# **Pharmacy Procedures Manual**

A Guide to Payment and Claiming under the Integrated Community Pharmacy Services Agreement

Effective October 2024 Version 13.0 Citation: Health New Zealand | Te Whatu Ora. 2024. Pharmacy Procedures Manual. A Guide to Payment and Claiming under the Integrated Community Pharmacy Services Agreement. Version 13.0. Wellington: Health New Zealand.

Published in October 2024 by Health New Zealand PO Box 793, Wellington 6140, New Zealand

# Health New Zealand Te Whatu Ora

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# 1. Preamble

This Version 13.0 of the Pharmacy Procedures Manual supersedes Version 12.0.

The new Version 13.0 notes:

- Quitcards being replaced by NRT 'Advice to Client' letters.
- Updates to the Error Code Booklet.
- Updates the Temporary Exemption from Signatures on Prescriptions without NZePS (no barcode) which now expires 31 October 2027.
- Clarification that prescriptions from Corrections attract a prescription co-payment that is paid by Corrections.
- Updates the Health NZ claiming process for medicines for Age-Related Residential Care (ARRC) and Community Residential Care (CRC) residents with the previous temporary removal for the need for an original (wet) signature on prescriptions now made permanent (provided certain conditions are met).

Version control is held by the Living Well, Pharmacy Services, National Commissioning, Planning Funding and Outcomes, Health New Zealand | Te Whatu Ora (Health NZ). The latest version may be found at the following website: <a href="www.tewhatuora.govt.nz/for-the-health-sector/community-pharmacy/procedures-and-payments/">www.tewhatuora.govt.nz/for-the-health-sector/community-pharmacy/procedures-and-payments/</a>.

Feedback on this document can be sent to: <a href="mailto:Pharmacy@tewhatuora.govt.nz">Pharmacy@tewhatuora.govt.nz</a>.

# **Version Control**

These tables are used to document amendments since Version 11.0 of the Pharmacy Procedures Manual:

Version	Effective Date	Clause	Topic	Action
13.0	October 2024	2 7.6	'Advice to client' letters (Quitcards)	Updated: printed Quitcards are no longer provided having been replaced by 'Advice to client' letters
13.0	August 2024	4.3 7.10.1	Error Code Booklet	Updated the links to the 'Error Codes for Community and PCT Pharmacy Electronic Claiming Booklet v11'
13.0	October 2024	5.6 7.6	Temporary Exemption from Signatures on Prescriptions without NZePS (no barcode)	Updated the new date on which the authorisation expires
13.0	October 2024	7.4.5	No co-payments	Deleted 'Items on a Prescription Form for prisoners'. Clarification that prescriptions from Corrections, as an unapproved provider, do attract a \$15 prescriptions co- payment, paid by Corrections.
13.0	October 2024	7.7	Medicines for Age-Related Residential Care (ARRC) Community Residential Care (CRC)	Updated the requirement for an original wet signature
12.0	July 2024	7.2 7.4.5 10.1 10.3	Prescription Co-payment	Updated to reflect Budget 24 reinstatement of standard \$5 Co-payment from 1 July 2024
12.0	July 2024	11	Contacts	Updated email for National Health NZ Pharmacy Services
12.0	July 2024			Update to naming convention for Health New Zealand   Te Whatu Ora (Health NZ)

# 2. Glossary

The following terms have the specific meaning as listed in the table below:

Term	Meaning
Agreement	The Integrated Community Pharmacy Services Agreement for the funding and provision of the Services that came into effect 1 October 2018.
Annotation	Notes made on the Prescription Form by the Pharmacist to assist with interpretation or claiming.
Approved Provider	As defined in Section 10.2 of this Manual.
Authorised Prescriber (see Section 5)	The Medicines Act 1981 defines an Authorised Prescriber as:  1. a nurse practitioner; or  2. an optometrist; or  3. a practitioner; or  4. a registered midwife; or  5. a designated prescriber.  Refer also to the definition of Designated Prescriber (see Section 5).
ARRC	Age-Related Residential Care.
Batch	The collated prescriptions to be claimed relating to Dispensing within a Claim Period.
CDOS	Co-Dispensed Opioid Services.
Claim	A batch of Claim Items in respect of a Claim Period submitted by a Pharmacy to Sector Operations (a business unit of Health NZ) for payment in accordance with the ICPSA.
Claim Item	The transaction relating to the Dispensing of a Pharmaceutical.
Claim Period	One of the four Claim Periods in a single calendar month as described in Part D, D.15 of the ICPSA.
CPAMS	The Community Pharmacy Anti-Coagulation Management Services, which are provided in accordance with Community Pharmacy Anti-Coagulation Management Services in Schedule 3B.5 of the ICPSA.
Community Pharmaceutical	A Pharmaceutical listed in Sections B to D or I of the Pharmaceutical Schedule that is funded by the Government.
Co-payment	The payment to be made by a Service User when they are provided with a subsidised Service or Dispensed a Pharmaceutical. For a full description see clause D.5 of the ICPSA.
CRC	Certified Repeat Copy.

Term	Meaning
CRC Service	Community Residential Care Service.
CSC	A Community Services Card as defined in the Health Entitlement Card Regulations 1993.
Designated Prescriber (see Section 5)	<ol> <li>The Medicines Act 1981 defines a Designated Prescriber as a person, other than a practitioner, nurse practitioner, optometrist, or a registered midwife, who:</li> <li>belongs to a class of registered health professionals authorised by regulations made under this Act to prescribe any specified prescription medicines, or any specified class or description of prescription medicines subject to the satisfaction of requirements specified in or imposed under those regulations; and</li> <li>satisfies any applicable requirement relating to competency, qualifications, or training specified in or imposed under regulations made under this Act.</li> <li>Refer also to the definition of Authorised Prescriber.</li> </ol>
District	A geographical area of Health NZ that a District Health Board previously represented.
Dispensing	The process of a pharmacist providing a Pharmaceutical to or for a Service User in accordance with Schedule 1 of the ICPSA.
EAR	Eligibility and Registration System. This system is located via the Pharmacy Portal; it is used to register Service Users for different services, such as LTC, CDOS and CRC. LTC Monthly Service Fee payments are based on the register. It is also where the Provider can view information about LTC service fee payments and case mix service fee payments.
Eligible Persons	Any individual who is a user of the Services and is eligible to receive Services as specified in regulations made under section 102 of the Pae Ora (Healthy Futures) Act 2022 or is eligible under a ministerial direction, including any ministerial direction continued under section 30 of Schedule 1 of that Act. Refer to: Guide to eligibility for public health services — Te Whatu Ora - Health New Zealand.
Endorsement	An Endorsement is text written on a Prescription Form by a Prescriber.  Unless otherwise specified, Endorsements should be either handwritten or computer generated by the practitioner prescribing the medication. The Endorsement can be written as 'certified condition', or state the condition of the patient, where that condition is specified for the Community Pharmaceutical in Section B of the Pharmaceutical Schedule. Where the practitioner writes 'certified condition' as the Endorsement, they are making a declaration that the patient meets the criteria as set out in Section B of the Pharmaceutical Schedule.
GP	General Practitioner.
Handling Fee	The applicable Handling Fee that serves as a marker of Dispensing activity as set out in the relevant Service Schedule of the ICPSA.

Term	Meaning
Health Payments Integrity Team (previously known as Audit and Compliance)	A business unit of Health NZ that provide assurance, through audit and risk assessment, to ensure that Provider claims for subsidies and fees meet contractual and legal obligations.
HUHC	High Use Health Card, as defined in the Health Entitlement Card Regulations 1993.
ICPSA	Integrated Community Pharmacy Services Agreement.
LTC	Long Term Condition as defined in the LTC Pharmacy Services Protocol. Refer to Integrated Community Pharmacy Services Agreement (ICPSA).
Manatū Hauora	Manatū Hauora – Ministry of Health.
NPPA	Named Patient Pharmaceutical Assessment.
NZePS	New Zealand Electronic Prescription Service.
NZePS Controlled Drug Prescription	A printed paper Prescription Form that contains a barcode that carries the same unique identifier as its electronic counterpart for a Controlled Drug produced by an electronic prescribing system that is an approved system for the purposes of Regulation 29(1)(b) of the Misuse of Drugs Regulations 1977 and is signed by the Prescriber. (Note: The Misuse of Drugs Amendment Regulations 2022 enables signature-exempt controlled drug prescriptions. However, work is still underway about how opioid access will work in practice – for updates see Getting started with NZePS / Controlled Drugs.
NZePS Signature Exempt Prescriptions (with barcode)	<ul> <li>An enduring Director-General of health alternative form of prescriptions permits Signature Exempt Prescriptions for barcoded NZePS prescriptions if certain conditions are met. The specific conditions that must be met for a signatureless prescription with an NZePS barcode to be valid include:</li> <li>The system that generates the prescription must have been authorised by Health NZ for Signature Exempt Prescriptions; and</li> <li>For prescriptions to be valid, the pharmacy must use the barcode at the point of dispensing otherwise the signed original prescription is required.</li> <li>For all conditions please refer to Signature Exempt Prescriptions and remote prescribing (Go to section: NZePS Signature Exempt Prescriptions - with barcode).</li> <li>For Controlled Drugs, see Section 6.</li> </ul>
Patient	For the purposes of this document, the term patient(s) also refers to the term Service User in the ICPSA.
Pharmaceutical	A medicine, therapeutic medical device or related product or thing as defined in Part E of the ICPSA.
Pharmaceutical Schedule	The Pharmaceutical Schedule produced by Pharmac.

Term	Meaning
Pharmacist	A person registered as a Pharmacist with the Pharmacy Council of New Zealand and who holds a current annual practising certificate under the Health Practitioners Competency Assurance Act 2003.
Pharmacy	A place where pharmacy practice is carried out as defined in the Medicines Act 1981.
PhMS	Pharmacy Management System used for dispensing and recording pharmacy service activity.
Pharmacy Procedures Manual OR Procedures Manual	This document. The publication entitled Pharmacy Procedures Manual, is available at Pharmacy Procedures Manual.
PHO	Primary Health Organisation.
Prescriber	A practitioner who is authorised under the Medicines Regulations 1984 or the Misuse of Drugs Regulations 1977 to prescribe Pharmaceuticals to Eligible People.
	For the purposes of this document, it is assumed that Prescribers are working within their scope of practice.
	Refer also to the definition of: Authorised Prescriber and Designated Prescriber (see Section 5).
Prescription Form	A Prescription Form, medicines order (including Bulk Supply Order or Practitioner's Supply Order), which is prepared by a practitioner in accordance with the Medicines Regulations 1984 or the Misuse of Drugs Regulations 1977, 'Advice to client' letters (Quitcard), or another request.
	Note 1: this same definition applies to a Prescription Form produced via the NZePS. Medicines orders and NRT 'Advice to client' letters (Quitcards) are not available through NZePS.
	Note 2: NRT 'Advice to client' letters (Quitcards) are not prescriptions, however they are handled in much the same way. Refer under Section 7.6 for specific provisions relating to NRT 'Advice to client' letters (Quitcards).
Prescription Subsidy Card (PSC)	Also known as a Pharmaceutical Subsidy Card as defined in the Health Entitlement Card Regulations 1993.
Provider	A Provider of pharmacy services as defined in the ICPSA, or a Pharmacist employed by a Provider.
Safety Medicine	A Community Pharmaceutical as defined in the Pharmaceutical Schedule General Rules Part 5.4 (Rules of the Schedule).
Service User	As defined in Part E (Definitions) of the ICPSA.
Sector Operations	A business unit within Health NZ responsible for providing strategic advice on the impact of sector changes on payment processes and for the administration of the core health payment processes (formally known as Sector Services).

Term	Meaning
Signature Exempt Prescription	Signature Exempt Prescriptions are electronic prescriptions that do not require a physical wet ink signature from an authorised prescriber.
	There are two types of Signature Exempt Prescriptions, including NZePS Signature Exempt Prescriptions (with barcode) and those falling under the Temporary Exemption from Signatures on Prescriptions without NZePS (no barcode). Each are described further below.
Te Aka Whai Ora	Māori Health Authority, established under section 17 of the Pae Ora (Health Futures) Act 2022.
Temporary Exemption from Signatures on Prescriptions without NZePS (no barcode)	A Director-General Authorisation (expiring 31 October 2027) permits Signature Exempt Prescriptions for non-barcoded NZePS prescriptions if certain conditions are met. This is further described in Section 5.6.
Health NZ	Health New Zealand   Te Whatu Ora, established under section 11 of the Pae Ora (Healthy Futures) Act 2022.
Transfers Guide	A guide to the processes involved when transferring the ownership of a Pharmacy and closing a Pharmacy available at <a href="Pharmacy transfer guide">Pharmacy transfer guide</a> .

# 3. Introduction

#### 3.1. Overview

The Procedures Manual is a resource for community pharmacy service Providers. It includes relevant procedures and processes required for claiming funding as part of the Integrated Community Pharmacy Services Agreement (ICPSA), and other relevant procedures and processes linked to the current legislation and service delivery.

This Manual should be read in conjunction with the following source documents as these documents form part of any audit process:

- the ICPSA
- all relevant legislation and regulations applicable to the practice of pharmacy in New Zealand
- the Pharmaceutical Schedule
- the Pharmaceutical Transactions Data Specification (Data Specification) (for applicable file formats and data to be provided for processing)
- service specifications within ICPSA
- New Zealand Standard Health and Disability Services Pharmacy Services Standards (also known as PSS).

Health Payments Integrity provides assurance to Health NZ through audit and risk assessment, that Provider claims for subsidies and fees meet contractual and legal requirements. Providers may be audited to ensure that they are compliant with these requirements.

# 3.2. Order of Priority

In the event of any conflict between the current ICPSA and the following documents the order of priority is:

- 1. all relevant legislation and regulations applicable to the practice of Pharmacy in New Zealand
- 2. the Pharmaceutical Schedule
- 3. the Data Specifications (solely in relation to file formats and data required to be provided to Sector Operations for claiming)
- 4. the ICPSA
- 5. the Pharmacy Procedures Manual.

# 3.3. Pharmacy Change of Ownership and Closures

Providers should always seek advice from their District Portfolio Manager or relevant Health NZ commissioning personnel and contact the Licensing Authority, Medicines Control as soon as they become aware of an intended change of ownership or the creation of a new legal entity. There are many issues that need to be considered when changing ownership of a Pharmacy, including contractual obligations and licensing implications. When closing a Pharmacy up to six months is required to terminate an ICPSA. For more information refer to clause C.40 to 48 of the ICPSA, and the Pharmacy transfers guide.

# 4. Submission of Claims

## 4.1. Claim Submission Requirements

All Claim Batches submitted by a Pharmacy must meet all legal and contractual requirements.

- 1. Batches submitted by a Provider must meet all legal and contractual requirements. All Claimed Items must be submitted electronically and following the process within the Pharmacy Management System (PhMS).
- 2. Following electronic submissions all Prescription Forms must be bundled into a Batch that reflects the Claim Period in which the Dispensing have been submitted to Health NZ for payment:
  - Each Claim Item must be supported by an original Prescription Form (refer to Section 5.6 for clarification regarding faxed NZePS-produced Prescription Forms and Prescriber signature requirements on prescriptions).
  - The Prescription Forms must be collated into Batches and submitted to Health NZ no later than five months after the end of the relevant Claim Period.
  - The Prescription Forms are to be collated in order of the date in which the items were Dispensed.
  - Any Prescription Form received by a Provider at a later date must be inserted into the original Batch at the corresponding date of Dispensing.
  - Each Batch must be accompanied by the approved Health NZ Batch Record form.
  - The approved Health NZ Batch Record form must be completed in full and signed on behalf of the Provider.
  - Variances between the original Prescription Form and the computer record or supply must be clearly Annotated on the Prescription Form.

# 4.2. Batch Delivery Instructions

All Prescription Forms for a Claim Period must be batched separately with the approved Health NZ Batch Record form and must replicate the electronic claim file and claiming cycle.

For example, if Claims are submitted once a week, the Batch must be bundled weekly. Where Claims are submitted fortnightly, the Batch must be bundled fortnightly.

Weekly Claim Periods	Fortnightly Claim Periods
1 - 7 day of the calendar month	
8 - 15 day of the calendar month	1 - 15 day of calendar month
16 - 23 day of calendar month	
24 - last day of the calendar month	16 - last day of calendar month

Procedure	е
Step 1	Collate Prescription Forms in order of date of Dispensing; the forms for each dispensing date must be secured tightly into a separate bundle.
Step 2	Collate into a Batch, with the date of dispensing bundles relevant to the Claim Period that reflecting the electronic claiming cycle used by the Provider.
Step 3	Complete the approved Health NZ Batch Record form, which can be printed from the PhMS. The form must include the following information:  1. Provider claimant number  2. Provider name  3. period from (start date of the Claim Period)  4. period to (end date of the Claim Period)  5. signature of a Pharmacist or person authorised by a Provider as its representative  6. date of signing.
Step 4	Attach the approved Health NZ Batch Record form to the front of the Claim Period Batch and tightly secure the entire Batch together.  The delivery address for Batches is:  Health NZ Archives Warehouse 137 London Street Whanganui 4500
Step 5	<ul> <li>More than one Batch may be sent to Health NZ at one time, but each Claim Period Batch must be sent as a separate Batch.</li> <li>Important Notes:</li> <li>Providers may retain Batches for up to five months.</li> <li>If an audit of the Provider is undertaken, Health NZ may request that a Batch be sent to them at any time before the five-month period is complete. Providers will be notified if this is the case and must comply with the time frames and delivery requirements.</li> <li>After the five-month period, Batches must be submitted to Health NZ.</li> <li>Batches may be returned to the Provider for correction if the Batch does not meet the procedure specified above.</li> <li>If Batches are not received by the due date Health NZ may send a warning letter requiring the Batch to be sent within 30 days.</li> <li>If the Batch has not been received within those 30 days, funding may be withheld for an amount equating to the value of that Batch.</li> <li>Certified repeat copies are not required to be printed and sent with Batches if they do not differ from the original prescription.</li> </ul>

## 4.3. Rejected Items

Claim Items can be rejected for payment because the item does not conform with the rules specified in the Pharmaceutical Schedule, the ICPSA, the Pharmaceutical Claim Data Specification, or this Manual. An explanation of the Error Codes appearing on the reports after processing of a claim can be found in the <u>Claiming Guidelines</u>.

A Claim Item will be rejected for payment in the circumstances set out in clause D.25 of the ICPSA, including if the Dispensing is submitted outside of the Claim Period (for example 120 days after the Claim Items have been entered into the computer), except in exceptional circumstances and as agreed by Health NZ.

