HE301*

Poisons Act 1964

Poisons Amendment Regulations (No. 2) 2008

Made by the Governor in Executive Council.

1. Citation

These regulations are the *Poisons Amendment Regulations (No. 2) 2008*.

2. Commencement

These regulations come into operation as follows —

(a) regulations 1 and 2 — on the day on which these regulations are published in the *Gazette*;

(b) the rest of the regulations — on the day after that day.

3. The regulations amended

The amendments in these regulations are to the *Poisons Regulations 1965*.

4. Regulation 2 amended

(1) Regulation 2 is amended as follows:

(a) by inserting before "In these regulations" the subregulation designation "(1)";

(b) by inserting in the appropriate alphabetical position —

"

"approved electronic prescribing system" means a system of electronic prescribing approved by the CEO under regulation 32B;

".

(2) At the end of regulation 2 the following subregulation is inserted —

"

(2) A prescription is issued electronically if it is issued under regulation 37(1A) or 51(1A).

".

5. Part 4A inserted

After Part 4 the following Part is inserted —

"

Part 4A — Electronic prescribing systems

32A. Terms used in this Part

(1) In this Part and Appendix K —

"access code", of an individual, means a password or other means by which the individual gains access to a system of electronic prescribing;

"inappropriate use", in relation to a system of electronic prescribing, includes using the system in a way that is not in accordance with the procedures that control access to and use of the system;

"system identifier", of an individual, means the code by which the identity of the individual is recorded by a system of electronic prescribing.

(2) For the purposes of this Part, an entry is made in a system of electronic prescribing if —

(a) a prescription is issued, amended or cancelled via the system; or

(b) a poison is dispensed in accordance with a prescription issued via the system; or

(c) information is otherwise entered into or retrieved from the system in relation to —

(i) issuing, amending or cancelling a prescription via the system; or

(ii) dispensing a poison in accordance with a prescription issued via the system.

32B. Approval of electronic prescribing systems

(1) The CEO may approve a system of electronic prescribing if satisfied that the system —

(a) is sufficiently secure; and

(b) is designed so that, to the extent practicable —

(i) for any particular poison — only persons authorised to prescribe that poison can use the system to prescribe the poison; and

(ii) for any particular poison — only a pharmaceutical chemist authorised to dispense the poison, or an assistant under the direct personal supervision of the pharmaceutical chemist, can use the system to dispense the poison; and

(iii) a poison dispensed in accordance with a prescription issued via the system is dispensed for the person for whom it was prescribed; and

(iv) a poison dispensed to a person in accordance with a prescription issued via the system is the poison prescribed for the person;

and

(c) complies substantially with the criteria in Appendix K; and

(d) complies with any other criteria the CEO thinks relevant.

(2) A reference in subregulation (1)(b) to a person authorised to prescribe or dispense a particular poison is a reference to a person authorised to do so under the Act.

(3) Before being satisfied that a system of electronic prescribing is sufficiently secure, the CEO must be satisfied that, to the extent practicable —

(a) personal information relating to prescribers, patients of prescribers and pharmaceutical chemists is protected; and

(b) access to and use of the system is controlled by appropriate procedures; and

(c) only persons permitted to have access to the system according to those procedures can have access to the system; and

(d) every occurrence of —

(i) a prescription being issued or amended via the system; and

(ii) a poison being dispensed in accordance with a prescription issued via the system,

is recorded by the system in a way that cannot be amended or erased.

(4) Subregulation (3) does not limit the matters that the CEO may take into account for the purposes of subregulation (1)(a).

(5) The CEO may approve a component of a system of electronic prescribing if satisfied as to the matters in subregulation (1) in relation to the component, to the extent relevant to the component.

32C. System administrators

A system of electronic prescribing is not approved while there is no individual who is designated as the administrator of the system by the CEO.

32D. Offence provisions

(1) A person must not access an approved electronic prescribing system unless the person —

(a) is permitted to have access to the system according to the procedures that control access to the system; and

(b) gained access according to those procedures.

Penalty: a fine of $5 000.

(2) A person who has an access code for an approved electronic prescribing system must not —

(a) reveal the person's access code to another person; or

(b) otherwise allow another person to have access to the system unless to do so is in accordance with the procedures that control access to the system.

Penalty: a fine of $5 000.

(3) A person must not make inappropriate use of an approved electronic prescribing system.

Penalty: a fine of $5 000.

(4) An administrator of an approved electronic prescribing system must ensure that —

(a) a person who is permitted to have access to the system in accordance with the procedures that control access to the system is not given more than one access code; and

(b) each person who is responsible to the administrator for the operation and control of the system does not make inappropriate use of the system.

