

28 March 2012

PROPOSED CHANGES TO THE PHARMACEUTICAL SCHEDULE RULES RELATING TO DISPENSING FREQUENCY

Introduction

DHBs have undertaken extensive engagement with the sector to consider reconfiguration of community pharmacy services. Their objective is to develop a new tiered patient-centred service model for pharmacy, with the aim of improving the management of patients' medicine. Information is available on <http://www.centraltas.co.nz/DHBSharedServices/Pharmacy/LatestRelease/tabid/242/Default.aspx>. To support the proposed new pharmacy agreement; PHARMAC is proposing changes to the Pharmaceutical Schedule rules relating to dispensing frequency.

In the event that the proposed new pharmacy agreement proceeds to implementation, any supporting changes within the Pharmaceutical Schedule rules relating to dispensing frequency would come into effect at the same time. If the proposed new pharmacy agreement does not proceed, or there are significant changes to it, then PHARMAC would reconsider the proposals set out in this consultation.

At the moment Close Control provides a mechanism to dispense medicines more frequently in a number of scenarios including for:

1. trialing new medicines,
2. high risk medicines,
3. stock management,
4. monthly dispensing into Community and Aged Residential Care facilities; and
5. patients who are intellectually impaired, frail, infirm or unable to manage their medicines.

Pharmacy is paid a dispensing fee each time an item is dispensed Close Control. A significant proportion of Close Control use, especially weekly Close Control, is for patients who are intellectually impaired, frail, infirm or unable to manage their medicines. It is proposed to remove the category of "intellectually impaired, frail, infirm or unable to manage medicine" from the Close Control rule in the Pharmaceutical Schedule and transition these patients into the Long Term Conditions service specified in the proposed new pharmacy services agreement. It is proposed the remainder of the scenarios in the Close Control rule (1-4 above) would be retained in the Pharmaceutical Schedule, however it is proposed that it would be renamed the 'Dispensing Frequency' rule.

We are also proposing changes to Section F "Certified Exemptions and Access Exemptions to Monthly Dispensing" to enable pharmacists to initiate longer dispensing periods for patients who are stabilised on long-term medication. This would reduce unnecessary repeat dispensings where patients can be appropriately managed, and would enable pharmacies to better manage workflows.

A summary of the proposed changes are outlined below, and proposed wording of the rule is detailed later in this consultation letter. An information sheet highlighting key changes and commonly asked questions and answers is attached.

Summary of proposed changes

The proposed changes would focus on enabling pharmacists to better manage dispensing frequency to meet patients' clinical needs, without being impacted financially.

Proposed change	Current Schedule rule that would be affected
<p>If considered clinically appropriate and there is no exclusion in the Schedule, then the pharmacist <i>may dispense less frequently (or all-at-once)</i>.</p> <p>We would value feedback on whether this should apply to any Community Pharmaceutical listed on the Schedule (excluding those with specific restrictions) or only to Community Pharmaceuticals that are identified with a ▲ (which means 3 months supply may be dispensed at one time).</p>	<p>Section F: Part II: Certified Exemptions & Access Exemptions to Monthly Dispensing</p>
<p>Changing the term "Close Control" to "Dispensing Frequency" and update all rules in Section A & Section F and notes on relevant pharmaceuticals listed in the Schedule accordingly.</p>	<p>Section A: General Rules – Definition of Close Control, Glossary, Part III Period and Quantity of Supply Rule 3.1.7c) Rule 3.2.2a) Rule 3.2.4</p> <p><u>The following current pharmaceuticals with Close Control restrictions would remain unchanged:</u></p> <ul style="list-style-type: none"> • Dabigatran • Nicotine • Varenicline tartrate <p>Section F: Part I</p>
<p>Amend the definition of Dispensing Frequency (Close Control) to exclude patients who are intellectually impaired, frail, infirm or unable to manage their medicines</p>	<p>Section A: General Rules – Definition of Dispensing Frequency/Close Control</p>

Note, under the proposed new pharmacy agreement a pharmacist would continue to claim for drug cost as and when dispensed (e.g. if dispensed in a monthly lot then it must be claimed as a monthly lot).

We are planning to consult on additional related proposals in the near future:

- A review of dispensing periods for all medicines in the Pharmaceutical Schedule with the aim of reducing inconsistencies in dispensing frequencies (e.g. paroxetine vs. fluoxetine). We intend to issue a consultation letter on this in the near future.
- Alternative distribution options for expensive medicines. This was included in a discussion document issued in October 2010. As a result of that document we received useful feedback and will be using this information in the development of a proposal for consultation. In the meantime current distribution mechanisms will remain.

Feedback sought

PHARMAC welcomes feedback on this proposal. All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

To provide feedback, please submit it in writing by **5pm Friday, 20th April 2012** to:

Rachel Mackay
Manager, Schedule & Contracts
PHARMAC
PO Box 10 254
Wellington 6143

Email: rachel.mackay@pharmac.govt.nz

Fax: 04 460 4995

Detail

Specific wording for proposed changes is outlined below.

