Pharmaceutical Society of Australia

Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists

PSA Committed to better health

The review of the *Guidelines for the continued dispensing of eligible prescribed medicines by pharmacists* has been funded by the Australian Government Department of Health.

The work to update the Guidelines has involved review by experts, stakeholder feedback, and consensus of organisations and individuals involved.

The Pharmaceutical Society of Australia (PSA) thanks all those involved in the review process and, in particular, gratefully acknowledges the contribution of the following individuals and organisations.

Pharmacist Consultant

Kylie Woolcock

Expert Review Group

Anne Develin, Pharmacy Guild of Australia

Dr Shane Jackson, Pharmaceutical Society of Australia

Dr Michael Nolan, Australian General Practice Network

Toni Riley, Pharmacy Guild of Australia

Dimitra Tsucalas

Glenn Ward

Vanessa McMahon, Department of Health and Ageing (observer)

David Pearson, Department of Health and Ageing (observer)

Project Working Group

Anne Develin, Pharmacy Guild of Australia

Claire Antrobus, Pharmaceutical Society of Australia

Dr Shane Jackson, Pharmaceutical Society of Australia

Vanessa McMahon, Department of Health and Ageing

David Pearson, Department of Health and Ageing

Toni Riley, Pharmacy Guild of Australia

PSA Project Team

Claire Antrobus

Simon Carroll

Sarah Curulli

Disclaimer

Neither the PSA, nor any person associated with the preparation of this document, accepts liability for any loss which a user of this document may suffer as a result of reliance on the document and, in particular, for:

- use of the Guidelines for a purpose for which they were not intended
- any errors or omissions in the Guidelines
- any inaccuracy in the information or data on which the Guidelines are based or which is contained in them
- any interpretations or opinions stated in, or which may be inferred from, the Guidelines.

Notification of any inaccuracy or ambiguity found in this document should be made without delay in order that the issue may be investigated and appropriate action taken. Please forward your notification to: Pharmaceutical Society of Australia, PO Box 42, Deakin West, ACT 2600.

Reviewed and updated by the PSA (September 2020)

Contents

Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists

Continued Dispensing is the supply of an eligible medicine to a patient under the Pharmaceutical Benefits Scheme when there is an immediate need for that medicine but it is not practicable to obtain a prescription, provided:

- the medicine has been previously prescribed, therapy is stable and there has been prior clinical review by the prescriber that supports continuation of the medicine; and
- the medicine is safe and appropriate for the patient.

1. About the document

1.1 Background

The effectiveness of a medicine prescribed for an individual 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] For example, poor adherence to a medicine regimen post-acute myocardial infarction results in a two to sixfold increase in the risk of death within a year of the event.[3]

Low adherence to prescribed therapies is common.[2] Adherence rates to long-term therapies are estimated to be on average around 50% in the general population.[1] However rates as low as 11% have been reported, depending on such things as the condition being treated, medicine type, demographics of the population and the method used to measure adherence.[1,4] Adherence rates reported for some specific medicines are described in Box 1.

Non-adherence may be intentional or unintentional and the contributing factors are diverse. Five interplaying factors have been identified that influence a person's medicine-taking behaviour: therapy-related factors; condition-related factors; health system/ healthcare team factors; social/economic factors; and patient-related factors.[1]

Improving adherence to medicines requires consideration of these contributing factors and an individualised approach to addressing the specific circumstances of the patient. Consultation and collaboration with the patient and other members of the healthcare team will best support improved adherence.

Pharmacists are well placed to support improved adherence with prescribed therapies. Adherence can be monitored using objective methods such as dispensing records to identify the frequency of prescriptions dispensed over a specified time period and medicine counts to identify the medicines removed from blister packages over a dosing period. Further information can be gathered through patient interviews and questionnaires to explore the patient's beliefs and attitudes about their condition, treatments and ability to take medicines, as these will significantly influence their medicine-taking behaviour.[5]

There are a number of different strategies that pharmacists can implement with the patient to support adherence to and persistence with medicines, depending on the contributing factors. These might include the provision of instructions and information, monitoring the effectiveness of medicines, motivational counselling, simplification of dose regimens, use of dose administration aids, telephone/email reminder systems, and facilitation of continuity of supply of medicines.

When a prescribed therapy is required and a valid prescription not available, it is not always possible to access the prescriber, even by phone. In most states/territories, pharmacists can dispense an emergency supply of the medicine without a prescription. However, the supply of the medicine under these arrangements is not subsidised under the Pharmaceutical Benefits Scheme (PBS), and the expense does not contribute to the patient reaching the PBS Safety Net threshold. The lack of access to the prescriber and the cost associated with obtaining the medicine without PBS subsidy can contribute to non-adherence to therapy and less than optimal health outcomes.

