2014/199

Misuse of Drugs Amendment Regulations 2014

Jerry Mateparae, Governor-General

Order in Council

At Wellington this 23rd day of June 2014

Present:
The Right Hon John Key presiding in Council

Pursuant to section 37 of the Misuse of Drugs Act 1975, His Excellency the Governor-General, acting on the advice and with the consent of the Executive Council, makes the following regulations.

Contents

Regulations

1 Title

These regulations are the Misuse of Drugs Amendment Regulations 2014.

2 Commencement

These regulations come into force on 1 July 2014.

3 Principal regulations

These regulations amend the Misuse of Drugs Regulations 1977 (the **principal regulations**).

4 Regulation 2 amended (Interpretation)

(1) In regulation 2(1), revoke the definitions of—

(a) **dentist**:

(b) **designated pharmacist prescriber**:

(c) **designated prescriber nurse**:
(d) **medical practitioner**:
(e) **midwife**:
(f) **pharmacist**.

(2) In regulation 2(1), insert in their appropriate alphabetical order:

"**controlled drug prescriber** means—
"(a) a medical practitioner:
"(b) a dentist:
"(c) a nurse practitioner:
"(d) a midwife:
"(e) a designated prescriber nurse:
"(f) a designated prescriber pharmacist:
"(g) a veterinarian

"**designated prescriber nurse** means a nurse who—
"(a) is a designated prescriber; and
"(b) is acting within his or her scope of practice

"**designated prescriber pharmacist** means a pharmacist who—
"(a) is a designated prescriber; and
"(b) is acting within his or her scope of practice".

(3) In regulation 2(1), definition of **practitioner**, delete "within the meaning of section 4 of the Veterinarians Act 2005".

5 Regulation 4 amended (Dealers' licences)

Replace regulation 4(5) with:

"(5) A dealer's licence may not authorise—
"(a) the supply of a controlled drug otherwise than pursuant to a prescription or order issued by a controlled drug prescriber; or
"(b) the administration of a controlled drug otherwise than in accordance with the advice of the controlled drug prescriber who supplied or prescribed the controlled drug.

"(6) Subclause (5) is subject to regulation 20."

6 Regulations 12A to 12C replaced

Replace regulations 12A to 12C with:

"**12A Authority for designated prescriber nurses, designated prescriber pharmacists, midwives, and nurse practitioners to prescribe certain controlled drugs**

"(1) For the purposes of section 8(2A)(a) of the Act,—

"(a) a designated prescriber nurse is authorised by this regulation to prescribe a controlled drug specified in Schedule 1A:

"(b) a designated prescriber pharmacist is authorised by this regulation to prescribe a controlled drug specified in Schedule 1B:

"(c) a midwife is authorised by this regulation to prescribe a controlled drug specified in Schedule 1C:

"(d) a nurse practitioner is authorised by this regulation to prescribe any—

"(i) Class A controlled drug:

"(ii) Class B controlled drug:

"(iii) Class C controlled drug.

"(2) The authorities given in subclause (1) are subject to—

"(a) sections 22 to 25 of the Act; and

"(b) any prohibitions, limitations, restrictions, or conditions imposed by or under those sections or by regulations made under the Act.

"**12B Permissions relating to prescription of controlled drugs authorised under regulation 12A**

"(1) This section applies to any person (a **patient**) for whom a controlled drug is—

"(a) supplied by a prescriber; or

"(b) prescribed by a prescriber and lawfully supplied.

"(2) The controlled drug may be administered to the patient by—

"(a) the patient himself or herself in accordance with the advice of the prescriber; or

"(b) a person who has the care of the patient in accordance with the advice of the prescriber.

"(3) Subclauses (1) and (2) contain permissions that—

"(a) are exceptions to the prohibitions in sections 6(1) and 7(1) of the Act; and

"(b) are subject to—

"(i) sections 22 to 25 of the Act; and

"(ii) any prohibitions, limitations, restrictions, or conditions imposed by or under those sections or by regulations made under the Act.

"(4) In this section, **prescriber** means any of the following authorised prescribers who prescribes a controlled drug in accordance with an authority given under regulation 12A:

"(a) a designated prescriber nurse:

"(b) a designated prescriber pharmacist:

"(c) a midwife:

"(d) a nurse practitioner."

7 Regulation 21 amended (Restrictions on application of section 8 of Act, etc)

Replace regulation 21(3) to (5) with:

"(3) No dentist may give a prescription for the supply of a controlled drug—

"(a) otherwise than for the treatment of a patient under the dentist's care; and

"(b) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 7 days.