A Provider can apply in writing to Health NZ if they consider that special circumstances apply to a specific item, and Health NZ may, at its discretion, allow the Provider to receive payment.

## 4.4. CPAMS Claiming and Invoicing

An invoice template that satisfies the Sector Operations' invoice requirements set out in clause 11.3 of Schedule 3B.5 of the ICPSA is available on the Health NZ website: <a href="Mailto:CPAMS">CPAMS</a> invoicing and reporting requirements.

Claims must be made manually at the end of the month. Valid IRD-approved invoices received will need to be approved by Health NZ before they can be released for payment. Invoices received by the 4<sup>th</sup> working day of the month are paid on the 20<sup>th</sup> (or the next business day).

Send invoices to:

Sector Operations c/- Health New Zealand Provider Payments Private Bag 1942 Dunedin 9054

Or providerinvoices@health.govt.nz.

To verify the Claim, the Monthly Service Users Report which contains the NHIs of active Service Users for the month must be attached. (Note: The Service User's name is not required, only the NHI). The reporting requirements for this service are outlined in the Community Pharmacy Anti-Coagulation Management Services service specification in the ICPSA (Schedule 3B.5, clause 10).

# 4.5. CPAMS Quarterly Reporting

Quarterly reporting must be provided to Sector Operations on the following dates:

Reporting Period	Report due
1 July – 30 September	20 October
1 October – 31 December	20 January
1 January – 31 March	20 April
1 April – 30 June	20 July

The Quarterly Report must include a summary of:

- number of Service Users registered by NHI with the CPAMS in the quarter (for example active Service Users plus new Service Users minus Service Users who have exited the CPAMS)
- average number of INR tests per quarter
- · documentation of Key Performance Indicators:
  - o compliance (test on time, 1-3 days, 4-7 days, 7+ days)
  - o control (test in range, tests above, tests below)
- adverse events (total recorded bleeds, total recorded hospital admissions)
- a brief narrative report outlining progress implementing the service in this quarter, and any issues experienced.

Quarterly Reports should be sent to:

performance reporting@health.govt.nz

or

Performance Reporting Team Sector Operations Health New Zealand Private Bag 1942 Dunedin 9054

## 4.6. Smoking Cessation Claiming and Invoicing

Claims must be made by submitting a valid tax invoice monthly with each invoice to be provided on or before the 20<sup>th</sup> day of the month following the month in which the Service Users were registered and set a Target Quit Date (TQD).

A tax invoice must contain the following information:

- Unique invoice number
- Invoice date (date invoice produced)
- GST number
- Provider name
- Claimant number
- Agreement number
- Address
- Contact details (phone, fax, and email)
- District name
- Service provided
- Volume (if required)
- · Period claiming for
- Amount excluding GST
- GST amount
- Total amount including GST
- Purchase unit number.

#### Send invoices to:

Sector Operations c/- Health New Zealand Provider Payments Private Bag 1942 Dunedin 9054

Or: providerinvoices@health.govt.nz

# 4.7. Smoking Cessation Reporting

The reporting requirements for this service are outlined in the Smoking Cessation Services service specification in the ICPSA (Schedule 3B.6, clauses 10 and 11).

# 5. Legal Requirements of Prescribing Under the Medicines Act 1981

#### 5.1. Authorised and Designated Prescribers

Authorised and Designated Prescribers are health professionals registered in New Zealand as a Medical Practitioner, Dentist, Midwife, Nurse Practitioner, Designated Prescriber Pharmacist, Designated Prescriber Nurse, or Veterinarian, who hold a current annual practising certificate under the Health Practitioners Competence Assurance Act 2003.

Practitioners who are not registered to practice in New Zealand (for example overseas registered practitioners) are not authorised to prescribe Pharmaceuticals to people in New Zealand. That means a Provider may not Dispense a Pharmaceutical that has been prescribed by an overseas Prescriber.

An Authorised Prescriber (except Medical Practitioners) may only prescribe Pharmaceuticals approved for use in New Zealand. Unapproved Pharmaceuticals may only be dispensed on a Prescription Form from a Medical Practitioner (see section 25 and 29 of the Medicines Act 1981).

Designated Prescribers may only prescribe a prescription medicine if it is included in the Schedule of Medicines they may prescribe under the Medicines Regulations 1984.<sup>1</sup>

When a Provider is unsure whether a Prescriber is registered or is unable to verify the signature of the Prescriber, the Provider should confirm that the Prescriber is registered by sighting their annual practising certificate or checking with their Regulatory Body.

#### 5.2. Under their Care

An Authorised Prescriber (including a Designated Prescriber) may only prescribe a prescription medicine for the treatment of a patient under their care.<sup>2</sup>

A Veterinarian may only prescribe a prescription medicine that is for the treatment of an animal under the veterinarian's care.<sup>3</sup> The Veterinary Council can be contacted for any queries regarding Veterinarians at www.vetcouncil.org.nz/.

# 5.3. Scope of Practice

An Authorised Prescriber (including a Designated Prescriber) may only prescribe in accordance with the Prescriber's scope of practice as granted under section 21 of the Health Practitioners Competence Assurance Act 2003.<sup>4</sup>

#### **Pharmacist Prescribers**

Pharmacist Prescribers are Designated Prescribers and are governed by the Medicines (Designated Pharmacist Prescribers) Regulations 2013.

<sup>&</sup>lt;sup>1</sup> Medicines Regulations 1984, reg 39(2)

<sup>&</sup>lt;sup>2</sup> Medicines Regulations 1984, reg 39(1)(a)(i)

<sup>&</sup>lt;sup>3</sup> Medicines Regulations 1984, reg 39(3)

<sup>&</sup>lt;sup>4</sup> Medicines Regulations 1984, reg 39(1)(a)(ii)

#### **Nurse Prescribers**

Nurse Prescribers are Designated Prescribers and are governed by the Medicines (Designated Prescriber - Registered Nurses) Regulations 2016.

#### **Midwives**

Registered Midwives can take responsibility for the care of a woman throughout her pregnancy, childbirth, and post-natal period. They may claim maternity, pharmaceutical and other related benefits relevant to pregnancy and childbirth.

Registered Midwives may prescribe:

- for the treatment of a patient under their care
- any Pharmaceutical for the mother providing it is during pregnancy, labour, and the postpartum period up to six weeks
- for the baby during this six-week period
- morphine, tramadol, fentanyl and pethidine, but no other controlled drug.

They must not prescribe for an underlying medical condition, such as asthma or hypertension.

In relation to a preterm baby, the Midwifery Council defines the six-week postpartum period as commencing from the expected date of birth rather than the actual date of birth. In other words, for preterm babies, the postpartum midwifery role may extend beyond six calendar weeks.

Midwives are entitled to use a Practitioner's Supply Order form to order Pharmaceuticals within their scope of practice and to verbally communicate Prescription Forms in an emergency situation.

The NZ College of Midwives Consensus Guideline – Midwife prescribing was updated in 2014 and is available via: <u>Guidance for practice</u>.

The Midwifery Council can be contacted for any queries regarding Midwives at www.midwiferycouncil.health.nz.

#### **Dietitians**

Dietitian Prescribers are Designated Prescribers and are governed by the Medicines (Designated Prescribers: Dietitian Prescribers) Regulations 2015.

They can write Prescription Forms for only those Pharmaceuticals specified in notices published in the NZ *Gazette*. If they are not qualified as a Designated Prescriber, a Dietitian may write Prescription Forms for funded Special Foods listed in Schedule D of the Pharmaceutical Schedule or any Pharmaceutical identified in Section D as being able to be prescribed by a Dietitian.

## 5.4. Limit on Supply

An Authorised Prescriber may only prescribe a three-month supply of any Pharmaceutical, except for an oral contraceptive, in which case six months may be supplied.<sup>5</sup>

An Item on a Prescription Form is legally able to be Dispensed up to six months from the date of prescribing, or for an oral contraceptive, up to nine months from the date of prescribing. However, it is only valid for subsidy purposes if it was first presented to the Pharmacy within three months from the date it was prescribed.

Only a quantity sufficient to provide treatment up to the legal period of supply limit will be Subsidised as specified in the Medicines Act 1981 and Medicines Regulations 1984 and the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977. Where there is no legal period of supply limit, only a quantity sufficient to provide treatment for a period up to 3 Months will be Subsidised.<sup>7</sup>

**Note**: Not all registered Pharmaceuticals are subsidised. Even when an item is not subsidised (NS), only a three-month quantity of supply is allowed to ensure that the patient is reviewed on a regular basis by the practitioner responsible for their care.

<sup>&</sup>lt;sup>5</sup> Medicines Regulations 1984, reg 39A(1)

<sup>&</sup>lt;sup>6</sup> Medicines Regulations 1984, reg 42(3)(c,d)

Pharmaceutical Schedule Section A: General Rules, rule 1.2

## 5.5. Legal and Contractual Requirements of a Prescription Form

#### Legal and Contractual Requirements of a Prescription Form<sup>8</sup>

The information supplied on a Prescription Form must be legible and indelible (written in pencil, for example, is not acceptable) and must include all the following:

- Prescriber's usual signature in their own handwriting (not being a facsimile or other stamp) subject to the Signature Exempt Prescription provisions (see section 5.6)
- The date on which the Prescription Form was signed
- Prescriber details, which includes:
  - o Prescriber's full name
  - Prescriber's physical work address, or postal address for those who do not have a place of work
  - o Prescriber's telephone number
- Patient details, which includes:
  - Surname and each given name of the patient
  - Physical address of the patient
  - Patient's Date of Birth if the Prescription Form is for a child under 14 years for prescription medicines
- Pharmaceutical details, which includes:
  - Name of the Pharmaceutical
  - Strength of the Pharmaceutical to be Dispensed (where appropriate)
  - Total amount of Pharmaceutical or the total period of supply to be Dispensed
  - Dose and frequency of the dose for internal Pharmaceutical
  - Method and frequency of use for external Pharmaceutical
- The following are all required to be added by the pharmacy to the Prescription Form:<sup>9</sup>
  - Name and address of the proprietor of the business at which the Prescription Form is Dispensed
  - Date on which each item on the Prescription Form is Dispensed
  - Each item Annotated with the quantity of the Pharmaceutical Dispensed
  - Each item Annotated with the strength of the Pharmaceutical Dispensed (where appropriate)
  - The unique identifying number for each item on the Prescription Form
  - Identity of the individual Dispensing each item<sup>10</sup>
  - Each item Annotated with the initials of the responsible Pharmacist for completeness and accuracy.

<sup>8</sup> Medicines Regulations 1984, reg 41

<sup>9</sup> Medicines Regulations 1984, reg 42(3)(b)

New Zealand Health and Disability Pharmacy Service Standards 5.2.3 (f)

## 5.6. Prescriber Signature

# **Director-General Temporary Authorisation for Unsigned Prescriptions August** 2024

A Temporary Authorisation for systems and settings that are not integrated with the NZePS allow non-NZePS signature exempt prescriptions to be issued if the requirements under that authorisation are met (<u>Temporary Exemption from Signatures on Prescriptions without NZePS (no barcode)</u> August 2024).

The Temporary Authorisation <u>does not</u> affect NZePS Signature Exempt Prescriptions (with barcode). The ability to generate signature exempt prescriptions using NZePS (ie, with barcodes) is an enduring capability.

For updates on ePrescriptions see New Zealand ePrescription Service (NZePS) – Te Whatu Ora - Health New Zealand.

#### **Emergencies**

Regulation 40A of the Medicines Regulations 1984 allows that in cases of an emergency, Pharmacists can Dispense a Pharmaceutical from a verbal order from an Authorised Prescriber or Veterinarian who is known personally by the Pharmacist.<sup>11</sup>

# 5.7. Prescriber Address Requirements<sup>12</sup>

The Prescriber's full physical work address must include:

- for an urban based Prescriber: the full street address (including unit number (if applicable)), street number/alpha, street name, suburb (if in common use), and town or city.
- for a rural Prescriber: street number and street name (if applicable) and RD number with the correct mail town.
- the address may not be a PO Box or Rural Delivery number, except where the Prescriber does not have a place of work. A Rural Address Property Identification (RAPID) Rural Number is acceptable.
- Prescriber's telephone number.

# 5.8. Patient Address Requirements

The patient's full home address must include:

- for an urban patient: the patient's full street address (including unit number (if applicable)), street number/alpha, street name, suburb (if in common use), and town or city.
- for a rural patient: street number and street name (if applicable) and RD number with the correct mail town. A RAPID Rural number is acceptable.
- the address must **not** be a PO Box or Rural Delivery number. For a patient with no fixed abode:
  - o The practice address of the Prescriber (full street address), including unit number (if

<sup>&</sup>lt;sup>11</sup> Medicines Regulations 1984, reg 40A

<sup>&</sup>lt;sup>12</sup> Medicines Regulations 1984, reg 41(2)(c)(ii)

applicable), street number/alpha, street name, suburb (if in common use), and town or city.

## 5.9. Prescribing Date

The date of Dispensing must not precede the prescribing date.

An item on a Prescription Form must not be dispensed where six months<sup>13</sup> have elapsed since the date on which it was written, unless it is for an oral contraceptive, where the time limit is nine months.<sup>14</sup>

Note: these timeframes are longer than those required to obtain a subsidy for the Pharmaceutical.

## 5.10. Quantity Dispensed

An Authorised Prescriber may not prescribe a quantity of any prescription medicine that exceeds:

- six months' supply in the case of an oral contraceptive; or
- three months' supply in any other case. 15

If the Prescriber has only written a period of supply, the Provider <u>must</u> Annotate the quantity to be Dispensed on each occasion.<sup>16</sup>

See also section 6 of this Manual (Legal Requirements of Prescribing Under the Misuse of Drugs Act 1975) for supply information for controlled drugs.

## 5.11. Unique Identifying Number for items on a Prescription Form

This will generally be the number generated by the PhMS, which are consecutive. This number is printed on the third part of the dispensary label and must be affixed onto the Prescription Form.

Handwritten, legible numbers are for emergency or exceptional circumstances only. See also section 6 of this Manual (Legal Requirements of Prescribing Under the Misuse of Drugs Act 1975).

# 5.12. Labelling

The label on a Pharmaceutical supplied by a Provider to a Service User must contain all of the following:

- the name of, or a description of the nature of, the contents
- the name of the Service User
- the name and address of the Provider
- in the case of a Pharmaceutical for internal use, the dose and frequency of dose
- in the case of a Pharmaceutical for external use, a statement of the directions for use

<sup>&</sup>lt;sup>13</sup> Medicines Regulations 1984, reg 42(3)(c)

<sup>&</sup>lt;sup>14</sup> Medicines Regulations 1984, reg 42(3)(d)

<sup>&</sup>lt;sup>15</sup> Medicines Regulations 1984, reg 39A(1)

<sup>&</sup>lt;sup>16</sup> Medicines Regulations 1984, reg 42(3)(b)(iii)

and frequency of use, and one or other of the following statements, or words of similar meaning: 'Caution: Not To Be Taken', or 'For External Use Only'

- a unique identifying number or code for the item or record of supply
- the date on which the Pharmaceutical was packed, sold, or supplied.

#### 5.13. Recalls

A recall is required when an affected therapeutic product(s)<sup>17</sup> is required to be removed from supply or use for reasons relating to deficiencies in the safety, quality, efficacy, or performance of the product. Guidance on recalls can be obtained from Medsafe. Each recall may be different due to the variety of reasons and products that may be recalled.

The Medsafe Recalls Code provides specific information on the responsibilities of Pharmacies and Healthcare Professionals in Sections 8 and 9. Should specific advice be required it will be provided by the sponsor company at the time of the recall.

A response should always be provided to a recall notice, even if it is a NIL return. Some companies will include an email address for the response; consider using this approach should the fax line be unavailable.

A Co-payment must not be charged when a replacement Dispensing is required. Health NZ has committed to ensuring that a recall dispensing transaction is cost neutral to the Provider from a patient Co-payment perspective.

A replacement Dispensing will not contribute to the patient count towards a Prescription Subsidy Card.

<sup>&</sup>lt;sup>17</sup> Therapeutic products can be categorised as medicines, related products, or medical devices'

# 6. Legal Requirements of Prescribing Under the Misuse of Drugs Act 1975

# 6.1. Controlled Drug Prescribing

# 6.1.1. Changes under the <u>Misuse of Drugs (Classification and Presumption of Supply) Order 2022</u>

The Misuse of Drugs (Classification and Presumption of Supply) Order 2022 classifies or reclassifies 49 substances under the Misuse of Drugs Act 1975. The commonly used prescription medicines that are affected are listed below and the commencement date under the Misuse of Drugs (Classification and Presumption of Supply) Commencement Order 2022:

Medicine	New Classification	Date of change	Important practice points
Fentanyl	Class B1	1 July 2023	No impacts on practice
Zopiclone and Zolpidem	Class C5	1 July 2023	Same requirements as other Class C5 controlled drugs, such as benzodiazepines
Tramadol	Class C2	1 October 2023	Same requirements as other Class C2 controlled drugs, such as codeine, dihydrocodeine
			Exemption is given to allow tramadol to be stored outside of a controlled drug safe <sup>18</sup>
Lisdexamfetamine	Class B2	15 December 2022	Maximum 3 months' supply (for both a NZePS electronic prescription or paper prescription)
			Note that one month maximum supply per dispensing also remains

# 6.1.2. Changes under the Misuse of Drugs Amendment Regulations 2022

The Misuse of Drugs Amendment Regulations 2022, which came into force on 22 December 2022, enables signature-exempt prescriptions for controlled drugs when prescribed through the NZePS. Prescribers will no longer need to provide a hard copy, signed version of any prescription for a controlled drug as long as they generate the prescription using an approved system which is integrated with the NZePS, and the barcode is used to dispense the prescription at the time of dispensing.

Some changes enabled under the Misuse of Drugs Amendment Regulations 2022 are

<sup>&</sup>lt;sup>18</sup> Misuse of Drugs Regulations 1977, reg 28(4)(f)

superseded by changes made under the Misuse of Drugs Amendment Regulations (No2) 2023 described in 6.1.3 below.

While the NZePS can be used to issue controlled drug prescriptions (which eliminates the need to hand-write triplicate controlled drug prescriptions) all other requirements for controlled drug prescriptions remain unchanged. For example, no forward dating of controlled drug prescriptions is allowed.

# 6.1.3. Changes under the Misuse of Drugs Amendment Regulations (No 2) 2023

The Misuse of Drugs Amendment Regulations (No 2) 2023 came into effect on 5 October 2023.

