

Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021

Explanatory notes for SL 2021 No. 5

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021

Authorising law

Section 180 of the *Health Act 1937*.

Policy objectives and the reasons for them

COVID-19 is caused by the novel coronavirus SARS-CoV-2. The World Health Organization (WHO) became aware of the virus on 31 December 2019 following a report of a cluster of cases of viral pneumonia in Wuhan, China.

Following rapid global spread and increased severity of the disease emerging in several countries, on 11 March 2020, the WHO made the assessment that COVID-19 could be characterised as a pandemic. The number of COVID-19 infections worldwide has soared into the millions. Global deaths caused by the virus had surpassed 2.03 million as at 18 January 2021.

On 19 August 2020, the Honourable Scott Morrison MP, Prime Minister of Australia, announced the Australian Government's intention to ensure every Australian will be able to receive the COVID-19 vaccine for free, if trials prove successful, safe and effective.

The Australian Government is responsible for the selection, procurement and regulatory approval for COVID-19 vaccines, and for distribution of vaccines from point-of-arrival to point-of-administration across the country. There are currently more than 50 COVID-19 vaccine candidates in human clinical trials worldwide. The Australian Government has agreements for the supply of COVID-19 vaccines, if they are proven to be safe and effective, with Pfizer-BioNTech; University of Oxford-AstraZeneca; Novavax; and COVAX Facility. The Australian Government has indicated that vaccines, if deemed safe and effective by the Therapeutic Goods Administration (TGA), will be available for distribution from mid-to-late February 2021.

On 7 January 2021, the Prime Minister announced that after considerable effort, including with the vaccine suppliers, subject to TGA approvals, Australia will be in a position to commence vaccinations of high priority groups in mid-to-late February 2021 and hopes to reach four million people by 31 March 2021.

The rollout of safe and effective vaccines will be guided by the *Australian COVID-19 Vaccination Policy* (Vaccination Policy). The Vaccination Policy sets out the roles and responsibilities of the Australian Government and state and territory governments to implement a COVID-19 vaccine program in Australia from early 2021, as follows:

- Key responsibilities of the Australian Government will include, but are not limited to:
 - selecting and purchasing safe and effective vaccines approved by the TGA;
 - arranging the safe transportation of vaccine doses from suppliers to storage and administration sites;
 - prioritising at-risk population groups for immunisation, as advised by the Australian Technical Advisory Group on Immunisation;
 - specifying the types of locations vaccination should take place;
 - ensuring that appropriate data collection and monitoring systems are in place; and
 - the national communications and information effort.
- Key responsibilities of state and territory governments will include, but are not limited to:
 - ensuring an appropriately qualified and trained workforce for vaccines delivered at their vaccination sites;
 - authorising the selected workforce to possess and administer COVID-19 vaccines;
 - providing sites where vaccinations can safely take place; and
 - ensuring immunisation providers remain compliant at all times with their safety, ethical and reporting obligations.

The Vaccination Policy states that, while the Australian Government strongly supports immunisation and will run a strong campaign to encourage vaccination, vaccination is not mandatory and individuals may choose not to be vaccinated.

Each state and territory will have a COVID-19 Vaccination Program Implementation Plan which gives effect to the requirements under the Vaccination Policy. The Australian Government has been leading development of Queensland's COVID-19 Vaccination Implementation Plan (Implementation Plan), seeking input from Queensland Health.

It is expected the vaccine rollout will involve a range of different service delivery arrangements, to cater for priority populations and Queensland's geography. For example, it is expected the rollout will involve a mix of public and private delivery models to reach the entire Queensland population and will need to be flexible to respond to the approval of new vaccines.

On 24 December 2020, the Australian Government signed contracts to ensure the COVID-19 vaccines are safely distributed to all Australians from March 2021 (noting the Prime Minister has since announced that, subject to TGA approvals, vaccinations of high priority groups will commence in mid-to-late February 2021).

The contracts cover three aspects of the vaccine rollout:

- Distribution and logistics — DHL Supply Chain and Linfox will undertake COVID-19 vaccine distribution and logistics.
- Data — Accenture will provide tracking of vaccine doses as well as enabling overall program implementation monitoring.

