

# Health (Drugs and Poisons) Amendment Regulation 2020

Explanatory notes for SL 2020 No. 74

made under the

*Health Act 1937*

## General Outline

### Short title

*Health (Drugs and Poisons) Amendment Regulation 2020*

### Authorising law

Section 180 of the *Health Act 1937*.

### Policy objectives and the reasons for them

On 29 January 2020, a public health emergency was declared under section 319 of the *Public Health Act 2005* due to the outbreak of COVID-19 (the COVID-19 public health emergency). The COVID-19 public health emergency was declared for all of Queensland. A copy of the public health emergency order was published in the Queensland Government Gazette on 31 January 2020. The COVID-19 public health emergency has been extended by regulation until 19 May 2020 and may be further extended.

On 26 March 2020, the Australian Government introduced telehealth arrangements that are intended to allow pharmaceutical benefits to be paid for some restricted (Schedule 4) drugs dispensed by pharmacists on receipt of a digital image of a prescription from a prescriber. This has been achieved by the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement).

The telehealth arrangements are one way to streamline health service delivery and reduce physical contact for vulnerable patients during the COVID-19 response. Amendments to the *Health (Drugs and Poisons) Regulation 1996* (HDPR) are necessary to implement these arrangements, which will strengthen Queensland's capacity to contain and respond to the spread of COVID-19 within the community and to reduce administrative burden on healthcare providers during the pandemic.

## Achievement of policy objectives

Section 193 of the HDPR requires that restricted (Schedule 4) drugs be dispensed on the presentation of a valid prescription written by an authorised prescriber. A valid prescription includes:

- a paper prescription (handwritten or computer generated) (section 190);
- an electronic prescription (section 190);
- a faxed prescription (section 192AA requires that a faxed prescription be confirmed by the prescriber telephoning the dispenser within 24 hours and followed up with the original paper prescription within 7 days); or
- an oral prescription (section 192 requires that an oral prescription given to a dispenser be followed up by a paper prescription sent by facsimile transmission within 24 hours and then sent by post or hand to the dispenser within 7 days).

The HDPR restricts transmission of a paper prescription to a dispenser by allowing for facsimile transmission only. There is a need to urgently modernise the legislation to allow for digital images of paper prescriptions to be sent via other types of electronic communication, such as an email, to allow for the Special Arrangement. Changes are also required to reduce the burden on prescribers and dispensers by temporarily easing the requirement for the prescriber to send a paper prescription to the dispenser within 7 days for restricted drugs where there is a low risk of abuse or illicit use.

It is also proposed to permanently remove the requirement for prescribers to telephone dispensers within 24 hours after faxing a prescription.

### *Prescriber*

If the prescription is for a restricted (Schedule 4) drug, other than a restricted drug of dependence or an anabolic steroid, it is proposed the prescriber will be temporarily exempt from the legal requirement (in the HDPR) to send the original prescription to the dispenser. Restricted drugs of dependence are listed in Appendix 8 of the HDPR and include benzodiazepines, codeine and phentermine.

As required for the Special Arrangement, the prescriber must retain the original paper prescription for a period of two years (whether for a PBS/RPBS or private prescription). A factsheet will be provided to prescribers, that will assist them for auditing purposes, on how to make a record on the prescription and in their clinical system when a copy or digital image is sent to a pharmacy, noting the particulars of the pharmacy and the method of transmission.

The temporary exemption for sending paper copies of prescriptions will be applied retrospectively from 26 March 2020 and will continue to apply while the Special Arrangement remains in place.

There are no changes to the requirement for the prescriber to send a paper prescription to the pharmacy for controlled drugs, restricted drugs of dependence and anabolic steroids. The paper prescription for these medicines must still be sent to the dispenser within 7 days of being faxed or sent as a digital image.

## ***Dispenser***

It is proposed to allow pharmacists to dispense on faxed copies and digital images of prescriptions (in addition to existing oral and paper prescriptions) sent to the dispenser by the prescriber.

Pharmacists are obliged to confirm the bona fides of all prescriptions including that they have been written and sent by an authorised prescriber. Pharmacists may meet the obligation to confirm the bona fides of a copy or digital image of a prescription if they are able to demonstrate that they are familiar with the prescriber's signature and contact details (e.g. email address or fax number). Otherwise, pharmacists must take reasonable steps to confirm prescriptions, such as phoning the prescriber (preferably on an independently obtained phone number) and should document the steps taken.