"(4) No designated prescriber nurse may (within the authority given by regulation 12A(1)(a)) give a prescription for the supply of a controlled drug—

"(a) otherwise than for the treatment of a patient under the designated prescriber nurse's care; and

"(b) in circumstances that are not cases of emergency; and

"(c) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 3 days.

"(5) No designated prescriber pharmacist may (within the authority given by regulation 12A(1)(b)) give a prescription for the supply of a controlled drug—

"(a) otherwise than for the treatment of a patient under the designated prescriber pharmacist's care; and

"(b) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 3 days.

"(5A) No midwife may (within the authority given by regulation 12A(1)(c)) give a prescription for the supply of a controlled drug otherwise than for the treatment of a patient under the midwife's care.

"(5B) No nurse practitioner may (within the authority given by regulation 12A(1)(d)) give a prescription for the supply of a controlled drug—

"(a) otherwise than for the treatment of a patient under the nurse practitioner's care; and

"(b) in any quantity greater than the quantity reasonably required for the treatment of the patient for—

"(i) a period of 1 month, in the case of a Class A controlled drug; or

"(ii) a period of 1 month, in the case of a Class B controlled drug; or

"(iii) a period of 3 months, in the case of a Class C controlled drug.

"(5C) No veterinarian may give a prescription for the supply of a controlled drug otherwise than for administration to an animal under the veterinarian's care."

8 Regulation 25 amended (Labelling of containers)

Replace regulation 25(3A) with:

"(3A) Subclause (1) does not apply in respect of any controlled drug supplied pursuant to a prescription signed by a controlled drug prescriber."

9 Regulation 29 replaced (Requirements in relation to prescriptions)

Replace regulation 29 with:

"**29 General requirements in relation to prescriptions**

"(1) A prescription for the supply of a controlled drug that is intended for human use and that is a Class A controlled drug, a Class B controlled drug, or a specified Class C controlled drug must be—

"(a) on a paper form provided by the Director-General and completed in the handwriting of the controlled drug prescriber; or

"(b) on a paper form that is electronically generated by the controlled drug prescriber from an approved system.

"(2) Notwithstanding subclause (1), a prescription for the supply of methadone given by a medical practitioner working in a place for the time being specified by the Minister under section 24(7)(b) of the Act may also be in any paper form approved by the Director-General.

"(3) Every prescription for the supply of a Class C controlled drug, not being a specified Class C controlled drug, must be on paper and in handwriting, in print, or both.

"(4) Every prescription for a controlled drug must—

"(a) be signed physically by the controlled drug prescriber in his or her own handwriting; and

"(b) be legible and indelible; and

"(c) be dated with the date on which it was signed; and

"(d) set out, or be stamped with, the address of the controlled drug prescriber; and

"(e) set out the surname, initials of the first names, and address of—

"(i) the person to whom the controlled drug is intended to be administered; or

"(ii) the person who has custody of the animal to which the controlled drug is intended to be administered; and

"(f) if it is for a person who is under the age of 12 years, set out in words the age in years and months of that person; and

"(g) bear the words 'for dental treatment only', if given by a dentist; and

"(h) bear the words 'for midwifery use only', if given by a midwife; and

"(i) bear the words 'for animal treatment only', if given by a veterinarian; and

"(j) set out the name of the controlled drug to be supplied; and

"(k) not be in cipher, or abbreviated, otherwise than by abbreviations recognised in the British Pharmacopoeia, the British Pharmaceutical Codex, or other standard reference books on materia medica or pharmacy; and

"(l) indicate the total amount of the controlled drug that may be sold or dispensed on the 1 occasion, or on each of the several occasions, authorised by that prescription; and

"(m) set out the dose and frequency of the dose, or, in the case of a controlled drug for external use, directions for use; and

"(n) where it prescribes an unusual dose, or what may be regarded as a dangerous dose, of any controlled drug, have the amount of the dose emphasised by being underlined, with the initials of the controlled drug prescriber set out in the margin opposite.

"(5) In this regulation,—

"**approved system** means a system approved by the Director-General by notice in the *Gazette*

"**specified Class C controlled drug**—

"(a) means—

"(i) a drug that is amobarbital, amobarbital sodium, buprenorphine, butobarbitone, glutethimide, ketamine, secobarbital, or secobarbital sodium; or

"(ii) a combination of 2 or more of the substances specified in subparagraph (i); but

"(b) does not include any substance referred to in paragraph (a)(i), or any combination of substances referred to in paragraph (a)(ii), if that substance or combination of substances is combined with any other pharmacologically active substance or substances that are not listed in clause 1 of Part 4 of Schedule 3 of the Act.