Achievement of policy objectives

The Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021 (Amendment Regulation) will facilitate the rollout of the COVID-19 vaccine in Queensland.

The rollout of Queensland's COVID-19 vaccination program in 2021 will be a significant undertaking, far exceeding any previous vaccination program. The program is being delivered in a collaborative approach between the Australian Government and Queensland Government, to rapidly respond to COVID-19 on a large scale and provide vaccine availability to the entire population through a mix of service delivery arrangements. The program is being delivered outside the usual National Immunisation Program. It will require a co-ordinated whole-of system approach to ensure successful implementation. Due to the nature and scale of the undertaking, the existing provisions of the *Health (Drugs and Poisons) Regulation 1996* are not fit for purpose to facilitate all aspects of the rollout.

The Amendment Regulation will not prevent existing provisions of the Health (Drugs and Poisons) Regulation being used for the vaccine rollout where those provisions are able to be used (for example, existing provisions may be sufficient for some arrangements with general practitioners, community pharmacists and nurse practitioners). Existing requirements in the Health (Drugs and Poisons) Regulation in relation to the business-as-usual model for immunisation, including wholesaling, supply, sale, administration, prescribing, obtaining and issuing will not change. The changes only apply to the rollout of the COVID-19 vaccine where existing arrangements are not appropriate to be used.

The Amendment Regulation provides for the development of a COVID-19 vaccination code, to be made by the chief executive of Queensland Health or their delegate, which meets Queensland's responsibilities under the Vaccination Policy. To enable the rollout, the vaccination code must include requirements in relation to:

- the qualifications, training or supervision necessary for workers for declared providers of COVID-19 vaccination services, who will administer the vaccine (section 213E(2)(a));
- the recording of information related to the provision of the services (section 213E(2)(b)); and
- the reporting of information, including personal information, about vaccination services (section 213E(2)(c)).

The COVID-19 vaccination code will also set out the operational requirements for providing COVID-19 vaccination services, including matters such as:

- specifications for providing the services or setting up COVID-19 vaccination centres (section 213E(3)(a));
- providing for eligibility for the staged rollout of the vaccine, such as determining priority populations (section 213E(3)(b));

- procedures for assessing the health and suitability of persons to be vaccinated (section 213E(3)(c));
- procedures for safely preparing the vaccine, such as the processes for labelling syringes when they are drawn up from multi-dose vials, for example this may include the date and time of preparation (section 213E(3)(d));
- procedures for the vaccine and related drugs to be safely obtained, sold, supplied, issued or disposed of (section 213E(3)(e)); and
- safe and secure storage of the vaccine and related drugs (section 213E(3)(f)).

The chief executive will be responsible for declaring persons as ‘declared providers’ of COVID-19 vaccines and must publish the name of the person and the contact details of the individual who is responsible for overseeing the provision of COVID-19 vaccination services on the Queensland Health website. This will be a ‘source of truth’ for members of the general public to be satisfied that they are receiving a legitimate COVID-19 vaccine from a government-authorised provider.

The Amendment Regulation authorises providers and workers to carry out activities for providing COVID-19 vaccination services, if they comply with the COVID-19 vaccination code (sections 213G to 213L).

The Amendment Regulation also includes an information sharing provision to facilitate data sharing with the Australian Government and other agencies to facilitate a safe and effective vaccination program (section 213M).

Medical practitioners, pharmacists in community pharmacies and nurse practitioners are already authorised to administer Schedule 4 (S4) vaccines under the Health (Drugs and Poisons) Regulation. This means that for vaccinations given by these health practitioners, it will not be necessary for them to be a ‘declared provider’. However, section 200 of the Health (Drugs and Poisons) Regulation requires vaccines to be obtained through a formal purchase order procedure. The Amendment Regulation amends section 200 of the Health (Drugs and Poisons) Regulation to provide that if an authorised person, such as a medical practitioner, pharmacist or nurse practitioner, obtains a COVID-19 vaccine under the Australian COVID-19 vaccination arrangements, they are not committing an offence by not obtaining a restricted drug on a purchase order. The ‘Australian COVID-19 vaccination arrangements’ is defined to mean the arrangements made under the Australian COVID-19 Vaccination Policy to provide COVID-19 vaccines for vaccinating members of the public.