From 5 October 2023, **all Class A, B and C opioids** classified under the Misuse of Drugs Act 1975 can be prescribed for a maximum amount that is required for one month of treatment (Regulation 21(5D)(a)). This limit applies to all controlled drug Prescribers (Medical Practitioners, Nurse Practitioners, Designated Prescriber Nurse, designated Prescriber Pharmacists. However, this does not impact the specific controlled drugs that some groups of prescribers are authorised to prescribe, such as OST prescribers.

Examples of commonly prescribed **opioid** controlled drugs that this will impact in practice include:

- Class B opioid controlled drugs: alfentanil, fentanyl, methadone (non-OST services), morphine, oxycodone, pethidine, remifentanil
- Class C opioid controlled drugs: buprenorphine, buprenorphine with naloxone, codeine, dihydrocodeine, tramadol

A Medical Practitioner, Nurse Practitioner, Designated Prescriber Nurse, Designated Prescriber Pharmacist, Midwife, or Dentist may issue a prescription for the supply of a Class A, Class B, or Class C opioid controlled drug in any quantity not greater than the quantity reasonably required for the treatment of the patient for one month.

A Medical Practitioner, Nurse Practitioner, Designated Prescriber Nurse, Designated Prescriber Pharmacist or Dentist may issue a prescription for the supply of a Class B or Class C non-opioid controlled drug in any quantity not greater than the quantity reasonably required for the treatment of the patient for three months, to be supplied in quantities no greater than one month per dispensing.

**Note:** Veterinarians may issue a prescription for a controlled drug in any quantity not greater than the quantity reasonably required for the treatment of the animal under their care for one month.

## Table summary of changes (from 5<sup>th</sup> October 2023) to controlled drug prescribing regulations

Criterion	Example	Change to maximum period of supply
Class B opioids	Alfentanil Fentanyl Methadone Morphine Oxycodone Pethidine Remifentanil	Maximum one month supply per prescription (for both NZePS electronic prescriptions and paper prescriptions)  Note that the 10-day default dispensing per the Pharmac Schedule remains
Class C opioids	Codeine Dihydrocodeine Tramadol (from 1 October 2023) Buprenorphine	Maximum one month supply per prescription (for both NZePS electronic prescriptions and paper prescriptions)
Class B and C opioids prescribed by medical practitioners working under a Gazette notice issued under s24A of the Misuse of Drugs Act that can issue prescriptions for the treatment of dependency	Methadone prescribed by Opioid Substitution Therapy (OST) services <sup>19</sup>	An exemption for OST services to prescribe for up to three months
Class C non-opioids	Benzodiazepines Zopiclone Zolpidem Phenobarbitone Phentermine Clobazam	Maximum three months' supply with a maximum of up to one month supply per dispensing (no change to the existing arrangement)  Note that as a 'safety medicine' in the Pharmaceutical Schedule the non-opioid Class C medicines are dispensed in one-month quantities without exemption
Class B non-opioids attention deficit hyperactivity disorder (ADHD) controlled drug medicines	Dexamfetamine sulfate Methylphenidate hydrochloride Lisdexamfetamine  Note Restrictions under Regulation 22 of the Misuse of Drugs Regulations	Maximum three months' supply with a maximum of up to one month supply per dispensing (no change to the existing arrangement)  Note one month maximum dispensing also remains
Prescribers	Medical practitioners Nurse practitioners Dentists Midwives Designated nurse prescribers Designated pharmacist prescribers	The changes above have been aligned for all Prescribers of controlled drugs. This does not change the specific controlled drugs that certain Prescribers are authorised to prescribe.

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<sup>&</sup>lt;sup>19</sup> OST providers are subject to separate authorisations and restrictions in accordance with the OST guidelines.

#### 6.1.4. Definitions

A controlled drug Prescriber means a Medical Practitioner, a Dentist, a Nurse Practitioner, a Midwife, a Designated Prescriber Nurse, a Designated Prescriber Pharmacist, or a Veterinarian who is registered in New Zealand in that profession **and** who holds a current annual practising certificate under the HPCA Act 2003.

A controlled drug Prescription Form written by overseas Prescribers who are not registered to practice in New Zealand are not legal.

When a Provider is unsure of the registration or signature of the Prescriber, the Provider should check the Prescriber's annual practising certificate or check the Prescriber's registration with the corresponding Regulatory Body.

#### 6.1.5. Summary of Prescribing Rules for Controlled Drugs

Legislation: Refer to: www.legislation.govt.nz.

Professional Group	Misuse of Drugs Act (1975) and Regulations (1977)	Repeats	Restrictions on Dispensing
Medical Practitioners and Nurse Practitioners (Authorised Prescriber)	For the medical treatment of a patient under their care: <sup>20</sup>	May authorise multiple repeats, eg, daily or at such other regular intervals, as the prescriber considers necessary. <sup>21</sup> The total quantity per repeat must not exceed one month.	Class B: Not more than <b>seven days</b> after the date of prescription. <sup>22</sup> Maximum quantity for any Dispensing is one-month supply. <sup>23</sup> Class C: First Dispensed within six months of prescribing. <sup>24</sup>
Dentists (an Authorised Prescriber)	For the dental treatment of a patient under their care: Every controlled drug Prescription Form must state 'for dental treatment only'. <sup>25</sup> Note: Not authorised to order telephone prescriptions for controlled drugs. <sup>26</sup>	May authorise repeats. The total quantity per repeat must not exceed one month.	Class B: Not more than <b>seven days</b> after the date of prescription. <sup>27</sup> Class C: First Dispensed within six months of prescribing. <sup>24</sup>

<sup>&</sup>lt;sup>21</sup> Misuse of Drugs Regulations 1977, reg 31A(7)

<sup>&</sup>lt;sup>22</sup> Misuse of Drugs Regulations 1977, reg 31(1)(b)

<sup>&</sup>lt;sup>23</sup> Misuse of Drugs Regulations 1977, reg 31A(2)

Misuse of Drugs Regulations 1977, reg 31(1)(c)

<sup>&</sup>lt;sup>25</sup> Misuse of Drugs Regulations 1977, reg 29(4)(g)

<sup>&</sup>lt;sup>26</sup> Misuse of Drugs Regulations 1977, reg 34(6)

<sup>&</sup>lt;sup>27</sup> Misuse of Drugs Regulations 1977, reg 31(1)(a)

Professional Group	Misuse of Drugs Act (1975) and Regulations (1977)	Repeats	Restrictions on Dispensing
Midwives (an Authorised Prescriber)	For the treatment of a patient under their care. <sup>28</sup> Midwives may <b>only</b> prescribe tramadol, pethidine, morphine, or fentanyl. <sup>29</sup> Therefore, the maximum period of supply is one month. <sup>30</sup> Every controlled drug Prescription Form must state 'for midwifery use only'. <sup>31</sup> Midwives may <b>not</b> prescribe any other controlled drugs, such as codeine and benzodiazepines.	May authorise repeats. The total quantity per repeat must not exceed one month.	Class B and C: First Dispensed no more than four days after the date of the prescription. <sup>32</sup> Repeats must be Dispensed no more than four days after the previous supply is exhausted.
Pharmacist Prescribers (a Designated Prescriber)	For the treatment of a patient under their care. <sup>33</sup> Limited to drugs listed in the Misuse of Drugs Regulations 1977, Schedule 1B. <sup>34</sup>	May authorise repeats. The total quantity per repeat must not exceed one month.	Class B: First Dispensed not more than seven days after the date of prescription.  Class C: First Dispensed within six months of prescribing. <sup>24</sup>
Designated Nurse Prescribers (a Designated Prescriber)	For the treatment of a patient under their care. <sup>35</sup> Limited to drugs listed in the Misuse of Drugs Regulations 1977, Schedule 1A. <sup>36</sup>	May authorise repeats. The total quantity per repeat must not exceed one month.	Class B: First Dispensed not more than seven days after the date of prescription. Note: The Nursing Council of NZ further limits medicines which may be prescribed by Designated Nurse Prescribers to medicines relevant to their practice. <sup>37</sup> The Nursing

<sup>&</sup>lt;sup>28</sup> Misuse of Drugs Regulations 1977, reg 21(5)(a)

Misuse of Drugs Regulations 1977, reg 21(5)(a)
Misuse of Drugs Regulations 1977, reg 12A(c)
Misuse of Drugs Regulations 1977, reg 31A(6)
Misuse of Drugs Regulations 1977, reg 29(4)(h)
Misuse of Drugs Regulations 1977, reg 31A(5)(a)
Misuse of Drugs Regulations 1977, reg 21(5)(a)
Misuse of Drugs Regulations 1977, reg 21(4)(a)
Misuse of Drugs Regulations 1977, reg 21(4)(a)
Misuse of Drugs Regulations 1977, reg 12A(1)(a)
Misuse of Drugs Regulations 1977, reg 12A(1)(a)

Nursing Council of NZ: Registered Nurse Prescribing

Professional Group	Misuse of Drugs Act (1975) and Regulations (1977)	Repeats	Restrictions on Dispensing
			Council provides separate lists for those practising in the scopes of Primary and specialty health teams, diabetes health, and community health and ECP. For more information see:  Registered Nurse Prescribing  Class C: First Dispensed within six months of prescribing. <sup>24</sup>
Veterinarians	For the treatment of an animal under their care: <sup>38</sup> Maximum period of supply is one month. <sup>39</sup> Every Prescription Form must state 'For animal treatment only. <sup>40</sup>	May <b>NOT</b> authorise any repeats. <sup>41</sup>	Veterinarians are not required to prescribe controlled drugs on a triplicate Prescription Form.  No veterinary prescriptions are funded.

Note: Optometrists have no prescribing rights for controlled drugs.

Misuse of Drugs Regulations 1977, reg 21(5C)
 Misuse of Drugs Regulations 1977, reg 31(1)(d)
 Misuse of Drugs Regulations 1977, reg 29(4)(i)
 Misuse of Drugs Regulations 1977, reg 31A(7)

## 6.2. Legal Requirements of a Controlled Drug Prescription Form

The following list refers to Class A and Class B controlled drugs plus specified Class C controlled drugs when they are intended for human use. Specified Class C controlled drugs include amobarbital, amobarbital sodium, buprenorphine, butobarbitone, glutethimide, ketamine, secobarbital, or secobarbital sodium either in combination or not. These products do not fall under this category if they are combined with another substance not in Schedule 3, Part 4 (1) of the Misuse of Drugs Act 1975.

For example, a Prescription Form for buprenorphine on its own must meet all the requirements specified on the list, whereas a Prescription Form for buprenorphine plus naloxone does not need to meet the requirements on the list.

There are two physical types of controlled drug Prescription Forms, a barcoded NZePS controlled drug Prescription Form and a hard copy paper triplicate Prescription Form.

# Legal and Contractual Requirements for Class A, B, and specified Class C Controlled Drug Prescriptions

A controlled drug Prescription Form can be either:

- An H572 or H572M triplicate Prescription Form provided by the Director General of Health and completed in the handwriting of the controlled drug Prescriber with the Prescriber signature in their own handwriting; or
- An NZePS controlled drug Prescription Form electronically generated by a system approved by the Director General of Health containing a barcode which is scanned (or the barcode number is manually entered if the scan fails). See notes specific to NZePS.

The information supplied on either form of the controlled drug Prescription Form must be legible and indelible (it cannot be written in pencil or printed on a removable sticker) and must include all of the following:

- Date on which it was signed or generated by the Prescriber in the case of NZePS prescriptions
- Prescriber details, which must be set out or stamped with the Prescriber's full name on all copies in the case of a H572 or H572M triplicate Prescription Form
- Prescriber's physical work address, or postal address for those who do not have a place of work
- Prescriber's telephone number
- Patient details of which the controlled drug is intended to be administered, which includes:
- Surname and each given name of the patient
- Physical address of the patient
- Patient's Date of Birth and set out in words the age in years and months of that person if the patient is under the age of 12 years
- Name of the controlled drug in full or abbreviated only using British Pharmacopoeia (BP), British Pharmaceutical Codex (BPC) or other recognised titles
- · Strength of the controlled drug
- Total amount of the controlled drug to be Dispensed

- The number of occasions on which the controlled drug may be Dispensed (where appropriate)
- Dose and frequency of the dose for internal controlled drugs
- Method and frequency of use for external controlled drugs
- Where the controlled drug Prescription Form has an unusual dose, or what may be regarded as a dangerous dose, the dose should be underlined and initialled by the Prescriber. Any alterations must be signed by the Prescriber
- For methadone prescribed by a Prescriber who is authorised by the Ministry of Health
  or its delegate or works in a place for the time being specified by the Minister of Health
  under the Misuse of Drug Act 1975, the Prescription Form must be legibly and indelibly
  written, or in a form approved from time to time by the Director General of Health
  (including electronically generated forms from an approved system).

The following are the legal requirements that all must be added by the Pharmacy to all three copies of the triplicate form or the NZePS controlled drug Prescription Form:

- Name and address of the proprietor of the business at which the controlled drug Prescription Form is Dispensed
- Each item Annotated with the:
  - o date of Dispensing on each occasion
  - o its unique identifying number on each occasion
  - the quantity of the controlled drug Dispensed on each occasion
  - o strength of the controlled drug Dispensed on each occasion
  - identity of the individual Dispensing each item
  - initials of the checking Pharmacist on each occasion for completeness and accuracy.

Telephoned Prescription Forms for controlled drugs are permitted from Medical Practitioners, Nurse Practitioners, Midwives, Designated Prescriber Pharmacists, and Designated Prescriber Nurses (when prescribing within their scope) personally known to the Pharmacist. However, no repeat of a telephone or faxed controlled drug Prescription Form is permitted until the original controlled drug Prescription Form is received by the Pharmacy.

Dentists and Veterinarians are not authorised to prescribe controlled drugs verbally or by telephone.<sup>42</sup>

The original of an electronically transmitted NZePS controlled drug Prescription Form is not required but the barcode/SCID must be used to dispense the prescription.

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<sup>&</sup>lt;sup>42</sup> Misuse of Drugs Regulations 1977, reg 34(6)

#### 6.2.1. Notes specific to NZePS

- A NZePS controlled drug Prescription Form is not a legal controlled drug Prescription Form until the barcoded Prescription Form has been downloaded from the electronic Prescription Form repository (the NZePS broker).
- If a BUS002 error is generated, the prescription has failed to download as the eprescription is temporarily delayed. The prescription must be linked to the prescription barcode and dispensed manually. More information on the BUS002 error is available Advisory Notice 1 / BUS002 error message.
- For all other errors types the controlled drug may not be Dispensed if the Prescription Form is unable to be downloaded.
- Any Provider can Dispense a barcoded controlled drug Prescription Form if the above criteria are met. It is not the responsibility of the Provider to have to check if the Prescriber is from a practice with Manatū Hauora approval to issue controlled drug barcode Prescription Forms.
- Prescribers are not able to hand write any amendments or alter any barcoded Prescription Form (ie, controlled drug or non-controlled drug barcoded Prescription Form) as the barcoded Prescription Form must match the NZePS record. If a Prescription Form needs a Prescriber's Endorsement, it must be referred back to the Prescriber to be amended and a new (amended) barcoded Prescription Form issued. Any Pharmacist annotations that do not require endorsement by a Prescriber can be annotated on the Prescription Form and the NZePS record.
- Approved barcoded NZePS prescriptions received via a secure message must be printed in the Pharmacy to capture the Pharmacist's annotations.
- Multiple controlled drug items can be printed on the same Prescription Form. If there are too many controlled drug items to fit on one page, then multiple pages will be printed. All pages will have the same barcode number and are treated as one Prescription Form.

# 6.2.2. Methadone and Buprenorphine with Naloxone Prescriptions for Opioid Dependent Clients

Methadone and buprenorphine with naloxone Prescription Forms for opioid dependent clients can only be written by any of the following:

- medical practitioners specified in a notice in the Gazette as able to prescribe controlled drugs for opioid substitution treatment, in the place specified in the Gazette notice
- medical practitioners approved by the specified medical practitioner
- other specified Prescribers working in approved addiction clinics or hospital care institutions.<sup>43</sup>

Approved clinics can use a different controlled drug Prescription Form for methadone (H572M), including electronically generated forms from a Director General of Health approved system, such as a barcoded NZePS controlled drug Prescription Form. Prescriptions for buprenorphine with naloxone are not required to be on a controlled drug Prescription Form (also refer to 6.2).

Nurse Practitioners, in accordance with the relevant Schedules attached to the Misuse of Drugs Regulations 1977, Designated Prescriber Nurses (Schedule 1), Designated Prescriber Pharmacists (Schedule 2), and Midwives (Schedule 3) can prescribe these Pharmaceuticals if listed on their relevant Schedules.

<sup>&</sup>lt;sup>43</sup> Misuse of Drugs Act 1975, s 24

## 6.2.3. Prescribers Address Requirements

The Prescriber's address can be stamped on the triplicate paper controlled drug Prescription Form but must be stamped on all three copies.<sup>44</sup>

# 6.2.4. Repeat Dispensing of Controlled Drug Prescription Forms

The restrictions for repeat dispensing of controlled drugs are shown in Section 6.1 above and are clarified below:

Repeats are required to be collected prior to the expiry of the prescription, which is one month from when the prescription is initially dispensed for Class, A, B and C opioid controlled drugs and three months from when the prescription is initially dispensed for Class B and C non-opioid controlled drugs. The exception to this rule is for Midwife prescriptions for both Class B and C controlled drugs, where the repeat must be dispensed no more than four days after the previous supply is exhausted. There is no need to reduce the supply on the final quantity dispensed.

If, for special reasons relating to the protection of the Service User or for limiting the quantity of any controlled drug in the possession of the Service User, the controlled drug Prescriber (not a Dentist or Veterinarian) may direct daily Dispensing or other Dispensing intervals, and the controlled drug may be supplied on that number of occasions and not more frequently than the intervals indicated. The total quantity covered by such Prescription Form cannot exceed three months.<sup>45</sup>

# 6.2.5. Controlled Drugs with Prescribing Restrictions<sup>46</sup>

Pseudoephedrine, ephedrine, methylphenidate and dexamfetamine are scheduled as Class B2 controlled drugs and Ministerial Approval is required before these Pharmaceuticals can be prescribed or supplied. Listed below are the circumstances under which approval are considered met. Further information can be found on the Medsafe website: Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977.

#### 6.2.5.1 Pseudoephedrine and Ephedrine

Prescriptions must only be written by medical practitioners registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance Act 2003.

No other Prescriber including Veterinarians may write a Prescription Form for ephedrine or pseudoephedrine unless they have a specific written authority from the Director General of Health.