Dispensing Frequency Rule

The Pharmaceutical Schedule specifies for community patients a default period of supply for each Community Pharmaceutical.

“Frequent Dispensing” means dispensing:

- in quantities less than one 90 Day Lot (or for oral contraceptives, less than one 180 Day Lot) for a Community Pharmaceutical referred to in Section F Part I, or
- in quantities less than a Monthly Lot for any other Community Pharmaceutical, where any of A), or B) or C) apply.
- The Dispensing Frequency rule defines patient groups or medicines eligible for more frequent dispensing periods; and the conditions that must be met to enable any claim for payment of handling fees for the additional dispensings made.

A. Frequency of dispensing for persons in residential care

Pharmaceuticals can be dispensed in quantities of not less than 28 days to:

- any person whose placement in a Residential Disability Care institution is funded by the Ministry of Health or a DHB; or
- a person assessed as requiring long term residential care services and residing in an age related residential care facility;

on the request of the person, their agent or caregiver or community residential service provider, provided the following conditions are met:

- I. the quantity or period of supply to be dispensed at any one time is not less than 28 days' supply (except under conditions outlined in B.i below); and
- II. the prescribing Practitioner or dispensing pharmacist has
 - 1) included the name of the patient's residential placement or facility on the prescription; and
 - 2) included the patient's NHI number on the prescription; and
 - 3) specified the maximum quantity or period of supply to be dispensed at any one time.

Any person meeting the criteria above who is being initiated onto a new medicine or having their dose changed is able to have their medicine dispensed in accordance with B.i below.

B. Flexible periods of supply for trial periods or safety

The Schedule specifies for community patients a default length of dispensing (monthly/three monthly) for each pharmaceutical. Prescribers can request, and pharmacists may dispense and claim payment for, a higher frequency of dispensing in the following circumstances:

i) Trial Periods

The Community Pharmaceutical has been prescribed for a patient who requires close monitoring due to recent initiation onto, or dose change for, the Community Pharmaceutical (applicable to the patient's first changed Prescription¹ only); and all of the following conditions must be met:

The prescribing Practitioner has:

- endorsed each Community Pharmaceutical on the Prescription clearly with the words "Trial Period", or "Trial"; and
- initialed the endorsement in their own handwriting; and
- specified the maximum quantity or period of supply to be dispensed at any one time.

All of the following conditions must be met:

The Community Pharmaceutical has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in clause A above.

The prescribing Practitioner has:

- initialed the 'Trial Period' or 'Trial' endorsement in their own handwriting; and
- specified the maximum quantity or period of supply to be dispensed at any one time.

ii. Safety

1) the Community Pharmaceutical is any of the following:

- a. a tri-cyclic antidepressant; or
- b. an antipsychotic; or
- c. a benzodiazepine; or
- d. a Class B Controlled Drug; or
- e. codeine

All of the following conditions must be met:

The Community Pharmaceutical has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in clause A above.

The prescribing Practitioner has:

- Assessed clinical risk and determined the patient requires more a frequent period of dispensing than specified in the Pharmaceutical Schedule; and
- specified the maximum quantity or period of supply to be dispensed at any one time.

C. Pharmaceutical Supply Management

More frequent dispensing may be required from time to time to manage stock supply issues or emergency situations. Pharmacists may dispense more frequently than the Schedule would otherwise allow when all of the following conditions are met:

i) PHARMAC has approved and notified pharmacists to annotate prescriptions for a specified Community Pharmaceutical(s) "out of stock" without prescriber endorsement for a specified time; and

ii) the dispensing pharmacist has:

- 1) clearly annotated each of the approved Community Pharmaceuticals that appear on the prescription with the words "out of stock" or "OOS"; and
- 2) initialed the annotation in their own handwriting; and
- 3) has complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

¹ Prescription is defined in the Pharmaceutical Schedule and means a quantity of a Community Pharmaceutical prescribed for a named person on a document signed by a Practitioner.

If a dispensing frequency is expressly stated in the Medicines Act, Medicines Regulations or Pharmacy Services Agreement a pharmacy can dispense at that specified dispensing frequency. However, no claim shall be made to any DHB for subsidised payment for dispensing fees in any case where dispensing occurs more frequently than authorised by the provisions of the Pharmaceutical Schedule.

Section F: Part II: Certified Exemptions and Access Exemptions to Monthly Dispensing (Page 203 of the Pharmaceutical Schedule)

A Community Pharmaceutical, other than a Community Pharmaceutical identified with a * within the others sections of the Pharmaceutical Schedule, may be dispensed in a 90 Day Lot if:

