

Internal Briefing for the Director-General

To: Sue Gordon, Acting Director-General of Health	For your: Action
Date: 27 March 2020	Timing: Routine (1 week)
From: Shayne Hunter, Deputy Director-General Data & Digital	Security: Unclassified

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Director-General waiver under Regulation 43 Medicines Regulations 1984

1. Background

The purpose of this paper is to gain authorisation by the Director-General of Health under regulation 43 of the Medicines Regulation 1984 (the Regulations) for prescriptions that are not signed personally by a prescriber with their usual signature to be recognised as legal prescriptions if they meet certain conditions, ensuring easy identification of the authorised prescriber and the healthcare facility.

This waiver is sought in response to the Covid-19 pandemic and the need to be able to deliver telehealth services including the ability to prescribe for a patient without needing to generate a paper prescription.

It has the support of the Telehealth Leadership Group, the Community Pharmacy Programme, the Pharmacy Guild, and the Pharmaceutical Society.

There has been consultation across the Ministry of Health, Health Legal, Medsafe, Audit & Compliance, NHCC Operations Team and Sector Operations are all supportive of this temporary change and agree that it is required under the current circumstances.

2. Key issues

The Regulations set out the requirements for a legal prescription. Regulation 41(a) requires that every prescription be legibly and indelibly printed, while 41(b) requires that each prescription be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp).

Regulation 43 of the Regulations allows the Director-General of Health to authorise a form of prescriptions that does not comply with all or any of the requirements of regulation 41.

This waiver mechanism has previously been used to allow the use of facsimile (fax) for sending scripts between GP practices and community pharmacies, and also to allow the electronic generation of prescriptions.

In 2018, the Director-General of Health, pursuant to regulation 43, authorised a form of prescription that did not comply with regulation 41(b), where a number of conditions were met, including:

- the original prescription was generated by an approved electronic system, which is certified for use with the NZePS
- the prescription contains a barcode generated by the NZePS

- the barcode is used at the point of dispensing to ensure auditability and authenticity of the original prescription
- the original prescription is kept on file (as required for original prescriptions) and submitted as required by the Community Pharmacy Services Agreement (CPSA) as a criteria for payment.

There remains a number of prescribers of medications dispensed by community pharmacies that are not yet able to use an approved electronic system that is certified to use with the NZePS including:

- Hospital outpatient or discharge prescribers
- Community prescribers eg, private specialist, nurse prescribers, midwives, dentists, allied health practitioners that do not use a practice management.

The Covid-19 pandemic has required new models for care including telehealth to enable care to be delivered in a manner that is safe for patients and clinicians. The requirement to print, sign and post a prescription to a pharmacy as required in the current regulations presents a number of issues:

- postal services will be disrupted during the Alert Level 4 restrictions
- exchanging paper prescriptions is a safety risk for community pharmacy
- many clinicians will be working away from their normal places of work and lack the equipment needed to print and scan or fax a signed script to pharmacy.

The requirement for a personal signature exists to provide a level of assurance that the prescription was created by an authorised prescriber and to protect against unauthorised alteration and multiple use. However, the prevalence of simple technologies has largely superseded the usefulness of a signature to mitigate these risks.

Waiving the need to physically sign a prescription will enable prescribers to electronically send the prescription directly to a community pharmacy.

These unsigned prescriptions have the inherent risks of alteration and multiple use. The risks will be mitigated by requiring certain conditions to be met before the waiver applies.

The authorisation should be limited in time and should be in place as long as the term of the Epidemic Preparedness (Covid-19) Notice 2020 which was gazetted on 25 March 2020 under the Epidemic Preparedness Act 2006. This notice is currently in place for three months but may be revoked earlier or renewed. This covers the period of time when telehealth will be a critical model of care and when the exchange of paper prescriptions will be challenging.

4. Advice

That you agree to authorise a form of prescription that does not meet the requirements of regulation 41(a) and (b) when all the following conditions are met:

- an electronic system to generate the prescription that requires the prescriber to log on with a unique ID and password
- the prescription does not include Controlled Drugs (Class A, B or C, but excluding an exempted drug or partially exempted drug) which are regulated by the Misuse of Drugs Act 1975
- the prescription or the digital communication that includes the prescription includes all of the following:
 - the prescribers HPI-CPN or the prescribers registration authority number (eg MCNZ) that uniquely identifies the prescriber

- for the contact details of the prescriber to enable the pharmacy to contact the prescriber to verify identify or request amendments to the prescription and
- contains the following statement “This Prescription meets the requirement of the Director-General of Health’s waiver of March 2020 for prescriptions not signed personally by a prescriber with their usual signature” .
- for the prescription to be in a format that cannot be easily altered by anyone other than the prescriber (eg PDF, photograph)
- to use a secure, electronic system to send the prescription to the pharmacy that identifies the prescriber name and facility. A secure email system¹ that identifies the prescriber and the healthcare facility through its email address would satisfy this requirement. A fax from a number that is recognised by the pharmacy as a valid prescriber also would satisfy this requirement
- the electronic prescription and the message is kept on and submitted as required by the Community Pharmacy Services Agreement (CPSA) as a criteria for payment.

This waiver will expire when the Epidemic Preparedness (Covid-19) Notice 2020 expires or is revoked.

4. Expected action of the Director-General of Health

For your approval.

5. Recommendations

It is recommended that you:

1	note	That the requirement for a prescription to be legibly and indelibly printed and signed personally by the prescriber with their usual signature is a significant barrier to delivering safe, efficient healthcare services during the Covid-19 pandemic. .	
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¹ Secure email is defined in the Secure Digital Communications within the NZ Health & Disability advisory that June 2019

<https://www.health.govt.nz/system/files/documents/publications/joint-acc-moh-advice-on-securing-email-and-fax-jun2019.pdf>

2.	<p>approve The authorisation of a form of prescription that does not meet the requirements of regulation 41(a) and (b), will apply only when the criteria are met in full:</p> <ul style="list-style-type: none"> • an electronic system to generate the prescription that requires the prescriber to log on with a unique ID and password • the prescription does not include Controlled Drugs (Class A, B or C, but excluding an exempted drug or partially exempted drug) which are regulated by the Misuse of Drugs Act 1975 • the prescription or the digital communication that includes the prescription includes all of the following: <ul style="list-style-type: none"> ○ the prescribers HPI-CPN or the prescribers registration authority number (eg MCNZ) that uniquely identifies the prescriber ○ for the contact details of the prescriber to enable the pharmacy to contact the prescriber to verify identify or request amendments to the prescription and ○ contains the following statement “This Prescription meets the requirement of the Director-General of Health’s waiver of March 2020 for prescriptions not signed personally by a prescriber with their usual signature” . • for the prescription to be in a format that cannot be easily altered by anyone other than the prescriber (eg PDF, photograph) • to use a secure, electronic system to send the prescription to the pharmacy that identifies the prescriber name and facility. A secure email system² that identifies the prescriber and the healthcare facility through its email address would satisfy this requirement. A fax from a number that is recognised by the pharmacy as a valid prescriber also would satisfy this requirement • the prescription and the message is kept on file (as required for original prescriptions) and submitted as required by the Community Pharmacy Services Agreement (CPSA) as a criteria for payment. 	Yes/No
3.	<p>note This authorisation will expire when the Epidemic Preparedness (Covid-19) Notice 2020 expires or is revoked.</p>	

Ministry Lead

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<https://www.health.govt.nz/system/files/documents/publications/joint-acc-moh-advice-on-securing-email-and-fax-jun2019.pdf>