# 6.2.5.2 Prescribing Dexamfetamine

Prescriptions of dexamfetamine may only be written by:

 Medical Practitioners with a vocational scope of practice of Paediatrics or Psychiatry, registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance Act 2003, for the treatment

<sup>44</sup> Misuse of Drugs Regulations 1977, reg 29(4)(d)

<sup>&</sup>lt;sup>45</sup> Misuse of Drugs Regulations 1977, reg 31A(7)

<sup>46</sup> www.medsafe.govt.nz/profs/riss/restrict.asp

of Attention Deficit and Hyperactivity Disorder (ADHD);

or

 Medical Practitioners with a vocational scope of practice of Internal Medicine, registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance Act 2003, for the treatment of narcolepsy;

or

 any other Medical Practitioner registered with the Medical Council of New Zealand ('registered Medical Practitioner'), or Nurse Practitioner practising within their area of practice, when acting on the written recommendation of one of the vocationally registered Medical Practitioners described above, for the conditions specified.

### 6.2.5.3 Prescribing Methylphenidate

Prescriptions of methylphenidate may only be written by:

 Medical Practitioners with a vocational scope of practice of Paediatrics or Psychiatry, registered with the Medical Council of New Zealand under the Health Practitioners Competence Assurance (HPCA) Act 2003, for the treatment of Attention Deficit and Hyperactivity Disorder (ADHD);

or

 Medical Practitioners with a vocational scope of practice of Internal Medicine, registered with the Medical Council of New Zealand under the HPCA Act 2003, for the treatment of narcolepsy;

or

- Any other Medical Practitioner registered with the Medical Council of New Zealand ('registered Medical Practitioner'), or Nurse Practitioner practising within their area of practice, when acting on the written recommendation of one of the vocationally registered Medical Practitioners described above, for the conditions specified.
- <u>For Palliative Care</u>: Only Medical Practitioners with a vocational scope of Palliative
  Medicine, registered with the Medical Council of New Zealand under the HPCA Act 2003,
  or a Nurse Practitioner practising within their area of practice, when acting on the written
  recommendation of one of the vocationally registered Medical Practitioners described
  above, for use of palliative care treatment.

No other Prescriber type or non-New Zealand registered Medical Practitioners may legally prescribe or recommend methylphenidate or dexamfetamine.

Information of the vocational scope of practice for Medical Practitioners can be found on the Medical Council of New Zealand website.

### 6.2.5.4 Dispensing Methylphenidate or Dexamfetamine

A Prescription Form written by a GP who does not have the appropriate vocational scope for methylphenidate or dexamfetamine prescribing **must be endorsed** by a New Zealand registered Medical Practitioner who has the appropriate vocational scope to prescribe these controlled drugs. Prescription Forms without this Endorsement cannot legally be Dispensed.

A Provider can Annotate the controlled drug Prescription Form with the appropriate vocationally registered Medical Practitioner's name if they have verification of the correct

information either from the Prescriber themselves or from the patient's medication record from a previous Prescription Form. Providers are permitted to accept the Endorsements provided on a Prescription Form at 'face value' unless there is reason to believe the Endorsements are incorrect.

The funding of methylphenidate and dexamfetamine is controlled through the Pharmac Pharmaceutical Schedule by the provision of a Special Authority number. A valid Special Authority number only means that Service User is eligible for funding. Medical Practitioners prescribing under written Endorsement from an appropriate vocationally registered New Zealand Medical Practitioner must still Endorse the Prescription Form with that Practitioner's name, even when a Special Authority number is provided. This is for the Prescription Form to be legal. For clarity, a non-subsidised Prescription for methylphenidate and dexamfetamine (one without a Special Authority number) must still be Endorsed with the vocationally New Zealand registered Practitioner's name.

# 6.3. Labelling Requirements<sup>47</sup>

The following must all be on the label for a controlled drug:

- a unique identification number
- name of Service User
- name and address of the Provider
- date of Dispensing
- general nature of the Pharmaceutical
- the name and strength of the Pharmaceutical
- the dose and frequency of dose for an internal Pharmaceutical, or the directions for use for an external Pharmaceutical.

For the treatment of an animal, the label must also contain the following:

- the name of the person in charge of the animal
- the words 'Not for human use' or 'For animal use only'.

# **6.4.** Completed Controlled Drug Prescriptions Forms

On the completion of all Dispensings from an approved triplicate paper controlled drug Prescription Form:

- the top copy (white) must be retained in the Pharmacy for four years<sup>48</sup>
- the second copy (yellow) and third copy (red) are filed in the bundle of prescriptions on the date of initial Dispensing or the bundle of prescriptions on the date of the final Dispensing. Whichever filing order system is chosen, filing must be consistent.
- if the second and third copies are filed on the day of the final Dispensing and a Service
  User does not collect the final repeat Dispensing, then the Pharmacy is required to refile
  the second and third copies of the controlled drug Prescription Form on the date of the
  next most recent Dispensing, as reflected in the date of Dispensing in the electronic
  claim.

<sup>&</sup>lt;sup>47</sup> Misuse of Drugs Regulations 1977, reg 25(4)

<sup>&</sup>lt;sup>48</sup> Misuse of Drugs Regulations 1977, reg 33(2)

On the completion of all Dispensings from an approved barcoded NZePS controlled drug Prescription Form:

- the original printed Pharmacy-annotated barcoded NZePS controlled drug Prescription Form is to be retained in the Pharmacy for four years.
- must include all the Dispensing dates and Annotations made by the Provider.

For the purposes of the Batch submission:

- the Provider is required to make a certified true copy of the original printed, barcoded NZePS controlled drug Prescription Form.
- the certified true copy (that must include all the Dispensing dates and Annotations made by the Provider) is filed in the Batch according to the last date of Dispensing.

# 7. Subsidy Requirements

To be eligible to receive subsidised Pharmaceuticals the following requirements must be met.

# 7.1. Patient Eligibility

In accordance with the Health and Disability Services Eligibility Direction 2011 only eligible people are entitled to receive subsidies for Pharmaceuticals in New Zealand. A Claim should not be made if the Prescription Form identifies the patient as ineligible.

The Provider is entitled to rely on the Prescriber's information about eligibility unless the Provider knows it to be incorrect. Where a Prescription Form is not coded, the person's eligibility can be checked with the Prescriber, or with the Service User in accordance with guidelines published by Health NZ (if any).

The following people are eligible for subsidised Pharmaceuticals in New Zealand:

- New Zealand citizens (including those from the Cook Islands, Niue, or Tokelau)
- New Zealand permanent residents
- an Australian citizen or permanent resident who has lived, or intends to live, in New Zealand for two years or more
- work visa holder eligible to be in New Zealand for two years or more
- people aged 17 years or younger, in the care and control of an eligible parent, legal guardian, adopting parent, or person applying to be their legal guardian
- interim visa holders
- New Zealand Aid Programme student receiving Official Development Assistance (ODA) funding
- Commonwealth scholarship students
- foreign language teaching assistants
- refugees and protected persons, applicants and appellants for refugee and protection status, and victims of people trafficking offences.
- For more information on eligibility for publicly funded health services, see <a href="here">here</a>.

# 7.1.1. Reciprocal Health Agreements

#### **Australia**

An Australian resident is eligible if they are temporarily visiting New Zealand for up to two years and in the opinion of the provider of medical treatment it is deemed that they need immediately necessary medical treatment while in New Zealand or the Medical Practitioner considers that treatment is clinically necessary for the diagnosis, alleviation, or care of the condition requiring attention.

#### **United Kingdom**

A United Kingdom (UK) citizen (passport holder) or person with a European Union (EU) passport with UK citizenship is eligible for treatment (medical, hospital and related) on the same basis as a New Zealand citizen if they:

 are an ordinarily resident in the UK (including England, Scotland, Wales, Northern Ireland, the Isle of Man, the Island of Jersey, and the Bailiwick of Guernsey, comprising the islands of Guernsey, Alderney, Herm, Jethou and Sark)

and

 are on a temporary stay in New Zealand (a temporary stay would be any stay that was not permanent, and to become permanent they would need to have a residence visa or NZ citizenship) and requires medical treatment which in the opinion of a medical practitioner (or dentist for people 19 years or younger)

and

 need prompt attention and

 require treatment for a condition that arose after arrival into New Zealand, or became, or without treatment would have become, acutely exacerbated after arrival.

The same prescription Co-payment rules that apply to New Zealanders also apply to Australian and UK citizens.<sup>49</sup>

## 7.1.2. Accidents and Personal Injury

People needing treatment for personal injuries can be covered by ACC regardless of their residential status. Note that this includes tourists and overseas students, even if they are not eligible for any other funded health services. The person needs to complete a claim form at the time of treatment, and the health service Provider decides whether a claim should be lodged. The claim must be accepted by ACC before they will contribute to on-going funding.

Prescriptions for ACC Service Users are deemed to be from Approved Providers.

#### 7.1.3. Other Circumstances

In some circumstances which differ from those discussed above, eligibility for a limited range of publicly funded health services may apply.

For details relating to other circumstances named below, see here:

- accidents and personal injuries
- Australian residents
- · compulsory health services
- emergency services
- · foreign diplomats and their family
- immunisations and Well Child
- infectious diseases
- maternity services
- pregnant women infected with HIV
- prisoners
- UK citizens

<sup>&</sup>lt;sup>49</sup> Eligibility for publicly funded health services

#### 7.1.4. NHI Number

The National Health Index number (NHI number) is a unique identifier assigned to every person who uses health and disability support services in New Zealand. A person's NHI number is stored on the National Health Index along with that person's demographic details.

A person does not need to be a New Zealand resident to be entitled to an NHI number.<sup>50</sup> The person will be registered as a non-resident until documentation is sighted by the person applying for the NHI number to prove the person's residency status.

Having an NHI does **not** mean the person is eligible for subsidised medical and pharmaceutical benefits (refer to the Definition of Eligible Person).

The NHI number is a mandatory field when registering a Service User for the following services: ARRC, CRC, LTC, CPAMS, CDOS, or Clozapine.

Where a Prescription Form is presented with an NHI number which is different from the NHI number already held for that Service User, then the NHI number on the presented Prescription Form should be used unless it is known to be incorrect, in which case the correct NHI number for that Service User should be used.<sup>51</sup>

An NHI number is not needed if the person is not eligible to receive subsidised Pharmaceuticals.

#### 7.1.5. Date of Birth

Date of Birth is a mandatory field when registering a Service User for ARRC, CRC Services and the LTC Service.

Date of Birth is a mandatory legal requirement on Prescription Forms for children for:

- prescription medicines for a child under the age of 13 years<sup>52</sup>
- Class B controlled drugs the Date of Birth and age of a child under 12 years must be set out in years and months.<sup>53</sup>

# 7.1.6. Aged-Related Residential Care

Before Dispensing to an ARRC Service User, the Provider must check that the residential care facility in which the Service User resides is listed as a certified provider by the Ministry of Health on the following website: Certified rest home providers.

If a Service User is a permanent resident of the facility, then the Dispensing must be recorded as such (for example tick the ARRC flag in the PhMS).

# 7.1.7. Community Residential Care

The following details are required when registering a Service User for CRC Services:

- Service User details: Name, NHI, Date of Birth
- · CRC Provider details: Name, Address.

<sup>&</sup>lt;sup>50</sup> National Health Index

<sup>51</sup> ICPSA Clause D.18(2)

<sup>&</sup>lt;sup>52</sup> Medicines Regulations 1984, reg 41(d)(2)

<sup>&</sup>lt;sup>53</sup> Misuse of Drugs Regulations 1977, reg 29(4)(f)

# 7.2. Approved Provider for A4/J4 Prescriptions

The Prescriber must be an 'Approved Provider' for the Service User to receive lower Copayments on Prescription Items (refer to section 10.2 of this Manual).

It does not include:

- prescribers providing completely privately funded services
- prescribers providing services under a Section 94 Notice alone that are not solely publicly funded (for example a specialist under a Maternity Notice, a practitioner or specialist under the General Practitioners Notice or a Specialist Notice).

#### 7.3. Prescriber Details

In every Claim, the Provider must include the Prescriber's health group code (for example NZMC) and registration number (Prescriber Identifier) if it is either listed on the Prescription Form or otherwise known to the Provider, for example:

- Medical Council of New Zealand registration number
- Nursing Council of New Zealand registration number
- Midwifery Council of New Zealand registration number
- Dental Council of New Zealand person ID number
- Pharmacy Council of New Zealand registration number
- Other registration number, as applicable.

The Prescriber identifier must match the identity of the Prescriber signing the Prescription Form. This information is also used by registration authorities who are required to monitor and audit the prescribing behaviour of their members.

Any Claim (excluding supply orders and brand switch fees) submitted with less than 90% of health professional group codes and registration numbers will be rejected for payment.

If a Prescription Form is received without a Prescriber identifier and the Provider is unable to determine the correct identifier of the Prescriber, to ensure that the Prescriber is eligible to prescribe the Pharmaceuticals, the registration number can be obtained from either the Prescriber directly or their professional organisation.

### 7.4. Health Entitlement Cards

# 7.4.1. Community Services Cards

Community Services Cards (CSCs) are available to provide targeted subsidies to selected Service Users to access Health and Disability Services, in particular Pharmaceuticals and General Practice services.

If a person qualifies for a CSC, they will receive an individual card. If the person is married (that is, legally married or living with someone in a relationship which is similar to marriage) both Service Users will have their own card. Either card can be used to cover dependent children.

People who qualify for NZ superannuation or a Veteran's Card and are eligible for a CSC will have the CSC entitlement noted on their SuperGold or Veteran's Card.

More information on the SuperGold Card may be found here: <u>Discover benefits with SuperGold</u>. For CSC verification, call 0800 855 066.

# 7.4.2. High Use Health Cards

High Use Health Card (HUHC) applications are made by a Medical Practitioner on behalf of their patient. HUHCs are for those people who visit their doctor on 12 occasions within a year for an on-going medical condition(s). There are specific requirements necessary for eligibility. See <u>High Use Health Card (HUHC)</u>.

Note: A HUHC is issued to an individual and not a family.

#### 7.4.3. Veterans

New Zealand Veterans can apply for a Disablement Pension which assists in the funding of pharmacy and medical expenses for disabilities that have been accepted as being attributable to, or aggravated by, their service.

Veterans with a Disability Pension are issued with a Treatment Card or treatment letter, which lists the disabilities that Veterans' Affairs will fund (any Pharmaceuticals provided for a disability not listed on the Treatment Card, will not be paid for).

The funding for accepted treatment may cover:

- any Co-payment for items on a Prescription Form
- premiums for non-fully subsidised Pharmaceuticals
- any non-subsidised Pharmaceutical costs (note: some non-subsidised Pharmaceuticals will require Case Manager approval)
- blister packaging.

If the Provider is unsure if a new Pharmaceutical or service is covered, they should contact Veterans' Affairs directly on 0800 483 8372, <u>Veterans Affairs Contact Us</u>, or <u>veterans@nzdf.mil.nz</u>

#### Veterans' Affairs procedures

#### If you're a doctor or pharmacy in NZ

Green Cross Health process invoices on our behalf for services provided by doctors and pharmacies within NZ.

You need to send your invoice details to Green Cross in a specific format. This helps ensure you get paid correctly and on time. If you haven't sent an invoice to Green Cross Health before, you should get in touch with them to discuss their requirements.

- Pharmacy veteranpharmacy@greencrosshealth.co.nz
- Medical veteranmedical@greencrosshealth.co.nz

The invoice must include the following information:

- the Veteran's name
- the Veteran's ID Number
- a copy of their Prescription Form Receipt.

If this is the first invoice sent to Veterans' Affairs, please include the Provider's verified bank details.

X

# 7.4.4. Prescription (Pharmaceutical) Subsidy Cards Patient Charges links

Claims, provider payments and entitlements

### **Definition related to Prescription Subsidy Cards**

As per the Health Entitlement Cards Regulations, 1993: Part 3 – Pharmaceutical Subsidy Cards:

A Family Unit means – as described in Section 22(1):

- a married or partnered couple with one or more dependent children
- a married or partnered couple with no dependent children
- one person with one or more dependent children
- one person who is not a member of a family unit described in paragraphs (a) to (c) of this definition.

Married or partnered means:

- being married to a spouse (subject to regulations 3(b) and 22(2)), or
- being in a civil union with a civil union partner, or
- any man and woman who, not being legally married or in a civil union, who have entered into a relationship in the nature of marriage.

#### Child means:

- A single person under the age of 18 years, other than a person who is:
  - o aged 16 or 17 years, and
  - o is financially independent

Dependent Child, from the Social Security Act 1964 Part 1 – Monetary benefits (Section 3(1)) means:

- Dependent child, in relation to any person, means a child:
  - o whose care is primarily the responsibility of that person, and
  - o who is being maintained as a member of that person's family, and
  - o who is financially dependent on that person, and
  - who is not a child in respect of whom payments are being made under Section 363 of the Children, Young Persons, and Their Families Act 1989.

In a shared care arrangement, a child can be a member of more than one Family Unit.

# 7.4.5. No Co-payments

Service Users must not be charged any Co-payments in the following situations and therefore do not count towards the PSC item count (refer to clause D.5 Co-payments in the ICPSA):

- subsidised Class B controlled drugs, except methylphenidate hydrochloride or dexamfetamine sulphate
- subsidised buprenorphine with naloxone sublingual tablets
- children aged under 14 years
- community services card (CSC) holders and their dependents
- adults aged 65 years and over
- Service Users enrolled with the Hokianga Health Enterprise Trust (HHET)
- antituberculotic (TB) items on a Prescription Form
- antileprotic items on a Prescription Form
- Service Users receiving antibiotics through the Rheumatic Fever Prevention Programme (RFPP) Sore Throat Management Service
- Repeat supplies if the full Co-payment (if any) has been made on previous Dispensings
- items on a Prescription Form that are not subsidised
- if the Service User specifically requests a change to a brand which is not listed in the Pharmaceutical Schedule where there is an alternative subsidised brand available
- Pharmaceuticals for approved Templeton Service Users who were residents at the Templeton Centre, Christchurch at the time of its closure
- any other Pharmaceuticals listed from time to time in the Pharmaceutical Schedule as having no Co-payment payable
- a Replacement Dispensing due to a recall of a subsidised Pharmaceutical.

# 7.4.6. Procedure for Issuing a Pharmaceutical Subsidy Card

The Provider must ensure that the PhMS maintains accurate links to the items on a Prescription Form of the family unit members, where known. These links may be audited.

- The PSC period is from 1 February in any year until 31 January of the next year.
- Once a family unit has received 20 initial Dispensings of Subsidised Pharmaceuticals that have attracted a Co-payment in the year commencing 1 February to 31 January, a PSC card endorsed with an identifying number can then be issued to the family by the Provider.
- The 20 initial Dispensings recorded may have been Dispensed by any number of Providers. Pharmaceuticals dispensed from another Provider can be checked on the Health NZ Prescription Subsidy Look-up System. If this is unavailable, Providers should verify Dispensings by a printout or receipt from the other Provider.
- All Service Users noted on the PSC are exempt from any Co-payment charges until that card expires.