Continued Dispensing provides an alternative supply arrangement for eligible prescribed medicines to support continuity of therapy. This is consistent with the objectives of the National Medicines Policy[9] and Community Pharmacy Agreements[10] of providing timely access to the medicines Australians need, at a cost individuals can afford.

1.2 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,[11] in particular:

- Standard 1: Fundamental pharmacy practice
- Standard 3: Counselling
- Standard 5: Dispensing.

Pharmacists should also be familiar with the 2011 Australian Standard (Quality Care Pharmacy Standard)12 specifically 4.1 and 4.2. These guidelines provide pharmacists with a procedure that contributes to adherence to *4.2 a) maintaining and following a system for dispensing prescribed medicines*.

In general terms, guidelines are not definitive statements of correct procedure but are designed to provide advice or guidance on professional process 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.

1.3 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/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.

It is expected that pharmacists will 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 are reminded that they have a professional and legal responsibility to ensure that medicines are appropriate and safe for patients to use. 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.

Box 1: Examples of adherence rates reported for specific medicines

- 18% of Australian patients prescribed an angiotensin-converting enzyme (ACE) inhibitor failed to collect the second prescription, and only 45% were persisting with therapy after 33 months.[6]
- Adherence rates of 36–58% have been reported for patients prescribed an HMG-CoA reductase inhibitor (statin) for secondary prevention of coronary heart disease. When prescribed for primary prevention, adherence rates of 25% have been reported.[7]
- Of women prescribed oral contraceptives, 62% have reported missing at least one pill in a 6 month period, 31% have reported missing one or two pills, and 11% have reported missing six or more pills.[8]

2. Introduction

2.1 Scope of Continued Dispensing

Both Commonwealth and state/territory legislation require that *Prescription Only* and *Controlled* medicines only be supplied on presentation of a prescription. Further, for medicines to be considered a pharmaceutical benefit under the PBS, a valid 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 Appendix 1 for relevant legislation.

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/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). Medicines supplied in this manner are not subsidised under the PBS.

Subject to state/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 Pathway[13] (see Figure 1), specifically in the review of the medicine order and issuing of the medicine.

2.2 Relevance to funding arrangements

The usual claiming process for supply of PBS medicines requires that the patient's signed acknowledgement of receipt of the medicine is captured on the paper prescription that was presented to the pharmacy for dispensing. This is then submitted to the Services Australia Medicare (hereafter SA-Medicare).

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 SA-Medicare claiming requirements to capture the patient's signed acknowledgement of receipt following dispensing.

It is expected that pharmacists will follow PBS guidelines to meet obligations in relation to pharmacy claims for PBS medicines supplied by Continued Dispensing.

3. Preparing for Continued Dispensing of eligible medicines

3.1 Privacy and confidentiality

Pharmacists must respect and safeguard the patient's privacy and confidentiality at all times,[14] 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.[15] Pharmacists should 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
- 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. It would be appropriate for the pharmacist who is requesting the information to facilitate the provision of consent.

Pharmacies should have a written policy for the management of personal health information which is readily available to patients. Pharmacists can refer to the *Guidelines for Pharmacists: Professional Practice and the Privacy Act*[15] for template policies.

3.2 Underpinning competencies

The competencies required by pharmacists supplying eligible prescribed medicines by Continued Dispensing are the same as those for dispensing with a valid prescription. Pharmacists should refer to the *National Competency Standards Framework for Pharmacists in Australia*,[16] specifically *Domain 4; Review and supply prescribed medicines and Domain 6; Promote and contribute to optimal use of medicines*.

The knowledge, skills and attributes used to improve adherence to medicines will enhance the service provided when dispensing under any supply arrangement. Where development in this area is required, continuing professional development (CPD) activities should explore the five interplaying factors that have been identified that influence a person's adherence to therapy:[1,5]

- Therapy-related factors (including the complexity of the regimen, duration of treatment, previous treatment failure, frequency of changes to treatment, lack of immediacy of beneficial effects, and side effects).
- Condition-related factors (including the permanency of the disease, presence of comorbidities, lack of symptoms, and the rate and severity of the condition).
- Health system/healthcare team factors (including short consultation times, lack of reimbursement for particular services, poor continuity of care, a lack of interprofessional collaboration, poor communication, poor access to healthcare providers, and limited community support).
- Social/economic factors (including financial burden, poor literacy/ health literacy, language/cultural barriers, lack of social support networks, and unstable living conditions).
- Patient-related factors (including poor sight, poor memory, lack of self-efficacy, rejection of diagnosis, limited understanding of the importance of medicines, and beliefs about perceived side effects, benefits or severity).