Penalty: a fine of $5 000.

32E. Miscellaneous rules

(1) In any proceedings under this Act or the *Misuse of Drugs Act 1981*, if it is proved that the system identifier of a person has been recorded in the system in respect of an entry, then, in the absence of proof to the contrary, that person is to be taken to have made the entry.

(2) Despite anything else in this Part, the administrator must make all records of the system available, on request, to a person authorised under section 52A of the Act.

".

6. Regulation 36 amended

(1) Regulation 36(1)(b) is amended by deleting "holder of a prescription written" and inserting instead —

"

person (or an agent of the person) in respect of whom a prescription for the poison was issued

".

(2) Regulation 36(3) is amended as follows:

(a) in paragraph (a) by deleting "thereon" and inserting instead —

" by it ";

(b) in paragraph (a) by deleting all of the paragraph from and including "prescription shall" in the second place where it occurs and inserting instead —

"

dispenser shall —

(i) in the case of a prescription that is not issued electronically — stamp or mark the prescription to show clearly the date upon which it is dispensed and the name and address of the pharmacy at which it is dispensed; and

(ii) in the case of a prescription that is issued electronically — indicate the date upon which it is dispensed and the name and address of the pharmacy at which it is dispensed using the means provided by the approved electronic prescribing system;

";

(c) in paragraph (b) by deleting "thereon, shall write in ink, stamp or mark in legible letters across such prescription the word "cancelled";" and inserting instead —

"

by it, shall —

(i) in the case of a prescription that is not issued electronically — write in ink, stamp or mark in legible letters across the prescription the word "cancelled"; and

(ii) in the case of a prescription that is issued electronically — cancel the prescription using the means provided by the approved electronic prescribing system;

";

(d) in paragraph (d)(i) by deleting "marked "cancelled";" and inserting instead —

" cancelled; ";

(e) in paragraph (e) by inserting after "defaced" —

" , or appears to have been altered ";

(f) in paragraph (f) by deleting "to whom" and inserting instead —

" given ";

(g) in paragraph (f) by deleting "is presented shall retain the prescription and" and inserting instead —

" shall ";

(h) in paragraph (f) by deleting "prescription." and inserting instead —

"

prescription, and, in the case of a prescription that was not issued electronically, retain it.

".

7. Regulation 37 amended

(1) Regulation 37(1) is amended as follows:

(a) by deleting paragraphs (a), (b) and (ba) and inserting instead —

"

(a) it shall include —

(i) the name and address of the prescriber; and

(ii) the name and address of the patient; and

(iii) the name and quantity of the substance; and

(iv) directions for use (if necessary); and

(v) the date on which it is issued; and

(vi) the maximum number of times it may be repeated, if any, and (where applicable) the intervals at which it may be repeated;

and

(b) it shall be issued in a manner provided for in subregulation (1A) or (1B); and

";

(b) in paragraph (c) by deleting "written" in both places where it occurs and inserting instead —

" issued ";

(c) in paragraph (c) by deleting "be marked as such" and inserting instead —

" indicate that ";

(d) in paragraph (c) by deleting "be marked", in the second place where it occurs, and inserting instead —

" include the words ";

(e) in paragraph (d) by deleting "by underlining that part of the prescription and initialling the same in margin;" and inserting instead —

"

by —

(i) in the case of a prescription that is not issued electronically — underlining that part of the prescription and initialling the same in the margin; and

(ii) in the case of a prescription that is issued electronically — the means provided by the approved electronic prescribing system;

".

(2) After regulation 37(1) the following subregulations are inserted —

"

(1A) A prescription that is issued electronically shall be issued via an approved electronic prescribing system.

(1B) A prescription that is not issued electronically shall be either —

(a) written in ink in the prescriber's own handwriting; or

(b) processed on a computer program that —

(i) complies with the criteria specified in Appendix L; or

(ii) is recommended by the Poisons Advisory Committee and approved in writing by the CEO.

The prescription shall be signed by the prescriber in his or her own handwriting.

".

8. Regulation 42 amended

Regulation 42(2) is amended as follows:

(a) by deleting "to whom" and inserting instead —

" in respect of whom ";

(b) by deleting "has been given" and inserting instead —

" is issued ".

9. Regulation 44 amended

(1) Regulation 44(1) is amended, in the definition of "authorised person", by deleting "from" and inserting instead —

" issued by ".

(2) Regulation 44(3)(d) is amended by deleting "wrote" and inserting instead —

" issued ".