#### When issuing a PSC:

- List the names of all eligible family members and the names of the issuing Pharmacist and contracted Provider (Pharmacy) on the card. The card must be endorsed with the pharmaceutical year for which it has been issued and an identifying number (currently both are pre-printed on PSCs supplied by the Ministry of Health).
- A record of the number of initial items from all involved Providers should be retained by the issuing Provider - the Ministry of Health Prescription Subsidy Look-up system can provide this.
- A duplicate card should not be issued under ordinary circumstances.
- A photocopy of the PSC can be used to inform another Provider of the family member's entitlement such as in the case of a child at a boarding school.

A member of a family unit can request to see a copy of the number of initial items Dispensed on the Family Prescription Record of the PSC.

The Provider will be provided with a supply of blank PSCs for each period by Blue Star Group (NZ) Ltd on behalf of Ministry of Health. Additional supplies are available from <u>Te Whatu Ora Sector Services Stationery Portal – Blue Star</u>. Username or Log in for this system is 'MOHP' followed by the Provider's claimant number.

## 7.4.7. Items on Prescription Form Count Service

The Ministry of Health provides a basic search service to assist Providers in determining eligibility for a PSC. The search service will enable a Provider to obtain a count of qualifying Dispensings for one or more NHIs. It will include items Dispensed by a Provider other than their own. The service will not adjudicate regarding the entitlement to a PSC for a person or family. Providers will assess entitlement as they do currently, and PSCs will continue to be issued. The PSC number will be available on the search results for an NHI where the PSC number has been submitted electronically with the Batch Claim.

The PSC Search Service is provided by the Ministry of Health, not the PhMS vendor. The PhMS vendors are not responsible for the count information by the service, nor the PSC scheme.

Contact Sector Operations with any queries regarding the count service.

### 7.4.8. The Dispensing Date

The date of Dispensing must be recorded on all Prescriptions Forms for which a subsidy is claimed and must be the same as, or later than, the prescribing date. This record must be stamped, legible, and hand-written or recorded on the third-part label. The date of Dispensing on the Prescription Form, including that on the third- part label, must be the same as the date of Dispensing in the computer record.

There is only one consistently recorded date in the current Dispensing process - the date on which the items on a Prescription Form are entered into the PhMS.

A Claim for payment cannot be made until the Dispensing process is complete. The process is complete when the Provider provides the Service User or their caregiver, or a Prescriber, with an item in accordance with the Prescription Form or order. It includes all the steps that occur from receipt of the Prescription Form or order at the Pharmacy to the item being collected by, or delivered to, the Service User or their caregiver or Prescriber.

Uncollected Pharmaceuticals must be deferred and not included in any Claim.

The Provider must not re-dispense any Pharmaceutical for which a Claim has been submitted.

# 7.5. Deferred item on a Prescription Form

A deferred item on a Prescription Form is an item which has been fully processed through the PhMS and which may or may not have been Dispensed to the Service User yet. A deferred item may **not** be Claimed (see potential reasons below) and involves marking an item as deferred in the Pharmacy PhMS to exclude it from the current Claim file.

Potential reasons for deferring an item include:

- Items on a Prescription Form may only be claimed for payment once they have been Dispensed to the Service User (clause D.26 in the ICPSA) so if the Service User has not yet collected their Pharmaceutical the Provider is not able to claim for it.
- Items may also be deferred for administrative reasons (such as waiting for the return of a signed Prescription Form following a telephone order or waiting for the original of a faxed Prescription Form) and the Claim may not be made until the Prescription Form is valid. The deferred item is excluded from any Claims submitted to Health NZ for payment until the Prescription Form is validated.

# 7.6. Fax/telephone/email/pharmacy-generated prescriptions

In October 2022 the Director-General of Health signed an authorisation. that prescriptions not signed personally by a Prescriber with their usual signature are acceptable if they meet certain conditions. This authorisation has been extended. Under the authorisation the following arrangements for faxed, phoned or pharmacy-generated prescriptions apply until 31 October 2027:

- Pharmacies do not need to obtain original copies of non-NZePS faxed/emailed Prescriptions Forms if the following conditions are met:
  - each faxed prescription must otherwise be fully compliant with regulation 41 of the Medicines Regulations 1984, and
  - the prescription must meet all the requirements of the Director General's authorisation (<u>Temporary Exemption for Signatures on Prescriptions without NZePS</u> (<u>without an NZePS barcode</u>) August 2024.

The authorisation **does not** apply for prescriptions containing one or more Class A, B, or some C controlled drugs (except Class C exempt or partially exempt controlled drugs).

Regulation 40A (2) of the Medicines Regulations 1984 states:

'Within 7 days after a communication made by an authorised prescriber or veterinarian to a pharmacist, the authorised prescriber or veterinarian must forward to the pharmacist a written prescription confirming the oral communication'.

A signature on a faxed non-electronic Prescription Form is not acceptable as a legal signature. The original Prescription Form must be obtained, or the Prescriber can indelibly sign the faxed copy.

If the original Prescription Form (or the faxed copy signed by the Prescriber as above) has not been received by the Provider within four weeks of the date of the original Dispensing, reimbursement can be claimed if attempts to obtain the original have been documented on the prescription. However, a valid Prescription Form or Annotated Certified True Copy must be submitted with the Claim Period Batch when it is sent to Health NZ five months after the claim date.

If no signed Prescription Form is submitted with the Batch within five months of the Claim, then the Provider must refund any money previously claimed in respect of this Claim Item by crediting the amount against its next Claim(s).

In circumstances where the Pharmacy is sent the original Prescription Form, filing both copies in the appropriate date of Dispensing bundle is acceptable and best practice, provided the fax copy and original prescription:

- are correctly matched, and
- are securely fastened to one another.

If the prescribing date returned on a signed telephone/faxed Prescription Form is after the date of Dispensing, for the purposes of payment, the signed Prescription Form and the faxed forms must be stapled together, and the date Annotated by the Provider to explain the discrepancy between the prescribing date and the date of Dispensing.

### NRT 'Advice to client' letters (Quitcards)

Printed Quitcards were discontinued from <u>1 October 2024</u> and replaced with 'Advice to client' letters printed by Smokefree Providers.

Community pharmacies that receive the 'Advice to Client' from authorised Smokefree Providers are not required to provide any additional motivational support. The responsibility for the advice and the ongoing oversight of the client continues to be with the Smokefree Provider issuing the written advice.

The 'Advice to Client' letters should be processed at a community pharmacy in the same way as Quitcards were and the prescriber coded as MC99999.

NRT 'Advice to client' letters (Quitcards) are not prescriptions and are not required to be physically signed by a NRT 'Advice to client' letter (Quitcard) provider. They do not meet the requirements of a prescription.<sup>54</sup>

The Director-General Temporary Authorisation for Unsigned Prescriptions August 2024 does not apply to NRT 'Advice to client' letters (Quitcards); however, the Provider is **not** required to obtain the original copy of a NRT 'Advice to client' letter (Quitcard) that has been directly faxed or emailed to the Provider from a Smokefree Provider. Only the annotated copy of the 'Advice to client' letter (Quitcard) is required to be submitted in the Provider's Claim Period Batch.

# 7.7. Medicines for Age-Related Residential Care (ARRC) Community Residential Care (CRC)

In March 2020, in response to the COVID-19 pandemic and national lockdowns, the Ministry of Health introduced a temporary change to the requirement for community pharmacies claiming for medicines dispensed to residents in ARRC/CRC facilities to make it easier and faster for pharmacies to be paid.

This responsibility transferred to Health NZ with the establishment of Health NZ, from 1 July 2022.

This change was made permanent in October 2024.

Pharmacies do not need to match telephone or pharmacy generated prescriptions with a Prescription Form signed by a General Practitioner to claim for the dispensing if the following conditions are met:

• an electronic medication chart is used by the ARRC/CRC facility, the prescriber, and the Pharmacy for the prescribing, dispensing and administration of residents' medicines

<sup>&</sup>lt;sup>54</sup> Medicines Regulations 1984, reg 41(3)(b)

- a telephone or pharmacy generated prescription is generated that matches the medication chart, and
- the telephone or pharmacy generated prescription is attached to the medication chart and is kept and submitted as required by the Integrated Community Pharmacy Services Agreement (ICPSA).

#### 7.8. Endorsements

An Endorsement is text written on a Prescription Form by a Prescriber. The Pharmaceutical Schedule defines these Endorsement requirements, which may vary from time to time.

Where an Endorsement has been altered or added to by the Provider, it must be initialled by the Prescriber, unless the Pharmaceutical Schedule permits the Provider to Annotate Endorsements.

Where an Endorsement is required on a Prescription Form it must be:

- hand-written or computer generated on the Prescription Form by the Prescriber, or
- initialled by the Prescriber (where it is not hand-written or computer generated by the Prescriber, and where it is specified in the Pharmaceutical Schedule), or
- initialled by the Prescriber where it has been altered or added to by the Provider unless the Pharmaceutical Schedule permits the Provider to Annotate the Endorsement themselves.

Where the Specialist's name and/or year of authorisation, Special Authority Number, or NPPA Number are omitted from a Prescription Form, and that information is in the Patient's Medication Record from a previous Prescription Form, provided that it is valid, the Provider can copy the information from the Patient Medication Record and **does not** need to return the Prescription Form to the Prescriber to initial.

# 7.9. Specialist Recommendation

A 'Specialist' for subsidy purposes is defined in the Pharmaceutical Schedule, Rules of the Schedule, Section A, Part 10, Definitions.

Prescription Forms originating from District Hospitals **on District stationery** for 'Specialist' items (that is, Hospital Pharmacy-Specialist) are deemed to have been prescribed by an appropriate Specialist or Authorised Prescriber employed within the hospital, irrespective of the status of the Medical Practitioner or Nurse Practitioner signing the Prescription Form.

Only Prescription Forms written by a Medical Practitioner or Nurse Practitioner in the hospital are eligible for a subsidy under this Pharmaceutical Schedule Rule. Other Prescriber types (such as Midwife, Pharmacist or Dentist) must include the name of the recommending Specialist and year of authorisation for the Service User to receive the corresponding subsidy.

# 7.10. Special Authority

For general information about Special Authorities see: Special Authority.

The Pharmaceutical Schedule specifies 'Special Authority' Pharmaceuticals and their access criteria. 'Special Authority' means that the Community Pharmaceutical is not eligible for subsidy unless it has been Prescribed and Dispensed to a Service User in accordance with all the restrictions and instructions specified for that Pharmaceutical in Sections B to D, and I of the Pharmaceutical Schedule.

Pharmac sets the criteria for Special Authority applications. For queries about criteria:

- call 0800 660 050
- email enquiry@pharmac.govt.nz.

Clinicians submit applications for Special Authorities on behalf of their patients to Sector Operations. If a Special Authority application is approved, this is added to the Claim for payment.

Applications for Special Authorities may be made electronically or by paper.

- Electronic Special Authority is a service available through the Connected Health Information Service.
- Electronic Special Authority applications return a response in seconds.
- Paper Special Authority application forms are processed within 10 working days.

To apply for Special Authority numbers electronically, a Prescriber needs:

- access to Connected Health
- a digital certificate
- a letter of audit.

See: Special Authority.

A Special Authority number entitles Service Users who comply with the relevant criteria to one of the following:

- a subsidy on Pharmaceuticals or Special Foods
- payment using the manufacturer's price, in cases where a premium would otherwise be payable. The entitlement to a full subsidy continues following an increase in price
- a higher subsidy than would be available without a Special Authority, but possibly still
  less than the manufacturer's price. This is known as an alternate subsidy and is
  sometimes linked to the price of cheaper alternate products. Although the entitlement
  may at times be equal to the manufacturer's price, this would not continue following an
  increase in price
- waive a restriction that would otherwise apply, such as a maximum quantity per Prescription Form
- Special Authority approvals are not granted retrospectively. A Special Authority, including a renewal for a previous Special Authority number, is only valid from the date a valid application is received by Sector Operations.

If a three-month item on a Prescription Form is first Dispensed before the Special Authority expiry date, the repeats will be reimbursed even if they are collected after the Special Authority expiry date, unless the Pharmaceutical has been delisted from the Pharmaceutical Schedule.

# 7.11. Obtaining Special Authority Information

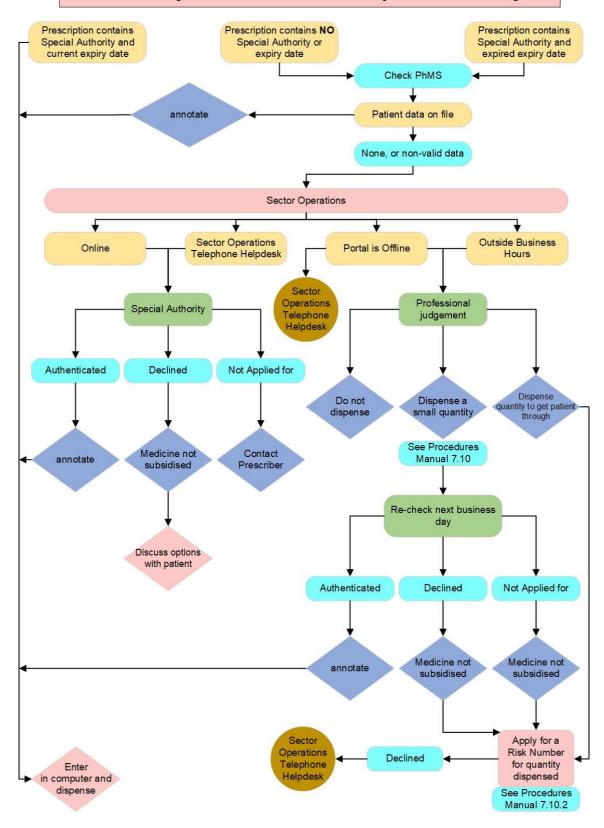
Special Authority information can be obtained from:

- the online Special Authority Look-up System. Online access is available 24 hours per day, seven days per week (unless an outage is notified by email by Sector Operations)
- Sector Operations. Available on 0800 855 066 from 8 am 5 pm Monday to Friday or email onlinehelpdesk@health.govt.nz

 when calling Sector Operations, before any information will be given, the Provider's claimant number must be provided.

To clarify the expiry date of a Special Authority approval the Provider should quote the approval number, or the Service User's name and NHI number (if known).

# **Pharmacy Procedures Manual Special Authority**



### **Special Authority Procedure**

Before an initial Dispensing of a Pharmaceutical with a Special Authority it is strongly recommended that the Provider verifies that the approval is still current:

- 1. check the expiry date of the Special Authority (the expiry date forms part of the Special Authority number), eg, the approval number is CHEM1234567890/Jan24. The month and year refer to the expiry date of the Special Authority (the approval will expire on the last day of the stated month)
- 2. dispense the Pharmaceutical either with a valid Special Authority number, or at a charge to the Service User, or as an ethical supply.<sup>55</sup>

Each item submitted with a Special Authority number for payment is validated by the claim system to ensure that:

- 1. the Special Authority number exists and covers the Pharmaceutical prescribed, and
- 2. the Dispensing date is within the Effective and Expiry Dates recorded on the Special Authority.

Any Claim unable to be validated will be rejected. The <u>Error Code Booklet</u> can assist with understanding this (and Section 3.3, Rejected Items in this Manual).

If the problem cannot be corrected (such as a Special Authority application that has not been submitted by the Prescriber, or the information as supplied cannot be validated) the Provider should contact Sector Operations on 0800 855 066 and advise that the correct procedures have been followed, but a correct number has not been available. After a review of the circumstances Sector Operations will provide a Risk Number (refer below) which is added to the Claim and the Claim resent/resubmitted.

### Options if there is a delay in receiving a Special Authority Approval

There could be a delay issuing a Special Authority when:

- an application has not been submitted by the Prescriber
- Sector Operations has returned a Special Authority application to the Prescriber for correction
- staff at Sector Operations are unable to contact anyone to ascertain the correct information. The following options are available when a Special Authority has not been issued:
  - delay the supply of the Pharmaceutical. If the Service User is not at risk, the supply of the Pharmaceutical can be delayed until the Special Authority is approved
  - o dispense a small unsubsidised quantity of Pharmaceutical. It is permitted to split the item on the Prescription Form and supply enough Pharmaceutical to the Service User until the Special Authority is approved. When approved, the balance of the item can be processed as a subsidised item (not to exceed in total the original prescribed amount). Dispense the balance of the item using a new unique number for the item.
  - supply the Pharmaceutical as an 'ethical supply'.55

<sup>&</sup>lt;sup>55</sup> Ethical supply. If the Service User will be at serious risk without the Pharmaceutical, the Provider can supply it as an 'ethical supply' and contact Sector Operations for a Risk Number to cover the Dispensing made in good faith (see Section 7.10.3 Risk Number Procedure).

### 7.11.1. Rejected Special Authority Claim Items

A Provider should take the following steps if a Claim Item submitted with a Special Authority Number has been rejected for payment:

- check the Error Code Booklet and see Section 3.3, Rejected Items in this Manual, and
- complete one of the following:
  - use the Electronic Special Authority Look-up system to verify whether the Service User has a valid Special Authority, or
  - Contact Sector Operations on 0800 855 066 to enquire about the validity of the Service User Special Authority, or
  - o Contact the Prescriber.

If the Special Authority information has been incorrectly recorded on the Prescription Form, the correct information should be added, and the Claim Item edited to include the correct information and resent/resubmitted in the next Batch claim for payment.

The Special Authority Number is effective from the date Sector Operations has received a correct Special Authority application.

#### 7.11.2. Risk Number Procedure

Sector Operations may issue a Provider with a Risk Number for a single item on a Prescription Form when:

- a Claim Item has been rejected for payment because the Special Authority information supplied on a Prescription Form is incorrect, or
- the Provider has Dispensed an 'ethical supply'.

When a Risk Number is issued, the approval covers the life of the item. The Risk Number can be submitted for the rejected Claim Item and resent/resubmitted in the next Claim.

'Ethical supply' Dispensings are not expected to be a frequent occurrence. The supply should only be enough to treat the Service User through until the Special Authority Number can be obtained, or while the Prescriber is contacted to submit an application. This process is only to be used as a last resort to protect Service Users that would be adversely affected from not receiving their Pharmaceuticals.

#### **Risk Number Procedure**

After a review of the circumstances Sector Operations may approve a Risk Number. This number is added to the Claim Item and resent/resubmitted in the next Claim for payment.