CPD activities should include consideration of the underlying factors influencing medicine-taking behaviour, interventions to improve patients' adherence to their medicines, communication skills and consultation and collaboration to optimise health outcomes.

3.3 Policies, procedures and documentation to meet professional obligations

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

Policies and procedures for responding to requests to supply eligible prescribed medicines in urgent or emergency situations without a valid prescription should be developed and available to all staff. Staff should record that they have read, and are familiar with, the policies and procedures.

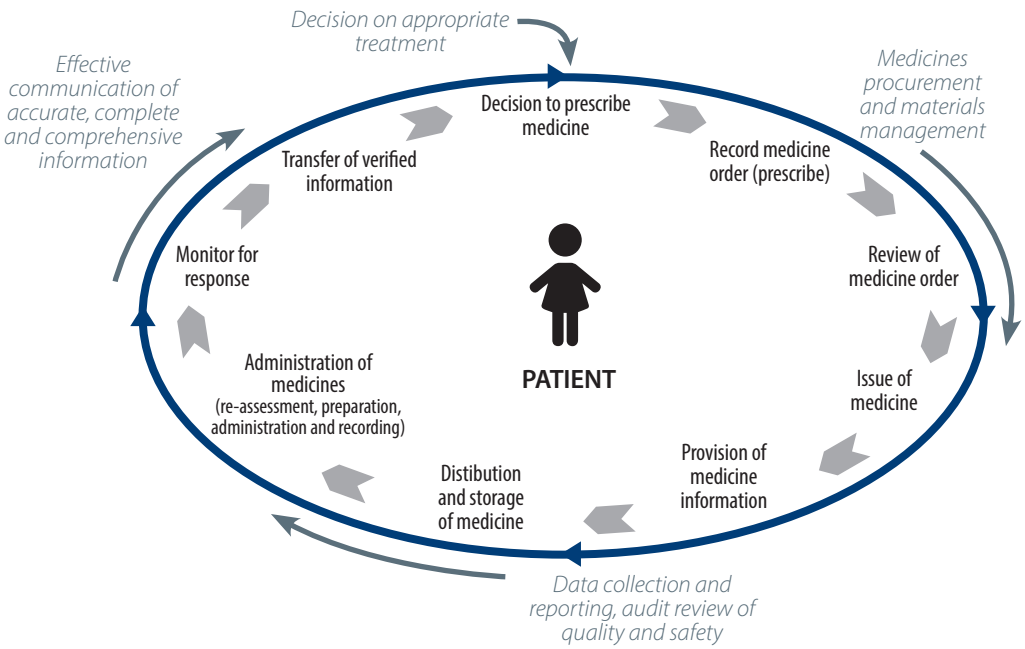
Pharmacists should ensure that the manner in which communication with the prescriber is to occur for Continued Dispensing is included in policies and procedures (e.g. Interprofessional Collaboration Policy in QCPP requirements manual).

The approach to responding to a request from a third party (e.g. carer/family member) to supply a prescribed medicine without a valid prescription should be included in policies and procedures. The indirect supply of medicines is viewed as a sub-optimal way of delivering a pharmacy service as communication may be compromised.[17] 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. However, where indirect supply is necessary in, or appropriate to, the patient's circumstances, pharmacists should consider whether the required information is available to ensure supply is appropriate (refer to Section 4).[11,17] Pharmacists should also consider whether patient consent can be obtained and privacy maintained.[11]

An appropriate **recording system** should be available to consistently document the information underpinning a decision to supply a medicine by Continued Dispensing. This might be an electronic system linked to the dispensing system or, if that is unavailable, a paper-based system.

Figure 1: the medicines management pathway

Modified from Stowasser, Allinson and O'Leary 2004[13]



Irrespective of the system used, the information that pharmacists should be prepared to record includes the:

- date of the request for medicine supply without a valid prescription
- patient details (name and address)
- medicine requested (including strength, form and directions for use)
- reason for request
- most recent prescriber and practice details
- dispensing history
- patient history (clinical) notes obtained during consultation with the patient
- details of any communication with other health professionals/ providers and the prescriber.