Consistency with policy objectives of authorising law

The regulation is consistent with the policy objectives of the *Health Act 1937*.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

The Amendment Regulation is the only effective means of ensuring the COVID-19 vaccine is safely rolled out and available to all Queenslanders as a key priority.

Due to the unprecedented nature and scale of the COVID-19 vaccination rollout, the existing provisions of the Health (Drugs and Poisons) Regulation are not fit for purpose.

The rapid rollout, the need to reach the entire population, the use of multiple vaccines and the mix of service delivery arrangements require the development of the COVID-19 vaccination code to guide key aspects of the rollout.

Benefits and costs of implementation

The Amendment Regulation will facilitate the safe and efficient rollout of the COVID-19 vaccination program. Vaccination is a simple, safe and effective way of protecting people against harmful diseases, before they come into contact with them. The safety and effectiveness of COVID-19 vaccines used in Australia are assessed and approved by the TGA.

The COVID-19 vaccination will be free for all Medicare-eligible Australians and visa-holders as described in Australia's COVID-19 Vaccination Policy.

The cost of the vaccine rollout in Queensland and cost-sharing arrangements with the Australian Government will form part of an inter-governmental funding agreement, aligned with the roles and responsibilities as set out in the Vaccination Policy and any associated bilateral implementation plans. The Queensland Government contribution to costs for the vaccine rollout will be considered in the context of existing Queensland Government COVID-19 funding packages and future government deliberations once cost-sharing arrangements with the Australian Government are finalised.

Consistency with fundamental legislative principles

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

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

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.

The Amendment Regulation provides powers for the chief executive. Under the *Public Service Act 2008*, the chief executive may delegate their powers to appropriate individuals who can make decisions on behalf of the chief executive within the scope of their roles and responsibilities. The Amendment Regulation provides for the following powers of the chief executive which may be the subject of delegations:

- section 213E(1) (COVID-19 vaccination code) provides that the chief executive may publish a COVID-19 vaccination code, which states the requirements for providing COVID-19 vaccination services;
- section 213F(1) (Declaring providers of vaccination services) provides that the chief executive may, by notice published on the Queensland Health website, declare a person to be a declared provider for providing COVID-19 vaccination services;

- section 213F(3) (Declaring providers of vaccination services) provides the information the chief executive must publish in a notice on the Queensland Health website under section 213F(1), being the name of each declared provider and the name and contact details of the individual responsible for overseeing the provision of the COVID-19 vaccination service; and
- section 213M(2) (Giving personal information for particular purposes) provides that the chief executive may give personal information to an entity to facilitate the safe and effective therapeutic treatment of persons vaccinated at a COVID-19 vaccination centre or to report to the entity or facilitate reporting to the entity about the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements.

The issue of whether delegated legislative power is sufficiently subjected to the scrutiny of the Legislative Assembly often arises when the power to regulate an activity is contained in a guideline or similar instrument that is not subordinate legislation and therefore is not subject to parliamentary scrutiny.

The Director-General of Queensland Health (as chief executive) is the accountable person for administration of health portfolio legislation on behalf of the Minister. Queensland Health has implemented a corporate delegations guideline and standard and also undertakes six-monthly reviews of their delegations to ensure that the appropriate persons continue to have delegated authority to make decisions.

Prior to having the delegated authority, the chief executive must satisfy themselves that the relevant employees have the appropriate skills and knowledge to effectively undertake the delegated roles and responsibilities. This includes ensuring relevant employees are aware of their legislative responsibilities, current legislative compliance activities and key documents for legislative compliance and have undertaken all mandatory training outlined in the relevant policies.

It is considered that the rigour around preparing delegations and ensuring only the appropriate people are given the delegation to make decisions on behalf of the chief executive justifies the need to delegate. It should also be noted that the chief executive does not have to delegate if they believe the decision making should not be delegated and should remain with them.

Does the legislation allow the sub-delegation of power only in appropriate cases and to appropriate persons – prescribing requirements in external documents?