A Risk Number to cover ethical supply will only be issued where:

- an item on a Prescription Form has been rejected for payment because an incorrect Special Authority Number is recorded on a Prescription Form, or
- the incorrect expiry date (or no expiry date) has been recorded on the Prescription Form, but the Pharmaceutical has been Dispensed in good faith that the expiry date was correct, or
- the Prescriber could not be contacted in advance of the Service User needing their medication, or

- the Prescription Form was presented at a time when:
  - the online Special Authority Look-up System was unavailable, such as a notification from Sector Operations had been received about an outage
  - it was outside the Sector Operations Contact Centre hours and the Service User could not wait to receive their medication, or
- the Service User was at serious risk without their Pharmaceutical, such as a lifethreatening condition or imminent hospitalisation. Examples of a life-threatening circumstance are when a Service User has a hyperglycaemic event and the appropriate insulin is not available, or they are at risk of a kidney graft rejection without the immediate availability of immunosuppressants.

'Ethical supply' does not cover Pharmaceuticals where it is unlikely there would be a serious deterioration in a Service User's condition due to a delay in not receiving the Pharmaceutical.

# 7.11.3. Types of Special Authority Approvals

There are different types of Special Authority approvals. The Special Authority prefix can be used to identify the type of Special Authority that has been approved for a Service User. The following table provides a description of each type of Special Authority.

Prefix	SA Type	Description
CHEM	Special Authority	Allows Service Users to receive Special Authority Pharmaceuticals through a Community Pharmacy
EXCP	Named Patient Pharmaceutical Assessment	Allows a Provider to Claim the full cost of the Pharmaceutical Dispensed. The application criteria are defined in the Pharmaceutical Schedule
RISK	Risk Number	Available where a Provider has made a Dispensing in good faith or if the Service User has a life-threatening condition
TEMP	Templeton	Enables a full subsidy for Service Users who were residents at the Templeton Centre at the time of closure
		A Templeton Approval covers any Pharmaceutical required by the Service User

# 7.12. Named Patient Pharmaceutical Assessment (NPPA)

NPPA provides a mechanism for Prescribers to apply for funding for Pharmaceuticals not listed in the Pharmaceutical Schedule (either at all or for their clinical circumstances). The NPPA Policy, which includes the prerequisite requirements and criteria for funding, is available on the Pharmac website. People approved for Exceptional Circumstances funding prior to 1 March 2012 will continue to receive Pharmaceutical funding and be considered for renewal funding (where applicable). according to the Exceptional Circumstances criteria under which funding was initially granted.

## 7.12.1. Reimbursement for NPPA Funded Pharmaceuticals

#### **NPPA Services A**

If the NPPA funded Pharmaceutical is listed on the Pharmaceutical Schedule, the Provider will be reimbursed with a multiplier on the Handling Fee as per NPPA Services A (PUC PH1004) in the ICPSA (Schedule 1, clause 30).

#### **NPPA Services B**

If the NPPA funded Pharmaceutical is **NOT** listed on the Pharmaceutical Schedule, the Provider will be reimbursed with a multiplier on the Handling Fee as per NPPA Services B (PUC PH1005) in the ICPSA.

Refer to ICPSA (Schedule 1, clause 31, Payment Terms) for the full payment calculation. Further information is available on the Pharmac website and the ICPSA.

# 7.13. Unique Identifying Numbers for Items on Prescription Forms

The following numbering system applies to all Prescriptions Forms and supply orders:

- numbers follow the following format: 123456789/number suffix
- the appropriate suffix for the item is included on the Prescription Form
- if the item is for a single supply (including those items dispensed stat), the suffix used is '0'. For the initial Dispensing of an item where repeats are prescribed, the suffix is '1'
- each subsequent Dispensing of a repeat of an item has the next consecutive number as its suffix.

The unique identifying number from the third part label is required to be placed next to the relevant item on the original Prescription Form, where possible.

If working from a faxed or telephoned copy, place the third part label on the copy, and then staple this to the original Prescription Form when it is received.

Unique identifying numbers are required on labelling for compliance packaged items.

#### 7.14. Annotations

An Annotation is text written by a Provider. Any Annotation should clearly differentiate the information added by the Provider from that written by the Prescriber. If possible, all Annotations should be adjacent to the relevant item on the Prescription Form. Any Annotations made should be in a different coloured pen to that used by the Prescriber.

Items on a Prescription Form should be Annotated where:

- it is required by legislation<sup>56</sup>
- it is necessary for clarification or is specified in the ICPSA or this Manual
- it is required for subsidy, including those outlined in the ICPSA or Pharmaceutical Schedule, such as Cost Brand Source, Multiple-Service Users, or
- there is no Patient Category code on the Prescription Form, or when it is known to be an error in the code (refer to the table in Section 10).

Changes made to the Patient Category code by the Provider **must** be initialled and reflected

<sup>&</sup>lt;sup>56</sup> Medicines Regulations 1984, reg 42(4)(e)(f)

in the electronic claim file. Attaching the third part label showing the Patient Category Code alongside each item fulfils this Annotation requirement.

Providers may Annotate Prescription Forms with clarifications to one or more of the following:

- dosage
- strength
- quantity
- brand (the Provider may only Annotate a change of brand subject to the substitution rules contained in regulation 42(4) of the Medicines Regulations 1984).

#### Points to note:

- 1. When Dispensing a subsidised alternative brand, the Provider must Annotate and sign the change and inform the Service User of the brand change (see Section 7.16, Substitution).
- 2. A Provider may Annotate an Endorsement required for subsidy within the Pharmaceutical Schedule only where the Pharmaceutical Schedule specifically permits the Provider to Annotate the Endorsement. All other Endorsements must be handwritten, or computer generated by the Prescriber or, where it has been altered or added by the Provider, initialled by the Prescriber.
- 3. Where a Specialist recommendation is required for subsidy on a Prescription Form or supply order, the Provider may Annotate the Prescription Form or supply order, following verbal confirmation from the Prescriber, with the name of the Specialist and date of recommendation. The Provider must also Annotate the Prescription Form with the words 'Confirmed by [practitioner's name]'. Where the Provider has an electronic record of such a valid Specialist recommendation from a previous Prescription Form for the same Community Pharmaceutical written by a Prescriber for the same Service User, the Provider may Annotate the Prescription Form accordingly.

# 7.15. Alteration to Quantity Dispensed

An alteration made by a Provider to the unit quantity Dispensed is one that does not affect the end amount of Pharmaceutical prescribed. Alternatively, a change in presentation of Pharmaceutical (such as from tablets to mixtures) is deemed appropriate as long as both the individual dose and total daily dose is not altered.

The Service User will receive the same dose of Pharmaceutical in the following example. In this case, the Provider has altered the unit quantity, and subsequent dosage instructions, without changing the total daily dose or frequency ordered by the Prescriber:

• the Prescription Form reads '500 mg, one tablet per day, 30' and the Provider Dispenses '250 mg tablets, two tablets per day, 60'.

For any alteration made by the Provider to the quantity Dispensed, if there is additional cost to Health NZ, the Provider must Annotate and sign the reason for the change.

In cases where Pharmac has approved and notified in writing a change in Dispensing of a named Pharmaceutical due to an out-of-stock event or short supply, the Provider must Annotate and initial the alteration. In this case, the Prescription Form does not need to be returned to the Prescriber for Endorsement.

# 7.16. Alteration to the Presentation of a Pharmaceutical Dispensed

When Dispensing a Community Pharmaceutical, the Provider may alter the presentation of a Pharmaceutical Dispensed to another subsidised presentation without requiring a signature from the Prescriber. The Provider cannot however alter the dose, frequency, and/or the total daily dose. The change in presentation may only occur when it is not practicable for the Provider to dispense the requested presentation. If the change will result in additional cost to Health NZ, then the Provider must Annotate the reason for the change on the Prescription Form and initial the change for the purpose of Audit.

For clarity the Provider may not alter the dose, frequency and/or the total daily dose without sending the altered Prescription Form to the Prescriber to be endorsed.

### 7.17. Substitution<sup>57</sup>

Where a Prescriber has prescribed a brand of a Community Pharmaceutical that has no subsidy, or has a manufacturer's price that is greater than the subsidy, or is no longer available in New Zealand and there is an alternative fully subsidised Community Pharmaceutical available with the same active ingredient/ingredients and no other active ingredients, a Provider may Dispense the fully subsidised Community Pharmaceutical, unless either or both of the following circumstances apply:

- · there is a clinical reason why substitution should not occur, or
- the Prescriber has marked the Prescription Form with a statement such as 'No brand substitution permitted'.

The substituted Pharmaceutical **must** be in the same dose form and strength as the prescribed brand. Where this is not possible or does not meet the Service User's needs, the substituted Pharmaceutical must provide a bioequivalent dose.

When Dispensing a subsidised alternative brand, the Provider must Annotate the brand substitution on the Prescription Form (for example, the brand used), sign and date the Form, and inform the Service User of the brand change.

Changes required to a controlled drug prescription should be re-written/regenerated and signed by the Prescriber for both NZePS controlled drug prescriptions and triplicate paper controlled drug prescriptions.<sup>58</sup>

# 7.18. Cost, Brand, Source (CBS)

Where CBS is required for a Pharmaceutical listed in the Pharmaceutical Schedule, or if the item is a NPPA Pharmaceutical not listed in the Pharmaceutical Schedule (as described in the ICPSA as NPPA Services B), the Pharmaceutical is eligible for subsidy based on the Provider's Annotate of purchase price, brand, and source of supply.

The purchase price should be GST exclusive. The Pharmaceutical Schedule requires that the purchase cost, brand, and source of supply be Annotated. A copy of the invoice for the purchase of the Pharmaceutical should be attached to the Prescription Form to be eligible for the subsidy.

<sup>&</sup>lt;sup>57</sup> Medicines Regulations 1984, reg 42(4)

<sup>&</sup>lt;sup>58</sup> Misuse of Drugs Regulations 1977, reg 32(3)

#### **Notes**

- Items are calculated for payment using the CBS price submitted.
- For items not listed in the Pharmaceutical Schedule, the CBS price should include any procurement costs, if applicable.
- The price paid is for each pack even when the whole pack is not used.
- The details of the purchase may be subject to audit and all receipts of purchase must be kept and available in case it is requested at audit.

# 7.19. Holding or Splitting a Prescription Form

A 'split script' or 'held script' is where items on a single Prescription Form are processed and dispensed on different days. The decision to 'split' or 'hold' a Prescription Form is made before processing and may be due, but is not limited to:

- the patient advising they are unable to afford or does not require all of the items on a Prescription Form at that time, or
- the Pharmacy holding items to allow for synchronisation.

When a Prescription Form is 'split' or 'held', the subsequent items dispensed will have a different date of Dispensing compared to the initial item Dispensed. A Certified True Copy of the Prescription Form must be made to ensure there is an original Prescription Form filed for each Dispensing (see Section 7.30, Certified True Copy).

A Prescription Form produced via NZePS may be 'split' by unselecting the items that are not required once the barcode has been scanned. A Certified True Copy of the printed copy of a NZePS prescription is still required.

Items on a controlled drug Prescription Form may have different start dates, for example they may be 'split', however all Dispensings must be recorded on the original controlled drug Prescription Form. While each item may be started on a different date, refer to the table in Section 5.1 to ensure that the date of the first Dispensing (for example the time it is 'held' for) is within the timeframe specified for that Prescriber. All Dispensings of controlled drugs must be Annotated on the original triplicate Prescription Form (no Certified True Copies) - (see Section 7.30, Certified True Copy).

# **7.20. Owings**

# 7.20.1. General Requirements

# **Item Owing Procedure**

- The Provider must consult with the Service User to achieve a mutually acceptable arrangement when it is not possible to Dispense a Pharmaceutical fully as prescribed.
- It is preferable to provide the full Dispensing, however if not possible, then the Provider should issue a part supply of an item on a Prescription Form in cases where the Service User is required to begin the treatment immediately.
- If the full quantity of the item is not available, there must be a reference in the Service User's record in the PhMS, or in an 'owes' file, and on the Prescription Form specifying the quantity of the Pharmaceutical Dispensed and the quantity of the Pharmaceutical owing.
- The Service User must be provided with written information on the quantity of

Pharmaceutical owed and the timeframe for collection for the owed item where the availability is known (eg, could be out of stock).

• The owed items **must** be collected or delivered within the period of supply on the Prescription Form.

Payment will only be made for any owed items when supplied to the Service User or their caregiver. No Service or Handling Fees will be paid for these owed balances.

### 7.20.2. Controlled Drug Owings

If stock of a controlled drug is unavailable and prevents the full amount from being Dispensed, the first dispensing (for the supply of Class B controlled drugs only) can be claimed as two Dispensings. This split Dispensing includes instances where both Dispensings are supplied on the same day. Subsequent repeats where insufficient stock is available must be claimed as one repeat and an 'owe'.

### **Owe/Out of Stock Dispensing for Class B Controlled Drugs Procedure**

- Claim for the first supply as an initial Dispensing.
- The second dispensing (i.e., the owe) should be claimed as a repeat Dispensing.
- Separate entries must be made on the controlled drug Prescription Form and in the Controlled Drug Register of the quantities and dates of the Dispensing for both supplies.

# 7.21. Repeat Supplies

### **7.21.1. Repeats**

Repeats can be Dispensed when:

- the Provider has previously Dispensed an initial Dispensing for a Prescription Item and repeat items are permitted in accordance with the Pharmaceutical Schedule, and
- the Service User or his/her caregiver has made a specific request for a repeat, and
- the Provider can reasonably assume that the supply has been exhausted or substantially exhausted, including any previous Prescription and repeats dispensed by that Pharmacy, or for a reason otherwise known to the Provider (such as the patient is travelling and signs the Prescription Form and certifies the criteria the patient meets to qualify for single Lot dispensing),<sup>59</sup> or
- where Pharmac advises that, to manage stock supply issues, the Provider may dispense
  more frequently than the Pharmaceutical Schedule would normally allow and specifies
  that 'out of stock' (OOS) can be Annotated on the Prescription Form.

As a general rule, for a Pharmaceutical subsidy to apply, 'substantially exhausted' means that either two thirds of the supply period have elapsed since the previous Dispensing, or two thirds of the supply has been used. In special circumstances where the patient has lost or damaged the previous supply or has an increased need for the Pharmaceutical due to a change in dose or frequency, the Provider can supply the Pharmaceutical earlier. If an earlier supply is made in these circumstances, the reason for the early supply **must** be Annotated on the Prescription Form or Certified Repeat Copy (CRC see Section 7.20.2) for

<sup>&</sup>lt;sup>59</sup> Pharmaceutical Schedule Section A: General Rules, rule 4.4.2

the Service User to be eligible for a subsidy.

The Provider responsible for any initial Dispensing on a Prescription Form must remain available to Dispense any authorised repeats requested by the Service User and/or their caregiver, and the Provider may not return the original Prescription Form to the Service User.

# 7.21.2. Certified Repeat Copy (CRC)

A Certified Repeat Copy (CRC) is a computer-generated record of a repeat Prescription Form. A CRC can be used for Dispensing a repeat item as an alternative to Dispensing from the original Prescription Form.

If not Dispensing from the original prescription, a CRC must be generated when repeats are different to what has been prescribed at the first Dispensing. This difference can occur when two repeats are Dispensed stat (all at once).

The CRC form must be filed in the date of Dispensing bundle on the date of the repeat Dispensing. A CRC does not need to be sent with the Claim Period batch to the Health NZ if it does not differ from the original Prescription Form (see Section 4.2, Batch Delivery Instructions).

However, if not sent in with the whole Claim Period batch, the CRC must be filed and retained in the Pharmacy for three years.<sup>60</sup>

# 7.22. Original Pack Dispensing

## **Original Pack Dispensing Procedure**

If an item has the letters 'OP' in the pack size column of the Pharmaceutical Schedule, then payment is made to the nearest original unit size. The pack size dispensed should be the closest size to meet the dosage instructions and will be reimbursed for the total subsidy per 'OP' dispensed.

For example, a collapsible tube (if defined as 'OP' in the Pharmaceutical Schedule): Locoid Lipocream 15 g. Even though the Prescription Form only calls for 15 g, the Provider can claim 1 x OP or 30 g. If the Locoid Lipocream Prescription Form had called for 50 g, the Provider can claim  $2 \times 0P$  or  $60 \times 0P$  or 60

#### 7.23. Broken Packs

If a Provider dispenses a part pack of a proprietary Pharmaceutical, the subsidy is based on the appropriate portion of the pack size listed in the Pharmaceutical Schedule, unless the item lists 'OP' in the pack size column of the Pharmaceutical Schedule.

For a Prescription Items written for a three-month supply of a Pharmaceutical that is supplied in a collapsible tube, only the total quantity required to complete the three-month course will be subsidised. **Funding is not provided for one tube per month**. However, if the Medicine Data Sheet states the product should be discarded after a specific period (eg, 30 days), then funding will be provided accordingly. This must be Annotated by the Provider on the Prescription Form.

For example, Ovestin Vaginal Cream is not required to be discarded one month after

<sup>60</sup> Health (Retention of Health Information) Regulations 1996; reg 5

opening. If the prescribed quantity equates to one tube per month, then this will be subsidised. In all other circumstances only the quantity that is prescribed will be subsidised.

# 7.24. Oral Antibiotic Liquids

Where a Prescriber has written a Prescription Item for a reconstitutable oral liquid antibiotic indicated in the Pharmaceutical Schedule, and the Dispensing of which would require the Provider to reconstitute another pack, the Provider should reduce the amount Dispensed to the quantity contained in a whole pack provided that the reduction in the amount Dispensed is less than 10% of the pack, and in the reasonable opinion of the Provider will not affect the efficacy of the course of treatment.

#### For example:

5 mL TDS for 7 days = 105 mL

Dispense 100 mL

#### For example:

10 mL stat, 5 mL TDS for 7 days = 110 mL Dispense 110 mL

The remainder of the oral liquid antibiotic can be claimed as wastage if unused. The Provider must record the quantity discarded and the date it was discarded on the Prescription Form.

# 7.25. Claiming Wastage

Using the 'Wastage' rule in the Pharmaceutical Schedule, Providers can claim wastage for certain Pharmaceuticals listed. This includes:

- all subsidised unapproved Pharmaceuticals supplied under section 29 of the Medicines Act 1981, but excluding any Pharmaceutical listed as Cost, Brand, Source of Supply
- any other Pharmaceutical that Pharmac determines and is identified within the Pharmaceutical Schedule that 'Wastage' is claimable.

A Provider should only claim wastage when the remainder of a pack is unlikely to be Dispensed in the future. If a Service User is on a long-term treatment where wastage is claimable, the Provider should not claim wastage on every Dispensing.

At the time of Dispensing the Provider must record the quantity discarded and the date it was discarded on the Prescription Form.

