

# **Guidelines for Applications for a Director-General of Health's Waiver to allow Electronic Prescribing**

## **Introduction**

Current requirements for the form of prescriptions, set out in regulation 41 of the Medicines Regulations 1984, are based on the use of paper prescriptions that must be indelibly printed and signed by the prescriber, so do not permit electronic prescribing.

The Electronic Transactions Act (2002) (ETA), which has the purpose of facilitating the use of electronic technology by providing that certain paper-based legal requirements may be met by using electronic technology, specifically excludes the Medicines Regulations 41 and 42. However, regulation 43 allows the Director-General of Health (the Director-General) to waive the requirements for the form of prescriptions set out in regulation 41. A waiver issued under regulation 43 may be subject to any conditions stipulated by the Director-General.

This document is intended to provide guidance to the sector when developing an application for a Director-General waiver from the requirements for prescriptions to enable electronic prescribing. Each application will be assessed on its own merits but it is noted that national consistency is desirable.

## **Controlled drugs**

The prescription requirements for controlled drugs are not regulated by the Medicines Regulations and waivers under regulation 43 of the Medicines Regulations do not apply. Controlled drugs are regulated by the Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977 which are not excluded enactments under the ETA. However due to the increased risk associated with the prescribing of controlled drugs any application for electronic prescribing that would involve prescribing controlled drugs must address, to the Director-General's satisfaction, the legal requirements for a signature (section 22) in the ETA.

## **Information for inclusion in a waiver application**

Any application for a waiver from the Director-General under regulation 43 to allow electronic prescribing must include a business case and project plan setting out the timeframes for implementation.

## **Business case**

The business case must address the business sustainability of the proposal, its interoperability and consistency with the National Health IT Plan and with other regional/national electronic prescribing and safer use of medicines initiatives. Any inconsistencies between the proposal and legislative requirements, contract/funding requirements and/or the Pharmaceutical Schedule must be identified and addressed.

There must be evidence of sufficient IT capability and resources (eg, a sufficient number of laptops, back up systems in the event of a power failure, offsite data storage, an appropriate level and source of funding etc). The costs and benefits of the electronic prescribing system must be clearly identified.

### **Setting for the waiver**

The applicant must clearly state the setting and scope of the waiver (eg, Wards X and Y in Z Hospital, or P Primary Health Organisation).

### **Information specific requirements**

Electronic prescriptions must contain all of the information that paper-based prescriptions contain (as set out in regulation 41 of the Medicines Regulations), and must meet all other requirements of the Medicines Regulations or Misuse of Drugs Regulations (if applicable).

The e-prescription proposal must:

- meet the requirements set out in the HISO standard 10030.1 (Electronic Pharmaceutical Business Process Standard) and 10030.2 (Electronic Pharmaceutical Messaging Standard).

The prescription must also include the:

- patient's National Health Index (NHI)
- prescriber's Health Practitioner Index (HPI).

### **Patient Health and Safety and Legislative Compliance**

Electronic prescribing must not unduly affect or inconvenience patients. The business case should indicate benefits to patient safety.

The application/business case must comply with the patient health and safety requirements of the Health and Disability Services (Safety) Act 2001 and the requirements of the Medicines Act 1981 and regulations and (if applicable) the Misuse of Drugs Act 1977 and regulations.

### **Security requirements**

The electronic prescribing system proposed must meet the Health Information Security Framework Standard (10029 as published by HISO).

<http://www.ithealthboard.health.nz/advisory/hiso/published-standards>

### **Authentication**

There must be robust authentication processes for prescribing and updating prescriptions. This means the system must be set up with functionality that requires the prescriber to authenticate themselves when prescribing or updating a prescription.

Authentication must be compatible with the Information Privacy, Authentication and Security Framework (PAS) – which is a part of the Health Information Security Framework Standard (as noted above).

The security of audit trails, recording the interface between the system of the prescriber and that of the recipient pharmacy, must be demonstrated to confirm the integrity (and unaltered nature) of any prescription sent. This must also be demonstrated in respect of any updated prescription.

### **Responsibilities relating to user identification and password**

After successfully completing training, all staff members must sign a document that records that they understand their responsibilities with regards to the use of their user identifications (IDs) and passwords. They must also confirm in writing that they accept responsibility for transactions and activity recorded under their user ID or password.

### **Privacy requirements**

The electronic prescribing system must ensure patient privacy.

### **Training requirements**

The application/business case must include information on staff training, including the quality of training and that a sufficient number of staff has been trained to provide a 24 hour service under the electronic prescribing system.

### **Duration of waiver**

If the waiver is for a finite time, the application must clearly state the timeframe for the waiver. If the intention is for the waiver to be ongoing, this must be clearly stated.

### **Review provision**

The waiver application must clearly state a regular review provision. Any review must be able to assess the costs and benefits of the electronic prescribing system and, if appropriate, identify areas where improvements can be made. The Director-General may define the reporting requirements.

### **Site visits**

Site visits by Ministry of Health staff may be needed, prior to the approval of a waiver, to enable assessment of the application.

### **Granting, varying or revoking a waiver**

The Director-General may issue, amend or revoke a waiver (including an ongoing waiver) at any time and subject to any conditions or other requirements that he or she thinks fit.