Prescribing requirements by reference to an external document may be seen to breach section 4(5)(e) of the Legislative Standards Act which states that whether subordinate legislation has sufficient regard to the institution of Parliament depends on whether the subordinate legislation allows the sub-delegation of power only in appropriate cases and to appropriate persons. A vaccination code is a document published by the chief executive of Queensland Health that states the requirements for providing COVID-19 vaccination services.

The task of ensuring COVID-19 vaccines are available to all Queenslanders, regardless of where they live, is unprecedented in modern healthcare. The COVID-19 vaccination program will be jointly rolled out by the Australian and Queensland Governments, with responsibilities shared for different aspects of the program. For example, the Australian Government is responsible for selecting and purchasing safe and effective vaccines approved by the TGA. A number of vaccines remain in clinical trials and may form part of the rollout if they are approved later in 2021.

The COVID-19 vaccination code will allow for flexibility for new vaccines to be added to the rollout, as they are approved by the TGA. The code will set out the detailed technical requirements for safe and secure storage of vaccines, as well as procedures to ensure vaccinations are safe for members of the community. The code will also set out the qualifications, training and supervision for providers and workers to ensure they are able to safely immunise the large number of people required.

Given the large scale of the rollout, it is expected a number of different service delivery models will be employed and the code will provide the necessary flexibility to ensure appropriate arrangements can be put in place for different settings. This is particularly important given Queensland's dispersed population and the need to reach vulnerable populations in remote First Nations communities, as well as rural and regional populations.

The COVID-19 vaccination code will be reviewed and updated to ensure it reflects the latest advice from the Australian Government and the TGA, as well as responds to any emerging issues for the rollout. The vaccination code will be published on the Queensland Health website (<http://www.health.qld.gov.au/>) to provide transparency and accountability about the requirement for declared providers and workers. The code will be developed with input from clinicians and experts to ensure a successful rollout of COVID-19 vaccines in Queensland. Given the detailed and technical nature of the matters required to be set out in the code and the urgent nature of the COVID-19 vaccination rollout, it is considered appropriate for these matters to be set out in the code.

Does the legislation adversely affect rights and liberties or impose obligations?

Section 4(3)(g) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation does not adversely affect the rights and liberties or impose obligations.

The Amendment Regulation may potentially breach the principle that legislation must have sufficient regard to individuals' rights and liberties, as it allows the chief executive of Queensland Health to share personal information about individuals who have been vaccinated in certain circumstances.

As outlined above, the COVID-19 vaccination program will be jointly rolled out by the Australian and Queensland Governments, with responsibilities shared for different aspects of the program. The Australian Government is responsible for ensuring that appropriate data collection and monitoring systems are in place. The Queensland Government will be required to report to the Australian Government on the rollout and it will be necessary to share information with the Australian Government for reporting and monitoring.

Most COVID-19 vaccines require at least two injections, provided at minimum intervals. Given the large-scale nature of the rollout, it is expected that members of the community may present to a different service or provider to receive their second or subsequent injection. To ensure the vaccine can be delivered safely and effectively, it will be important for Queensland Health to be able to share information about previous vaccinations with providers, such as the type of vaccine received, the date of the first vaccination, the dosage and the individual's personal information so they can be identified.

The Amendment Regulation will also allow Queensland Health to disclose personal information to facilitate the safe and effective therapeutic treatment of persons vaccinated at COVID-19 vaccination centres. For example, Queensland Health may engage a third-party provider to SMS a person on certain days after receiving the vaccination to determine their health and whether they have encountered any side-effects. The third party may also send reminder messages to ensure the person books in for their second vaccination.

Queensland Health will also be able to disclose information to report, or to facilitate reporting, about the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements. For example, giving personal information to another state entity or an Australian Government entity for monitoring adverse reactions to the vaccination or monitoring the impacts of vaccination. On 3 December 2020, the Honourable Greg Hunt MP, Federal Minister for Health, announced amendments to be made at a national level to ensure all vaccination providers report vaccines given, including any COVID-19 vaccine to the Australian Immunisation Register. The legislation supports these amendments by ensuring any immunisations given in Queensland can meet this requirement.