Wastage should only be claimed where the remainder of a Pharmaceutical has been discarded, that is, a Provider cannot claim wastage and then use the wastage amount for any subsequent Prescription Forms.

# 7.26. Liquid Pharmaceutical Dilution

Where the dose of the liquid Pharmaceutical prescribed is not easily measurable for the Service User or their caregiver, the Provider may add a compatible diluent to the Pharmaceutical if satisfied that:

- such dilution is necessary to adjust the dose to a quantity easily measurable by the Service User or by any other person on behalf of the Service User, and
- the addition of that diluent will not injuriously affect the composition of the Pharmaceutical.<sup>61</sup>

<sup>&</sup>lt;sup>61</sup> Medicines Regulations 1984, reg 5

# 7.27. Supply Orders

# 7.27.1. Practitioner Supply Orders (PSOs)

Practitioner Supply Orders (PSOs) must be supplied in accordance with <u>Pharmaceutical</u> Schedule Rules.

Pharmac publish a list of funded pharmaceuticals which may be prescribed on a PSO. The list is updated monthly and can be found on the Pharmac website under the section 'Schedule Resources' (Practitioner Supply Order (PSO) List).

Any PSO for a Pharmaceutical that is required to be written on a triplicate controlled drug form for a Service User (for example, a Class B controlled drug) is required to be written on a controlled drug PSO form (there is currently no electronic PSO forms).

Except for antipsychotic injections for mental health day clinics, PSOs will not be reimbursed where the Pharmaceuticals are supplied to hospitals or clinics.

Except for ivermectin, Bulk Supply Orders (BSOs) and PSOs will not be reimbursed where the Pharmaceuticals are supplied to the Armed Services or the Department of Corrections (including Prisons).

Ivermectin tablets are subsidised when prescribed on a PSO for institutional use (age related residential care facilities, disability care facilities or penal institutions only). Up to 100 tablets of ivermectin will be subsidised on a PSO, which must be endorsed with the name of the institution and a valid Special Authority for a Service User of that institution. Ivermectin is also fully subsidised on a BSO where there is a valid Special Authority for a Service User of that institution.

# 7.28. Practitioner Supply Orders (PSOs) for the Rheumatic Fever Prevention Programme

Pharmac has specified the quantities of certain antibiotics that Medical Practitioners, Nurse Prescribers, and Provider Prescribers can order on a Practitioners Supply Order (PSO) if they are taking part in the Rheumatic Fever Prevention Programme (RFPP).<sup>62</sup>

They are ordered on a normal PSO with the following additional requirements:

the antibiotics must be in course-specific quantities, for example,

30 x amoxicillin capsules, or

20 x phenoxymethylpenicillin 500 mg capsules, or

20 x erythromycin 400 mg tablets, or

100 mL bottles of granules of oral antibiotic liquids.

 The RFPP provider name (such as the clinic providing the service) must be written on the PSO.

Note that while the RFPP Programme as a Better Public Service target ended on 30 June 2017, Rheumatic Fever prevention continues in some Districts and this guidance still applies.

<sup>62</sup> Pharmaceutical Schedule Section A: General Rules, rule 1.3.4

### Dispensing of PSOs for a Rheumatic Fever Prevention Programme<sup>63</sup>

- Check the PSO complies with Pharmaceutical Schedule rules, for example only certain antibiotics and specific quantities.
- Process through the PhMS in course-specific amounts, eg, if 10 x 20 amoxicillin 500 mg capsules are ordered then enter each quantity as a separate line and repeat this process 10 times.
- Specific labels are required on each container (see detailed instructions below).
   Ensure a place is left on the label for the Prescriber to write the patient's name.
- Each container needs to be labelled.
- Antibiotic granules of oral liquids are dispensed in un-reconstituted powder form.

#### **Labelling of Antibiotics for a Rheumatic Fever Prevention Programme**

Specific quantity, dose and frequency instructions are required on each label, for example:

Amoxicillin 250 mg capsules

30

Take THREE capsules ONCE a DAY for 10 days

Amoxicillin 500 mg capsules

20

Take TWO capsules ONCE a DAY for 10 days

Amoxicillin 250 mg/5 mL

< 30 kg

200 mL

Take 15 mL ONCE a DAY for 10 days

Amoxicillin 250 mg/5 mL

> 30 kg

200 mL

Take 20 mL ONCE a DAY for 10 days

#### Definite or possible anaphylaxis to penicillin or amoxicillin

Erythromycin Ethyl Succinate, children, and adults: 40mg/kg/day in 2-3 divided doses, Maximum adult daily dose 1000mg orally for 10 days.

For the un-reconstituted granules:

• Add the Cautionary Advisory information: 'Shake the Bottle', 'Keep in the fridge' and 'Discard any remainder after 10 days'.

Ensure the Cautionary Advisory label does not obscure the reconstituting instructions.

#### Notes:

- For each course-specific amount of antibiotic dispensed, the pharmacy system will claim a service fee according to the ICPSA.
- Service Users receiving antibiotics through the RFPP Sore Throat Management service must not be charged any Co-payment.

<sup>63</sup> Ministry of Health. 2015. <u>Using Practitioner Supply Orders and Standing Orders in the Rheumatic Fever Prevention Programme: Guidance for sore throat management services.</u> Wellington: Ministry of Health.

# 7.28.1. Practitioners Supply Orders (PSOs) for Rural Areas

Designated rural practices are not restricted to the Pharmaceuticals on the PSO list and can order any product listed in the Pharmaceutical Schedule, provided that all the funding requirements of the listing are met.

• Exceptions: If the listing in the Schedule states 'only on a prescription', or the product requires a Special Authority, then it is not funded on a rural PSO.

A quantity reasonable for up to one month's supply, under the conditions normally existing in the practice, can be ordered on a rural PSO.

Health NZ decide what practices are designated rural.

# 7.28.2. Bulk Supply Orders (BSO)

For Pharmaceuticals to be Subsidised on a Bulk Supply Order (BSO), the BSO must meet all of the following:

- be for supply of Community Pharmaceuticals to Private Hospitals that employ a Registered Nurse, for the treatment of people under the care of that facility
- be on a form supplied or approved by the Health NZ and signed by a Hospital Care Operator
- for a Class B controlled drug or for buprenorphine hydrochloride, be written on a triplicate BSO Controlled Drug Form supplied by the Health NZ
- not exceed what is a reasonable Monthly allocation for the particular institution
- meet all the Subsidy requirements of Section B of the Schedule applicable to that Community Pharmaceutical
- not be supplied to Armed Forces or Prisons unless specified in Section B of the Schedule.<sup>64</sup>

If a funded extemporaneously compounded product is supplied on a BSO, a compounding service fee is claimed.

# 7.29. Prescriptions for Multiple Service Users

When items for multiple Service Users are on one Prescription Form, such as antifungal or scabies treatments, they should be treated as separate items for each Service User. All the Service User's names must be included on the Prescription Form or annotated by the Pharmacist. Normal Co-payment rules will apply for each Service User, that is, if a Co-payment may be charged under clause D.5(2) of the ICPSA, only one Co-payment may be charged per Service User.

Note: a NZePS prescription cannot accommodate multiple users and there can only be one patient per SCID (barcode number). A SCID cannot be used a second time to dispense for the second patient or more. For this situation one prescription would be needed per Service User via the NZePS.

<sup>&</sup>lt;sup>64</sup> Pharmaceutical Schedule Section A: General Rules, rule 1.3.5

# 7.30. Bulk/Merged Prescription Forms

Pharmacies <u>do not</u> need to match telephone or pharmacy generated prescriptions with a prescription signed by a general practitioner to claim for the dispensing if the following conditions are met:

- an electronic medication chart is used by the ARRC facility, GP, and Pharmacy for prescribing, dispensing and administration
- a telephone or pharmacy generated prescription is generated that matches the medication chart, and
- the telephone or pharmacy generated prescription is attached to the medication chart and is kept and submitted as required by the Integrated Community Pharmacy Services Agreement (ICPSA).

Where the above conditions are not met, a Prescription Form generated for multiple ARRC Service Users, must comply with the following:

- the Prescriber has initialled beside each Service User on the page, and
- · each Service User's NHI number is listed, and
- · the name of the ARRC facility is Annotated, and
- this statement acknowledging that each Service User is under the Prescriber's care is noted – 'I have read and authorised these Prescription orders for the above-named Service Users', and
- each page has a full Prescriber's signature and date at the bottom of the page.

Due to the requirement for the close association between the Provider and Prescribers for ARRC Service Users, only fully completed items on a Prescription Form may be claimed. For clarity, the provision for the submission of uncompleted items on a Prescription Form in Section 7.6 of the Procedures Manual does **not** apply to ARRC bulk Prescription Forms.

# 7.31. Certified True Copy

A Certified True Copy of a Prescription Form is used when:

- the original Prescription Form has been requested by the NZ Police, Medicines Control, a Medical Officer of Health, or the Coroner
- an item needs to be Dispensed by another Provider
- all items on a multi-item Prescription Form are not processed on the same day
- the Service User wishes to retain the Prescription Form when items remain undispensed.

A Certified True Copy of the original Prescription Form should be made by the Provider and is retained and submitted as part of the Claim Period batch in the normal manner. A photocopy of the original Prescription Form is the preferred method of obtaining a copy. However, in special circumstances the Certified True Copy can be handwritten, or computer generated and the reason Annotated by the Provider.

A Certified True Copy must be Annotated with the words: 'Certified True Copy' or words of similar meaning and be signed and dated by a Provider.

Once a Certified True Copy has been created, the original Prescription Form it was taken from cannot be altered. The Certified True Copy must be an exact copy of the original Prescription Form when the original is submitted to the Health NZ for claiming.

A Certified True Copy is still required for a Prescription Form produced via NZePS when not

all of the items are required to be Dispensed at the time of the initial presentation of the Prescription Form. The undispensed lines must also be flagged with the NZePS Broker by placing them on hold. The Certified True Copy is needed to meet the requirement for each item in the electronic Claim to be supported by an original Prescription Form.

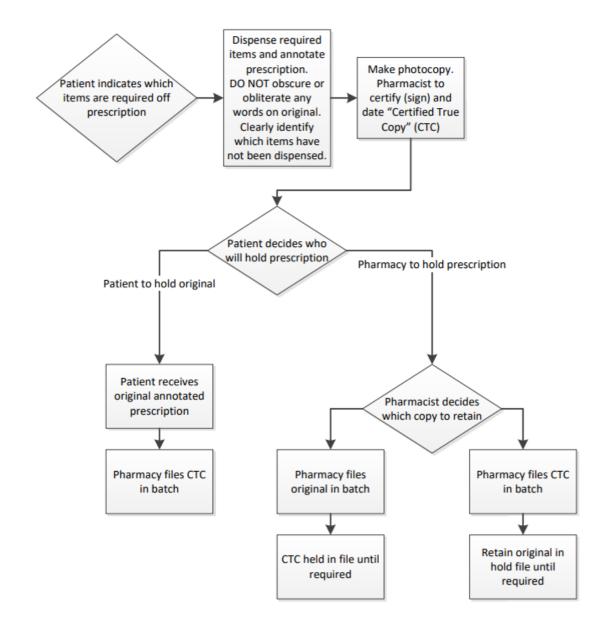
Certified True Copies **cannot** be made of controlled drugs prescriptions other than for Batch filing records for NZePS controlled drug Prescription Forms. All Dispensing's must be recorded on the original Prescription Form. While each controlled drug item may be started on a different date, refer to the table in Section 6.1.3 to ensure that the date of the first Dispensing of the controlled drug is within the timeframe specified for that Prescriber.

### **Certified True Copy Procedure**

- The items to be Dispensed on the first occasion are Dispensed and supplied to the Service User as normal and clearly indicated on the original Prescription Form. No words on the original Prescription Form are obscured or obliterated.
- Items that have not been Dispensed are clearly identified on the original Prescription Form (for example, by writing 'not dispensed' or 'held').
- Once the Dispensing process is complete for the first occasion and the recording
  of the necessary information on the Prescription Form is completed, a photocopy of
  the original Prescription Form is made and certified by the Provider as a 'Certified
  True Copy' and the date of the certification is added.
- The Certified True Copy of the original Prescription Form should only be created once all the relevant information is recorded on the original Prescription Form (for example, pharmacy stamp, third part label and required Annotations).
- Scenario One: The Service User wishes to hold onto the original Prescription Form:
  - The Service User receives the fully Annotated original Prescription Form with the Dispensed items clearly identified and the original Prescription Form clearly indicates the item(s) Dispensed (for example, by drawing a line through each Dispensed item and writing 'dispensed').
  - The Certified True Copy of the original Prescription Form is filed in the Batch in date order as described in Section 4.1. for the day that those initial Dispensings were completed.
- Scenario Two: The Service User wishes the remainder of the Prescription Form to be placed in the Hold file in the Pharmacy (such as a 'split' or 'held' Prescription Form):
  - o either follow the process described in Scenario One, or
  - the original Prescription Form (fully Annotated) is filed in the Batch in date order for the day that those initial Dispensings were completed.
  - the Certified True Copy of the original Prescription Form is placed in the Hold file for future use.
  - when the Service User requires an item Dispensed from the 'held' Prescription Form, the Certified True Copy is used as the original Prescription Form and the process begins again (this process can continue until all the items are initially Dispensed or the Prescription Form expires).
  - if further initial Dispensings are required then the Provider takes a copy of the first Certified True Copy and creates a second Certified True Copy but only after all the relevant information is recorded on the first Certified True Copy

- (for example Provider stamp, third part label and required Annotations).
- the first Certified True Copy is then placed in the Batch for the day that those initial Dispensings were completed, and the second Certified True Copy is then filed in the Hold file for further initial Dispensing(s) to occur at a later date.

# **Certified True Copy Diagram**



# 7.32. Receipts

The following information is required for each item on a Prescription Form on the Receipt:

- the Service User's name
- name of the Pharmaceutical(s)
- cost to the Service User of each.

# 7.33. Flavours of Special Foods

When Dispensing more than one flavour of a Special Food, if the Provider is permitted to charge a Co-payment in accordance with clause D.5(2), only one Co-payment is to be charged, as written in the ICPSA (Schedule 3B.4, Special Foods services, Clause 6.1).

### 7.34. Data Retention

This section provides a summary of the regulated timeframes for retaining Pharmacy-related data and information. The following should be considered when storing data:

- Data and records must be kept at a secure place in the Pharmacy or in some other place authorised by the Licensing Authority<sup>65</sup>
- All retention dates commence on the date of last dispensing or last entry<sup>66</sup>
- Health information is information that relates to an identifiable individual<sup>67</sup>
- Paper records such as compounding job sheets for individual Service Users or Compliance Unit Dose Packaging Records must initially be retained for three years.
   Because these records also contain patient information they must be retained for 10 years in total. However, a Pharmacy can store the records in any acceptable, retrievable form (eg, electronic) which will be retained for 10 years
- All documents or data which have reached their expiry date must be securely destroyed
- Electronic records must be maintained in a retrievable form.<sup>68</sup>

<sup>65</sup> Medicines Regulations 1984, reg 58(2)

<sup>66</sup> Health (Retention of Health Information) Regulations 1996, reg 5

<sup>67</sup> Health (Retention of Health Information) Regulations 1996, reg 2

<sup>68</sup> Health (Retention of Health Information) Regulations 1996, reg 9(1)

Data Type	Retention Period		
Prescriptions			
Original physical copy			
<ul> <li>Subsidised</li> </ul>	<ul> <li>five months (then sent to Health NZ Sector Operations)</li> </ul>		
o Non-subsidised	• three years <sup>69</sup>		
<ul> <li>Certified Repeat Copies (or daily dispensing/recording sheets)</li> </ul>	• three years <sup>70</sup>		
Controlled Drug Prescriptions (top white	• four years <sup>71</sup>		
copy)	Note: Physical prescriptions containing patient information must be kept in a secure, retrievable format (eg, electronic dispensing system) for a further seven years (total 10 years) after completion of the Medicines legislation and NZ Pharmacy Services Standards		
	retention requirements. <sup>71</sup>		
Other Records			
Computer Records (for example, PhMS)	• 10 years <sup>72</sup>		
Controlled Drugs Register	• four years <sup>73</sup>		
	<ul> <li>Note: Details of any dispensing which contain patient information should subsequently be retained in a retrievable format for another seven years (total 10 years)<sup>74</sup></li> </ul>		
Incident Reports on Errors/Near Misses	• 10 years <sup>75</sup>		
Compliance Unit Dose Packaging Records (with identifiable patient information)	• 10 years <sup>76</sup>		
Compounding Job Sheets for Individual Service Users (with identifiable patient information)	• 10 years <sup>77</sup>		
Batch Compounding Sheets	• three years <sup>78</sup>		
Extemporaneous Compounding Sheets	• three years <sup>79</sup>		

<sup>69</sup> Medicines Regulations 1984, reg 58(1)

Health (Retention of Health Information) Regulations 1996, reg 2
 Misuse of Drugs Regulations 1977, reg 33

Health (Retention of Health Information) Regulations 1996, reg 5

<sup>73</sup> Misuse of Drugs Regulations 1977, reg 42(1)
74 Health (Retention of Health Information) Regulations 1996, reg 2
75 Health (Retention of Health Information) Regulations 1996, reg 5

<sup>&</sup>lt;sup>76</sup> Health (Retention of Health Information) Regulations 1996, reg 2

Health (Retention of Health Information) Regulations 1996, reg 2

NZ Standard Health & Disability Services Pharmacy Service Standard NZS 8134.7:2010; Standard 5.6.2

Misuse of Drugs Regulations 1977, reg 33

## 7.35. Supply of Pharmaceuticals to School Principals and Masters of Ships

The supply of bronchodilators to schools<sup>80</sup> and the supply of Pharmaceuticals to masters of ships for maritime use<sup>81</sup> is not funded, therefore the details regarding this process are not covered in this document.

For further information refer to the Pharmacy Practice Handbook, available on the Pharmaceutical Society of New Zealand website (members only access).

<sup>80</sup> Medicines Regulations 1984, reg 44(I)

<sup>81</sup> Medicines Regulations 1984, reg 44(i)(ia)

## 8. Reimbursement Interpretations

There are several specific rulings that provide an interpretation for Providers on the quantity of Pharmaceuticals that can be reimbursed under the Pharmaceutical Schedule General Rules and the ICPSA for the provision of Pharmacy services. Where necessary for clarification, the Provider should Annotate the Prescription.

### 8.1. Co-payments for Anti-androgen Oral Contraceptives

Prescribers may code Prescription Forms with the 'contraceptive' code 'O' when a Pharmaceutical is used as indicated for contraception. The period of supply may be written for up to six month's supply.

