soon as practicable, but no later than the end of the next business day, after the incident. The offence carries a maximum penalty of 40 penalty units.

Clause 226(3) provides that subsection (2) does not apply if the medicine is lost or stolen from an RFDS medicine chest kept by the Royal Flying Doctor Service of Australia and a report about the incident is given to the senior medical officer of the Royal Flying Doctor Service of Australia.

Reporting failure to give written prescriptions

Clause 227 provides that this section applies if a prescriber fails to comply with a relevant provision relating to a prescription for a medicine, a person dispenses, gives or administers the medicine on the prescription and the person is not aware of a reasonable excuse for the prescriber's failure to comply.

Clause 227(2) provides it is an offence if the person fails to give notice about the prescriber's failure to comply with the relevant provision:

- to the relevant manager of the prescriber as soon as practicable, if the person is employed by the same entity as the prescriber;
- otherwise, the chief executive in the approved form within 48 hours after the end of the period for compliance mentioned in subsection (1).

The offence carries a maximum penalty of 20 penalty units.

Clause 227(3) provides that subsection (4) applies if the person notifies the relevant manager of the prescriber of the prescriber's failure to comply and the prescriber does not rectify the failure within 48 hours after the notification.

Clause 227(4) provides it is an offence if the relevant manager fails to give notice about the failure to the chief executive in the approved form as soon as practicable. The offence carries a maximum penalty of 20 penalty units.

Clause 227(5) provides for this section definitions of *relevant manager* and *relevant provision*.

Reporting and preventing use of unlawful documents

Clause 228 provides that this section applies if a person who is authorised to deal with a medicine receives any of the following documents:

- a purchase order for stock of a medicine;
- a prescription for dispensing a medicine;
- a prescription for giving a treatment dose of a medicine.

Clause 228(2) provides that if the person reasonably believes the document has been unlawfully obtained or made, it is an offence if the person fails to take the following action:

- record the name and address of whoever gave the person the document;
- notify the police service as soon as practicable;
- if the document is for a diversion-risk medicine, give notice to the chief executive in the approved form as soon as practicable;
- for a hard copy of a purchase order, keep the purchase order or a copy of the order;
- for a purchase order given electronically, process the purchase order in the system in which it is kept to prevent stock of the medicine being supplied;
- for a paper prescription, keep the prescription or a copy of the prescription;
- for an electronic prescription, process the prescription in the system in which it is kept to prevent the medicine being dispensed or given.

The offence carries a maximum penalty of 60 penalty units.

Clause 228(3) provides that the person is required to comply with subsection (2) only to the extent it is safe for the person to comply.

Marking non-compliant paper prescriptions

Clause 229 provides that this section applies if:

- a person who is authorised to dispense a medicine, or give a treatment dose of a medicine, does not dispense or give the medicine, on a paper prescription;
- the person did not take the action mentioned in paragraph (a) because the person reasonably suspects the prescription has been unlawfully obtained or made, the prescription has been given by a person who is not authorised under the Medicines and Poisons Act, or permitted under a corresponding law or another law, to prescribe the medicine, or the prescription does not otherwise comply with the Medicines and Poisons Act.

Clause 229(2) provides it is an offence if the person fails to mark the prescription with:

- a statement that the prescription is cancelled or not to be dispensed or given; and
- the date of marking the prescription; and
- the person's name and signature; and
- the address of the place where the prescription was presented.

The offence carries a maximum penalty of 60 penalty units.

Clause 229(3) provides that the person is required to comply with subsection (2) only to the extent it is safe for the person to comply.

Reporting supply on false prescription or purchase order for diversion-risk medicine

Clause 230 provides that this section applies if, after supplying a diversion-risk medicine on a prescription or purchase order, the supplier of the medicine reasonably suspects any of the following incidents has happened:

- false information, material to the prescription or purchase order, was given to the person who prescribed the medicine or gave the purchase order;
- the prescription or purchase order was changed by a person other than the prescriber of the prescription or the dispenser of the medicine for the prescription, for a prescription, or the person who gave the purchase order, for a purchase order;
- the prescription or purchase order was false in any material particular.

Clause 230(2) provides it is an offence if a supplier fails to give notice about the incident to the chief executive in the approved form and to the police service no later than 24 hours after becoming aware of the incident. The offence carries a maximum penalty of 60 penalty units.

Clause 230(3) provides for this section a definitions of *supplier*.

Notification of loss or theft

Clause 231 provides that this section applies to a person (each the ***wholesaler***) who is authorised to supply medicines by wholesale or is a wholesale representative.

Clause 231(2) provides it is an offence if a wholesaler fails to report the loss or theft of a diversion-risk medicine that was in the possession of the wholesaler immediately before the loss or theft. The offence carries a maximum penalty of 40 penalty units.

Clause 231(3) provides it is an offence if the report is not made to the police service and to the chief executive in the approved form as soon as practicable and no later than the end of the next business day, after the loss or theft. The offence carries a maximum penalty of 40 penalty units.

Return of transactions for wholesale representatives

Clause 232 provides that a wholesale representative must, periodically but at least every three months, give the representative's employer a return complying with subsection (2) about the transactions carried out by the representative for the period. The offence carries a maximum penalty of 40 penalty units.

Clause 232(2) provides that the return must state the following information:

- the period of the return;
- the total amount of each type of medicine in the representative's possession at the start and end of the period;
- the amount of each type of monitored medicine received by the representative;
- the amount of each type of monitored medicine given as a sample, or returned, by the representative;
- the invoice number for each monitored medicine given as a sample or return.

Clause 232(3) provides it is an offence if the wholesale representative fails to keep a copy of each return sent to the representative's employer. The offence carries a maximum penalty of 40 penalty units.

Clause 232(4) provides it is an offence if the wholesale representative's employer fails to keep a copy of each return received from the wholesale representative. The offence carries a maximum penalty of 40 penalty units.

Clause 232(5) provides for this section a definition of *employer*.

Giving chief executive information about particular diversion-risk medicines

Clause 233 provides that this section applies if:

- a person seeks a supply of a diversion-risk medicine from a pharmacist, other than a medicine that is also a monitored medicine; and
- the pharmacist reasonably suspects the amount of the medicine sought exceeds the amount or frequency of doses that the person could reasonably be seeking for the therapeutic treatment of the person or the person's animal.

Clause 233(2) provides it is an offence if the pharmacist fails to give notice to the chief executive in the approved form, unless the pharmacist has a reasonable excuse. The offence carries a maximum penalty of 40 penalty units.

Part 6 Advertising and vending machines

Unlawful advertising of medicines

Clause 234 provides it is an offence for a person to advertise, or cause a person to advertise, as S3, S4 or S8 medicine. The offence carries a maximum penalty of 80 penalty units.

Clause 234(2) provides that subsection (1) does not apply in relation to an advertisement of an S3, S4 or S8 medicine, in a journal, a price list or other promotional material that relates only to the therapeutic use of the medicine in the practise of a profession, or in accordance with the document called *Price Information Code of Practice*, published by the Therapeutic Goods Administration and an advertisement of an S3 medicine listed in Appendix H of the Poisons Standard.

Offence to install medicine vending machines

Clause 235 provides it is an offence for a person who is the owner or occupier of premises to install a medicine vending machine on the premises. The offence carries a maximum penalty of 30 penalty units.

Clause 235(2) provides for this section a definition of *medicine vending machine*.

Chapter 9 Miscellaneous

Part 1 Administration by chief executive

Matters to be considered before making extended practice authorities—Act, s 232

Clause 236 provides that for section 232(2) (Making extended practice authorities) of the Medicines and Poisons Act, the following matters are prescribed in relation to a dealing with a medicine:

- the nature of the dealing;
- whether there is community need for any service to be facilitated by the extended practice authority;
- the way in which any health risks associated with the dealing are to be managed under the authority;
- whether there is a need for a review of the authority and the timing of any review needed;
- the governance capability of the entity, if the approved person is subject to the governance of an entity under the authority;
- if the medicine is a restricted medicine or unregistered medicine, whether it is in the public interest to make the authority, considering the particular health risks associated with restricted medicines and unregistered medicines.

Chief executive may approve alternative ways of labelling or packaging medicines

Clause 237 provides that the chief executive may approve a way (an ***alternative way***) of labelling or packaging a medicine that is different to the Poisons Standard.

Clause 237(2) provides that the chief executive may approve the alternative way only if the chief executive is satisfied it is unlikely to adversely affect public safety, having regard to the nature of the medicine and the purpose for which it is to be used.

Clause 237(3) provides that the chief executive must publish, on the department's website a notice stating the requirements of the alternative way, the day, no earlier than the day the notice is published, that the approval of the alternative way takes effect and the period, if any, for which the approval of the alternative way has effect.

Clause 237(4) provides that subsection (5) applies if an appropriate authority, for a purpose or in another State, has authorised, whether by approval, exemption or some other way, another way to label or package a medicine for the purpose or other State.

Clause 237(5) provides that to the extent authorised by the appropriate authority, the other way is taken to be an alternative way approved under this section, unless the chief executive publishes a statement on the department's website that the other way is not approved for Queensland.

Part 2 Fees

Division 1 General

Definitions for part and schedule 19

Clause 238 provides for this part definitions of *licencing fee* and *site*.

Fees payable

Clause 239 provides that the fees payable under the Medicines and Poisons Act in relation to a substance authority for a dealing with a medicine are stated in schedule 19.

Clause 239(2) provides that a licensing fee for a substance authority is payable for site for the authority for each year of the term of the authority.

Clause 239(3) provides that for any part of the term of a substance authority that is not a full year, the licensing fee payable in relation to that part of the term is the proportion of the licensing fee attributable to the number of months, rounded up to whole months, of that year that are in the term.

Division 2 Exemptions

Manufacturing licence for S2, S3 or S4 medicines

Clause 240 provides that no licencing fee is payable for an initial application or renewal application for a manufacturing licence for an S2, S3 or S4 medicine (each a ***later application***) if:

- an initial application or renewal application for a manufacturing licence for a manufacturing licence for an S7 poison (each a ***first application***) has been made, and not withdrawn or refused, under the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*; and
- the site the subject of the later application is the same as the site the subject of the first application; and
- the term proposed for the later application ends no later than the last month of the term proposed in the first application or, if the chief executive has granted the first application, the term of the substance authority granted on the first application; and
- all fees payable under the Medicines and Poisons Act for the first application have been paid.

Wholesale licence for S2, S3 or S4 medicines

Clause 241 provides that no licencing fee is payable for an initial application or renewal application for a wholesale licence for an S2, S3 or S4 medicine (each a ***later application***) if:

- an initial application or renewal application for a manufacturing licence for a manufacturing licence of wholesale licence for an S7 poison (each a ***first application***) has been made, and not withdrawn or refused, under the *Medicines and Poisons (Poisons and Prohibited Substances) Regulation 2021*; and
- the site the subject of the later application is the same as the site the subject of the first application; and
- the term proposed for the later application ends no later than the last month of the term proposed in the first application or, if the chief executive has granted the first application, the term of the substance authority granted on the first application; and
- all fees payable under the Medicines and Poisons Act for the first application have been paid.

Division 3 Refunds

Rejected or withdrawn application

Clause 242 provides that this section applies if an applicant has paid the licencing fee for an application for a substance authority for a medicine and the application is refused by the chief executive or withdrawn by the applicant.

Clause 242(2) provides that the chief executive must refund the applicant the licensing fee for the application.

Authority granted for shorter term

Clause 243 provides that this section applies if an applicant has paid the licensing fee for an application for a substance authority for a medicine for a particular term (the ***proposed term***) and the application is granted for a period (the ***granted term***) that is shorter than the proposed term.

Clause 243(2) provides that the chief executive must refund the applicant the amount that is the proportion of the paid licensing fee attributable to the number of months, rounded up to whole months, that is the difference between the proposed term and granted term.

Clause 243(3) provides that no refund is payable if the amount of subsection (2) is zero or less than zero.

Surrender of authority

Clause 244 provides that this section applies if the holder of a substance authority for a medicine paid the licensing fee for an application for the authority for a particular term (the ***granted term***) and the substance authority is surrendered before the end of the granted term.

Clause 244(2) provides that the chief executive must refund the applicant the amount that is the proportion of the paid licensing fee attributable to the number of months, rounded up to whole months, remaining in the granted term after the surrender.

Clause 244(3) provides that no refund is payable if the amount of subsection (2) is zero or less than zero.

Chapter 10 Repeal and transitional provisions

Part 1 Repeal

Repeal

Clause 245 provides that the *Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020* is repealed.