Records should be maintained by pharmacists in a manner consistent with other dispensing and medicine supply records. Record management must comply with Commonwealth and state/ territory legislation.

The policies, procedures and recording system used for Continued Dispensing should be systematically reviewed and updated as required, and at regular intervals. Also refer to Section 5.2.

3.4 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.'[17] The pharmacist must retain responsibility for 'assessing the appropriateness of the medicines in relation to the full medication history, the final check of dispensed medicines and the counselling of the patient.'[17]

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.

4. Establishing if Continued Dispensing is appropriate for an individual

4.1 Options for supply without a prescription

When a patient requests supply of a medicine for which they do not have a valid prescription, 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;
3. provide the medicine by Continued Dispensing; or
4. do not supply the medicine.

In addition to considering what is permitted according to state/ territory legislation, pharmacists will need to use their professional judgement to determine the most appropriate course of action.

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, pharmacists should consider the potential confusion this may cause for the patient. The risk of confusion should be balanced with the benefit of continuation of therapy in determining the appropriate manner for supply.

4.2 Defined circumstances for Continued Dispensing

Pharmacists can supply medicines by Continued Dispensing under the following circumstances:

- The medicine requested is identified in the relevant legislation as eligible for supply by Continued Dispensing (see Section 4.3).
- There is an immediate need for supply of the medicine to facilitate continuity of therapy, and it is not practicable for the person to obtain a prescription for the medicine from an authorised prescriber.
- The medicine has been previously prescribed for the person, the patient's therapy is stable, and there has been prior clinical review by the prescriber that supports continuation of the medicine (see Section 4.4).
- There is an ongoing need for supply, and the medicine is safe and appropriate for that patient (see Section 4.5).

4.3 Eligibility of medicines for supply by Continued Dispensing

A legislative instrument under the National Health Act 1953 identifies eligible medicines for supply by Continued Dispensing. State/Territory legislation should be consulted to identify application in the respective jurisdictions.

Medicines that are not included in the Schedule of Pharmaceutical Benefits, or medicines that would normally be available as PBS benefits but are dispensed as private supplies, are not able to be supplied by Continued Dispensing. PBS medicines requiring prior authority approval from SA-Medicare for supply as a PBS benefit also cannot be supplied by Continued Dispensing.

The most recent prescriber of the medicine can have been any health professional approved to prescribe the eligible medicine on the PBS, and subject to relevant state/territory legislation.

PBS medicines that have been supplied by any pharmacy by Continued Dispensing in the 12 months prior to this request cannot be supplied again by Continued Dispensing. This should initially be identified through consultation with the patient. In addition, SA-Medicare systems will reject payment for attempted Continued Dispensing supplies made within this 12 month period, provided past Continued Dispensing records are held by SA-Medicare.

Pharmacists should note that SA-Medicare claim information will not include any under co-payment data prior to 1 April 2012 nor any medicines supplied as private (non-PBS) supplies. Pharmacists should not rely solely on SA-Medicare PBS claiming information to determine if a Continued Dispensing supply is appropriate.

Patients may request the supply of a number of medicines without a valid prescription in an urgent or emergency situation, of which only some may be eligible for supply by Continued Dispensing.

4.4 Therapy is stable and there has been prior clinical review by the prescriber

The decision to prescribe, or 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.

Pharmacists should be cognisant that by supplying a medicine by Continued Dispensing, further clinical review by the prescriber may be delayed beyond the prescriber's original intentions. 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, will assist pharmacists to identify the prescriber and determine whether they have had the opportunity to adequately review the patient for suitability of continuing the medicine.

When the patient is not a regular customer of the pharmacy, the pharmacy that has dispensed the medicine most recently and regularly should be consulted for the most recent prescriber, an accurate dispensing history and to validate information obtained from the patient.

Indicators that pharmacists could use 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 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).

Where the pharmacist is not satisfied they can confirm the stability of therapy for the patient (including adherence to and persistence with therapy) and the occurrence of prior clinical review by the prescriber, alternative supply and referral arrangements to Continued Dispensing should be pursued.

4.5 Safety and appropriateness of the medicine

When dispensing under any supply arrangement, the pharmacist must exercise professional judgement to ensure the medicine is safe and appropriate for the patient.[17]

A review of the pharmacy's dispensing record and consultation with the patient will assist pharmacists to ascertain if:[18]

- There is a clear indication for continuing therapy with the medicine.
- The dose and frequency appear to be appropriate for the PBS subsidised indication.
- 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.