10. Regulation 44A amended

Regulation 44A(1) is amended by deleting "from" and inserting instead —

" issued by ".

11. Regulation 51 amended

(1) Regulation 51(1) is repealed and the following subregulations are inserted instead —

"

(1) A prescription for the supply of a drug of addiction shall comply with the following conditions —

(a) it shall include —

(i) the name and address of the prescriber; and

(ii) the name, address and date of birth of the patient or, in the case of a prescription for veterinary use, the name and address of the person having the care of the animal for which the prescription is intended; and

(iii) the description and quantity of the drug to be dispensed; and

(iv) precise directions for the use of the drug, including the dose to be taken or administered and the frequency with which the dose is to be taken or administered; and

(v) the date when it was written; and

(vi) if the drug is to be dispensed more than once under the prescription — the maximum number of times it may be repeated and the intervals at which it may be dispensed;

(b) it shall not prescribe more than one drug of addiction, or any other substance, but may prescribe the same drug in more than one form;

(c) if issued by a dentist — it shall include the words "for dental treatment only" and if issued by a veterinary surgeon — it shall include the words "for animal treatment only";

(d) if it prescribes an unusual dose it shall indicate that such a dose was intended by —

(i) in the case of a prescription that is not issued electronically — that part of the prescription being underlined and initialled by the prescriber in the margin; and

(ii) in the case of a prescription that is issued electronically — the means provided by the approved electronic prescribing system;

(e) it shall be issued in a manner provided for in subregulation (1A) or (1B).

(1A) A prescription that is issued electronically shall be issued via an approved electronic prescribing system.

(1B) A prescription that is not issued electronically shall be either —

(a) written in ink in the prescriber's own handwriting; or

(b) processed on a computer program that —

(i) complies with the criteria specified in Appendix L; or

(ii) is recommended by the Poisons Advisory Committee and approved in writing by the CEO.

The prescription shall be signed by the prescriber in his or her own handwriting.

".

(2) Regulation 51(2) is amended by inserting after "his" in both places where it occurs —

" or her ".

12. Regulation 52 amended

(1) Regulation 52(3) is amended as follows:

(a) in paragraph (a)(ii) and (iii) by deleting "signed" and inserting instead —

" issued ";

(b) in paragraph (b) by deleting "on" in both places where it occurs and inserting instead —

" by ";

(c) in paragraph (ba) by deleting subparagraphs (i) and (ii) and inserting instead —

"

(i) in the case of a prescription that is not issued electronically — sign the prescription clearly in ink using his or her usual signature and clearly indicate the date on which the drug is dispensed; and

(ii) in the case of a prescription that is issued electronically — indicate that the drug of addiction was dispensed and the date on which it was dispensed using the means provided by the approved electronic prescribing system;

";

(d) in paragraph (bb) by deleting "shall stamp or otherwise mark the prescription clearly in ink with the name and address of the dispensary;" and inserting instead —

"

shall —

(i) in the case of a prescription that is not issued electronically — stamp or otherwise mark the prescription clearly in ink with the name and address of the dispensary; and

(ii) in the case of a prescription that is issued electronically — provide, in relation to the prescription, the name and address of the dispensary using the means provided by the approved electronic prescribing system;

";

(e) in paragraph (d) by deleting "presentation of the prescription" and inserting instead —

" a particular occasion ";

(f) in paragraph (d) by deleting "dispensed, note on the prescription clearly in ink the amount dispensed and the date on which it was dispensed;" and inserting instead —

"

dispensed —

(i) in the case of a prescription that is not issued electronically — note on the prescription clearly in ink the amount

dispensed and the date on which it was dispensed; and

(ii) in the case of a prescription that is issued electronically — indicate, in relation to the prescription, the amount dispensed and the date on which it was dispensed using the means provided by the approved electronic prescribing system;

";

(g) in paragraph (e)(i) by deleting "mark the prescription with" and inserting instead —

" indicate, in relation to the prescription, ";

(h) in paragraph (e)(ii) by deleting "subject to subregulation (7), retain" and inserting instead —

"

in the case of a prescription that is not issued electronically — retain, subject to subregulation (7),

";

(i) in paragraph (f) by inserting before "the dispenser" —

"

in the case of a prescription that is not issued electronically —

";

(j) by inserting after paragraph (f) —

"

(fa) in the case of a prescription that is issued electronically — the dispenser shall indicate that the prescription is cancelled using the means provided by the approved electronic prescribing system if one or more of the conditions in paragraph (f) are met;

";

(k) in paragraph (h)(ii), by deleting "full" in both places where it occurs;

(l) in paragraph (h)(viii), by inserting before "a note" —

"

in the case of a prescription that is not issued electronically —

".