"(6) This regulation does not apply—

"(a) to a prescription for a controlled drug communicated under regulation 34(1); or

"(b) in respect of an exempted drug or partially exempted drug."

10 Regulation 30 replaced (Exemption for certain prescriptions)

Replace regulation 30 with:

"**30 Exemption for certain prescriptions**

"(1) This regulation applies if there is imposed on a licence a condition prohibiting the acquisition of controlled drugs otherwise than pursuant to the prescription of—

"(a) a controlled drug prescriber; or

"(b) a named controlled drug prescriber; or

"(c) a controlled drug prescriber belonging to a particular class of controlled drug prescribers.

"(2) The following regulations do not apply to the extent that they are inconsistent with the terms of the licence in respect of anything done for the purpose of enabling compliance with the condition imposed on the licence:

"(a) regulation 21(2) to (5C):

"(b) regulation 29(4)(e), (f), (g), (h), (i), (m), and (n)."

11 Regulation 31 replaced (Restrictions on supply on prescription)

Replace regulation 31 with:

"**31 Restrictions on supply on prescription**

"(1) A person may not supply a controlled drug on a prescription—

"(a) more than once on that same prescription; or

"(b) more than 7 days after the date of the prescription, in the case of a Class A controlled drug or a Class B controlled drug; or

"(c) more than 6 months after the date of the prescription, in the case of a Class C controlled drug; or

"(d) in a quantity that, having regard to the dose and frequency of dose or the directions given by the controlled drug prescriber, is greater than a quantity sufficient for use for a period of 1 month.

"(2) Subclause (1) is subject to regulation 31A.

"(3) A person may not supply a controlled drug on an oral prescription more than once before receiving the written confirmation of that prescription under regulation 34(4).

"(4) On the first occasion of dispensing a prescription or, in the case of an oral prescription, on receipt of the written confirmation of that prescription, there must be written or stamped on the face of the prescription, above the signature of the controlled

drug prescriber, in such manner and place that no part of the prescription is obliterated,—

"(a) the name of the proprietor of the business at which the prescription is dispensed; and

"(b) the address of the premises from which the prescription is dispensed; and

"(c) the date on which the prescription is dispensed.

"(5) On every subsequent occasion of dispensing a prescription, there must be written or stamped on the face or back of the prescription, in such manner and place that no part of the prescription is obliterated,—

"(a) the name of the proprietor of the business at which the prescription is dispensed; and

"(b) the address of the premises from which the prescription is dispensed; and

"(c) the date on which the prescription, or any indicated part or portion of the prescription, is dispensed.

"(6) In this regulation, **oral prescription** means a prescription communicated under regulation 34(1).

"**31A Exceptions to restrictions in regulation 31(1)**

"(1) A medical practitioner or nurse practitioner who signs a prescription for a Class A controlled drug or a Class B controlled drug may direct on the prescription that the drug be supplied on 2 occasions at a specified interval, with—

"(a) the first occasion being not more than 7 days after the date of prescription; and

"(b) the second occasion being not more than 7 days after the termination of that interval.

"(2) In the case of a controlled drug supplied pursuant to a direction under subclause (1), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the medical practitioner or nurse practitioner, must not be greater than a quantity sufficient for use for a period of 1 month.

"(3) A medical practitioner or nurse practitioner who signs a prescription for a Class C controlled drug may direct on the prescription that the drug be supplied on not more than 3 occasions, which, unless specified otherwise, are to be at monthly intervals.

"(4) In the case of a controlled drug supplied pursuant to a direction under subclause (3), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the medical practitioner or nurse practitioner, must not be greater than a quantity sufficient for use for a period of 3 months.

"(5) A midwife who signs a prescription for a controlled drug specified in Schedule 1C may direct on the prescription that the drug be supplied on 2 occasions at a specified interval, with—

"(a) the first occasion being not more than 4 days after the date of the prescription; and

"(b) the second occasion being not more than 4 days after the termination of that interval.

"(6) In the case of a controlled drug supplied pursuant to a direction under subclause (5), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the midwife, must not be greater than a quantity sufficient for use for a period of 1 month.

"(7) If, for special reasons relating to the protection of the patient, or for the purpose of limiting the quantity of any controlled drug in the possession of any person, the controlled drug prescriber (not being a dentist or veterinarian) who signs a prescription directs on the prescription that the controlled drug is to be dispensed daily or at such other regular intervals as the controlled drug prescriber considers necessary for a specified period not exceeding 1 month, the controlled drug may be supplied on not more than the number of occasions indicated, and not more frequently than the intervals directed.