Prescription Forms coded in any other way are subject to Service User Co-payment Prescription charges and the non-contraceptive period of supply. That is, Prescription Forms may be written for up to three month's supply.

For example, a Private Specialist Prescription Form for cyproterone acetate with ethinylestradiol:

private specialist (unapproved Provider) has coded the Prescription Form 'O'
 Period of supply is six months

Co-payment = \$5

 private specialist (unapproved Prescriber) has coded the Prescription Form A3, so not 'O'

Period of supply is three months, as the Prescriber has not indicated the item is being prescribed as an oral contraceptive.

Co-payment = \$15

### 8.2. Eye Drops

For most eye drops, if an item on a Prescription Form is written for a three-month supply of eye drops, at least one original pack will be subsidised per month, even if the directions are such that one pack would suffice for the complete three-month course. This follows the requirement to discard eye drops 30 days after first opening.

Where the manufacturer states a longer than 30-day expiry date once the original pack of eye drops is unsealed, such as Poly-Tears, this data can be used to calculate the number of original packs to Dispense.

The Provider must annotate the Prescription Form when claiming for quantities more than dose and frequency prescribed.

The following guidelines should be used for calculating quantities of eye drops:

12 drops = 1 mL60 drops = 5 mL

Where the manufacturer states the number of drops per mL, this data can be used to calculate the number of original packs to dispense, alongside any manufacturer's information on expiry dates once unsealed.

### 8.3. Insulin Vials and Cartridges

If an item on a Prescription Form is written for a three-month supply of insulin, at least one vial or one cartridge will be subsidised per month, even if the directions are such that one pack would suffice for the complete three-month course. This follows the need to discard insulin vials or cartridges 30 days after first opening.

**Note:** Insulin priming - Insulin pen users are now instructed to prime a Penfill prior to each dose by using a 2 unit 'airshot'. If priming is included in the prescription, it can be dispensed. In general, this would not be more than 2 units per dose. 82 The Provider must Annotate the Prescription Form when claiming for quantities more than the dose and frequency prescribed.

### 8.4. Mucilaginous Laxatives

These Pharmaceuticals are reimbursed as an original pack. The following guidelines should be used to calculate quantities.

- One teaspoon = 7 grams
- One dessertspoon = 14 grams
- One tablespoon = 28 grams

Where the manufacturer states a different quantity, this data can be used to calculate the number of original packs to Dispense.

### 8.5. Bronchodilator Asthma Inhalers Prescribed PRN

Where a Prescription Item for a bronchodilator inhaler has a 'when required' component in the dosing schedule, up to 1,200 doses will be reimbursed per three months.

For example, salbutamol inhaler:

- 2 puffs Q2H PRN for 3/12 = 2,160 doses (or 11 x 200 dose inhalers)
- Only 6 inhalers (1,200 doses) for three months will be subsidised.

These inhalers (up to six funded per three months) should be Dispensed in quantities as required by the Service User for their needs.

Six inhalers can be Dispensed as 2+2+2 or 3+2+1 or 4+1+1.

In instances where a quantity larger than 1,200 doses is required and the reason for the extra quantity is Annotated on the Prescription Form by the Prescriber, the quantity prescribed will be reimbursed.

### 8.6. Bronchodilator Asthma Inhalers Prescribed Without PRN

If the dosing frequency does not have a 'when required' component, then the quantity supplied must relate to the total number of doses ordered.

For example, salbutamol inhaler:

2 puffs Q2H for 3/12 = 2,160 doses (or 11 x 200 dose inhalers).

<sup>&</sup>lt;sup>82</sup> Pharmac. Questions and answers for pharmacists

### 8.7. Steroid Inhalers

For steroid inhalers without a definitive dosing and frequency instruction, only one inhaler can be claimed in each monthly Dispensing.

For example, beclomethasone inhaler:

- 100 microgram/dose 2-4 puffs PRN
- Maximum of three inhalers

Prescription Forms which specify both a dose and frequency of dose will be reimbursed up to the maximum number of inhalers as provided for by the Prescriber's instructions.

For example, beclomethasone inhaler:

- 100 microgram/dose 2-4 puffs bd increasing to 4 puffs bd prn for 3/12
- Maximum dosage is 720 puffs (or 4 inhalers)
- A maximum of 4 x 200-dose inhalers would be reimbursed on these instructions

### 8.8. Extemporaneously Compounded Preparations (ECP)

An ECP is an extemporaneously compounded preparation that is not available as a proprietary product and is therefore required to be compounded by a Provider (Pharmacist or an appropriately qualified Technician). For an ECP to be subsidised under the ICPSA, it must contain two or more subsidised component Pharmaceuticals listed in the Pharmaceutical Schedule. An ECP does not include reconstitution of antibiotic liquids.<sup>83</sup>

For further information on which products are eligible for a subsidy, refer to the <u>Pharmaceutical Schedule, Section A, General Rules, Part 7</u>.

## 8.9. Modified Dispensing Quantities

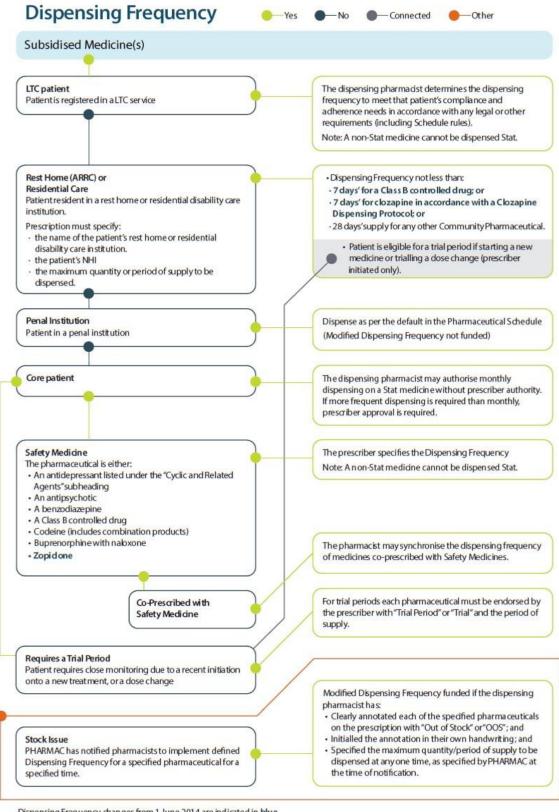
## 8.9.1. Modified Dispensing Quantity Rule

Refer to the Pharmaceutical Schedule Section A, General Rules, Part 5 for the detailed wording on the Modified Dispensing Quantities Rule.

The 'Modified Dispensing Quantities Flowchart' below provides a summary overview.

<sup>83</sup> ICPSA Part E: Definitions

### Modified Dispensing Quantities Flowchart - Pharmac:84



Dispensing Frequency changes from 1 June 2014 are indicated in blue. If you have any questions regarding the Dispensing Frequency rule call PHARMAC on **0800 66 00 50** 

<sup>84</sup> pharmac.govt.nz/assets/dispensing-frequency-flowchart.pdf

### 8.9.2. Certified Exemption by Providers

Where clinically appropriate, to enable some Prescription Items to be Dispensed all-at-once, Providers, as well as Prescribers, can initiate 'Certified Exemption' Dispensing (Pharmaceutical Schedule, Section A General Rules, Part 4). This applies to items identified within the Pharmaceutical Schedule with an '\(^{\delta}\).

The Service User must be stabilised on the Pharmaceutical and the Provider or Prescriber has reason to believe the Service User will continue on the Pharmaceutical and is compliant. The Provider will need to Annotate the Prescription Form with the words 'Certified Exemption'.

### 8.9.3. Brand-Switch Fees

Brand-switch Fees (BSF) are payments to Pharmacy by Health NZ to recognise the additional counselling required for switching Service Users between brands of certain Pharmaceuticals. The Pharmaceutical Schedule identifies the Pharmaceuticals and time periods in which Pharmaceuticals are paid a BSF.

One BSF is claimable per Service User per Pharmaceutical. When a Service User is on two or more strengths of the same Pharmaceutical, only one BSF can be claimed.

Payment can be claimed via a BSF Pharmacode specific to each eligible Pharmaceutical. Claiming is dependent on the dispensary software (PhMS) the Provider uses. No Prescription Co-payment is payable with a BSF, and it does not count towards a PSC.

## 9. Pharmacy services

Documents and guidelines describing the most current service requirements, protocols and standards required for the services below can be found via the Health NZ website:

Community Pharmacy.

- Opioid Substitution Treatment including Co-Dispensed Opioid Services (CDOS)
  - o See also: NZ Practice Guidelines for Opioid Substitution Treatment 2014
  - See also: <u>Prescribing Controlled Drugs in Addiction Treatment 2018: Guidance for nurse practitioners, designated prescriber nurses and designated prescriber pharmacists.</u>
- Aseptic services
- Sterile manufacturing services
- Clozapine (monitored therapy medicine services)
  - A generic protocol is available on the Health NZ website but for local variation please contact your District
- Influenza Immunisation
- Long Term Conditions (LTC)
- Community Residential Care (CRC)
- Age-Related Residential Care (ARRC)
- Community Pharmacy Anti-Coagulation Management Service (CPAMS)
- Smoking Cessation
- Locally commissioned services
  - Please contact your local District for information regarding locally commissioned services.

# 10. Service User Categories and Co-payment Requirements

### 10.1. Eligible Persons and Co-payments

If a Service User is an Eligible Person who has been prescribed or supplied a subsidised Pharmaceutical by an Approved Provider, a Co-payment may be charged.

If the Provider is permitted to charge a Co-payment for a subsidised Pharmaceutical under clause D.5(2) of the ICPSA, that Co-payment must be no more than the maximum Co-payment amount for the relevant Service User category.

The maximum Co-Payment amount for each Service User category is determined by the Ministry of Health.

A description of Approved Providers is set out in Section 10.2.

More detailed information about the maximum Co-payment amount for each Service User category is set out in Section 10.3.

The requirement in this section applies whether or not an Eligible Person is enrolled in a PHO.

The fact that a Service User has an NHI number does not mean that the Service User is an Eligible Person. In determining whether a Service User is an Eligible Person, a Provider is entitled to rely on the information provided by a Prescriber about a Service User's eligibility on the Prescription Form.

A guide to Service User eligibility for publicly funded health services can be found on the Health NZ website: <u>Guide to eligibility for public health services</u>. Pharmacy Providers can choose not to charge patients Co-payments and cover the cost themselves.

## 10.2. Approved Providers

As set out in section 10.1, any Co-payment charged to an Eligible Person for a Subsidised Pharmaceutical that has been prescribed by an Approved Prescriber must be no more than the maximum Co-payment amount for the relevant Service User category.

The following are 'Approved Providers':

- An Authorised Prescriber or Designated Prescriber in the following circumstances:
  - o employed by Health NZ, for example, a Prescriber in a public hospital.
  - o a provider or Prescriber under an access or service agreement with Health NZ or a PHO. For example, a Prescriber when providing services at a family planning clinic, youth health clinics funded by Health NZ or PHO, services at a hospice funded by Health NZ, a General Practitioner who is part of a PHO, a Dentist if the service being provided is funded by Health NZ, services for which there is an ACC claim (even if the Service User is not eligible for any other publicly funded health services in New Zealand such as tourists and overseas students).
  - an after-hours provider under an access or service agreement with Health NZ or a PHO. For example, an accident and medical services providers that are funded by Health NZ or a PHO.
  - A provider providing a fully publicly funded service under a Section 94 Notice. For example, a midwife.
- Pharmacists when directly providing a medicine under the provisions in Part I of Section

A of the Pharmaceutical Schedule (eg, emergency contraception, nicotine replacement therapy).

 A Quitcard Provider when funded by Health NZ for a service under which a Quitcard is issued (For example, Quitline)

If a Subsidised Pharmaceutical is prescribed or provided for an Eligible Person aged 14 or over by a Prescriber/Provider who is **not** an Approved Provider, the maximum Co-payment that may be charged is up to \$15 for adults.

The following are **not** 'Approved Providers' (unapproved Provider):

- general practitioners who are not part of a PHO unless they have a service agreement with Health NZ for publicly funded services.
- private specialists if the Prescription Form does not relate to a Service User receiving a publicly funded service contracted by Health NZ.
- private specialists issuing a Prescription Form in the course of their private practice that relates to a Service User receiving a privately funded service.
- providers/prescribers providing a service that is privately funded and who do not have a contract with Health NZ or a PHO.
- a general practitioner that Health NZ has advised is not an Approved Providers (Districts may provide a list of the general practitioners in their District who are unapproved Providers).

### 10.3. Service User Subsidy Categories

The Service User categories described in the tables below indicate the eligibility status of a Service User, and the maximum Co-payment amount that the Service User may be charged.

### Key for the following tables:

Y	Youth (0-13 years)
J	Junior (14-17 years)
Α	Adult (18-64 years)
S	Senior (65 years and over)
Z	HUHC Holder/Care Plus Service User
Н	Hokianga resident enrolled with the HHET (see below)
0	Oral Contraceptive
1	CSC Card Holder
3	No CSC, and not Approved Provider
4	Approved Provider
NS	Not subsidised
С	Community Pharmacy Minor Health Conditions Service

#### Notes:

- Health NZ may change the Service User Category codes, or the maximum Co-payment listed in the tables below from time to time.
- Providers will be notified of these changes via the Pharmaceutical Schedule and/or directly by Health NZ.
- The Prescription Subsidy Card (PSC) will be retained for prescription Co-payments. People (family units) are eligible for no prescription Co-payments after 20 prescription Co-payments have been paid in the PSC year (1 February to 31 January the following year).
- The Community Pharmacy Minor Health Conditions Service C Code takes precedence over other subsidy code categories that may apply to the Service User.

### Youth (ages 0 to 13 years) - Y Code\*

	HUHC Holder / Care Plus Service User	Service User* category	Maximum prescription Co- payment	
			No PSC	With PSC
Approved Provider	Yes	Y4Z	\$0	\$0
	No	Y4	\$0	\$0
CSC Holder	Yes	Y1Z	\$0	\$0
	No	Y1	\$0	\$0
Neither of the above	Yes	Y3Z	\$0	\$0
	No	Y3	\$0	\$0

<sup>\*</sup> The Service User must be an Eligible Person

### Junior (ages 14 to 17 years) - J Code\*

	HUHC Holder / Care Plus Service User	Service User* category	Maximum prescription Co- payment	
			No PSC	With PSC
Approved Provider	Yes	J4Z	\$5	\$0
	No	J4	\$5	\$0
	-	O4	\$5	\$0
CSC Holder / child	Yes	J1Z	\$0	\$0
dependent	No	J1	\$0	\$0
	-	O1	\$0	\$0
Neither of the above	Yes	J3Z	\$5	\$0
	No	J3	\$10	\$0
	-	O3	\$5	\$0

<sup>\*</sup> The Service User must be an Eligible Person

### Adult (ages 18 to 64 years) - A Code\*

	HUHC Holder / Care Plus Service User	Service User* category	Maximum prescription Co- payment	
			No PSC	With PSC
Approved Provider	Yes	A4Z	\$5	\$0
	No	A4	\$5	\$0
	-	O4	\$5	\$0
CSC Holder	Yes	A1Z	\$0	\$0
	No	A1	\$0	\$0
	-	O1	\$0	\$0
Neither of the above	Yes	A3Z	\$5	\$0
	No	А3	\$15	\$0
	-	O3	\$5	\$0

<sup>\*</sup> The Service User must be an Eligible Person

### Senior (ages 65 and over) – S Code\*

	HUHC Holder / Care Plus Service User	Service User* category	Maximum prescription Co- payment	
			No PSC	With PSC
Approved provider	Yes	S4Z	\$0	\$0
	No	S4	\$0	\$0
CSC holder	Yes	S1Z	\$0	\$0
	No	S1	\$0	\$0
Neither of the above	Yes	S3Z	\$5	\$0
	No	S3	\$15	\$0

<sup>\*</sup> The Service User must be an Eligible Person

### Hokianga Ward of the Northland District – H Code\*

	HUHC Holder / Care Plus Service User	Service User* category	Maximum prescription Co- payment	
			No PSC	With PSC
Approved Provider	Yes	H4Z	\$0	\$0
	No	H4	\$0	\$0
CSC Holder	Yes	H1Z	\$0	\$0
	No	H1	\$0	\$0
Neither of the above	Yes	H3Z	\$0	\$0
	No	H3	\$0	\$0

<sup>\*</sup> The Service User must be an Eligible Person

A 'H' code is used for an Eligible Person who is usually resident in the Hokianga Ward of the Northland District and is enrolled with the Hokianga Health Enterprise Trust (HHET). A Copayment may not be charged, and Prescribers do not need to be employed by the HHET, nor use their Prescription Forms.

If a Provider receives an unmarked Prescription Form from an Eligible Person whose Prescription Form should have been coded H, or if another code is used but the Provider knows that the H code should have been used, the Provider may Annotate the Prescription Form with the H code in accordance with Section 5.5.

### Community Pharmacy Minor Health Conditions - C Code\*

		Service User* category	Maximum pre payr	escription Co- ment
			No PSC	With PSC
CSC Holder	Yes	C1	\$0	\$0
	No	C4	\$0	\$0

<sup>\*</sup> May only be used under agreement with Health NZ in accordance with an approved Community Pharmacy Minor Health Conditions Service.

## 11.Contacts

Blue Star Group (NZ) Ltd	0800 855 066
Medicines Control and Licencing Authority	04 4 816 2444 (Licensing) 0800 163 060 (Drug Abuse Containment) or medicinescontrol@health.govt.nz
National Health NZ Pharmacy Services	Pharmacy@tewhatuora.govt.nz
NZePS Help Desk	onlinehelpdesk@health.govt.nz
Pharmac	0800 660 050 or enquiry@pharmac.govt.nz
RxOne	09 300 7007 or support@rxone.co.nz
Sector Operations (Health NZ)	customerservice@health.govt.nz  Pharmacy Online System Support including pharmacy payments, NHI National Contact Centre, and Special Authority look up - 0800 855 066
ScriptSense	sales@scriptsense.co.nz
Toniq	03 341 0195
Work and Income	Community Service Cards - 0800 999 999 SuperGold Cards - 0800 552 002

## 11.1. Prescriber Registration check

Dentists	Dental Council of NZ
Dietitians	NZ Dietitians Board
Medical Practitioners	Medical Council of New Zealand
Midwives	Midwifery Council
Nurse Prescribers	Nursing Council of NZ
Optometrist Prescribers (TPA Endorsement)	Optometrists and Dispensing Opticians Board
Pharmacist Prescribers	Pharmacy Council of NZ
Veterinarians	Veterinary Council of New Zealand