It is important that when a vaccine is administered that the information is provided to the Australian Immunisation Register to ensure health professionals have access to a person's vaccination history. This information could be vital in an emergency, when undertaking medical treatment and in managing an individual's health and wellbeing.

There are appropriate safeguards to protect personal information, including the requirement that the chief executive must ensure the privacy of any persons to whom the information relates is protected from unjustified intrusion.

Given the important role that monitoring the rollout of the COVID-19 vaccine plays in ensuring the health and wellbeing of individuals receiving the vaccine and for future vaccination participants, it is considered justified that Queensland Health share information, while still ensuring a person's privacy to the extent possible.

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

Section 4(3)(k) of the Legislative Standards Act states that whether legislation has sufficient regard to the rights and liberties of individuals depends on whether the legislation is unambiguous and drafted in a sufficiently clear and precise way.

The Amendment Regulation may potentially breach this principle because the authorisation of declared providers, and the exclusion of purchase order requirements for particular authorised persons, is done under the Australian COVID-19 vaccination arrangements, which are defined as the arrangements made under the Australian COVID-19 vaccination policy.

The Australian COVID-19 vaccination policy sets out key principles, such as the COVID-19 vaccines that will be made available for free to all Australian citizens, permanent residents, and most visa-holders. Further, it outlines how COVID-19 vaccines will be accessible on a rolling basis, dependent on vaccine delivery schedules and the identification of groups for most urgent vaccination. The vaccination policy also describes the shared and separate responsibilities of the Australian, State and Territory governments, as well as other key stakeholders. Each jurisdiction, including the Australian Government, will develop supporting Implementation Plans, which will articulate how it will give effect to its responsibilities under the policy.

The Amendment Regulation does not detail the specific arrangements, contracts or dated documents that are relied upon to form the Australian COVID-19 vaccination arrangements. Those arrangements are not yet complete and will be subject to change to deliver the complex roll-out of COVID-19 vaccinations. However, the vaccination policy does provide the framework for the development of these arrangements, including the development of the implementation plans to be managed by the Australian, State and Territory Governments, which require endorsement by the Australian Government.

Given the detail contained within the vaccination policy on how the COVID-19 vaccination will be rolled out, including the responsibilities for the Australian, State and Territory Governments and the urgent nature of the COVID-19 vaccination rollout, it is considered appropriate for the Amendment Regulation to incorporate the changing arrangements made under the vaccination policy, rather than being tied to a particular document, contract or other arrangement.

Consultation

Specific consultation was not undertaken on the Amendment Regulation due to the urgent timeframes for an imminent rollout of the COVID-19 vaccine. It is important that Queensland removes any legislative barriers, while still ensuring Queenslanders are kept safe during the rollout of the COVID-19 vaccine. It is also important that Queensland be ready to commence vaccinations as soon as vaccines become available.

The Australian Government and the Queensland Government will work together to promote and provide information about the COVID-19 vaccine rollout. The approved COVID-19 vaccines used in Australia will be subject to the well-established and rigorous assessment and approval process by the TGA.

The Amendment Regulation was assessed by the Office of Best Practice Regulation in accordance with *The Queensland Government Guide to Better Regulation* as being excluded from further regulatory analysis, as it is reasonably clear there are no significant adverse impacts.

Notes on provisions

Short Title

Clause 1 states the short title of the regulation is the *Health (Drugs and Poisons) (COVID-19 Vaccination Services) Amendment Regulation 2021*.

Regulation amended

Clause 2 states the regulation amends the *Health (Drugs and Poisons) Regulation 1996*.

Amendment of s 143 (Offence to wholesale restricted drug without licence)

Clause 3 amends section 143 by inserting a note that refers to new section 213G (Effect of authorisation for regulation offences). The effect of section 213G is it is not an offence to sell a restricted drug by wholesale if the drug is used to carry out particular activities for providing a COVID-19 vaccination service and provided the person is authorised under new part 9A, division 3 (Authorised activities for vaccination services).

