



Guidelines for the continued dispensing of eligible prescribed medicines by pharmacists

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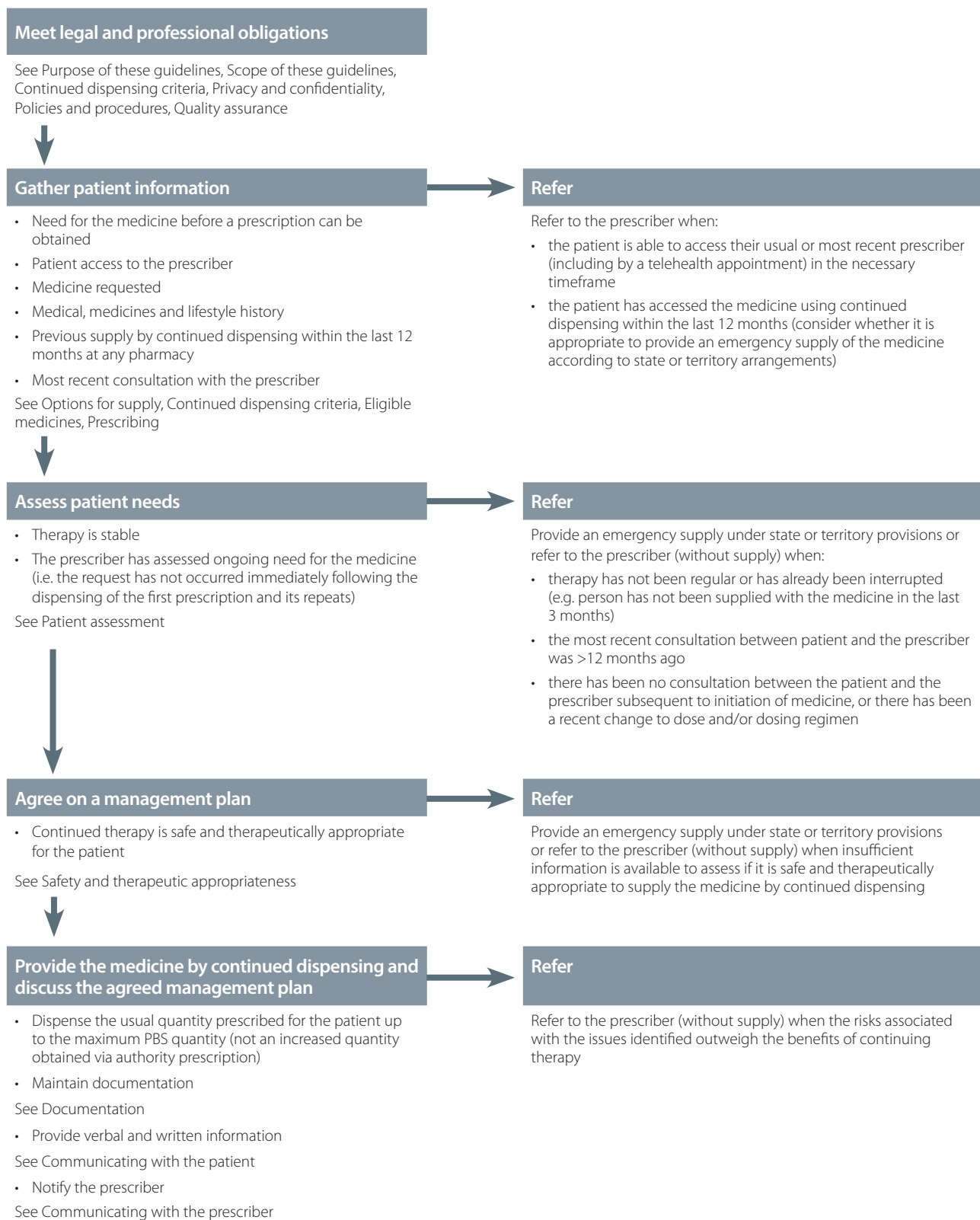
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Service overview



Introduction

Continued dispensing is the supply of an eligible medicine to a person by an approved pharmacist, where there is a need for that medicine but the prescriber is unable to be contacted or is unable to provide an electronic prescription. Additional conditions for continued dispensing apply.