Part 2 Transitional provisions

Division 1 Monitored medicines database

Prescribed day when database is fully operational—Act, s 281

Clause 246 provides that for section 281(1)(b) (Procedure until monitored medicines database operational) of the Medicines and Poisons Act, 27 October 2021 is prescribed to be the day that the monitored medicines database is fully operational.

Information transitioned to database—Act, s 225

Clause 247 provides that this section applies in relation to information recorded in the monitored medicines database under the repealed *Medicines and Poisons (Monitored Medicines Database Testing) Regulation 2020* immediately before the repeal of that regulation; and given to, or held by, the chief executive under section 281 (Procedure until monitored medicines database operational) of the Medicines and Poisons Act relating to an approval in effect during the transition period under that section.

Clause 247(2) provides that the information is prescribed for section 225(1) (Information recorded in database) of the Medicines and Poisons Act.

Division 2 Special arrangement period

Sending and keeping particular prescriptions during special arrangement period

Clause 248 provides that this section applies if, during the special arrangement period, a prescriber gives a digital copy of a paper prescription for an S4 medicine, other than a diversion-risk medicine, to a dispenser.

Clause 248(2) provides that the prescriber is taken to have complied with section 84(4) if the prescriber keeps the paper prescription for a period of two years after giving the dispenser a digital copy of the paper prescription.

Clause 248(3) provides for this section definitions of *special arrangement and special arrangement period.*

Division 3 Transitioned approvals, documents and records

Definition for division

Clause 249 provides for this division definition of *HDPR* and *new clinical protocol*.

Certified way of packaging

Clause 250 provides that this section applies if the chief executive certified a container for packing a medicine under section 10(3) of the repealed *Health (Drugs and Poisons) Regulation 1996* and the certification was in effect immediately before the commencement.

Clause 250(2) provides that the certification is taken to be an alternative way for packaging the medicine under section 237 until:

- if an expiry day is stated in the certification, the day stated; or
- otherwise, the day that is one year after the commencement.

Certified way of labelling

Clause 251 provides that this section applies if the chief executive certified an alternative way of labelling a package for a medicine under section 11(3) of the repealed *Health (Drugs and Poisons) Regulation 1996* and the certification was in effect immediately before the commencement.

Clause 251(2) provides that the certification is taken to be an alternative way of labelling a package for the medicine under section 237 until:

- if an expiry day is stated in the certification, the day stated; or
- otherwise, the day that is one year after the commencement.

Controlled drugs registers

Clause 252 provides that this section applies if, immediately before the commencement, a person kept a controlled drugs register under section 50 of the repealed *Health (Drugs and Poisons) Regulation 1996*.

Clause 252(2) provides that the controlled drugs register is taken to be a medicine register for S8 medicines.

Clinical protocols

Clause 253 provides that this section applies if, immediately before the commencement, an existing clinical protocol was in effect for a person practicing a profession at a place.

Clause 253(2) provides that the existing clinical protocol is taken to be a new clinical protocol for the person practising the profession at the place until the earlier of the day the existing protocol is revoked, or the day stated to be the expiry date in the existing clinical protocol.

Clause 253(3) provides for this section a definition of *existing clinical protocol*.

Orthoptist protocols

Clause 254 provides that this section applies if immediately before the commencement, a health management protocol was in effect for a person who was an orthoptist under the repealed *Health (Drugs and Poisons) Regulation 1996* practicing orthoptics and on the commencement, the person is an orthoptist mentioned in schedule 8, section 6.

Clause 254(2) provides that the health management protocol is taken to be a new clinical protocol applying to the person for practicing orthoptics until the earlier of the day the protocol is revoked or the day stated to be the expiry date in the health management protocol.

Clause 254(3) provides for this section definitions of *health management protocol* and *orthoptist DTP*.

Practice plans

Clause 255 provides that this section applies if, immediately before the commencement a practice plan was in effect under the repealed *Health (Drugs and Poisons) Regulation 1996* for either an Aboriginal and Torres Strait Islander health practitioner or a physician's assistant.

Clause 255(2) provides that the practice plan is:

- taken to be the practice plan for the practitioner under schedule 3 part 1, if the practitioner is an Aboriginal and Torres Strait Islander health practitioner mentioned in in that part on or after the commencement; or
- taken to be the practice plan for the practitioner under schedule 6, part 3, if the practitioner is a physician assistant mentioned in that part on or after the commencement.

Chief executive's approvals or certifications for bodies and facilities

Clause 256 provides that this section applies if, immediately before the commencement, an approval or certification by the chief executive was in effect under the repealed *Health (Drugs and Poisons) Regulation 1996* for a professional body, a facilities accreditation body, a laboratory or another facility.

Clause 256(2) provides that the approval or certification continues in effect to the extent the chief executive's approval is required for the same purpose under this regulation for which the body or facility was approved or certified for and until it is revoked by the chief executive.

Chapter 11 Amendment of regulations

Part 1 Amendment of Planning Regulation 2017

Regulation amended

Clause 257 provides that this part amends the *Planning Regulation 2017*.

Amendment of s 20A (When material change of use for providing COVID-19 vaccination service is not assessable development)

Clause 258 omits and replaces section 20A(3) of the Planning Regulation.

Amendment of sch 6 (Development local categorising instrument is prohibited from stating is assessable development)

Clause 259 omits and replaces schedule 6, section 7(2) and (3) of the Planning Regulation.

Amendment of sch 7 (Accepted development)

Clause 260 omits and replaces schedule 7, section 4A(2) of the Planning Regulation.

Part 2 Amendment of State Penalties Enforcement Regulation 2014

Regulation amended

Clause 261 provides that this part amends the *State Penalties Enforcement Regulation 2014*.

Amendment of sch 1 (Infringement notice offences and fines for nominated laws)

Clause 262 omits the entries from schedule 1 of the State Penalties Enforcement Regulation in relation to the *Pest Management Act 2001* and the *Pest Management Regulation 2003*.

Clause 262(2) inserts a new schedule into the State Penalties Enforcement Regulation, which prescribes new penalty infringement notice offence for the Medicines and Poisons Act.

Part 3 Amendment of other regulations

Other regulations amended

Clause 263 provides that schedule 23 amends the regulations mentioned in it.

Schedule 1 Extended practice authorities and departmental standards

Part 1 Approved extended practice authorities

Part 1 provides for a list of named approved extended practice authorities and their version number.

Part 2 Approved departmental standards

Part 2 provides for a list of named approved departmental standards and their version number.

Schedule 2 Categories of medicines

Part 1 Restricted medicines

Part 1 provides for a list of restricted medicines.

Part 2 High-risk medicines

Part 2 provides for a list of high-risk medicines.

Part 3 Diversion-risk medicines

Part 3 provides for a list of diversion-risk medicines.

Part 4 Monitored medicines

Part 4 provides for a list of monitored medicines.

Schedule 3 Aboriginal and Torres Strait Islander health professions

Part 1 Aboriginal and Torres Strait Islander health practitioners in isolated practice areas

Division 1 Preliminary

Definitions for part

Clause 1 provides for this part, definitions of *Aboriginal and Torres Strait Islander health practitioner*, *practice plan*, *primary clinical supervisor* and *relevant health service*.

Division 2 Aboriginal and Torres Strait Islander health practitioners

Class of person

Clause 2 provides that this division applies to an Aboriginal and Torres Strait Islander health practitioner (an ***Aboriginal and Torres Strait Islander health practitioner***) employed by a relevant health service and practising in an isolated practice area.

Dealing authorised

Clause 3 provides that an Aboriginal and Torres Strait Islander health practitioner can perform the following regulated activities:

- give a treatment dose of a medicine mentioned in the *Aboriginal and Torres Strait Islander health practitioners* extended practice authority, if the medicine is given under the extended practice authority and in accordance with a practice plan for the Aboriginal and Torres Strait Islander health practitioner.

- repackage a medicine mentioned in the *Aboriginal and Torres Strait Islander health practitioners* extended practice authority, if the medicine is repackaged for giving a treatment dose under the extended practice authority.
- administer a medicine mentioned in the *Aboriginal and Torres Strait Islander health practitioners* extended practice authority, if the medicine is administered under the extended practice authority and in accordance with a practice plan for the Aboriginal and Torres Strait Islander health practitioner.
- give a purchase order for stock of medicine mentioned in the *Aboriginal and Torres Strait Islander health practitioners* extended practice authority, if the purchase order is given under the extended practice authority.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 2 Indigenous health workers in remote areas

Division 1 Preliminary

Definitions for part

Clause 4 provides for this part the definition of *Indigenous health worker*.

Division 2 Indigenous health workers in remote areas

Class of person

Clause 5 provides that this division applies to an Indigenous health worker (an ***Indigenous health worker***) who is practising in an isolated practice area and is employed by any of the following Hospital and Health Services:

- Cairns and Hinterland Hospital and Health Service;
- North West Hospital and Health Service;
- Torres and Cape Hospital and Health Service.

Dealing authorised

Clause 6 provides that an Indigenous health worker can perform the following regulated activities:

- give a treatment dose of a medicine mentioned in the *Indigenous health workers* extended practice authority, if the medicine is given for a patient under the extended practice authority.
- repackage a medicine mentioned in the *Indigenous health workers* extended practice authority, if the medicine is repackaged for giving a treatment dose under the extended practice authority.
- administer a medicine mentioned in the *Indigenous health workers* extended practice authority, if the medicine is administered under the extended practice authority.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 3 Practitioners employed by approved Aboriginal health services

Class of person

Clause 7 provides that this division applies to a person (a ***practitioner employed by approved Aboriginal health service***) who is employed by an approved Aboriginal health service under the *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017* (Cwlth).

Dealing authorised

Clause 8 provides that a practitioner employed by Aboriginal health service can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the stock is for the approved Aboriginal health service.
- possess stock of an S4 or S8 medicine, if the stock is possessed for the Aboriginal health service.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Schedule 4 Dentistry professions

Part 1 Dentists

Division 1 Dentists generally

Definition for division

Clause 1 provides for this division a definition of *immediate release formulation*.

Class of person

Clause 2 provides that this division applies to a person (a ***dentist***) who is registered under the Health Practitioner Regulation National Law to practise in the dentists division of the dental profession.

Dealing authorised

Clause 3 provides that a dentist can perform the following regulated activities:

- prescribe:
  - an S2, S3 or S4 medicine, other than a restricted medicine.
  - any of the following S8 medicines, if the medicine is an immediate release formulation, for which a repeat prescription is not given and that is no more than three days supply of the medicine:
    - codeine;
    - hydromorphone;
    - morphine ;
    - oxycodone.
- give a treatment dose of an S2, S3 or S4 medicine, other than a restricted medicine.

- repackage an S2, S3 or S4 medicine, other than a restricted medicine, if the medicine is repackaged for giving a treatment dose for a patient.
- administer:
  - an S2, S3 or S4 medicine, other than a restricted medicine.
  - any of the following S8 medicines, if the medicine is in an immediate release formulation:
    - codeine;
    - hydromorphone;
    - morphine;
    - oxycodone.
- give a purchase order for stock of an S4 or S8 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Division 2 Endorsed conscious sedation dentists

Class of person

Clause 4 provides that this division applies to a dentist (an ***endorsed conscious sedation dentist***) who is an endorsed for conscious sedation.

Dealing authorised

Clause 5 provides that an endorsed conscious sedation dentist can perform the following regulated activities:

- administer fentanyl or pethidine.
- give a purchase order for stock of fentanyl or pethidine, if the stock is not for a specified place.
- possess fentanyl or pethidine.

Division 3 Specialist dentists

Class of person

Clause 6 provides that this division applies to a dentist (a ***specialist dentist***) who is a specialist registrant in oral medicine.

Dealing authorised

Clause 7 provides that a specialist dentist can perform the following regulated activities:

- prescribe hydroxychloroquine.
- give a treatment dose of hydroxychloroquine.
- administer hydroxychloroquine.

- give a purchase order for stock of hydroxychloroquine, if the stock is not for a specified place.
- possess hydroxychloroquine.

Part 2 Dental hygienists

Class of person

Clause 8 provides that this division applies to a person (a ***dental hygienist***) who is registered under the Health Practitioner Regulation National Law to practise in the dental hygienists division of the dental profession.

Dealing authorised

Clause 9 provides that a dental hygienist can perform the following regulated activities:

- administer:
  - any of the following S2 or S3 medicines:
    - an adrenaline (epinephrine) autoinjector;
    - local anaesthetics in preparations for topical human therapeutic use, other than eye drops;
    - fluorides in preparations for topical human therapeutic use;
    - silver salts.
  - local anaesthetics, whether alone or in combination with adrenaline (epinephrine) or felypressin.
- give a purchase order for an S4 medicine that is a local anaesthetic, if the stock is not for a specified place.
- possess an S4 medicine mentioned that is a local anaesthetic.