If the prescription is for a restricted drug, other than a restricted drug of dependency or an anabolic steroid, pharmacists will be required to retain the faxed copy, digital image or a printout of the digital image of a prescription on which they have dispensed for a period of two years for audit and compliance purposes. For all other prescriptions, the usual requirement for a prescriber to send the paper prescription by post or by hand within seven days will continue to apply.

Existing requirements in the HDPR about keeping records of all dispensed medicines will not change. However, for audit and compliance purposes, a factsheet will be provided to dispensers recommending that pharmacists record in their dispensing system when they have made a supply on a faxed copy or digital image of a prescription and where the faxed copy or digital image is stored or saved.

The Special Arrangement requires that all remaining repeats be retained and supplied at the original dispensing pharmacy. The original dispensing pharmacy must also retain and supply any repeats on private prescriptions. A pharmacist must not supply a repeat supply on a faxed copy or digital image of a prescription whose initial dispensing was made at another pharmacy. Under sections 81AA and 192AA a faxed prescription or digital image of a prescription is only a lawful prescription if it is given to the dispenser by the prescriber. If there are multiple dispensers working in that dispensary any one of them may action the fax/email/text. However, the faxed/emailed prescription would become invalid if taken to another dispensary as it was not given to that dispensary by the prescriber.

## **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 Health (Drugs and Poisons) Amendment Regulation 2020 (Amendment Regulation) is the only effective means of implementing the Australian Government's telehealth arrangements.

The Queensland amendments have no functional impact on the general community other than facilitating those changes.

## **Benefits and costs of implementation**

The HDPR restricts the transmission of a paper prescription to a dispenser by facsimile transmission only. There is a need to urgently modernise the legislation to allow for digital images of paper prescriptions to be sent via other types of electronic communication such as emails, in line with the Special Arrangement.

With the increasing use of telehealth arrangements by prescribers to reduce the risk of transmission of COVID-19, the changes reduce the burden on prescribers and dispensers by temporarily easing the requirement for the prescriber to send a paper prescription to the dispenser within 7 days for restricted drugs where there is a low-risk of abuse or illicit use. For these low-risk restricted drugs, reducing the transfer of paper prescriptions further reduces opportunities for virus transmission whilst balancing to public health and safety risks of fraud and unauthorised access to drugs with a higher risk of abuse and illicit use. The prescriber must continue to retain the original paper prescription for a period of two years

## **Consistency with fundamental legislative principles**

The regulation is consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

***Does the subordinate legislation adversely affect rights and liberties, or impose obligations, retrospectively?***

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

Clause 12 inserts new section 320 (Validation of giving, dispensing on, digital images of prescriptions during relevant period). Section 320 provides that this section applies if, during the period starting on the commencement of the Special Arrangement, 26 March 2020, and ending on the commencement of this section, if under the Special Arrangement a prescriber gave a dispenser a digital image of a prescription for a controlled drug or restricted drug and the dispenser dispensed the controlled drug or restricted drug on the digital image.

New section 320(2) provides that the prescriber is taken to have lawfully given the digital image to the dispenser under the HDPR. New sections 320(3) provides that the dispenser is taken to have lawfully dispensed the controlled or restricted drug on the digital image under the HDPR.

Clause 12 is beneficial as it allows prescribers to send digital images of paper prescriptions via other types of electronic communications such as emails, in line with the Special Arrangement. The amendments reduce the burden on prescribers and dispensers by temporarily easing the requirement for the prescriber to send a paper prescription to the dispenser within 7 days for restricted drugs where there is a low-risk of abuse or illicit use. The prescriber must continue to retain the original paper prescription for a period of two years.

Clause 12 may be seen to breach section 4(3)(g) of the Legislative Standards Act as it operates retrospectively. The retrospective operation of a beneficial provision is expressly permitted under section 34 of the *Statutory Instruments Act 1992*. Section 34 defines ‘beneficial provision’ to mean a provision that does not operate to the disadvantage of a person (other than the State, a State authority or a local government) by decreasing the person’s rights or imposing liabilities on the person.