Background

The effectiveness of a medicine prescribed for a person and the health outcomes achieved are dependent on the extent to which a person adheres to and persists with the dosing regimen for that medicine.^{1,2} Low adherence to prescribed therapies is common.²

Pharmacists can implement strategies with the patient to support adherence to and persistence with medicines. These might include providing instructions and information, monitoring the effectiveness of medicines, motivational counselling, simplifying dose regimens, providing dose administration aids, using telephone/email reminder systems, and facilitating continuity of supply of medicines.³

When a prescribed therapy is required and a valid prescription not available, it is not always possible to access the prescriber. Difficulty accessing the prescriber, which can occur for a variety of reasons, can contribute to non-adherence to therapy. There are various arrangements for supply enabled by legislation to support people in this situation.

Continued dispensing is one of these supply arrangements to support continuity of therapy. This is consistent with the objectives of the *National Medicines Policy*⁴ and community pharmacy agreements⁵ of providing timely and affordable access to the medicines Australians need.

About the document

Purpose of these guidelines

These guidelines are intended to provide advice and guidance to assist pharmacists to meet their professional responsibilities, exercise professional judgement in individual circumstances and manage risks associated with the continued dispensing of eligible prescribed medicines.

It is important that pharmacists read these guidelines in conjunction with relevant *Professional Practice Standards*.⁶ See Figure 1.

Community pharmacists should also be familiar with Australian Standard 85000 (Quality Care Community Pharmacy Standard).⁷

In general terms, guidelines are not definitive statements of correct procedure but are designed to provide advice or guidance on professional issues, desired behaviour for good practice and how responsibilities may be best fulfilled.

Standards are objective statements of the minimum requirements necessary to ensure a service is delivered with a desirable level of acceptable or intended performance or results.

The standards relate to the systems pharmacists should have in place for the delivery of a service and provide a benchmark against which performance can be assessed.

See Figure 2 for information about the relationship between documents that articulate, govern and guide pharmacist practice.

Scope of these guidelines

These guidelines focus on the best-practice process for the continued dispensing of eligible prescribed medicines and are not intended to provide any clinical information or advice.

Details of legislative requirements are not comprehensively addressed in these guidelines. For the continued dispensing of eligible medicines, pharmacists must comply with relevant Commonwealth or state or territory legislation governing therapeutic goods, drugs and poisons, pharmacists (health practitioners), pharmacies (premises), privacy and confidentiality. Where continued dispensing requirements are specified in legislation and there is conflict with the requirements specified in these guidelines, the legislative requirements take precedence over these guidelines.

Pharmacists are expected to apply professional judgement in the continued dispensing of eligible medicines and manage any associated risks. They will need to make risk–benefit assessments and other professional judgements from time-to-time based on the best available information and current evidence. Records should be kept of assessments, ensuring that all significant decisions are documented.


















Pharmacists have a professional and legal responsibility to confirm that medicines are safe and therapeutically appropriate for patients to use.⁶ While these guidelines have been developed to assist pharmacists with continued dispensing, they may also provide some guidance for the supply of medicines by other arrangements in urgent or emergency situations.

About continued dispensing

Scope of continued dispensing

Commonwealth and state and territory legislation require that Schedule 4 (*Prescription Only*) medicines are only supplied on presentation of a prescription. Further, for medicines to be considered a pharmaceutical benefit under the Pharmaceutical Benefits Scheme (PBS), a valid PBS prescription is required. However, there are allowances included in the corresponding regulations that enable a pharmacist to supply a prescription medicine in urgent or emergency situations. See www.psa.org.au/resource/state-and-territory-legislation for relevant legislation.