Part 3 Dental therapists

Class of person

Clause 10 provides that division applies to a person (a ***dental therapist***) who is registered under the Health Practitioner Regulation National Law to practise in the dental therapists division of the dental profession.

Dealing authorised

Clause 11 provides that a dental therapist can perform the following regulated activities:

- administer:
  - any of the following S2 or S3 medicines:
    - an adrenaline (epinephrine) autoinjector;
    - local anaesthetics in preparation for topical human therapeutic use, other than eye drops;
    - ether;
    - ferric sulphate;

  - fluorides in preparations for topical human therapeutic use;
  - phenol;
  - silver salts.
- any of the following S4 medicines:
  - local anaesthetics, whether alone or in combination with adrenaline (epinephrine) or felypressin;
  - antibiotics and corticosteroids in combination for topical endodontic use;
  - mercury for human therapeutic use.

- give a purchase order for an S4 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 medicine mentioned in this provision.

Part 4 Oral health therapists

Class of person

Clause 12 provides that this division applies to a person (an ***oral health therapist***) who is registered under the Health Practitioner Regulation National Law to practise in the oral health therapists division of the dental profession.

Dealing authorised

Clause 13 provides that an oral health therapist can perform the following regulated activities:

- administer:
  - any of the following S2 and S3 medicines:
    - an adrenaline (epinephrine) autoinjector;
    - local anaesthetics in preparations for topical human therapeutic use, other than eye drops;
    - ether;
    - ferric sulphate;
    - fluorides in preparations for topical human therapeutic use;
    - phenol;
    - silver salts.
- administer:
  - any of the following S4 medicines:
    - local anaesthetics, whether alone or in combination with adrenaline (epinephrine) or felypressin;
    - antibiotics and corticosteroids in combination for topical endodontic use;
    - mercury for human therapeutic use.
- give a purchase order for an S4 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 medicine mentioned in this provision.

Schedule 5 Emergency service providers

Part 1 Queensland Ambulance Service officers

Division 1 Commissioner or delegates

Class of person

Clause 1 provides that this division applies to a person (the ***commissioner or delegates***) who is the commissioner of the Queensland Ambulance Service under the *Ambulance Service Act 1991* or is exercising a power under the Act as the commissioner's delegate.

Dealing authorised

Clause 2 provides that the commissioner can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for the Queensland Ambulance Service;
- possess stock of an S4 or S8 medicine, if the stock is possessed for the Queensland Ambulance Service;
- dispose of waste from a diversion-risk medicine that is an S4 or S8 medicine.

Division 2 Ambulance officers

Class of person

Clause 3 provides that this division applies to a person (an ***ambulance officer***) who is an ambulance officer under the *Ambulance Service Act 1991*.

Dealing authorised

Clause 4 provides that an ambulance officer can perform the following regulated activities:

- give a treatment of a medicine mentioned in the *Queensland Ambulance Service* extended practice authority, if the medicine is given under the extended practice authority;
- administer a medicine mentioned in the *Queensland Ambulance Service* extended practice authority, if the medicine is administered under the extended practice authority;
- possess an S4 or S8 medicine mentioned in the *Queensland Ambulance Service* extended practice authority, if the medicine is possessed under the extended practice authority;
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 2 First aid providers

Class of person

Clause 5 provides that this part applies to a person (a ***first aid provider***) who has a current certificate granted by a registered training organisation for the provision of first aid.

Dealing authorised

Clause 6 provides that a first aid provider can perform the following regulated activities:

- administer:
  - methoxyflurane, if the medicine is administered on a prescription and the first aid provider has completed methoxyflurane training;
  - adrenaline (epinephrine) autoinjector, if the first aid provider has completed anaphylaxis training;
  - naloxone, if the first aid provider has completed naloxone training;
  - an inhaled asthma reliever, other than an S4 medicine, if the first aid provider has completed asthma training;
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this column.

Part 3 Royal Flying Doctor Service workers

Definition for part

Clause 7 provides for this part a definition of *RFDS medicine chest*.

Class of person

Clause 8 provides that this part applies to a person (a ***medicine chest controller***) who is a worker for the Royal Flying Doctor Service of Australia and is in charge of an RFDS medicine chest.

Dealing authorised

Clause 9 provides that a medicine chest controller can perform the following regulated activities:

- give a treatment dose of a medicine from the RFDS medicine chest, if the medicine is given on a prescription;
- administer a medicine from the RFDS medicine chest, if the medicine is administered on a prescription;
- possess an S4 or S8 medicine from the RFDS medicine chest, if the medicine is possessed for a purpose mentioned in this provision.

Schedule 6 Medical practitioners and assistants

Part 1 Medical practitioners generally

Division 1 Dealing with non-restricted medicines and waste from diversion-risk medicines

Class of person

Clause 1 provides that this division applies to a person (a ***medical practitioner***) who is registered under the Health Practitioner National Law to practise in the medical profession.

Dealing authorised

Clause 2 provides that a medical practitioner can perform the following regulated activities:

- prescribe a non-restricted medicine;
- make a standing order for a non-restricted medicine;
- dispense a non-restricted medicine;
- give a treatment dose for a non-restricted medicine;
- administer a non-restricted medicine;
- repackage a non-restricted medicine;
- give a purchase order for stock of an S4 or S8 medicines, that is a non-restricted medicine, if the stock is not for a specified place;
- possess an S4 or S8 medicine that is a non-restricted medicine;
- dispose of waste from a diversion-risk medicine.

Division 2 Dispensing restricted medicines prescribed by other practitioners

Class of person

Clause 3 provides that this division applies to a medical practitioner.

Dealing authorised

Clause 4 provides that a medical practitioner can perform the following regulated activities:

- dispense a restricted medicine, if the medicine is dispensed on a prescription from another medical practitioner;
- repackage a restricted medicine, if the medicine is repackaged for a patient to dispense a prescription from another medical practitioner;
- give a purchase order for stock of a restricted medicine, if the stock is:
  - required for dispensing prescriptions from other medical practitioners; and
  - not for a specified place;
- possess a restricted medicine, if the medicine is possessed for a purpose mentioned in this provision.

Division 3 Continuing treatment with restricted medicines at particular institutions

Definition for division

Clause 5 provides for this division a definition of *continuing institutional treatment*.

Class of person

Clause 6 provides that this division applies to a medical practitioner.

Dealing authorised

Clause 7 provides that a medical practitioner can perform the following regulated activities:

- prescribe a restricted medicine, if the medicine is prescribed, under the supervision of a registrar or specialist medical practitioner authorised to prescribe the medicine, for:
  - administration by a health practitioner; and
  - the continuing institutional treatment of a patient;
- administer a restricted medicine, if the medicine is administered, under the supervision of a registrar or specialist medical practitioner authorised to administer the medicine, for the continuing institutional treatment of a patient;
- possess a restricted medicine, if the medicine is possessed, under the supervision of a registrar or specialist medical practitioner authorised to possess the medicine, for the continuing institutional treatment of a patient.

Division 4 Continuing treatment with hydroxychloroquine

Definition for division

Clause 8 provides for this division a definition of *continuing hydroxychloroquine treatment*.

Class of person

Clause 9 provides that this division applies to a medical practitioner.

Dealing authorised

Clause 10 provides that a medical practitioner can perform the following regulated activities:

- prescribe hydroxychloroquine, if the medicine is prescribed for the continuing hydroxychloroquine treatment of a patient;
- give a treatment dose of hydroxychloroquine, if the medicine is given for the continuing hydroxychloroquine treatment of a patient;
- dispense hydroxychloroquine, if the medicine is dispensed for the continuing hydroxychloroquine treatment of a patient;
- administer hydroxychloroquine, if the medicine is administered for the continuing hydroxychloroquine treatment of a patient;
- give a purchase order for stock of hydroxychloroquine, if the stock is purchased for the continuing hydroxychloroquine treatment of a patient, other than patients at a specified place;
- possess hydroxychloroquine, if the medicine is possessed for a purpose mentioned in this provision.

Division 5 Dealing with amfetamines or methylphenidates

Definition for division

Clause 11 provides for this division a definition of *relevant condition*.

Class of person

Clause 12 provides that this division applies to a medical practitioner.

Dealing authorised

Clause 13 provides that a medical practitioner can perform the following regulated activities:

- prescribe amfetamines or methylphenidates, if the medicine is prescribed for the treatment of a relevant condition;
- give a treatment dose of amfetamines or methylphenidates, if the medicine is given for the treatment of a relevant condition;
- dispense amfetamines or methylphenidates, if the medicine is dispensed for the treatment of a relevant condition;
- administer amfetamines or methylphenidates, if the medicine is administered for the treatment of a relevant condition;
- give a purchase order for stock of amfetamines or methylphenidates, if the stock is for the treatment of a relevant condition, other than at a specified place;
- possess amfetamines or methylphenidates, if the medicine is possessed for a purpose mentioned in this provision.

Division 6 Giving purchase orders at relevant institutions

Class of person

Clause 14 provides that this division applies to a medical practitioner who is in charge of clinical or medical services at a relevant institution.

Dealing authorised

Clause 15 provides that a medical practitioner who is in charge of clinical or medical services at a relevant institution can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for the relevant institution and the purchase order is given for the therapeutic treatment of patients at the relevant institution.
- possess stock of an S4 or S8 medicine, if the stock is possessed at the relevant institution.

Part 2 Specialist medical practitioners

Division 1 Registrars

Definition for division

Clause 16 provides for this division a definition of *relevant restricted medicine*.

Class of person

Clause 17 provides that this division applies to a medical practitioner (a ***registrar***) employed as a registrar in a hospital working under the supervision of a medical practitioner who is a specialist in the specialty area of practice in which the registrar is working.

Dealing authorised

Clause 18 provides that a registrar can perform the following regulated activities:

- prescribe a relevant restricted medicine;
- give a treatment dose of a relevant restricted medicine;
- dispense a relevant restricted medicine;
- administer a relevant restricted medicine;
- give a purchase order for stock of a relevant restricted medicine, if the stock is not for a specified place;
- possess a relevant restricted medicine.

Division 2 Cardiologists

Class of person

Clause 19 provides that this division applies to a medical practitioner (a ***cardiologist***) who is a specialist registration in cardiology.

Dealing authorised

Clause 20 provides that a cardiologist can perform the following regulated activities:

- prescribe ambrisentan, bosentan, macitentan or riociguat;
- give a treatment dose of ambrisentan, bosentan, macitentan or riociguat;
- dispense ambrisentan, bosentan, macitentan or riociguat;
- administer ambrisentan, bosentan, macitentan or riociguat;
- give a purchase order for stock of medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 3 Dermatologists

Class of person

Clause 21 provides that this division applies to a medical practitioner (a ***dermatologist***) who is a specialist registrant in dermatology.

Dealing authorised

Clause 22 provides that a dermatologist can perform the following regulated activities:

- prescribe acitretin, bexarotene, etretinate, hydroxychloroquine, isotretinoin for human oral use, thalidomide or tretinoin for human oral use;
- give a treatment dose of acitretin, bexarotene, etretinate, hydroxychloroquine, isotretinoin for human oral use, thalidomide or tretinoin for human oral use;
- dispense acitretin, bexarotene, etretinate, hydroxychloroquine, isotretinoin for human oral use, thalidomide or tretinoin for human oral use;
- administer acitretin, bexarotene, etretinate, hydroxychloroquine, isotretinoin for human oral use, thalidomide or tretinoin for human oral use;
- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 4 Emergency medicine physicians

Class of person

Clause 23 provides that this division applies to a medical practitioner (an ***emergency medicine physician***) who is a specialist registrant in emergency medicine.

Dealing authorised

Clause 24 provides that an emergency medicine physician can perform the following regulated activities:

- prescribe hydroxychloroquine;
- give a treatment dose of hydroxychloroquine;
- dispense hydroxychloroquine;
- administer hydroxychloroquine;
- give a purchase order for stock of hydroxychloroquine, if the stock is not for a specified place;
- possess hydroxychloroquine.

Division 5 Endocrinologists

Class of person

Clause 25 provides that this division applies to a medical practitioner (an ***endocrinologist***) who is a specialist registrant in endocrinology.