When the patient is not a regular customer of the pharmacy, pharmacies that have dispensed any medicines recently and regularly should be consulted for a dispensing history and to validate information obtained from the patient.

The risks associated with issues identified during this review and consultation should be balanced with the benefit of continuity of therapy in determining whether Continued Dispensing of the requested medicine is appropriate for the individual.

5. Supplying an eligible medicine by Continued Dispensing

5.1 Dispensing

It is expected that the supply of eligible medicines by Continued Dispensing will be performed to the same standards as dispensing with a valid prescription. Pharmacists should review the Professional Practice Standards[11], particularly Fundamental Pharmacy Practice and Dispensing.

Medicines should be supplied to patients in the standard PBS quantity. If the prescriber has previously obtained authority approval for supply of an increased quantity, only the standard PBS quantity may be supplied by Continued Dispensing.

5.2 Recording requirements

The supply of the medicine by Continued Dispensing must be recorded in the dispensing system in a manner consistent with the recording of dispensing with a valid prescription. Two forms will be generated by the pharmacy dispensing system. The first form is a standard repeat authorisation form which allows the patient's acknowledgement of receipt and will support the SA-Medicare claim process. The second form supports the patient declaration that they understand and consent to the supply and may also be used for written notification to the prescriber (see Section 6.2).

The pharmacist should document any information used to support the decision to supply the medicine by Continued Dispensing. This includes the:

- details of any dispensing history obtained from other pharmacies
- patient history (clinical) notes obtained during consultation with the patient
- details of any communication with other health professionals/ providers and the prescriber
- directions for use.

Consistent with the standard dispensing process, information will be required to support the pharmacy claim to SA-Medicare for PBS medicines. This includes the:

- patient's name, address, SA-Medicare number and any entitlement numbers
- medicine name, strength and quantity supplied
- date of supply.

The standard repeat authorisation form with the patient's signed acknowledgement of receipt will be required for the SA-Medicare claim process.

Also refer to Section 3.3.

6. Communication

6.1 Communication with the patient

It is expected that counselling and the provision of Patient Medicine Information (CMI) that occurs with the supply of eligible medicines by Continued Dispensing will be performed to the same standards expected for any other professional service in the pharmacy. Pharmacists should review the Professional Practice Standards[11], particularly Fundamental Pharmacy Practice and Counselling.

When multiple medicines have been requested in an urgent or emergency situation and where different supply arrangements apply, it is expected that pharmacists will attempt to minimise potential confusion about the different supply arrangements within their counselling of that patient.

Patients should be informed that the most recent prescriber of that medicine will be notified of the supply by Continued Dispensing. Also see Section 3.1.

Pharmacists should emphasise the importance of the patient having their therapy and health reviewed regularly with their prescriber. They should advise the patient 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.

6.2 Communication with the prescriber

Pharmacists must provide written communication to, but not limited to, the most recent prescriber advising of the supply of the medicine to the patient by Continued Dispensing. This should occur without delay (and within 24 hours).

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

- patient details (name and address)
- date the medicine was supplied without a valid prescription
- details of any medicine dispensed (including strength, form and instructions for use)
- reason for Continued Dispensing
- declaration co-signed by the patient indicating their understanding of, and consent to, the supply.

As an active participant in the healthcare team, pharmacist communication to the prescriber supports continuity in medication management of the patient.

7. Considerations for quality assurance

To ensure the supply of eligible medicines by Continued Dispensing meets the quality requirements of professional practice, pharmacists should introduce procedures for quality control, quality assurance and monitoring.

Examples of activities pharmacists may need to implement include:

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

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

Results of the audits should be analysed and recorded together with any action taken or outcome. The findings of audits can inform future system improvements and any actions taken can be integrated as part of the improved system.

The supply of eligible medicines by Continued Dispensing is also subject to the usual SA-Medicare compliance and audit program.