Amendment of s 146 (Endorsement needed for restricted drugs)

Clause 4 amends section 146 by inserting a note that refers to new section 213G (Effect of authorisation for regulation offences). The effect of section 213G is that a person does not require an endorsement to possess, obtain, dispose of, issue, purport to prescribe, sell or administer a restricted drug if the drug is used to carry out particular activities for providing a COVID-19 vaccination service and provided the person is authorised under new part 9A, division 3 (Authorised activities for vaccination services).

Amendment of s 200 (Authorised persons to obtain restricted drugs on purchase order)

Clause 5 inserts new subsection (5A) which states that section 200 does not apply to an authorised person who obtains a COVID-19 vaccine under the Australian COVID-19 vaccination arrangements. This means that if an authorised person, such as a medical practitioner, pharmacist or nurse practitioner, obtains a COVID-19 vaccine under the Australian COVID-19 vaccination arrangements, they are not committing an offence by not obtaining a restricted drug on a purchase order. The *Australian COVID-19 vaccination arrangements* means the arrangements made under the Australian COVID-19 Vaccination Policy to provide COVID-19 vaccines for vaccinating members of the public.

Clause 5(2) renumbers subsections (5A) and (6) to subsections (6) and (7).

Insertion of new ch 3, pt 9A

Clause 6 inserts new chapter 3, part 9A (Special provisions for COVID-19 vaccination services). Part 9A comprises new sections 213B to 213M.

Part 9A Special provisions for COVID-19 vaccination services

Division 1 Preliminary

Section 213B (Purpose of part) provides that the purpose of part 9A is to allow the chief executive to publish a code to facilitate the provision of COVID-19 vaccination services, subject to special requirements; to declare particular persons to be declared providers for providing those services; to authorise those declared providers, and workers for those providers, to undertake particular activities to provide those services; and to allow the chief executive to give personal information reported to the chief executive under the code to other entities for particular purposes.

Section 213C (Relationship with other regulation provisions) provides that part 9A does not limit another provision of the *Health (Drugs and Poisons) Regulation 1996* applying to a person who is authorised to carry out an activity in relation to a COVID-19 vaccine or related drug, or prevents a person carrying out an activity in relation to a COVID-19 vaccine or related drug that is lawful without an endorsement, such as obtaining adrenaline as a Schedule 3 poison.

Section 213D (Definitions for part) defines the terms *COVID-19 vaccination centre*, *COVID-19 vaccination code*, *COVID-19 vaccination service*, *declared provider*, *health service*, *personal information*, *related drug* and *worker*.

Division 2 Code for, and declared providers of, vaccination services

Section 213E (COVID-19 vaccination code) provides that the chief executive may publish a COVID-19 vaccination code on the Queensland Health website, which states the requirements for providing COVID-19 vaccination services.

Section 213E(2) provides that the COVID-19 vaccination code must include requirements in relation to:

- the qualifications, training or supervision necessary for workers for declared providers of COVID-19 vaccination services;
- the recording of information related to the provision of the services; and
- the reporting of information, including personal information, related to the provision of the services.

Section 213E(3) provides that, without limiting subsections (1) or (2), the COVID-19 vaccination code may also include the following requirements for COVID-19 vaccination services:

- specifications for providing the services or setting up COVID-19 vaccination centres;
- procedures for prioritising who to vaccinate;
- procedures for assessing the health and suitability of persons to be vaccinated;
- procedures for safely preparing COVID-19 vaccines or related drugs;
- procedures for obtaining, selling, supplying, issuing or disposing of COVID-19 vaccines or related drugs;
- procedures for safely or securely storing COVID-19 vaccines or related drugs.

Section 213E(4) provides that the COVID-19 vaccination code takes effect either on the day it is published on the Queensland Health website or if a later date is specified in the code, on the specified date.

Section 213F (Declaring providers of vaccination services) provides that the chief executive may, by notice published on the Queensland Health website, declare a person to be a declared provider for providing a COVID-19 vaccination service under part 9A.

Section 213F(2) provides a declaration may be made under subsection (1) only if the chief executive is satisfied of the following:

- the person, and workers for the person, are able to comply with the COVID-19 vaccination code when providing the COVID-19 vaccination service; and
- an appropriately qualified individual will be responsible for overseeing the provision of the COVID-19 vaccination service.