Dealing authorised

Clause 26 provides that an endocrinologist can perform the following regulated activities:

- prescribe clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone, teriparatide or urofollitropin (human follicle stimulating hormone);
- give a treatment dose of clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone, teriparatide or urofollitropin (human follicle stimulating hormone);
- dispense clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone, teriparatide or urofollitropin (human follicle stimulating hormone);
- administer clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone, teriparatide or urofollitropin (human follicle stimulating hormone);
- give a purchase order for stock of medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 6 Geriatricians

Class of person

Clause 27 provides that this division applies to a medical practitioner (a ***geriatrician***) who is a specialist registrant in geriatrics.

Dealing authorised

Clause 28 provides that a geriatrician can perform the following regulated activities:

- prescribe teriparatide;
- give a treatment dose of teriparatide;
- dispense teriparatide;
- administer teriparatide;
- give a purchase order for stock of teriparatide, if the stock is not for a specified place;
- possess teriparatide.

Division 7 Gynaecologists and obstetricians

Class of person

Clause 29 provides that this division applies to a medical practitioner (a ***gynaecologist or obstetrician***) who is a specialist registrant in gynaecology or obstetrics.

Dealing authorised

Clause 30 provides that a gynaecologist or obstetrician can perform the following regulated activities:

- prescribe clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone or urofollitropin (human follicle stimulating hormone);
- give a treatment dose of clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone or urofollitropin (human follicle stimulating hormone);
- dispense clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone or urofollitropin (human follicle stimulating hormone);
- administer clomifene, corifollitropin alfa, cyclofenil, dinoprost, dinoprostone, follitropin alpha, follitropin beta, luteinising hormone or urofollitropin (human follicle stimulating hormone);
- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 8 Haematologists

Class of person

Clause 31 provides that this division applies to a medical practitioner (a ***haematologist***) who is a specialist registrant in haematology.

Dealing authorised

Clause 32 provides that a haematologist can perform the following regulated activities:

- prescribe bexarotene, hydroxychloroquine, lenalidomide, pomalidomide, thalidomide or tretinoin for human oral use;
- give a treatment dose of bexarotene, hydroxychloroquine, lenalidomide, pomalidomide, thalidomide or tretinoin for human oral use;
- dispense bexarotene, hydroxychloroquine, lenalidomide, pomalidomide, thalidomide or tretinoin for human oral use;
- administer bexarotene, hydroxychloroquine, lenalidomide, pomalidomide, thalidomide or tretinoin for human oral use;
- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 9 Immunologists

Class of person

Clause 33 provides that this division applies to a medical practitioner (an ***immunologist***) who is a specialist registrant in immunology and allergy.

Dealing authorised

Clause 34 provides that an immunologist can perform the following regulated activities:

- prescribe hydroxychloroquine;
- give a treatment dose of hydroxychloroquine;
- dispense hydroxychloroquine;
- administer hydroxychloroquine;
- give a purchase order for stock of hydroxychloroquine, if the stock is not for a specified place;
- possess hydroxychloroquine.

Division 10 Infectious diseases specialists

Class of person

Clause 35 provides that this division applies to a medical practitioner (an ***infectious diseases specialist***) who is a specialist registrant in infectious diseases.

Dealing authorised

Clause 36 provides that an infections diseases specialist can perform the following regulated activities:

- prescribe hydroxychloroquine or thalidomide;
- give a treatment dose of hydroxychloroquine or thalidomide;
- dispense hydroxychloroquine or thalidomide;
- administer hydroxychloroquine or thalidomide;
- give a purchase order for stock of hydroxychloroquine or thalidomide, if the stock is not for a specified place;
- possess hydroxychloroquine or thalidomide.

Division 11 Intensive care physicians

Class of person

Clause 37 provides that this division applies to a medical practitioner (an ***intensive care physician***) who is a specialist registrant in intensive care medicine.

Dealing authorised

Clause 38 provides that an intensive care physician can perform the following regulated activities:

- prescribe hydroxychloroquine;
- give a treatment dose of hydroxychloroquine;
- dispense hydroxychloroquine;
- administer hydroxychloroquine;
- give a purchase order for stock of hydroxychloroquine, if the stock is not for a specified place;
- possess hydroxychloroquine.

Division 12 Medical oncologists

Class of person

Clause 39 provides that this division applies to a medical practitioner (a ***medical oncologist***) who is a specialist registrant in medical oncology.

Dealing authorised

Clause 40 provides that a medical oncologist can perform the following regulated activities:

- prescribe bexarotene, enzalutamide, lenalidomide, pomalidomide and thalidomide;
- give a treatment dose of bexarotene, enzalutamide, lenalidomide, pomalidomide and thalidomide;
- dispense bexarotene, enzalutamide, lenalidomide, pomalidomide and thalidomide;
- administer bexarotene, enzalutamide, lenalidomide, pomalidomide and thalidomide;
- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 13 Nephrologists

Class of person

Clause 41 provides that this division applies to a medical practitioner (a ***nephrologist***) who is a specialist registrant in nephrology.

Dealing authorised

Clause 42 provides that a nephrologist can perform the following regulated activities:

- prescribe hydroxychloroquine;
- give a treatment dose of hydroxychloroquine;
- dispense hydroxychloroquine;
- administer hydroxychloroquine;
- give a purchase order for stock of hydroxychloroquine, if the stock is not for a specified place;
- possess hydroxychloroquine.

Division 14 Neurologists

Class of person

Clause 43 provides that this division applies to a medical practitioner (a ***neurologist***) who is a specialist registrant in neurology.

Dealing authorised

Clause 44 provides that a neurologist can perform the following regulated activities:

- prescribe sodium oxybate;
- give a treatment dose of sodium oxybate;
- dispense sodium oxybate;
- administer sodium oxybate;
- give a purchase order for stock of sodium oxybate, if the stock is not for a specified place;
- possess sodium oxybate.

Division 15 Paediatricians

Definition for division

Clause 45 provides for this subdivision a definition of *relevant child condition*.

Class of person

Clause 46 provides that this division applies to a medical practitioner (a ***paediatrician***) who is a specialist registrant in paediatrics.

Dealing authorised

Clause 47 provides that a paediatrician can perform the following regulated activities:

- prescribe:
  - amfetamine or methylphenidate, if the medicine is prescribed for the treatment of a relevant child condition;
  - hydroxychloroquine or sodium oxybate;
- give a treatment dose of:
  - amfetamine or methylphenidate, if the medicine is prescribed for the treatment of a relevant child condition;
  - hydroxychloroquine or sodium oxybate;
- dispense:
  - amfetamine or methylphenidate, if the medicine is prescribed for the treatment of a relevant child condition;
  - hydroxychloroquine or sodium oxybate;
- administer:
  - amfetamine or methylphenidate, if the medicine is prescribed for the treatment of a relevant child condition;

- hydroxychloroquine or sodium oxybate;

- give a purchase order for stock of:
  - amfetamine or methylphenidate, if the stock is for the treatment of a relevant child condition, other than at a specified place;
  - hydroxychloroquine or sodium oxybate, if the stock is not for a specified place;
- possess:
  - amfetamine or methylphenidate, if the medicine is possessed for a purpose mentioned in this provision;
  - hydroxychloroquine or sodium oxybate.

Division 16 Psychiatrists

Definition for division

Clause 48 provides for this division definitions for *maximum dosage*, *relevant adult condition* and *relevant child condition*.

Class of person

Clause 49 provides that this division applies to a medical practitioner (a ***psychiatrist***) who is a specialist registrant in psychiatry.

Dealing authorised

Clause 50 provides that a psychiatrist can perform the following regulated activities:

- prescribe:
  - clozapine;
  - amfetamine or methlphenidate, if the medicine is prescribed, within the maximum dosage, for the treatment of a relevant adult condition;
  - amfetamine or methlphenidate, if the medicine is prescribed for the treatment of a relevant child condition;
- give a treatment dose of:
  - clozapine;
  - amfetamine or methlphenidate, if the medicine is given, within the maximum dosage, for the treatment of a relevant adult condition;
  - amfetamine or methlphenidate, if the medicine is given on a prescription for the treatment of a relevant child condition;
- dispense:
  - clozapine;
  - amfetamine or methlphenidate, if the medicine is dispensed, within the maximum dosage, for the treatment of a relevant adult condition;
  - amfetamine or methlphenidate, if the medicine is dispensed on a prescription for the treatment of a relevant child condition;
- administer:
  - clozapine;

  - amfetamine or methlphenidate, if the medicine is administered, within the maximum dosage, for the treatment of a relevant adult condition;
  - amfetamine or methlphenidate, if the medicine is administered on a prescription for the treatment of a relevant child condition;
- give a purchase order for stock of:
  - clozapine, if the stock is not for a specified place;
  - amfetamine or methlphenidate, if the stock is for treating relevant adult or child conditions, other than at a specified place;
- possess clozapine, amfetamine or methlphenidate.

Division 17 Respiratory and sleep medicine specialists

Class of person

Clause 51 provides that this division applies to a medical practitioner (a ***respiratory and sleep medicine specialist***) who is a specialist registrant in respiratory medicine or sleep medicine.

Dealing authorised

Clause 52 provides that a respiratory medicine or sleep medicine specialist can perform the following regulated activities:

- prescribe sodium oxybate;
- give a treatment dose of sodium oxybate;
- dispense sodium oxybate;
- administer sodium oxybate;
- give a purchase order for stock of sodium oxybate, if the stock is not for a specified place;
- possess sodium oxybate.

Division 18 Rheumatologists

Class of person

Clause 53 provides that this division applies to a medical practitioner (a ***rheumatologist***) who is a specialist registrant in rheumatology.

Dealing authorised

Clause 52 provides that a rheumatologist can perform the following regulated activities:

- prescribe ambrisentan, bosentan, hydroxychloroquine, macitentan, riociguat or teriparatide;
- give a treatment dose of ambrisentan, bosentan, hydroxychloroquine, macitentan, riociguat or teriparatide;
- dispense ambrisentan, bosentan, hydroxychloroquine, macitentan, riociguat or teriparatide;
- administer ambrisentan, bosentan, hydroxychloroquine, macitentan, riociguat or teriparatide;

- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 19 Specialist gynaecology practitioners

Class of person

Clause 55 provides that this division applies to a medical practitioner (a ***specialist gynaecology practitioner***) who, under the Health Practitioner Regulation National Law is a specialist general practitioner and has advanced skills in gynaecology.

Dealing authorised

Clause 56 provides that a specialist gynaecology practitioner can perform the following regulated activities:

- prescribe dinoprost or dinoprostone;
- give a treatment dose of dinoprost or dinoprostone;
- dispense dinoprost or dinoprostone;
- administer dinoprost or dinoprostone;
- give a purchase order for stock of dinoprost or dinoprostone, if the stock is not for a specified place;
- possess dinoprost or dinoprostone.

Division 20 Specialist physicians

Class of person

Clause 57 provides that this division applies to a medical practitioner (a ***specialist physician***) who is a specialist registrant in general medicine.

Dealing authorised

Clause 58 provides that a specialist physician can perform the following regulated activities:

- prescribe acitretin, ambrisentan, bexarotene, bosentan, enzalutamide, etretinate, hydroxychloroquine, isotretinoin for human oral use, lenalidomide, macitentan, pomalidimide, riociguat, teriparatide, thalidomide or tretinoin for human oral use;
- give a treatment dose of acitretin, ambrisentan, bexarotene, bosentan, enzalutamide, etretinate, hydroxychloroquine, isotretinoin for human oral use, lenalidomide, macitentan, pomalidimide, riociguat, teriparatide, thalidomide or tretinoin for human oral use;
- dispense acitretin, ambrisentan, bexarotene, bosentan, enzalutamide, etretinate, hydroxychloroquine, isotretinoin for human oral use, lenalidomide, macitentan, pomalidimide, riociguat, teriparatide, thalidomide or tretinoin for human oral use;
- administer acitretin, ambrisentan, bexarotene, bosentan, enzalutamide, etretinate, hydroxychloroquine, isotretinoin for human oral use, lenalidomide, macitentan, pomalidimide, riociguat, teriparatide, thalidomide or tretinoin for human oral use;

- give a purchase order for stock of a medicine mentioned in this provision, if the stock is not for a specified place;
- possess a medicine mentioned in this provision.

Division 21 Urologists

Class of person

Clause 59 provides that this division applies to a medical practitioner (a ***urologist***) who is a specialist registrant in urology.

Dealing authorised

Clause 60 provides that a urologist can perform the following regulated activities:

- prescribe enzalutamide;
- give a treatment dose of enzalutamide;
- dispense enzalutamide;
- administer enzalutamide;
- give a purchase order of stock of enzalutamide, if the stock is not for a specified place;
- possess enzalutamide.

Part 3 Physician assistants

Definition for part

Clause 61 provides for this part a definition of *practice plan*.