- a) the Community Pharmaceutical is identified with a ▲ within the other sections of the Pharmaceutical Schedule and the prescriber has endorsed the Prescription item(s) on the Prescription to which the exemption applies "certified exemption". In endorsing the Prescription items for a certified exemption, the prescriber is certifying that:
 - i) the patient wished to have the medicine dispensed in a quantity greater than a Monthly Lot; and
 - ii) the patient has been stabilised on the same medicine for a reasonable period of time; and
 - iii) the prescriber has reason to believe the patient will continue on the medicine and is compliant; or
- b) a patient, who has difficulty getting to and from a pharmacy, signs the back of the Prescription to qualify for an Access Exemption. In signing the Prescription, the patient or his or her nominated representative must also certify which of the following criteria they meet:
 - ii) Have limited physical mobility;
 - iii) Live and work more than 30 minutes from the nearest pharmacy by their normal form of transport;
 - iiii) Are relocating to another area;
 - iv) Are travelling extensively and will be out of town when the repeat prescriptions are due; or
- c) the patient has been stabilised on the same medicine for a reasonable period of time; and using good clinical judgement the pharmacist has reason to believe the patient will continue on the medicine and is compliant. The pharmacist must annotate the Prescription item(s) on the Prescription to which the exemption applies "certified exemption".

The following Community Pharmaceuticals are identified with a ▲ within the other sections of the Pharmaceutical Schedule and may be dispensed in a 90 Day Lot if endorsed as a certified exemption in accordance with paragraph (a) in Section F Part II above.

We note that changes to the Close Control rule were implemented 1 October 2011. In the consultation and notification letters for those changes we noted that further changes may be required to Schedule rules to align them with the proposed new pharmacy contract. A brochure explaining the 1 October 2011 changes can be found at <http://www.pharmac.govt.nz/2011/10/26/Changes%20to%20Close%20control.pdf>

Summary of proposed changes - key points

- The name of the “Close Control” rule is proposed to change. It would be called the “Dispensing Frequency” rule.
- The following parts of the rule remain largely the same (proposed changes in italics):
 - trialling new medicines or a change in dose,
 - high risk medicines (*it is proposed to add codeine to the list & remove the need for the prescriber to annotate the prescription with the words “Safety” or “Safety Period”*),
 - stock management,
 - monthly dispensing into Community and Aged Residential Care facilities (*it is proposed to provide pharmacy with an updated list of supported living providers*)
- The section “patients who are intellectually impaired, frail, infirm or unable to manage their medicines” would be deleted.
 - Patients who meet the ‘Long Term Conditions Services’ Assessment criteria included in the Community Pharmacy Services Agreement would access compliance and adherence support through those services.
 - Patients who do not meet the assessment criteria would need to be transitioned to normal dispensing periods.
- We are proposing changes to Section F “Certified Exemptions and Access Exemptions to Monthly Dispensing” to enable pharmacists to initiate longer dispensing periods for patients who are stabilised on long-term medication. This would reduce unnecessary repeat dispensings where patients can be appropriately managed, and enable pharmacies to better manage workflows.
 - We would value your feedback on whether this should apply to any Community Pharmaceutical listed on the Schedule (excluding those with specific restrictions) or only to Community Pharmaceuticals that are identified with a ▲ (which means 3 months supply may be dispensed at one time).
- It is proposed the changes would come into effect in conjunction with the implementation of the proposed new pharmacy agreement. If the proposed new pharmacy agreement does not proceed, or there are significant changes to it then PHARMAC intends to reconsider the form of the rule change.
- The proposed changes will need to be considered by the PHARMAC Board for approval.
- We plan on consulting on a list of medicines in the Schedule that could change from monthly dispensing to 3-monthly dispensing, with the aim of reducing inconsistencies in dispensing frequencies (e.g. paroxetine vs fluoxetine).

Questions

1. *What will be the new dispensing fee for frequent dispensings?*

Pharmacy will be paid a handling fee for each item every time it is dispensed. The rest of the clinical services will be reimbursed through the Transition Payment during the transition phase of the pharmacy agreement.

2. *How will current Close Control prescriptions be managed once the rules change?*

Patients who have had more frequent dispensings due to being “intellectually impaired, frail, infirm or unable to manage their medicines” should continue to receive the same frequency of dispensings until they are assessed to see if they are eligible for additional support under the Long-Term Conditions service. The structure of the remainder fee payment provides funding for pharmacy to continue to provide more frequent dispensings for patients until they are assessed.

Patients who meet the ‘Long Term Conditions Services’ Assessment criteria (included in the Pharmacy Agreement) would access compliance and adherence support through those services.

If the patient does not meet the criteria they will need to transition to normal dispensing periods.

3. *How will I manage blister / compliance packaging?*

Compliance packaging is not funded under the Dispensing Frequency rule. It is included as one of the available tools that pharmacists can use to support their patients in the Long-Term Conditions service. See the pharmacy agreement currently being consulted on for details of the LTC tools.

4. *How will I manage rest homes?*

The distribution frequency for rest homes doesn’t change.

5. *Is the list of medicines that can be dispensed more frequently for safety reasons the same?*

We are proposing to add codeine to the list and seek your views on this.

6. *Will mental health patients have access to appropriate levels of pharmacy support services?*

Mental health patients would be able to access more frequent dispensings for medicines they may be on that meet the “safety” criteria e.g. anti-psychotics, as they currently do. In addition, they will be able to access further support services if they meet the Long-Term Conditions eligibility criteria.