(2) Regulation 52(3a) is amended by inserting after "subregulation (3)(a)(iii)," —

" if the prescription is not issued electronically, ".

(3) Regulation 52(4) is amended by deleting "prescription marked "cancelled" or that is more than 6 months old." and inserting instead —

"

prescription —

(a) that is more than 6 months old; or

(b) that —

(i) in the case of a prescription that is not issued electronically — is marked "cancelled"; or

(ii) in the case of a prescription that is issued electronically — is cancelled using the means provided by the approved electronic prescribing system.

".

(4) Regulation 52(5) is amended by inserting after "which appears" —

" to have been altered or ".

(5) Regulation 52(6) is repealed and the following subregulation is inserted instead —

"

(6) If a pharmaceutical chemist is presented with or accesses a prescription which he or she suspects of being false in any particular he or she shall —

(a) in the case of a prescription that is not issued electronically — retain possession of the prescription for such reasonable period of time as will enable him or her to satisfy the requirements of paragraph (b); and

(b) in any case — make enquiries concerning the genuineness of the prescription, the identity of the person who issued it and the bona fides of the person wishing to have the drug dispensed under it.

".

(6) Regulation 52(6a) is amended by deleting all of the subregulation from and including "regulations" and inserting instead —

"

regulations, he or she shall —

(a) in the case of a prescription that is not issued electronically —

(i) mark on the prescription "cancelled", the address of the dispensary and, in his or her own handwriting, the date and his or her usual signature; and

(ii) forward the prescription to the CEO; and

(iii) inform the CEO of the relevant circumstances and the reasons for his or her refusal to dispense the drug of addiction under the prescription;

and

(b) in the case of a prescription that is issued electronically —

(i) cancel the prescription using the means provided by the approved electronic prescribing system; and

(ii) inform the CEO that the prescription has been cancelled, and of the reasons for his or her refusal to dispense the drug of addiction under the prescription.

".

(7) Regulation 52(7) is amended by inserting after "prescription" —

" that is not issued electronically ".

13. Regulation 53 amended

(1) Regulation 53(1) is repealed and the following subregulation is inserted instead —

"

(1) If a medical practitioner, dentist or veterinary surgeon in a case of emergency directs, orally or by telephone or other electronic means, the dispensing of a poison included in Schedule 8, he or she shall, within 24 hours, issue to the person by whom the poison was dispensed a prescription complying with regulation 51 that clearly indicates that it is in confirmation of the direction given by him or her under this subregulation.

".

(2) Regulation 53(2) is amended by deleting "him" and inserting instead —

"

, or accessible via an approved electronic prescribing system to, him or her

".

14. Regulation 53A amended

(1) Regulation 53A(1) is amended as follows:

(a) in paragraphs (a) and (b) by inserting after "he" —

" or she ";

(b) in paragraph (b) by deleting "written by him." and inserting instead —

"

issued by him or her; or

(c) the prescription is issued electronically via an approved electronic prescribing system.

".

(2) Regulation 53A(2) is amended by inserting after "he" —

" or she ".

15. Regulations 54 and 55 amended

Regulations 54(2) and 55 are amended by inserting after "his" —

" or her ".

16. Appendix K inserted

After Appendix J the following Appendix is inserted —

"

Appendix K

[r. 32B]

Criteria for electronic prescribing systems

The electronic prescribing system must be designed so that —

(a) the system records each person who was given an access code, when it was given and (where relevant) when it was cancelled and each person who has a current access code, in a way that cannot be amended or erased; and

(b) for each entry made in the system —

(i) a unique, sequential number is given to that entry; and

(ii) the time and date is recorded; and

(iii) the system identifier of the person whose access code was used to make the entry is recorded;

and

(c) the system requires that persons with access to it change their access code in accordance with standard industry practice; and

(d) appropriate backup arrangements are in place; and

(e) the system records the details of the administrator or each person who is an administrator of the system, and retains those details for 7 years after the person ceases to be an administrator; and

(f) the system can generate appropriate reports from its records, for example —

(i) of persons with, or who were given, an access code;

(ii) of access to the system, or entries made in the system, during a certain period;

(iii) of entries made in the system during a certain period, sorted according to drug type, strength or dose or according to patient;

(iv) of corrections to entries made during a certain period;

and

(g) the records of the system can be printed.

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By Command of the Governor,

M. C. WAUCHOPE, Clerk of the Executive Council.