Class of person

Clause 62 provides that this part applies to a person (a ***physician assistant***) appointed and employed as a physician assistant by a Hospital and Health Service or the chief executive.

Dealing authorised

Clause 63 provides that a physician assistant can perform the following regulated activities:

- prescribe a non-restricted medicine, if the medicine is prescribed under the supervision of a medical practitioner and a practice plan for the physician assistant;
- give a treatment dose of a non-restricted medicine, if the medicine is given under the supervision of a medical practitioner and a practice plan for the physician assistant;
- administer a non-restricted medicine, if the medicine is administered under the supervision of a medical practitioner and a practice plan for the physician assistant;
- possess an S4 or S8 non-restricted medicine, if the medicine is possessed for a purpose mentioned in this provision.

Schedule 7 Nursing and midwifery professions

Part 1 Nurse practitioners

Definitions for part

Clause 1 provides for this part definitions of *continuing hydroxychloroquine treatment* and *continuing institutional treatment*.

Class of person

Clause 2 provides that this part applies to a person (a ***nurse practitioner***) who is a registered nurse and endorsed under the Health Practitioner Regulation National Law as being qualified to practise as a nurse practitioner.

Dealing authorised

Clause 3 provides that a nurse practitioner can perform the following regulated activities:

- prescribe:
  - a registered medicine, other than a restricted medicine or hydroxychloroquine.
  - any restricted medicine other than hydroxychloroquine, if the medicine is prescribed for administration for the continuing institutional treatment of a patient.
  - hydroxychloroquine, if the medicine is prescribed for the continuing hydroxychloroquine treatment of a patient.
- make a standing order, other than a clinical protocol, for an S2, S3 or S4 medicine, other than an S4 diversion-risk medicine or restricted medicine.
- give a treatment dose of:
  - a registered medicine, other than a restricted medicine.
  - a restricted medicine, other than hydroxychloroquine, if the medicine is administered for the continuing institutional treatment of a patient.
  - hydroxychloroquine, if the medicine is given for the continuing hydroxychloroquine treatment of a patient.
- administer:
  - a registered medicine, other than a restricted medicine.
  - a restricted medicine, other than hydroxychloroquine, if the medicine is administered for continuing institutional treatment of a patient.
  - hydroxychloroquine, if the medicine is administered for the continuing hydroxychloroquine treatment of a patient.
  - any medicine, including a restricted medicine, if the medicine is administered on a prescription.
- repackage any medicine, if the medicine is repackaged for giving a treatment dose for a patient.
- give a purchase order for stock of:
  - an S4 or S8 medicines that is a registered medicine, if the stock is not for a specified place.

- hydroxychloroquine, if the stock is for the continuing hydroxychloroquine treatment of patients.

- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 2 Midwives

Division 1 Preliminary

Definition for part

Clause 4 provides for this part a definition of *childbirth*.

Division 2 Midwives

Class of person

Clause 5 provides that this part applies to a person (a ***midwife***) who is registered under the Health Practitioner Regulation National Law to practise in the midwifery profession as a midwife.

Dealing authorised

Clause 6 provides that a midwife can perform the following regulated activities:

- give a treatment dose of:
  - an S2 or S3 medicine, if the medicine is given at a rural hospital or in an isolated practice area.
  - any medicine, if the medicine is given on a standing order.
  - an S4 or S8 medicine, if the medicine is given on a prescription.
  - an S4 or S8 medicine mentioned the *Midwives* extended practice authority, if the medicine is given under the extended practice authority.
- administer:
  - an S2 or S3 medicine.
  - a nitrous oxide mixture, if the medicine is administered as an analgesic to treat a woman during childbirth.
  - any medicine, if the medicine is administered on a standing order.
  - an S4 or S8 medicine, if the medicine is administered on a prescription.
  - an S4 or S8 medicine, if the medicine is administered in accordance with the medicine's approved label.
  - an S4 or S8 medicine mentioned in the *Midwives* extended practice authority, if the medicine is administered under the extended practice authority.
- repackage any medicine, if the medicine is repackaged for giving a treatment dose for a patient on a prescription.
- give a purchase order for stock of a medicine mentioned in the *Midwives* extended practice authority, if the purchase order is given under the extended practice authority.

- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision;
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Division 3 Endorsed midwives

Class of person

Clause 7 provides that this division applies to a midwife who is endorsed (an ***endorsed midwife***).

Dealing authorised

Clause 8 provides that an endorsed midwife can perform the following regulated activities:

- prescribe a medicine, other than a restricted medicine.
- give a treatment dose of a medicine, other than a restricted medicine.
- administer a medicine, other than a restricted medicine.
- repackage a medicine, if the medicine is repackaged for giving a treatment dose for a patient.
- give a purchase order for stock of an S4 or S8 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 3 Registered nurses

Division 1 Preliminary

Definitions for part

Clause 9 provides for this part definitions of *dose administration aid repackaging guidelines*, *prison patient* and *rural discharge circumstances*.

Division 2 Nurses generally

Class of person

Clause 10 provides that this division applies to a person (a ***registered nurse***) who is registered under the Health Practitioner Regulation National Law to practise in the registered nurses division of the nursing profession.

Dealing authorised

Clause 11 provides that a registered nurse can perform the following regulated activities:

- give a treatment dose of a medicine mentioned in the *Registered nurses* extended practice authority, if the treatment dose is given under the extended practice authority.

- administer:
  - an S2 or S3 medicine.
  - any medicine, if the medicine is administered on a standing order.
  - an S4 or S8 medicine, if the medicine is administered on a prescription.
  - an S4 or S8, if the medicine is administered in accordance with the medicine's approved label.
  - an S4 or S8 medicine mentioned in the *Registered nurses* extended practice authority, if the medicine is administered under the extended practice authority.
- give a purchase order for stock of an S4 or S8 medicine mentioned in the *Registered nurses* extended practice authority, if the purchase order is given under the extended practice authority.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Division 3 Nurses giving purchase orders at relevant institutions

Class of person

Clause 12 provides that this division applies to a registered nurse (a ***nurse giving purchase orders at relevant institutions***) who is a nurse manager at a relevant institution.

Dealing authorised

Clause 13 provides that a nurse giving purchase orders at relevant institutions can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for the relevant institution and the purchase order is given for the therapeutic treatment of patients at the relevant institution.
- possess stock of an S4 or S8 medicine, if the stock is possessed at the relevant institution.

Division 4 Rural and isolated hospital nurses

Class of person

Clause 14 provides that this division applies to a registered nurse (a ***rural and isolated hospital nurse***) who is employed at a rural hospital or at a hospital in an isolated practice area and is the hospital's nurse manager.

Dealing authorised

Clause 15 provides that a rural and isolated hospital nurse can perform the following regulated activities:

- give a treatment dose of any medicine, if the medicine is given on a prescription in rural discharge circumstances.
- repackage any medicine, if the medicine is repackaged:

- for giving a treatment dose for a patient on a prescription; and
- if repackaged in a dose administration aid, under the dose administration aid repackaging guideline.

- possess an S4 or S8 medicine, if the medicine is possessed for a purpose mentioned in this provision.

Division 5 Prison nurses

Class of person

Clause 16 provides that this division applies to a registered nurse (a ***prison nurse***) who is employed at a prison.

Dealing authorised

Clause 17 provides that a prison nurse can perform the following regulated activities:

- give a treatment dose of an S2, S3 or S4 medicine, if the medicine is given:
  - for a prison patient on a prescription from a prescriber employed to provide health services at the prison; and
  - in an amount that is not more than seven days' supply.
- repackage any medicine, if the medicine is repackaged:
  - for giving a treatment dose for a prison patient on a prescription; and
  - if repackaged in a dose administration aid, under the dose administration aid repackaging guideline.
- possess an S4 medicine, if the medicine is possessed for a purpose mentioned in this provision.

Part 4 Enrolled nurses

Class of person

Clause 18 provides that this part applies to a person (an ***enrolled nurse***) who is registered under the Health Practitioner Regulation National Law to practise in the enrolled nurses division of the nursing profession, including a person with provisional registration or limited registration but not including a person:

- who is registered to practise in the profession only as a student or for training purposes; or
- whose registration contains a notation indicating the enrolled nurse is not qualified to administer medicines.

Dealing authorised

Clause 19 provides that an enrolled nurse can perform the following regulated activities:

- administer:
  - any medicine, if the medicine is administered under the direct supervision of a medical practitioner administering anaesthesia and for the safety of the patient before, or during, the patient's anaesthetic procedure at a hospital.

- any medicine, if the medicine is administered under the supervision of a dentist, medical practitioner, midwife or registered nurse and in accordance with the medicine's approved label or on a prescription or a standing order.

- possess and S4 or S8 medicine, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine that is an S4 or S8 medicine.

Part 5 Restricted enrolled nurses

Class of person

Clause 20 provides that this part applies to a person (a ***restricted enrolled nurse***) who is registered in the enrolled nurses division of the nursing profession but whose registration contains a notation indicating the enrolled nurse is not qualified to administer S4 or S8 medicines.

Dealing authorised

Clause 21 provides that a restricted enrolled nurse can administer an S2 or S3 medicine, if the medicine is administered under the supervision of a dentist, medical practitioner, midwife or registered nurse and in accordance with the medicine's approved label or on a prescription or a standing order.

Part 6 Trainee enrolled nurses

Class of person

Clause 22 provides that this part applies to a person (a ***trainee enrolled nurse***) who is undertaking training to obtain a qualification required to be registered under the Health Practitioner Regulation National Law to practise in the enrolled nurses division of the nursing profession.

Dealing authorised

Clause 23 provides that a trainee enrolled nurse can perform the following regulated activities:

- administer any medicine, if the medicine is administered to the extent authorised for an enrolled nurse under the direct supervision of a dentist, medical practitioner, midwife or registered nurse and in accordance with the medicine's approved label or on a prescription or a standing order.
- possess an S4 or S8 medicine, if the medicine is possessed to the extent authorised for an enrolled nurse under the direct supervision of a registered nurse at the place where the registered nurse is practising.

Schedule 8 Ocular treatment professions

Part 1 Preliminary

Definitions for schedule

Clause 1 provides for this schedule definitions of *ophthalmologist, Optometry Board* and *optometry guidelines.*

Part 2 Optometrists

Class of person

Clause 2 provides that this part applies to a person (an ***optometrist***) who is registered under the Health Practitioner Regulation National Law to practise in the optometry profession.

Dealing authorised

Clause 3 provides that an optometrist can perform the following regulated activities:

- administer a topical S2, S3 or S4 medicine stated in Appendix B of the *Guidelines for use of scheduled medicines*, made by the Optometry Board, if the medicine is administered under the guidelines.
- give a purchase order for stock of an S4 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.

Part 3 Endorsed optometrists

Class of person

Clause 4 provides that this part applies to an endorsed optometrist.

Dealing authorised

Clause 5 provides that an endorsed optometrist can perform the following regulated activities:

- prescribe an S2, S3 or S4 medicine stated in Appendix B or Appendix C of the *Guidelines for use of scheduled medicines*, made by the Optometry Board, if the medicine is administered under the guidelines.
- give a treatment dose of an S2, S3 or S4 medicine stated in Appendix B or Appendix C of the *Guidelines for use of scheduled medicines*, made by the Optometry Board, if the medicine is administered under the guidelines.
- administer an S2, S3 or S4 medicine stated in Appendix B or Appendix C of the *Guidelines for use of scheduled medicines*, made by the Optometry Board, if the medicine is administered under the guidelines.
- give a purchase order for stock of an S4 medicine mentioned in this provision, if the stock is not for a specified place.

- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.

Part 4 Orthoptists

Class of person

Clause 6 provides that this part applies to a person (an ***orthoptist***) whose name is recorded in the register of orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd.

Dealing authorised

Clause 7 provides that an orthoptist can perform the following regulated activities:

- administer a topical ophthalmic preparation, if the medicine is administered on a prescription from an ophthalmologist.
- administer any of the following S4 medicines, if the medicine is administered on a clinical protocol made by an ophthalmologist:
  - proxymetacaine hydrochloride of a strength of 0.5% or less;
  - oxybuprocaine hydrochloride of a strength of 0.4% or less;
  - amethocaine hydrochloride of a strength of 0.5% or less;
  - lidocaine (lignocaine) of a strength of 4% or less combined with fluorescein of a strength of 0.25%
  - cyclopentolate hydrochloride of a strength of 1% or less
  - homatropine hydrobromide of a strength of 2% or less
  - atropine of a strength of 1% or less
  - tropicamide of a strength of 1% or less
  - pilocarpine hydrochloride nitrate of a strength of 4% or less
  - phenylephrine of a strength of 2.5% or less in eye drops.
- give a purchase order for stock of an S4 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.