"(8) If a Medical Officer of Health has issued to a person a notice under section 25 of the Act that authorises him or her to supply a controlled drug for a restricted person on more than 2 occasions on any prescription, that person may supply the controlled drug in such quantity, at such frequency, and for such period as the notice specifies."

12 Regulation 32 amended (Verification of prescriptions)

(1) In regulation 32(1) and (4)(a), replace "practitioner, midwife, designated pharmacist prescriber, or designated prescriber nurse" with "controlled drug prescriber".

(2) In regulation 32(2)(a), replace "practitioner, midwife, designated pharmacist prescriber, or designated prescriber nurse," with "controlled drug prescriber".

(3) Replace regulation 32(3) with:

"(3) However, subclause (2) does not apply to a controlled drug prescriber who, after signing a prescription, alters that prescription in his or her own handwriting and then signs the prescription again beside the alteration."

13 Regulation 34 replaced (Emergencies)

Replace regulation 34 with:

"**34 Emergencies**

"(1) In the case of an emergency, a prescriber may communicate orally or by telephone a prescription for a controlled drug to a pharmacist who personally knows the prescriber (an **oral prescription**).

"(2) A pharmacist may supply a controlled drug to any person on an oral prescription.

"(3) Immediately after communicating an oral prescription, a prescriber must—

"(a) prepare a prescription in accordance with the requirements of regulation 29 confirming the oral prescription; and

"(b) endorse the prescription with—

"(i) a statement to the effect that the prescription is intended only as confirmation of the oral prescription; and

"(ii) the date of the oral prescription.

"(4) Not later than 2 business days after the date of the oral prescription, the prescriber must deliver the prescription to the pharmacist to whom the oral prescription was communicated.

"(5) After delivery of the prescription in accordance with subclause (4), the prescription and the pharmacist are subject to all provisions in these regulations relating to prescriptions for the supply of controlled drugs and to the duties of persons in respect of such prescriptions.

"(6) In this regulation, **prescriber** means any of the following persons:

"(a) a medical practitioner:
"(b) a nurse practitioner:
"(c) a midwife:
"(d) a designated prescriber nurse:
"(e) a designated prescriber pharmacist."

14 Regulation 35 amended (Duty to supply information)

(1) In regulation 35(1), replace "practitioner, midwife, designated pharmacist prescriber, or designated prescriber nurse shall" with "controlled drug prescriber must".

(2) In regulation 35(2), replace "practitioner, midwife, designated pharmacist prescriber, or designated prescriber nurse, shall" with "controlled drug prescriber must".

(3) Replace regulation 35(2)(b) with:

"(b) the name and address of the controlled drug prescriber:".

(4) In regulation 35(4),—

(a) after "In this regulation", insert ","; and

(b) replace "practitioner, midwife, designated pharmacist prescriber, or designated prescriber nurse" with "controlled drug prescriber".

15 Regulation 36 amended (Special provisions for hospitals)

In regulation 36(1) and (2), replace "midwife, designated pharmacist prescriber, or designated prescriber nurse" with "nurse practitioner, midwife, designated prescriber nurse, or designated prescriber pharmacist".

16 New Schedule 1C inserted

After Schedule 1B, insert the Schedule 1C set out in the Schedule of these regulations.

Schedule

r 16

New Schedule 1C inserted

Schedule 1C

r 12A(1)(c)

Controlled drugs that midwives may prescribe

A reference in this schedule to a substance is a reference to the substance in every compound, form, mixture, or preparation that is declared to be a controlled drug under the Act.

1 Fentanyl

2 Morphine

3 Pethidine

Michael Webster,
Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on 1 July 2014, amend the Misuse of Drugs Regulations 1977.

The amendments—

- provide for nurse practitioners to prescribe (and therefore also to supply and administer) any controlled drug, subject to the same restrictions as currently apply to other prescribers:
- provide for midwives to prescribe (and therefore also to supply and administer) the controlled drugs listed in *new Schedule 1C*, subject to the same restrictions as currently apply to other prescribers:
- provide that prescriptions for Class A controlled drugs, Class B controlled drugs, and specified Class C controlled drugs may be either on a handwritten form or on a form electronically

generated by a system approved for the purpose by the Director-General of Health and notified in the *Gazette*.

Issued under the authority of the Legislation Act 2012.
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These regulations are administered by the Ministry of Health.

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