### ***Fundamental legislative principles not contained in Legislative Standards Act***

Clause 9 inserts new section 192AB (Keeping prescriptions during special arrangement period). New section 192AB(3) provides that it is an offence if the prescriber does not comply with section 192AA(2) and fails to keep the paper prescription for two (2) years after the acceptable electronic copy is given. New section 192AB(4) provides that subsection (3) applies even if the Special Arrangement is no longer in force before the end of the two (2) years. The offence carries a maximum penalty of 40 penalty units.

The maximum penalty of 40 penalty units, is equivalent to other offences under the HDPR. These offences include sections 84(5)(b), 133, 199 and 222. The above penalty has been reviewed and the penalty is proportionate to the seriousness of the offence and is justified due to the need to limit access to controlled and restricted drugs. The retention of records provides for monitoring and investigation of unauthorised access, such as fraudulent prescriptions and enforcement.

## **Consultation**

Specific consultation was not undertaken on the regulation due to the urgent timeframes and demand from doctors and pharmacists for the amendments. Queensland Health will provide factsheets and guidance material to affected stakeholders when the regulation commences, in addition to the information made available by the Australian Government about the Special Arrangements.

The Australian Medical Association Queensland; Royal Australian College of General Practitioners; The Pharmacy Guild of Australia, Queensland Branch; Pharmaceutical Society of Australia (Queensland); and individual medical practitioners and pharmacists have all made public statements, or written directly to Queensland Health, expressing their strong support for amendments enabling the use of digital images of paper prescriptions and to have the effect of the amendments apply from the start of the Special Arrangements on 26 March 2020.

The Australian Government consulted extensively on the Special Arrangements and received support for the amendments from national peak bodies of medical practitioners, pharmacists and consumers.

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 impact analysis under category (k) – regulatory proposals designed to reduce the burden of regulation, or that clearly do not add to the burden, and it is reasonably clear there are no significant adverse impacts.

## Notes on provisions

### Short Title

Clause 1 provides the short title of the regulation as *the Health (Drugs and Poisons) Amendment Regulation 2020*.

### Regulation amended

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

### Amendment of s 81 (Oral prescription)

Clause 3 amends section 81(2) by replacing the phrase ‘a paper prescription for the drug is sent by facsimile transmission’ with ‘an acceptable electronic copy of a paper prescription for the drug is sent’. This amendment modernises the provision by allowing for digital images of paper prescriptions to be sent by the prescriber to the dispenser via other types of electronic communication, such as an email or text message. A digital image of a prescription sent to the dispenser by a person other than the prescriber is not ‘an acceptable electronic copy of a paper prescription’.

An *acceptable electronic copy* is defined in appendix 9 (Dictionary), as inserted by clause 13, as, for a paper prescription, a digital image or facsimile copy of the prescription sent by electronic transmission. For example, a scan of the prescription sent in an email, a digital photograph of the prescription sent from a smart phone or a copy of the prescription sent on a fax machine.

Clause 3(2) amends section 81(3) by replacing ‘a paper prescription’ with ‘the paper prescription’.

Clause 3(3) amends section 81(4) by replacing ‘a paper or’ with ‘the paper prescription or an’.

### Amendment of s 81AA (Faxed prescription)

Clause 4 amends the heading of section 81AA to replace ‘Faxed prescription’ with ‘Acceptable electronic copies of prescriptions’.

Clause 4(2) amends section 81AA(1) by replacing ‘a faxed prescription’ with ‘an acceptable electronic copy of a paper prescription’.

Clause 4(3) omits sections 81AA(2) and (5).

Clause 4(4) amends section 81AA(3) by replacing the phrase ‘faxed prescription, the prescriber must send a’ to ‘acceptable electronic copy, the prescriber must send’. A digital image of a prescription sent to the dispenser by a person other than the prescriber is not ‘an acceptable electronic copy of a paper prescription’.

Clause 4(5) amends section 81AA(4) by replacing the phrase ‘a paper or electronic prescription for the drug from the prescriber within 14 days after being given the faxed prescription’ to ‘the paper prescription or an electronic prescription for the drug from the prescriber within 14 days after being given the acceptable electronic copy’.

Clause 4(6) renumbers sections 81AA(3) and (4) to 81AA(2) and (3). This is necessary due to the omission of section 81AA(2) by clause 4(3).