Schedule 9 Pharmaceutical professions

Part 1 Pharmacists

Division 1 Pharmacists generally

Class of person

Clause 1 provides that this division applies to a person (a ***pharmacist***) who is registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession but not including an intern pharmacist or a trainee pharmacist.

Dealing authorised

Clause 2 provides that a pharmacist can perform the following regulated activities:

- dispense any medicine;
- supply stock of any medicine, if he stock is supplied:
  - on a compliant purchase order to a person under section 33 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (Cwlth);
  - to another pharmacist to urgently fill a shortage of stock held by the other pharmacist, as part of an arrangement with the pharmacist to prevent the stock from expiring or for satisfying an order made by a client of the other pharmacist;
  - from a pharmacy to an approved person, other than a pharmacist, who is authorised to give a purchase order for the medicine or administer the medicine.
- sell, other than on a prescription:
  - an S2, S3 or S4 medicine;
  - a medicine that is mentioned as a pharmaceutical benefit in a Continued Dispensing Determination, if the medicine is sold in the circumstances mentioned in the Continued Dispending Determination;
  - a medicine mentioned in the *Pharmacists* extended practice authority, if the medicine is sold under the extended practice authority.
- give a treatment dose of any medicine, if the medicine is given on a standing order at a public hospital;
- administer:
  - a medicine mentioned in the *Pharmacists* extended practice authority, if the medicine is administered under the extended practice authority.
  - an approved opioid, if the medicine is administered on a prescription.
- repackage any medicine, if the medicine is repackaged for selling to a patient, for supply to an approved person, other than another pharmacist or for supply to, or possession of stock at, a clinical area of a hospital.
- compound:
  - an S2 or S3 medicine, if the medicine is compounded for the treatment of a patient.
  - an S4 or S8 medicine, if the medicine is compounded to fulfil a prescription from a prescriber for a patient.
- give a purchase order for stock of an S4 or S8 medicine, if the stock is not for a specified place.
- possess an S4 or S8 medicine, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine that is an S4 or S8 medicine.

Division 2 Pharmacists giving purchase orders at relevant institutions

Class of person

Clause 3 provides that this division applies to a person (a ***pharmacist giving purchase orders at relevant institutions***) who is in charge of a dispensary at a relevant institution.

Dealing authorised

Clause 4 provides that a pharmacist giving purchase orders at relevant institutions can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for the relevant institution and the purchase order is given for the therapeutic treatment of patients at the relevant institution.
- possess stock of an S4 or S8 medicine, if the stock is possessed at the relevant institution.

Division 3 Intern pharmacists

Class of person

Clause 5 provides that this division applies to a person (an ***intern pharmacist***) who is registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession with provisional registration and employed as an intern undertaking supervised practice.

Dealing authorised

Clause 6 provides that an intern pharmacist can perform a dealing mentioned in the table in division 1 with a medicine mentioned in the table in division 1, if the dealing with the medicine is carried out to the extent authorised for a pharmacist under the supervision of a pharmacist.

Division 4 Trainee pharmacists

Class of person

Clause 7 provides that this division applies to a person (a ***trainee pharmacist***) who is registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession as a student or for training purposes.

Dealing authorised

Clause 8 provides that a trainee pharmacist can perform the following regulated activities:

- sell by retail a medicine mentioned in the table in division 1, if the sale is carried out to the extent authorised for a pharmacist under the direct supervision of a pharmacist.
- administer a medicine mentioned in the table in division 1, if the medicine is administered to the extent authorised for a pharmacist under the direct supervision of a pharmacist.
- compound a medicine mentioned in the table in division 1, if the medicine is compounded to the extent authorised for a pharmacist under the direct supervision of a pharmacist.
- possess a medicine mentioned in the table in division 1, if the medicine is possessed to the extent authorised for a pharmacist under the direct supervision of a pharmacist.

Part 2 Pharmacy assistants

Division 1 Hospital pharmaceutical technicians

Definitions for part

Clause 9 provides for this division definitions of *pharmaceutical imprest duties* and *specific health service*.

Class of person

Clause 10 provides that this part applies to a person (a ***hospital pharmaceutical technician***) who has a qualification, or statement of attainment, recognising the person has the skills and knowledge required to carry out pharmaceutical imprest duties for a specific health service and carries out pharmaceutical imprest duties for a specific health service.

Dealing authorised

Clause 11 provides that a hospital pharmaceutical technician can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given under the supervision of a pharmacist in charge of a dispensary for a specific health service and the purchase order is given for the therapeutic treatment of patients of the specific health service.
- possess an S4 or S8 medicine, if the medicine is possessed under the supervision of a pharmacist.

Division 2 Dispensary pharmacy assistants

Class of person

Clause 12 provides that this division applies to a person (a ***dispensary pharmacy assistant***) who is 16 years or more and employed at a pharmacy and is appropriately qualified to assist with compounding at the pharmacy.

Dealing authorised

Clause 13 provides that a dispensary pharmacy assistant can compound a medicine, if the medicine is compounded under the direct supervision of a pharmacist.

Division 3 General pharmacy assistants

Class of person

Clause 14 provides that this division applies to a person (a ***general pharmacy assistant***) who is 16 years or more and employed at a pharmacy.

Dealing authorised

Clause 15 provides that a general pharmacy assistant can perform the following regulated activities:

- sell by retail an S2 medicine, if the medicine is sold under the direct supervision of a pharmacist.
- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given, under the direct supervision of a pharmacist, for stock of medicines for the pharmacy to be delivered to the pharmacy.
- possess an S4 or S8 medicine, if the medicine is possessed under the direct supervision of a pharmacist.

Schedule 10 Podiatry professions

Part 1 Preliminary

Definitions for schedule

Clause 1 provides for this schedule definitions of *endorsed podiatrist*, *podiatric surgeon* and *Podiatry Board*.

Part 2 Podiatrists

Class of person

Clause 2 provides that this part applies to a person (a ***podiatrist***) who is registered under the Health Practitioner Regulation National Law to practise in the podiatry profession.

Dealing authorised

Clause 3 provides that a podiatrist can perform the following regulated activities:

- administer:
  - an S2 medicine.
  - an adrenaline (epinephrine) autoinjector.
  - any of the following medicines, other than when combined with adrenaline (epinephrine) or another vasoconstrictor medicine:
    - bupivacaine of a strength of 0.5% or less;
    - levobupivacaine of a strength of 0.5% or less;
    - lidocaine (lignocaine) of a strength of 2% or less;
    - prilocaine of a strength of 2% or less
- give a purchase order for stock of an S4 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 medicine mentioned in this provision.

Part 3 Endorsed podiatrist

Class of person

Clause 4 provides that this part applies to an endorsed podiatrist, whether or not the podiatrist is also a podiatric surgeon.

Dealing authorised

Clause 5 provides that an endorsed podiatrist can perform the following regulated activities:

- prescribe a medicine mentioned in attachment A of the *Registration standard: endorsement for scheduled medicines*, made by the Podiatry Board, if the medicine is prescribed under the standard.
- give a treatment dose of a medicine mentioned in attachment A of the *Registration standard: endorsement for scheduled medicines*, made by the Podiatry Board, if the medicine is given under the standard.
- administer a medicine mentioned in attachment A of the *Registration standard: endorsement for scheduled medicines*, made by the Podiatry Board, if the medicine is administered under the standard.
- give a purchase order for stock of an S4 or S8 medicine mentioned in this provision, if the stock is not for a specified place.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 4 Podiatric surgeons

Class of person

Clause 6 provides that this part applies to a podiatric surgeon who is not endorsed.

Dealing authorised

Clause 7 provides that a podiatric surgeon who is not endorsed can perform the following regulated activities:

- prescribe:
  - diclofenac, fexofenadine, ibuprofen, loratadine, naproxen, promethazine, if the medicine is prescribed as an oral preparation for no more than a 10 day course of treatment.
  - hydrocortisone, if the medicine is prescribed as a topical preparation for no more than a 10 day course of treatment with each dose being of a strength of 1% or less.
  - amoxycillin or amoxycillin with clavulanic acid, cephalexin, dicloxacillin, doxycycline, erythromycin, metronidazole, roxithromycin, if the medicine is prescribed as an oral preparation for no more than a 10 day course of treatment.
  - codeine, if the medicine is prescribed as an oral preparation of no more than 20 doses with each dose being not more than 30mg in combination with each 500mg of paracetamol.

  - diazepam, if the medicine is prescribed as an oral preparation of no more than 10 doses of 5mg each.
  - mupirocin, if the medicine is prescribed as a topical preparation for no more than a 10 day course of treatment.
  - temazepam, if the medicine is prescribed an oral preparation of no more than two doses of 10mg each.
  - oxycodone, if the medicine is prescribed as an oral preparation in a short acting form of no more than 10 doses of 5mg each.
- administer any of the following S4 medicines:
  - dexamethasone as a local injection;
  - ropivacaine of a strength of 1% or less;
  - epinephrine (adrenaline) when combined with lidocaine (lignocaine), bupivacaine or prilocaine.
- give a purchase order for stock of an S4 medicine the podiatric surgeon may administer, if the stock is not for a specified place.
- possess an S4 or S8 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Schedule 11 Veterinary professions

Part 1 Veterinary surgeons

Class of person

Clause 1 provides that this part applies to a veterinary surgeon.

Dealing authorised

Clause 2 provides that a veterinary surgeon can perform the following regulated activities:

- prescribe:
  - a non-restricted medicine, other than a diversion-risk medicine.
  - a diversion-risk medicine, if the medicine prescribed is no more than the amount necessary for treating an animal for six months.
- dispense:
  - a non-restricted medicine, other than a diversion-risk medicine.
  - a non-restricted diversion-risk medicine, if the medicine dispensed is no more than the amount necessary for treating an animal for six months.
- give a treatment dose:
  - of a non-restricted medicine, other than a diversion-risk medicine.
  - of a diversion-risk medicine, if the medicine given is no more than the amount necessary for treating an animal for six months.
- supply an S4 medicine or medicated feed, if the medicine or feed is to be mixed with food for administration to a group of animals by the farmer of the animals.

- administer any medicine.
- compound a non-restricted medicine, if the medicine is compounded for the treatment of an animal.
- repackage a non-restricted medicine, if the medicine is repackaged for an animal.
- give a purchase order for stock of an S4 or S8 medicines that is a non-restricted medicine, if the stock is not for a specified place.
- possess an S4 or S8 medicine, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine.

Part 2 Veterinary nurses

Class of person

Clause 3 provides that this part applies to a person (a ***veterinary nurse***) who is employed to practise veterinary nursing and holds a qualification that makes the person eligible for full membership of the Veterinary Nurses Council of Australian Inc.

Dealing authorised

Clause 4 provides that a veterinary nurse can perform the following regulated activities:

- administer:
  - an S8 medicine, if the medicine is administered at veterinary premises:
    - when a veterinary surgeon is not able to be physically present but is available to be contacted using technology to communicate with a veterinary nurse in real time; and
    - the medicine has been pre-prepared into a treatment dose by a veterinary surgeon or a pharmacist; and
    - the medicine is administered on a prescription or in accordance with the medicine's approved label.
  - an S2, S3 or S4 medicine, if the medicine is administered at veterinary premises:
    - under the supervision of a veterinary surgeon; and
    - on a prescription or in accordance with the medicine's approved label.
  - an S2, S3 or S4 medicine, if the medicine is administered:
    - under the direct supervision of a veterinary surgeon; and
    - on a prescription or in accordance with the medicine's approved label.
- possess an S4 or S8 medicine, if the medicine is possessed for a purpose mentioned in this provision.

Part 3 Trainees

Division 1 Trainee veterinary surgeons

Class of person

Clause 5 provides that this division applies to a person (a ***trainee veterinary surgeon***) undertaking training to obtain a qualification required to be a veterinary surgeon.

Dealing authorised

Clause 6 provides that a trainee veterinary surgeon can perform the following regulated activities:

- administer a medicine mentioned in the table in part 1, if the medicine is administered to the extent authorised for a veterinary surgeon and under the direct supervision of a veterinary surgeon.
- possess a medicine mentioned in the table in part 1, if the medicine is possessed to the extent authorised for a veterinary surgeon and under the direct supervision of a veterinary surgeon.

Division 2 Trainee veterinary nurses

Class of person

Clause 7 provides that this division applies to a person (a ***trainee veterinary nurse***) undertaking training to obtain a qualification required to be a veterinary nurse.