Section 213F(3) provides a notice published under subsection (1) must state the name of the person declared and the name and contact details of the individual who is responsible for overseeing the provision of the COVID-19 vaccination service.

Division 3 Authorised activities for vaccination services

Section 213G (Effect of authorisation for regulation offences) provides that a person authorised under division 3 to carry out an activity does not commit an offence against another provision of the Health (Drugs and Poisons) Regulation provided the person is acting in accordance with division 3 and if the person carrying out the activity is a worker for a declared provider of a COVID-19 vaccination service, the worker is permitted by the provider to carry out the activity for the provider and the granting of permission does not contravene the COVID-19 vaccination code.

Section 213H (Obtaining, selling and supplying vaccines and related drugs) provides that a declared provider of a COVID-19 vaccination service, or a worker for the provider, may obtain COVID-19 vaccines or related drugs for the service under the COVID-19 vaccination code. A person does not require an authority to obtain a Schedule 3 adrenaline. However, in the Health (Drugs and Poisons) Regulation a seller must only sell to specified persons.

Section 213H(2) provides that an authorised supplier of COVID-19 vaccines or related drugs may, under the COVID-19 vaccination code, sell or supply the vaccines or drugs to a declared provider of a COVID-19 vaccination service, or a worker for the provider.

Section 213H(3) provides that a declared provider of a COVID-19 vaccination service, or a worker for the provider, may, under the COVID-19 vaccination code, sell or supply COVID-19 vaccines or related drugs to another declared provider, or a worker for the other provider. The definition of 'sell' under the *Health Act 1937* is broad and includes giving away, bartering, lending, offering or attempting to sell. It is intended that the vaccination code will deal with on-selling of the vaccine stock for commercial gain ensuring it will not be allowed when one declared provider supplies stock to another provider. Declared suppliers may only supply to entities within the program. Further details about this will be included in the COVID-19 vaccination code.

Section 213I (Possessing vaccines and related drugs for transportation) provides that a person engaged to transport a COVID-19 vaccine or related drug to or from a relevant place may possess the vaccine or drug under the COVID-19 vaccination code.

Section 213J (Issuing vaccines and related drugs) provides that a declared provider of a COVID-19 vaccination service may, under the COVID-19 vaccination code, issue a COVID-19 vaccine or related drug to a worker for the provider.

Section 213J(2) provides that a worker for a declared provider of a COVID-19 vaccination service may, under the COVID-19 vaccination code, issue a COVID-19 vaccine or related drug to another worker for the service.

Section 213K (Possessing and administering at vaccination centres) provides that a worker for a declared provider of a COVID-19 vaccination service may, under the COVID-19 vaccination code, possess or administer a COVID-19 vaccine or related drug at a COVID-19 vaccination centre.

Section 213L (Disposing of vaccines and related drugs) provides that a declared provider of a COVID-19 vaccination service, or a worker for the provider, may dispose of a COVID-19 vaccine or related drug under the COVID-19 vaccination code.

Division 4 Information sharing

Section 213M (Giving personal information for particular purposes) provides that this section applies to personal information reported to the chief executive under the COVID-19 vaccination code.

Section 213M(2) provides that the chief executive may give personal information to an entity to facilitate the safe and effective therapeutic treatment of persons vaccinated at COVID-19 vaccination centres or report to the entity, or facilitate reporting to the entity, in relation to the use of COVID-19 vaccines under the Australian COVID-19 vaccination arrangements. For example, giving personal information about persons who have been vaccinated to the provider of a messaging service to notify and monitor the health of those persons, or giving personal information about persons who have been vaccinated to a Commonwealth, State or Territory entity under the Australian COVID-19 vaccination arrangements.

Section 213M(3) provides that when giving the personal information, the chief executive must ensure the privacy of the person to whom the information relates is protected, to the extent possible, from unjustified intrusion.

Amendment of appendix 9 (Dictionary)

Clause 7 inserts new definitions for Australian COVID-19 vaccination arrangements, Australian COVID-19 vaccination policy, COVID-19 vaccination centre, COVID-19 vaccination code, COVID-19 vaccination service, COVID-19 vaccine, declared provider, health service, personal information, related drug and worker and amends the definition of approval.