### **Amendment of s 84 (Dealing with paper prescriptions and particular written instructions)**

Clause 5 replaces section 84(1) to provide that this section applies to a dispenser who:

- dispenses a controlled drug on a paper prescription;
- dispenses a controlled drug on an acceptable electronic copy of a paper prescription and later receives the paper prescription; or
- administer or supplies a controlled drug on a written instruction.

Clause 5(2) amend section 84(2) by replacing ‘when’, in relation to when a dispenser is dispensing, with ‘at the relevant time for’. Clause 5(3) inserts the definition of relevant time into section 84(13). *Relevant time*, for dispensing, administering or supplying a controlled drug, means:

- if the drug is dispensed on a paper prescription—when the drug is dispensed;
- if the drug is dispensed on an acceptable copy of a paper prescription later received by a dispenser—as soon as practicable after the paper prescription is received by the dispenser; or
- if the drug is administered or supplied—when the drug is administered or supplied.

This provision makes it clear that the dispenser must indicate that a controlled drug was dispensed on the paper prescription sent to the dispenser by the prescriber following the sending of an acceptable electronic copy of the prescription.

### **Amendment of s 84A (Dealing with electronic prescriptions)**

Clause 6 replaces section 84A(1) to provide that this section applies to a dispenser who:

- dispenses a controlled drug on an electronic prescription; or
- dispenses a controlled drug on an acceptable electronic copy of a paper prescription and later receives an electronic prescription for the controlled drug.

Clause 6(2) amends section 84A(2) by replacing ‘when’, in relation to when a dispenser is dispensing, with ‘at the relevant time for dispensing the controlled drug, enter the following information in the electronic prescription’.

Clause 6(3) replaces section 84(3) to provide that the dispenser must send the chief executive the electronic prescription by electronic means:

- within 7 days after the end of the week in which the controlled drug is dispensed; or
- within 7 days after the dispenser receives the electronic prescription if a dispenser dispenses a controlled drug on an acceptable electronic copy of a paper prescription and later receives an electronic prescription for the controlled drug; or
- if it is a repeat prescription, within 7 days after the end of each other week in which the controlled drug is dispensed on a repeat, including the final repeat of the prescription.

Clause 6(4) inserts the definition of relevant time into section 84A. *Relevant time*, for dispensing a controlled drug, means:

- if the drug is dispensed on an electronic prescription-when the drug is dispensed; or
- if the drug is dispensed on an acceptable electronic copy of a paper prescription and an electronic prescription for the drug is later received by a dispenser-as soon as practicable after the electronic prescription is received by the dispenser.

This provision makes it clear that the dispenser must indicate that a controlled drug was dispensed on an electronic prescription sent to the dispenser by the prescriber following the sending of an acceptable electronic copy of the prescription.

### **Amendment of s 192 (Oral prescription)**

*Clause 7* amends section 192(2) by replacing the phrase ‘a paper prescription for the drug is sent by facsimile transmission’ with ‘an acceptable electronic copy of a paper prescription for the drug is sent’. This amendment allows for digital images of paper prescriptions to be sent via other types of electronic communication, such as an email or text message. A digital image of a prescription sent to the dispenser by a person other than the prescriber is not ‘an acceptable electronic copy of a paper prescription’.

Clause 7(2) amends section 192(3) by replacing ‘a paper prescription’ with ‘the paper prescription’.

Clause 7(3) amends section 81(4) by replacing ‘a paper or’ with ‘the paper prescription or an’.

### **Amendment of s 192AA (Faxed prescription)**

*Clause 8* amends the heading of section 192AA to replace ‘Faxed prescription’ with ‘Acceptable electronic copies of prescriptions’.

Clause 8(2) amends section 192AA(1) by replacing ‘a faxed prescription’ with ‘an acceptable electronic copy of a paper prescription’.

Clause 8(3) omits sections 192AA(2) and (5).

Clause 8(4) amends section 192AA(3) by replacing the phrase ‘faxed prescription, the prescriber must send a’ to ‘acceptable electronic copy, the prescriber must send the’. A digital image of a prescription sent to the dispenser by a person other than the prescriber is not ‘an acceptable electronic copy of a paper prescription’.