Dealing authorised

Clause 8 provides that a trainee veterinary nurse can perform the following regulated activities:

- administer a medicine mentioned in the table in part 2, if the medicine is administered under the direct supervision of a veterinary surgeon.
- possess a medicine mentioned in the table in part 2, if the medicine is possessed under the direct supervision of a veterinary surgeon at the place where the veterinary surgeon is practising.

Part 4 Veterinary assistants

Class of person

Clause 9 provides that this part applies to a person (a ***veterinary assistant***) assisting a veterinary surgeon to manage stock of medicines at veterinary premises.

Dealing authorised

Clause 10 provides that a veterinary assistant can possess an S4 medicine, other than pentobarbital, if the medicine is possessed under the direct supervision of a veterinary surgeon.

Schedule 12 Other health practitioners

Part 1 Anaesthetic technicians

Class of person

Clause 1 provides that this part applies to a person (an ***anaesthetic technician***) who holds a qualification acceptable to the Australian and New Zealand College of Anaesthetists to be an anaesthetic technician.

Dealing authorised

Clause 2 provides that an anaesthetic technician can perform the following regulated activities:

- administer any medicine, if the medicine is administered at a hospital under the direct supervision of a medical practitioner to ensure the safety of a patient in relation to an anaesthetic procedure.
- possess an S4 or S8 medicine, if the medicine is possessed for administration to the extent mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 2 Clinical perfusionists

Class of person

Clause 3 provides that this part applies to a person (a ***clinical perfusionist***) who is employed as a clinical perfusionist at a Hospital and Health Service, private health facility or approved health facility or is accredited or certified to work as a clinical perfusionist by a professional body approved by the chief executive.

Dealing authorised

Clause 4 provides that a clinical perfusionist can perform the following regulated activities:

- administer any medicine, if the medicine is administered into extracorporeal circulation equipment to prepare for an anaesthetic, intensive care or surgical procedure for a patient under the supervision of an anaesthetist, cardiothoracic surgeon or another intensive care physician or on a clinical protocol applying to the clinical perfusionist.
- possess an S4 or S8 medicine, if the medicine is possessed for administration to the extent mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 3 Nuclear medicine technologists

Class of person

Clause 5 provides that this part applies to a person (a ***nuclear medicine technologist***) who is registered under the Health Practitioner Regulation National Law to practise in the nuclear medicine technology division of the medical radiation practice profession.

Dealing authorised

Clause 6 provides that a nuclear medicine technologist can perform the following regulated activities:

- administer:
  - an S2 or S3 medicine, other than an adrenaline (epinephrine) autoinjector, if the medicine is administered on a clinical protocol applying to the nuclear medicine technologist or on a written prescription.
  - an S3 adrenaline (epinephrine) autoinjector, if the nuclear medicine technologist has completed anaphylaxis training and the medicine is administered to treat anaphylaxis on a clinical protocol applying to the technologist or on a written prescription
  - an S4 medicine that is an angiotensin-converting enzyme inhibitor or angiotensin II receptor antagonist, whether alone or in combination with a diuretic, or a diuretic or a histamine H2 receptor antagonist, if the medicine is administered on a clinical protocol applying to the nuclear medicine technologist or on a written prescription.
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for administration to the extent mentioned in this provision.

Part 4 Physiotherapists

Class of person

Clause 7 provides that this part applies to a person (a ***physiotherapist***) who is registered with the Physiotherapy Board of Australia, established under the Health Practitioner Regulation National Law, to practise in the physiotherapy profession.

Dealing authorised

Clause 8 provides that a physiotherapist can perform the following regulated activities:

- prescribe a medicine mentioned in the *Physiotherapists* extended practice authority, if the medicine is prescribed under the extended practice authority.
- administer:
  - an S2 medicine;
  - a nitrous oxide mixture, if the medicine is administered in a hospital on a written prescription;
  - an S3 medicine for pain relief, if the medicine is administered on a written prescription or has been lawfully supplied to the patient being treated with the medicine;
  - an S3 or S4 medicine for the physiotherapy treatment of a respiratory condition, if the medicine is administered on a written prescription or has been lawfully supplied to the patient being treated with the medicine;
  - a medicine mentioned in the *Physiotherapists* extended practice authority, if the medicine is administered under the extended practice authority.
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 5 Respiratory scientists

Class of person

Clause 9 provides that this part applies to a person (a ***respiratory scientist***) who is employed as a respiratory scientist at a Hospital and Health Service, private health facility or approved health facility or is accredited or certified to work as a respiratory scientist by a professional body approved by the chief executive.

Dealing authorised

Clause 10 provides that a respiratory scientist can perform the following regulated activities:

- administer:
  - an S2 or S3 medicine, other than an adrenaline (epinephrine) autoinjector, if the medicine is administered on a clinical protocol applying to the respiratory scientist or on a written prescription.
  - an S3 adrenaline (epinephrine) autoinjector, if the respiratory scientist has completed anaphylaxis training and the medicine is administered to treat anaphylaxis on a clinical protocol applying to the scientist or on a written prescription.
  - an S4 medicine that is an anti-histamine for systemic use or a broncho-constrictor agent or bronchodilator agent, if the medicine is administered on a clinical protocol applying to the respiratory scientist or on a written prescription.
- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.

Part 6 Speech pathologists

Definition for part

Clause 11 provides for this part a definition of *medication safety course*.

Class of person

Clause 12 provides that this part applies to a person (a ***speech pathologist***) who has completed the medication safety course and is employed as a speech pathologist at a Hospital and Health Service, private health facility or in another government entity under section 24 of the *Public Service Act 200*8 or accredited or certified to work as a speech pathologist by a professional body approved by the chief executive.

Dealing authorised

Clause 13 provides that a speech pathologist can perform the following regulated activities:

- administer:
  - an S2 or S3 medicine, other than an adrenaline (epinephrine) autoinjector, if the medicine is administered on a clinical protocol applying to the speech pathologist or on a written prescription.
  - an adrenaline (epinephrine) autoinjector, if the speech pathologist has completed anaphylaxis training and the medicine is administered to treat anaphylaxis on a clinical protocol applying to the speech pathologist or on a written prescription.

- an S4 medicine that is a topical antibiotic or a topical corticosteroid, if the medicine is administered on a clinical protocol applying to the speech pathologist or on a written prescription.

- possess an S4 medicine mentioned in this provision, if the medicine is possessed for a purpose mentioned in this provision.

Part 7 Trainee health practitioners in other professions

Definitions for part

Clause 14 provides for this part definitions of *health trainee* and *relevant class*.

Class of person

Clause 15 provides that this part applies to a health trainee.

Dealing authorised

Clause 16 provides that a health trainee can perform the following regulated activities:

- administer a medicine mentioned in the table for the relevant class in relation to the health trainee, if the medicine is administered to the extent authorised for the relevant class under the direct supervision of a person authorised to administer the medicine, other than a person who is another health trainee or authorised to administer the medicine only under the supervision of someone else.

- possess a medicine mentioned in the table for the relevant class in relation to the health trainee, if the medicine is possessed to the extent authorised for the relevant class under the direct supervision of a person authorised to possess the medicine, other than a person who is another health trainee or authorised to possess the medicine only under supervision of someone else.

Schedule 13 Workers at institutions and facilities

Part 1 Detention institution workers

Division 1 Executive directors of detention centres

Class of person

Clause 1 provides that this division applies to a person who is the executive director of a detention centre.

Dealing authorised

Clause 2 provides that the executive director of a detention centre can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for medicines for the therapeutic treatment of children detained at the detention centre.

- possess stock of an S4 or S8 medicine, if the stock is possessed at the detention centre.

Division 2 General managers of prisons

Class of person

Clause 3 provides that this division applies to a person who is the general manager of a prison.

Dealing authorised

Clause 4 provides that the general manager of a prison can perform the following regulated activities:

- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for medicines for the therapeutic treatment of persons detained at the prison or children accommodated with the person detained.
- possess stock of an S4 or S8 medicine, if the stock is possessed at the prison.

Division 3 Custodial officers

Definition for division

Clause 5 provides for this division definitions of *corrective services officer*, *court* and *proper officer*.

Class of person

Clause 6 provides that this division applies to a person (a ***custodial officer***) who is a proper officer of a court or a corrective services officer.

Dealing authorised

Clause 7 provides that a custodial officer can supply any medicine, if the medicine is supplied by giving it to a police officer or another custodial officer to possess for the therapeutic treatment of the person in custody and was lawfully supplied to the person in custody for the therapeutic treatment of the person.

Part 2 School workers

Division 1 Principals or delegates

Class of person

Clause 8 provides that this division applies to a person who is the principal of a school or the principal's delegate.

Dealing authorised

Clause 9 provides that a principal of a school or the principal's delegate can perform the following regulated activities:

- administer any medicine, if the medicine:
  - was dispensed for a child attending the school or supplied for the child by the child's parent or guardian; and

- is administered in accordance with the medicine's approved label or on a written instruction from the prescriber of the medicine.

- possess an S4 or S8 medicine, if the medicine is possessed for administration to the extent mentioned in this provision.

Division 2 Trained staff

Class of person

Clause 10 provides that this division applies to a person who is employed at a school.

Dealing authorised

Clause 11 provides that a person employed at a school can perform the following regulated activities:

- administer an adrenaline (epinephrine) autoinjector, if the medicine is administered to a child attending the school and the person has completed anaphylaxis training.

- administer an inhaled asthma reliever, other than an S4 medicine, if the medicine is administered to a child attending the school and the person has completed asthma training.

- possess a medicine mentioned in this provision, if the medicine is possessed for administration to the extent mentioned in this provision.

Part 3 Child care facilities

Division 1 Heads or delegates

Definition for division

Clause 12 provides for this division a definition of *head*.

Class of person

Clause 13 provides that this division applies to a person (a ***head or delegate***) who is the head of a child care facility or the head's delegate.

Dealing authorised

Clause 14 provides that a head or delegate can perform the following regulated activities:

- administer any medicine, if the medicine:
  - was dispensed for a child attending the child care facility or supplied for the child by the child's parent or guardian; and
  - is administered in accordance with the medicine's approved label or on a written instruction from the prescriber of the medicine.

- possess an S4 or S8 medicine, if the medicine is possessed for administration to the extent mentioned in this provision.

Division 2 Trained staff

Class of person

Clause 15 provides that this division applies to a person (***trained staff***) who is employed at a child care facility.

Dealing authorised

Clause 16 provides that trained staff can perform the following regulated activities:

- administer an adrenaline (epinephrine) autoinjector, if the medicine is administered to a child attending the child care facility and the person has completed anaphylaxis training.
- administer an inhaled asthma reliever, other than an S4 medicine, if the medicine is administered to a child attending the child care facility and the person has completed asthma training.
- possess a medicine mentioned in this provision, if the medicine is possessed for administration to the extent mentioned in this provision.

Part 4 Hospital employees

Class of person

Clause 17 provides that this part applies to a person (a ***hospital employee***) who is an adult employed at a hospital whose duties include storing and distributing medical gas at the hospital.

Dealing authorised

Clause 18 provides that a hospital employee can possess an S4 medical gas, if the medicine is possessed in accordance with any procedures in place at the hospital for the possession of the medicine.

Part 5 Ship employees

Division 1 Preliminary

Definitions for part

Clause 19 provides for this part definitions of *master* and *ship*.

Division 2 Ship's master

Class of person

Clause 20 provides that this division applies to a person (a ***ship's master***) who is the master of a ship.

Dealing authorised

Clause 21 provides that a ship's master can perform the following regulated activities:

- administer any medicine, if the medicine is administered:
  - to a person on the ship who it is necessary to treat; and
  - in accordance with the medicine's approved label.
- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for medicines for ensuring the health or safety of persons on the ship.
- possess stock of an S4 or S8 medicine, if the stock is possessed on the ship.

Division 3 Ship's staff

Definition for division

Clause 22 provides for this division a definition of *ship's medicine*.

Class of person

Clause 23 provides that this division applies to a person (a ***ship's staff***) who is employed on a ship.

Dealing authorised

Clause 24 provides that a ship's staff can perform the following regulated activities:

- administer a ship's medicine, if the medicine is administered:
  - to a person on the ship who it is necessary to treat; and
  - in accordance with the medicine's approved label.
- possess a ship's medicine, if the medicine is possessed for administration to a person on the ship.

Part 6 Mine employees

Division 1 Preliminary

Definition for part

Clause 25 provides for this part a definition of *S4 inhaled analgesic*.

Division 2 Mine manager

Class of person

Clause 26 provides that this division applies to a person (a ***mine manager***) who is in charge of a mine.