Figure 1: Professional practice standards relevant to continued dispensing

| Domains | Standards | Stage of the service the standard addresses |
|------------------------------|--|--|
| FUNDAMENTAL |  Person-centred care | Standards in the fundamental domain always apply to all aspects of a specific service or professional activity a pharmacist delivers |
| |  Responsibility and accountability | |
| |  Collaborative practice | |
| SERVICE DELIVERY |  Service delivery | Follow systematic procedures |
| PATIENT ASSESSMENT |  Patient assessment | Identify patient, validate ongoing therapeutic need for medicine |
| PRESCRIBING |  Prescribing | Decide to prescribe medicine – safe, indicated and appropriate timing |
| DISPENSING AND PREPARATION |  Dispensing | Dispense the medicine |
| |  Compounding | |
| |  Medicine packing | |
| |  Safe and secure handling of therapeutic goods | Store the medicine |
| ADMINISTRATION |  Administration of a medicine | |
| REVIEW AND MONITORING |  Medication review | |
| |  Medicine use evaluation | |
| |  Patient monitoring | |
| PROVIDING HEALTH INFORMATION |  Providing health information (patient counselling) | Provide information about the medicine and condition |
| PUBLIC HEALTH |  Screening, case-finding and risk assessment | |
| |  Health promotion | |

Reference: Pharmaceutical Society of Australia⁶

Figure 2. Guidance and regulation of pharmacist practice in Australia



Reference: Pharmaceutical Society of Australia⁶

In an urgent case, a prescriber may communicate a prescription to a pharmacist personally by telephone or other means. The prescriber is then obliged to supply a prescription to the pharmacist within a specified timeframe. The prescription also allows the pharmacist to claim payment for the supply of the medicine under the PBS, if applicable.

Where it is not possible to contact the prescriber, state and territory legislation allows for an 'emergency supply' of medicines without a prescription. The quantity supplied is generally limited to no more than that required for three days' treatment or the smallest standard pack for specific medication forms (this varies between states and territories, but examples include liquids, topical preparations and aerosols). However, patients may not always be able to arrange for a new prescription before the emergency supply runs out. Medicines supplied in this manner are not subsidised under the PBS.

Subject to state or territory legislation, continued dispensing enables pharmacists to supply a standard pack of an eligible medicine to patients in a community pharmacy under defined circumstances when a valid prescription is not available.

Continued dispensing is intended to complement but not replace the provisions of other supply arrangements in urgent or emergency situations as referred to above.

The continued dispensing of eligible prescribed medicines must be considered as part of the Medicines Management Cycle⁸ (see Figure 3), specifically in the review of the medicine order and issuing of the medicine.

Figure 3: The medicines management cycle



Reference: Stowasser⁸

Options for supply

When a patient requests supply of Schedule 4 medicine for which they do not have a valid prescription or authorisation to supply, a pharmacist has four options:

1. Dispense the medicine on receipt of an order from the prescriber by telephone or other means (with a written prescription to follow).
2. Provide an emergency supply of the medicine according to state or territory provisions.
3. Provide the medicine by continued dispensing.
4. Decline to supply the medicine.

Use professional judgement to determine the most appropriate option for the patient with consideration of Commonwealth and state or territory legislation.

A patient may request multiple medicines without valid prescriptions. If supplying one medicine by continued dispensing and other medicines under other supply provisions or not at all, consider the potential confusion this may cause for the patient. Balance the risk of confusion with the benefit of continuation of therapy to determine the most appropriate option for supply.

Continued dispensing criteria

Pharmacists can supply medicines by continued dispensing under the following circumstances:

- The prescriber who most recently prescribed the medicine is unable to be contacted and/or is unable to provide an electronic prescription. The most recent prescriber of the medicine can have been any health professional approved to prescribe the eligible medicine, subject to relevant state or territory legislation.
- The medicine requested is identified in the relevant legislation as eligible for supply by continued dispensing (see Eligible medicines).
- The medicine has been previously supplied to the patient using a valid prescription.
- The last supply of the medicine was based on a valid prescription.
- The patient's therapy is stable (see Patient assessment).
- The patient has been taking the medicine regularly for an uninterrupted period, and in that time the prescriber has assessed their condition and determined there is a need for ongoing treatment with the medicine (see Patient assessment).
- The medicine has not been supplied to the person under continued dispensing arrangements in the 12 months before the requested supply (Services Australia-Medicare systems will reject PBS payment for attempted continued dispensing supplies made within this 12 month period, provided past continued dispensing records are held by Services Australia-Medicare).
- There is an ongoing need for supply to facilitate continuity of therapy, and the medicine is safe and therapeutically appropriate for that patient (see Safety and therapeutic appropriateness of the medicine).