Clause 8(5) amends section 192AA(4) by replacing the phrase ‘a paper or electronic prescription for the drug from the prescriber within 14 days after being given the faxed prescription’ to ‘the paper prescription or an electronic prescription for the drug from the prescriber within 14 days after being given the acceptable electronic copy’.

Clause 8(6) renumbers sections 192AA(3) and (4) to 192AA(2) and (3). This is necessary due to the omission of section 192AA(2) by clause 8(3).



## Insertion of new s 192AB

*Clause 9* inserts after section 192AA a new section 192AB (Keeping particular prescriptions during special arrangement period). Section 192AB(1) provides that this section applies if, during the special arrangement period, a prescriber gives a dispenser an acceptable electronic copy of a paper prescription for a low-risk restricted drug.

A *low-risk restricted drug* means a restricted drug other than an anabolic steroidal agent or a restricted drug of dependency.

The *special arrangement period* means the period starting on the commencement of this section and ending at the end of the day the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (Cth) (special arrangement) is repealed or expires.

Section 192AB(2) provides that the prescriber and dispenser are not required to comply with section 192AA(2) and (3) during the special arrangement period. Section 192AA(2), as renumbered by clause 8(6), requires a prescriber to send a paper prescription by post or by hand or send an electronic prescription for the drug to the dispenser within seven (7) days after giving the faxed prescription. Section 192AA(3), as renumbered by clause 8(6), requires the dispenser to immediately give a written report to the chief executive about the circumstance if the dispenser does not receive a paper prescription or an electronic prescription within 14 days after being sent the acceptable electronic copy of the prescription

Section 192AB(3) provides that it is an offence (with a maximum penalty of 40 penalty units) if the prescriber does not comply with section 192AA(2) and fails to keep the paper prescription for two (2) years after the acceptable electronic copy is given.

Clause 9(4) provides that section 192AB(3) applies even if the special arrangement is repealed or expires before the end of the two (2) years.

## Amendment of s 197 (Dealing with prescriptions)

*Clause 10* amends subsection 197(1) by replacing ‘when dispensing a restricted drug on a paper prescription, legibly and permanently indicate the following information on the prescription’ with ‘at the relevant time for dispensing a restricted drug, legibly and permanently indicate the following information on a paper prescription for the drug’. Clause 10(3) inserts the definition of relevant time into section 197(5). *Relevant time*, for dispensing a restricted drug, means:

- if the drug is dispensed on an acceptable copy of a paper prescription that is later received by a dispenser—as soon as practicable after the paper prescription is received by the dispenser;
- if the drug is dispensed on an acceptable electronic copy of a paper prescription and an electronic prescription for the drug is later received by a dispenser—as soon as practicable after the electronic prescription is received by the dispenser; or
- otherwise—when the drug is dispensed.

This provision makes it clear that the dispenser must indicate that a restricted drug was dispensed on the paper prescription sent to the dispenser by the prescriber following the sending of an acceptable electronic copy of the prescription.

Clause 10(2) amends section 192(2) by replacing ‘when dispensing a restricted drug on an electronic prescription, enter the following information in the prescription’ with ‘at the relevant time for dispensing a restricted drug, enter the following information in an electronic prescription for the drug’.

### **Amendment of ch 5, pt 2, hdg (Transitional provisions)**

*Clause 11* amends the heading in chapter 5, part 2 to refer to transitional and validation provisions. *Clause 12* inserts a validation provision for this Amendment Regulation.

### **Insertion of new ch 5, pt 2, div 6**

*Clause 12* inserts new division 6 (Validation provision for Health (Drugs and Poisons) Amendment Regulation 2020). Division 6 inserts new section 320.

New section 320 (Validation of giving, dispensing on, digital images of prescriptions during relevant period) provides that this section applies if, during the period starting on the commencement of the special arrangement, 26 March 2020, and ending on the commencement of this section, if under the special arrangement a prescriber gave a dispenser a digital image of a paper prescription for a controlled drug or restricted drug or the dispenser dispensed a controlled drug or restricted drug on a digital image of a paper prescription for the drug.

New section 320(2) provides that the prescriber is taken to have lawfully given the digital image to the dispenser.

New section 320(3) provide that the dispenser is taken to have lawfully dispensed the controlled drug or restricted drug on the digital image under this regulation.

### **Amendment of appendix 9 (Dictionary)**

*Clause 13* defines the term *acceptable electronic copy*.