Dealing authorised

Clause 27 provides that a mine manager can perform the following regulated activities:

- give a purchase order for stock of an S4 inhaled analgesic, if the purchase order is given for the medicines for the first aid treatment of persons at the mine.
- possess stock of an S4 inhaled analgesic, if stock is possessed at the mine.

Division 3 Mine's first aid provider

Class of person

Clause 28 provides that this division applies to a first aid provider employed at a mine (a ***mine's first aid provider***) who has completed training from a registered training organisation about using an S4 inhaled analgesic.

Dealing authorised

Clause 29 provides that a mine's first aid provider can perform the following regulated activities:

- administer an S4 inhaled analgesic that does not include methoxyflurane, if the medicine is administered for the first aid treatment of a person at the mine.
- administer an S4 inhaled analgesic that includes methoxyflurane, if the medicine is administered for the first aid treatment of a person at the mine and in one dose of no greater than 3 millilitres unless the medicine is administered on a prescription.
- possess a medicine mentioned in this provision, if the medicine is possessed for administration to a person at the mine.

Part 7 Health department employees

Definitions for part

Clause 30 provides for this part a definition of *registered vaccine service provider*.

Class of person

Clause 31 provides that this division applies to a person (a ***health department employee***) who is employed in the department and approved by the chief executive to deal with vaccines for an immunisation program.

Dealing authorised

Clause 32 provides that a health department employee can perform the following regulated activities:

- supply stock of a vaccine, if the stock is supplied to a registered vaccine service provider;
- give a purchase order for stock of a vaccine, if the stock is to supply a registered vaccine service provider;
- possess stock of a vaccine, if the stock is possessed for an immunisation program.

Part 8 Local government environmental health officers

Class of person

Clause 33 provides that this part applies to a person (a ***local government environmental health officer***) who is employed as an environmental health officer for a local government.

Dealing authorised

Clause 34 provides that a local government environmental health officer can perform the following regulated activities:

- give a purchase order for stock of an S4 medicine that is a vaccine for human therapeutic use, if the purchase order is given for medicines for an immunisation program carried out by the department, the local government or a Hospital and Health Service.
- possess stock of an S4 medicine that is a vaccine for human therapeutic use, if the stock is possessed for an immunisation program.

Schedule 14 Suppliers and representatives

Part 1 Commonwealth law manufacturers

Class of person

Clause 1 provides that this part applies to a person (a ***commonwealth law manufacturer***) who is permitted to manufacture a medicine under a Commonwealth law to manufacture a medicine.

Dealing authorised

Clause 2 provides that a commonwealth law manufacturer can perform the following regulated activities:

- supply stock of any medicine, if:
  - the stock is supplied in compliance with any conditions of the person's permission under the Commonwealth law; and
  - the stock is supplied from a place where the person is permitted to manufacture the medicine under the Commonwealth law; and
  - the supply is not otherwise authorised under section 50 of the Medicines and Poisons Act.
- give a purchase order for stock of an S4 or S8 medicine, if the purchase order is given for stock required for an activity permitted in the person's permission under the Commonwealth law, to the extent not otherwise authorised under section 50 of the Medicines and Poisons Act.
- dispose of waste from a diversion-risk medicine mentioned in this provision.

Part 2 Corresponding law wholesalers

Class of person

Clause 3 provides that this part applies to a person (a ***corresponding law wholesaler***) permitted under a corresponding law to supply a medicine by wholesale.

Dealing authorised

Clause 4 provides that a corresponding law wholesaler, can supply stock of any medicine, if:

- the stock is supplied in compliance with any conditions of the entity's permission under the corresponding law; and
- the person arranges the delivery of the medicine only to someone within Queensland who is authorised, or for whom it is not unlawful, to buy the medicine; and
- the person does not possess the medicine by storing it at a place in Queensland or arrange for the medicine to be collected from a storage facility located in Queensland; and
- the supply is not otherwise authorised under section 50 of the Medicines and Poisons Act.

Part 3 Corresponding law retailers

Class of person

Clause 5 provides that this part applies to a person (a ***corresponding law retailer***) permitted under a corresponding law to supply a medicine by retail.

Dealing authorised

Clause 6 provides that a corresponding law retailer, can supply by retail stock of any medicine, if:

- the stock is supplied in compliance with any conditions of the entity's permission under the corresponding law; and
- the person arranges the delivery of the medicine only to a person within Queensland who is authorised to buy the medicine; and
- the person does not possess the medicine by storing it at a place in Queensland or arrange for the medicine to be collected from a storage facility located in Queensland; and
- the supply is not otherwise authorised under section 50 of the Medicines and Poisons Act.

Part 4 Wholesale representatives

Definition for part

Clause 7 provides for this part the definition of *authorised practitioner*.

Class of person

Clause 8 provides that this part applies to a person (a ***wholesale representative***) employed to display or give starter packs of medicines for an entity, other than a pharmacist, authorised to supply a medicine by wholesale under the Medicines and Poisons Act or a person otherwise permitted under a corresponding law to supply a medicine by wholesale.

Dealing authorised

Clause 9 provides that a wholesale representative can perform the following regulated activities:

- supply stock of an S2, S3 or S4 medicine in a starter pack, other than a monitored medicine, if the stock is supplied:
  - to an authorised practitioner for the medicine; and
  - to the extent stated in the purchase order for the medicine from the practitioner.
- possess an S4 medicine in a starter pack, other than a monitored medicine, if the medicine possessed is not more than is reasonably necessary to meet the business needs of the representative for a six-month period.

Schedule 15 Miscellaneous

Part 1 Carrier

Class of person

Clause 1 provides that this part applies to a person (a ***carrier***) engaged to deliver a medicine from place to place.

Dealing authorised

Clause 2 provides that a carrier can possess an S4 or S8 medicine, if the medicine is possessed for the purposes of delivery of the medicine.

Part 2 Health practitioner assistants

Class of person

Clause 3 provides that this part applies to a person (a ***health practitioner assistant***) assisting a health practitioner to manage stock of medicines as part of the person's employment at a place.

Dealing authorised

Clause 4 provides that a health practitioner assistant can possess an S4 medicine, if the medicine is possessed at the place under the direct supervision of the health practitioner.

Part 3 Farmers of animals

Class of person

Clause 5 provides that this division applies to a farmer of a group of animals (a ***farmer of animals***) who has a prescription for an S4 medicine or medicated feed to be mixed with food for administering to the animals.

Dealing authorised

Clause 6 provides that a farmer of animals can perform the following regulated activities:

- administer an S4 medicine or medicated feed, if the medicine or feed is administered to the group of animals on the prescription.
- possess an S4 medicine or medicated feed, if the medicine or feed is possessed for administering to the group of animals.

Schedule 16 Classes of general approvals

Part 1 Acute health conditions at isolated sites

Definitions for part

Clause 1 provides for this part definitions of *isolated site* and *senior person*.

Classes of persons and dealings

Clause 2 provides that a general approval (acute health conditions at isolated sites) is for the following classes of persons carrying out the dealings to treat acute health conditions at an isolated site:

- a medical practitioner employed by the holder of the approval, giving a purchase order for stock of medicines for an isolated site stated in the approval;
- a nurse practitioner employed by the holder of the approval, giving a purchase order for stock of medicines for an isolated site stated in the approval;
- a senior person at an isolated site stated in an approval who is employed by the holder of the approval, possessing stock of medicines for the isolated site;
- a registered nurse employed by the holder of an approval:
  - possessing stock of medicines for an isolated site stated in the approval;
  - giving a treatment dose of an S2, S3 or S4 medicine stated in the approval on a prescription from a medical practitioner or nurse practitioner.

Part 2 Emergency first aid

Definitions for part

Clause 3 provides for this part definitions of *emergency medicine, first aid provider, paramedic, senior person* and *site*.

Classes of person and dealings

Clause 4 provides that a general approval (emergency first aid) is for the following classes of persons carrying out the dealings to provide emergency first aid:

- a medical practitioner working for the holder of an approval, giving a purchase order for stock of medicines for a site for the approval;
- a nurse practitioner working for the holder of an approval, giving a purchase order for stock of medicines for a site for the approval;

- a senior person at a site for an approval, working for the holder of the approval, possessing stock of medicines at the site;
- a paramedic working at a site for an approval:
  - administering an emergency medicine on an oral prescription or a standing order made under the approval;
  - possessing an emergency medicine under the approval;
  - disposing of waste from an emergency medicine that is a diversion-risk medicine under the approval;
- a registered nurse working at a site for an approval:
  - administering an emergency medicine on an oral prescription or a standing order made under the approval;
  - possessing an emergency medicine under the approval;
- a first aid provider working at a site for an approval:
  - administering glyceryl trinitrate on a prescription from a medical practitioner or nurse practitioner made under the approval;
  - possessing glyceryl trinitrate under the approval.

Part 3 Emergency management of animals

Definitions for part

Clause 5 provides for this part definitions of *qualified person* and *senior person*.

Classes of persons and dealings

Clause 6 provides that a general approval (emergency management of animals) is for the following classes of persons carrying out the dealings for the emergency management of animals:

- a veterinary surgeon working for the holder of an approval:
  - giving a purchase order for stock of medicines for a location stated in the approval;
  - making a standing order under the approval;
- a senior person at a location stated in the approval, working for the holder of an approval, possessing stock of medicines at the location;
- a qualified person working for the holder of an approval:
  - possessing stock of medicines;
  - administering a medicine on an oral prescription or a standing order from a veterinary surgeon working under an approval;
- a person training to become a qualified person for the holder of the approval, administering or possessing a medicine under the direct supervision of a veterinary surgeon working under an approval;
- a person working for the holder of the approval, possessing stock of medicines for working under the approval.

Schedule 17 Substance management plans—regulated places and responsible persons

Definitions for schedule

Clause 1 provides for this schedule the definitions of *manager*, *senior officer* and *specified pharmacy*.

Regulated places and responsible persons

Clause 2 provides a list for the definition of a *regulated place* and *responsible person* in section 92 (Definitions for part) of the Medicines and Poisons Act, the places are prescribed in column 1 of the table in this part and the responsible person is prescribed in column 2.

Schedule 18 Monitored medicines database

Part 1 Relevant practitioners required to check database

Part 1 provides a list of relevant practitioners required to check the monitored medicines database.

The list includes all health practitioners authorised to prescribe or dispense a monitored medicine, except for physician assistants and physiotherapists practising under their extended practice authority. Currently there are technical limitations preventing physician assistants and physiotherapists from accessing the monitored medicines database, and as such, they cannot be compelled to check the database at this time.

Part 2 Information providers and relevant information

Part 2 provides that for the definitions of *information provider* and *relevant information* in section 226 (Giving information) of the Medicines and Poisons Act, the information providers are prescribed in column 1 of the table in this part and the relevant information is prescribed in column 2.

Dispensers, other than dispensers practising in a public sector hospital, are compelled to provide the chief executive information in a dispensing record for a monitored medicine for a patient. This is necessary to ensure the real-time prescription monitoring system works as intended, as comprehensive information about the monitored medicines a patient has been dispensed is necessary to support the clinical decision-making of health practitioners using the database.

Dispensers practising in a public sector hospital are not compelled to provide dispensing records at this time, as there are technical limitations currently preventing the capture of this information from public sector hospital pharmacy clinical software systems. It is intended that the database will capture dispensing records generated in these pharmacies once technical barriers have been addressed.

At this time, prescribers are not compelled to provide prescribing records for the database. This is because upon establishment of the database, the data collection focus is on capturing information about dispensing events, as this is when a patient actually receives a monitored medicine, and thus is where the most significant patient safety risks exist. Although prescribers are not compelled to provide prescribing records at this time, the Medicines Regulation does

not preclude the collection, use and disclosure of this information by the department if it is voluntarily provided for the database.

Part 3 Users and purposes for disclosure

Part 3 provides that for the definition of *user* in section 227(4) (Use of information) of the Medicines and Poisons Act, the users are prescribed in column 1 of the table and the purpose is prescribed in column 2.

Schedule 19 Fees

Schedule 19 provides that the fees payable under the Medicines and Poisons Act are stated in the schedule.

Schedule 20 Isolated practice areas—local governments

Schedule 20 provides for a list of local government areas for isolated practice areas.

Schedule 21 Rural hospitals—places

Schedule 21 provides for a list of rural hospitals.

Schedule 22 Dictionary

Schedule 22 defines certain words and terms used throughout the regulation.

Schedule 23 Regulations amended

Schedule 23 provides for the regulations amended as a consequence to the making of the Medicines and Poisons Act and its supporting regulations.