Relevance to funding arrangements

Continued dispensing enables pharmacists to supply eligible prescribed medicines under the PBS without a valid prescription. In such cases, dispensing software will facilitate compliance with the Services Australia-Medicare claiming requirements to capture the patient's signed acknowledgement of receipt following dispensing.

When eligible medicines are supplied by continued dispensing under the PBS, the following apply:

- PBS patient contributions and refund requirements.
- Immediate supply 20 day and 4 day rules.
- PBS safety net and safety net threshold.
- Closing the Gap PBS Copayment Program (reduction or removal of the PBS copayment for eligible Aboriginal and Torres Strait Islander people).

Guidance for supplying PBS medicines by continued dispensing is available on the PBS website www.pbs.gov.au/info/general/continued-dispensing

Eligible medicines

A legislative instrument under the National Health Act 1953 identifies medicines eligible for supply by continued dispensing under the PBS. The list of medicines is available under Schedule 1 of the National Health (Continued Dispensing) Determination 2022. These medicines will be flagged in dispensing software and PBS Online.

Medicines eligible for continued dispensing under the PBS are predominantly for the management of chronic disease, such as asthma and other lung conditions, diabetes and heart disease, as well as medicines for the treatment of human immunodeficiency virus (HIV). Schedule 8 (*Controlled*) medicines are not eligible for continued dispensing. Authority Required (Streamlined) and Authority Required medicines are eligible for continued dispensing. However, only up to the PBS maximum quantity or number of units may be supplied (i.e. increased quantities under Authority arrangements are not included).

State or territory legislation should be consulted to identify how continued dispensing applies in the respective jurisdictions. In some states or territories, some Schedule 4 (*Prescription Only*) medicines that are not eligible for continued dispensing under the PBS are eligible for continued dispensing under non-PBS or 'private' funding arrangements.

Before a medicine is supplied by continued dispensing arrangements, provide the patient with information about the cost of the medicine. Also provide the patient with information about alternative options for supply to enable them to make an informed decision about the supply arrangement that best suits their needs.

Preparing for the service

Privacy and confidentiality

Always respect and safeguard the patient's privacy and confidentiality,⁹ particularly in relation to information acquired in the course of pharmacy practice.

In the process of continued dispensing, pharmacists may need to gather information from other pharmacies or health professionals. Only the information necessary to meet quality standards and legislative requirements for continued dispensing should be collected and the information should only be used for this purpose.¹⁰ Take reasonable steps to ensure the patient understands:

- what information is being collected
- why the information is being collected
- who within the pharmacy will have access to the information
- how the information will be used and shared
- the consequences of not collecting the information.

Pharmacists who are contacted to share health and medical information for the purpose of continued dispensing (e.g. dispensing records) must obtain consent from the patient prior to disclosing any information.¹⁰ The pharmacist who is requesting the information can facilitate the provision of consent.

Pharmacists must be aware of restrictions that apply to the disclosure of health information and government-related identifiers. The website of the Office of the Australian Information Commissioner contains useful guidance on the use and disclosure of information www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy

Required pharmacist competencies

The competencies required by pharmacists supplying eligible prescribed medicines by continued dispensing are the same as those for dispensing with a valid prescription. See the *National Competency Standards Framework for Pharmacists in Australia*.¹¹

Policies and procedures

Effective documentation is essential for optimal safety, quality and efficiency in the supply of medicines.

Develop and maintain policies and procedures for responding to requests to supply eligible prescribed medicines in urgent or emergency situations without a valid prescription. Review and update policies and procedures at regular intervals and as required. Staff should record that they have read, and are familiar with, the policies and procedures.

Policies and procedures relating to continued dispensing should include details about:

- the purpose, principles, risks and limitations of continued dispensing
- roles and responsibilities of staff involved in delivering the service (including locum or temporary staff)
- staff training
- responding to a request from a third party for supply of a prescribed medicine without a valid prescription
- obtaining patient consent, including financial consent, consent to access medical records and consent to communicate with relevant persons involved in their care
- managing patient health information
- documenting continued dispensing (see Documentation)
- communicating with the prescriber
- procedures for dealing with complaints
- quality control, quality assurance and monitoring (see Quality assurance).

It is not the intent of these guidelines that supply of a medicine by continued dispensing be made to a third party on behalf of a patient (indirect supply). However, where indirect supply is necessary in, or appropriate to, the patient's circumstances, consider whether the required information is available to ensure supply is therapeutically appropriate (see Patient assessment and Safety and therapeutic appropriateness) and whether patient consent can be obtained and privacy maintained.^{6,12}

Staff responsibilities

It is important that all pharmacy staff members:

- are informed about the general nature of the service
- are clear about their respective roles and responsibilities
- are familiar with relevant policies and procedures
- understand the responsibility of the pharmacist in the delivery of the service.

Pharmacists may be assisted in the continued dispensing of eligible medicines by a dispensary assistant or technician. However, the pharmacist in charge is responsible for ensuring that the dispensary assistant or technician's functions are limited to those functions that do not require them to exercise professional judgement or discretion.¹² The pharmacist must retain responsibility for assessing the therapeutic appropriateness of the medicines in relation to the full medication history, the final checking of dispensed medicines and providing advice and information to the patient.¹²

Adequate provision must be made for staff time and resources required to explain the supply arrangement to, and liaise with, patients, prescribers and other health professionals.

Prescribing

The decision to continue prescribing a medicine is one that the prescriber makes with a patient based on a clinical review of the patient's condition and the best available evidence, according to the patient's treatment goals. This clinical review by the prescriber may be delayed beyond the prescriber's original intentions when a medicine is supplied by continued dispensing. The risk of delaying this review should be balanced with the benefit of continuity of therapy in determining whether continued dispensing of the requested medicine is appropriate for the individual.

The pharmacist must be able to identify the most recent prescriber of the requested medicine and their practice address. The dispensing record, together with consultation with the patient, can be used to identify the prescriber and determine whether they have had the opportunity to adequately review the patient for suitability of continuing the medicine.

If the patient is not a regular customer of the pharmacy, the pharmacist must be able to confirm the patient has been taking the medicine without significant interruption of therapy. Examples of ways to verify this information include, but are not limited to:

- contacting the pharmacy that has dispensed medicines for the patient most recently and regularly
- accessing the patient's My Health Record
- viewing the most recently dispensed package of the medicine with the affixed dispensing label.

Patient assessment

Before supplying a medicine by continued dispensing, establish that the patient's therapy is stable, and the prescriber has assessed the need for ongoing treatment with the medicine (prior clinical review).

Indicators that can be used to establish that therapy is stable and there has been adequate prior clinical review by the prescriber include, but are not limited to, the following:

- The medicine has been prescribed for the patient with the same dosage regimen at subsequent consultations after the initial prescription for the medicine (e.g. the request for the medicine has not occurred immediately following the dispensing of the first prescription and its repeats).
- The medicine has been taken regularly by the patient, without significant interruption, prior to the request for its supply.
- The most recent prescription for the medicine included the same (not fewer) number of repeats as usually prescribed for the patient.
- The patient has not had a hospital admission since last having the medicine prescribed.
- The patient has had a consultation with the prescriber (or prescriber's medical practice) in the past 12 months (e.g. the previous prescription was not provided without a consultation).
- The medicine has been prescribed under 60-day dispensing arrangements.

Alternative supply and referral arrangements to continued dispensing should be pursued if the pharmacist is not satisfied they can confirm the stability of therapy for the patient, uninterrupted supply and prior clinical review by the prescriber (see Options for supply).

Dispensing

Supply of eligible medicines by continued dispensing is expected to be performed to the same standards as dispensing with a valid prescription. See *Professional Practice Standards*⁶, *Dispensing Practice Guidelines*¹³ and the Good dispensing practice chapter of *Australian Pharmaceutical Formulary and Handbook*¹⁴.

For continued dispensing under the PBS, provide the quantity of medicine that is usually prescribed for the patient up to the PBS maximum quantity or number of units. If the patient's previous prescription for the medicine was a 60-day maximum quantity PBS item, provide the 60-day dispensing quantity. If the prescriber has previously obtained authority approval for supply of an increased quantity, only the standard PBS maximum quantity may be provided by continued dispensing.

Safety and therapeutic appropriateness of the medicine

When dispensing under any supply arrangement, use professional judgement to confirm the medicine is safe and therapeutically appropriate for the patient.¹²

Review the patient's My Health Record and dispensing record and consult with the patient to determine¹³⁻¹⁵:

- there is a clear indication for continuing therapy with the medicine
- the dose and frequency appear to be appropriate
- the dose form continues to be appropriate for that patient
- there are no contraindications (due to allergies/adverse medicine events or clinical conditions)
- the patient has been taking the medicine as prescribed or directed
- there is no duplication of medicines or medicine classes
- the patient has not commenced or ceased any other medicine that would affect their response to the medicine or lead to an interaction
- the patient has not had a change to their health status (e.g. conditions, lifestyle) that could affect their response to the medicine or lead to an interaction
- the patient understands their therapy and there is no significant confusion that cannot be resolved.

Balance the risks identified during this review and consultation with the benefit of continuity of therapy to determine whether continued dispensing of the requested medicine is appropriate for the individual.

Documentation

Record the supply of the medicine by continued dispensing in the dispensing system consistent with the recording of dispensing with a valid prescription. Two forms will be generated by the pharmacy dispensing system. See Table 1.

Document any information used to support the decision to supply the medicine by continued dispensing, including the:

- patient's name, address, date of birth, Services Australia-Medicare number and any entitlement numbers
- details obtained from the patient's My Health Record
- details of any dispensing history obtained from other pharmacies or from the most recent dispensing label affixed to the medicine packaging
- most recent prescriber and practice details
- patient history (clinical) notes obtained during consultation with the patient, including the reason for request
- details of any communication with other health professionals and the prescriber
- medicine name, strength, form, quantity supplied and directions for use
- date of supply.

The continued dispensing record must include a statement that:

- the medicine supplied is a pharmaceutical benefit that can be supplied under continued dispensing arrangements (if supplied under the PBS);
- the specified conditions for continued dispensing have been satisfied; and
- the medicine needs to be supplied to facilitate continuity of treatment.

Record and report any incidents or near misses associated with continued dispensing according to established policies and procedures for recording and reporting incidents or near misses.⁶

Maintain continued dispensing records in a manner consistent with other dispensing and medicine supply records. A copy of completed and signed forms must be kept for two years from the date of supply. Record management must comply with Commonwealth and state or territory legislation.

Communication

Communicating with the patient

Counselling and the provision of supporting written information (e.g. Consumer Medicine Information) that occurs with the supply of eligible medicines by continued dispensing is expected to be performed to the same standards that apply for any other professional service in the pharmacy. Provide information to the patient in a way that meets their needs, taking into account their health literacy, digital literacy and medicine literacy. See the *Professional Practice Standards* www.psa.org.au/practice-support-industry/pps.⁶

When multiple medicines have been requested in an urgent or emergency situation and different supply arrangements apply, inform patients about the different supply arrangements during counselling to minimise potential confusion.

Table 1. Forms generated by pharmacy dispensing system

| | Modified repeat authorisation form | Consumer declaration and prescriber notification form |
|---------------------------------|--|---|
| Patient consent | Patient to sign a declaration providing consent for supply by continued dispensing and to acknowledge receipt of the medicine (to support claim for payment through Services Australia-Medicare) | To indicate the patient understands they were supplied the medicine without consultation with the prescriber |
| Record of supply | Record details of the continued dispensing supply | |
| Prescriber communication | | Notify the patient's most recent prescriber (or practice) that the medicine was supplied without a prescription by continued dispensing (see Communicating with the prescriber) |

Emphasise the importance of the patient having their therapy and health reviewed regularly with the prescriber. Advise the patient that a prescription was not required for this supply of the medicine. However, they will need to organise an appointment for a consultation with the prescriber immediately, as a subsequent supply of the medicine by continued dispensing by any pharmacy will not be allowed within the next 12 months. Inform patients that the most recent prescriber (and the patient's usual prescriber, if different) will be notified of the supply by continued dispensing. See Policies and procedures and Communicating with the prescriber.

Communicating with the prescriber

Communication with the prescriber supports continuity in medication management of the patient. The pharmacist must provide written communication to the most recent prescriber (and the patient's usual prescriber, if different) advising them of the supply of the medicine to the patient by continued dispensing. This should occur within 24 hours.

The information that should be provided to the prescriber includes the:

- patient details (name, address, date of birth)
- date the medicine was supplied without a valid prescription
- details of any medicine dispensed (including strength, form, quantity supplied and directions for use)
- reason for continued dispensing
- declaration co-signed by the patient indicating their understanding of, and consent to, the supply (the form generated by the dispensing software can be used to satisfy this requirement, see Documentation).

Quality assurance

Quality control, quality assurance and monitoring activities are used to ensure the supply of eligible medicines by continued dispensing meets the quality requirements of professional practice.

Examples of quality control, quality assurance and monitoring activities include:

- staff education
- reflective (peer or self-reflective) performance reviews
- audits of workload and impact on resources
- communication audits
- reviews of policies and procedures manuals
- patient satisfaction surveys
- procedures for dealing with complaints.

Audits and reviews should be carried out at least annually. More frequent audits and reviews may be useful or warranted during the early stages of establishment for this supply arrangement.

Analyse and record the results of surveys, audits and reviews together with any action taken or outcome. The findings from these activities can inform future system improvements. Any actions taken can be integrated as part of the improved system.

The supply of eligible medicines by continued dispensing under the PBS is subject to the usual Services Australia-Medicare compliance and audit program.

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Appendix 1 – Practice Tool for Continued Dispensing



Medicine requested without a valid prescription

Date:

Patient details

Pharmacist:

Name:

D.O.B:

Address:

Consent provided to obtain information from other sources (tick if yes)

Information source details (e.g. other pharmacy details):

| | | |
|---|---|-------|
| Medicine requested | Generic name | |
| | Brand name | |
| | Strength | |
| | Dose form | |
| | Last prescription <ul style="list-style-type: none"> • Prescriber • Date prescribed • Date last dispensed | |
| | Indication | |
| | Dosing regimen | |
| | Duration on this medicine at this dosage | |
| | Taken regularly, without interruption? | |
| | Previous supply without a valid prescription in the past 12 months? | |
| Health and medical status | Approximate date of last consultation with the prescriber? | |
| | Current medications (including OTC and complementary medicines) | |
| | Changes to health status since last consultation? <ul style="list-style-type: none"> • Hospital admissions? • Changes to medications? • Changes to medical conditions? • Lifestyle factors that may influence response to therapy? • Possible adverse effects being experienced? | |
| Other issues influencing supply decision? | | |
| Supply decision* | | |

*NS = No supply; TO = Telephone order provided; ES = Emergency supply; CD = Continued Dispensing; R = Referred to prescriber

Note: This form is intended as a general template for the pharmacist to use to gather patient information when a medicine is requested without a valid prescription. This information should be used in conjunction with pharmacy dispense records (and other sources of information) in considering the supply of a medicine without a valid prescription. At all times, pharmacists are expected to exercise professional judgement in using it for specific presenting circumstances.

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