References

1. World Health Organization. Adherence to long-term therapies: evidence for action. Geneva: World Health Organization; 2003.
2. McDonald H, Garg A, Haynes R. Interventions to enhance patient adherence to medication prescriptions. JAMA. 2002; 288(22):2868–79.
3. Muszbek N, Brixner D, Benedict A, et al. The economic consequences of noncompliance in cardiovascular disease and related conditions: a literature review. Int J Clin Pract. 2008; 62:338–51.
4. Ho P, Bryson C, Rumsfield J. Medication adherence: its importance in cardiovascular outcomes. Circulation. 2009; 119(23):3028–35.
5. Improving adherence in cardiovascular care. A toolkit for health professionals. Melbourne: National Heart Foundation of Australia; 2011.
6. Simons L, Ortiz M, Calcino G. Persistence with antihypertensive medication: Australian-wide experience, 2004-2006. Med J Aust. 2008; 188:224–7.
7. Muller-Nordhorn J, Willich S. Effectiveness of interventions to increase adherence to statin therapy. Dis Manage Health Outcomes. 2005; 13(2)73–82.
8. Fisher W, Black A. Contraception in Canada: A review of method choices, characteristics, adherence and approaches to counselling. CMAJ. 2007; 176(7):953–61.
9. National Medicines Policy. Accessed at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-1 on 23/6/20
10. Community Pharmacy Agreement. Accessed at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/New-7th-Community-Pharmacy-Agreement on 23/6/20.
11. Professional Practice Standards, version 5. Canberra: Pharmaceutical Society of Australia; 2017.
12. Pharmacy Guild of Australia. Quality Care Pharmacy Standard – quality management system for pharmacies in Australia. Sydney: SAI Global Ltd; 2010.
13. Stowasser D, Allinson A, O'Leary K. Understanding the medicines management pathway. J Pharm Pract Res. 2004; 34:293–6.
14. Code of conduct for registered health practitioners. Melbourne: Pharmacy Board of Australia; 2014.
15. Guidelines for Pharmacists: Professional Practice and the Privacy Act. Canberra: Pharmaceutical Society of Australia; 2001.
16. National Competency Standards Framework for Pharmacists in Australia. Canberra: Pharmaceutical Society of Australia; 2016.
17. Guidelines for the dispensing of medicines. Melbourne: Pharmacy Board of Australia; 2015.
18. Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Canberra: Commonwealth of Australia; 2005.

Appendix 1 – Relevant legislation

At the time of printing, the following legislation describes the manner in which a pharmacist may supply a prescription medicine in urgent or emergency situations in the different jurisdictions.

Commonwealth	National Health Act 1953 https://www.legislation.gov.au/Series/C1953A00095 National Health (Pharmaceutical Benefits) Regulations 2017 https://www.legislation.gov.au/Series/F2017L00313
Australian Capital Territory	Medicines, Poisons and Therapeutic Goods Act 2008 www.legislation.act.gov.au/a/2008-26 Medicines, Poisons and Therapeutic Goods Regulations 2008 www.legislation.act.gov.au/sl/2008-42/
New South Wales	Poisons and Therapeutic Goods Act 1966 https://www.legislation.nsw.gov.au/view/html/inforce/current/act-1966-031 Poisons and Therapeutic Goods Regulation 2008 https://www.legislation.nsw.gov.au/view/whole/html/inforce/current/sl-2008-0392
Northern Territory	Medicines, Poisons and Therapeutic Goods Act 2012 https://legislation.nt.gov.au/en/Legislation/MEDICINES-POISONS-AND-THERAPEUTIC-GOODS-ACT-2012
Queensland	Health Act 1937 https://www.legislation.qld.gov.au/view/html/inforce/current/act-1937-031 Health (Drugs and Poisons) Regulation 1996 https://www.legislation.qld.gov.au/view/html/inforce/current/sl-1996-0414#sec.171
South Australia	Controlled Substances Act 1984 www.austlii.edu.au/au/legis/sa/consol_act/csa1984242/ Controlled Substances (Poisons) Regulations 2011 http://www.austlii.edu.au/au/legis/sa/consol_reg/csr2011451/
Tasmania	Poisons Act 1971 https://www.legislation.tas.gov.au/view/html/inforce/current/act-1971-081 Poisons Regulations 2018 https://www.legislation.tas.gov.au/view/html/inforce/2019-04-17/sr-2018-079
Victoria	Drugs, Poisons and Controlled Substances Act 1981 https://content.legislation.vic.gov.au/sites/default/files/85877eed-1917-39a0-9f5e-3dd3948be0a8_81-9719aa128%20authorised.pdf Drugs, Poisons and Controlled Substances Regulations 2017 https://content.legislation.vic.gov.au/sites/default/files/2020-03/17-29sra006.pdf
Western Australia	Medicines and Poisons Act 2014 https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_13172_homepage.html Medicines and Poisons Regulation 2016 https://www.legislation.wa.gov.au/legislation/statutes.nsf/law_s48030.html

Appendix 2 – Protocol for the Continued Dispensing of eligible medicines

This document is designed to provide guidance to pharmacists on a range of issues including appropriate and effective processes, desired behaviour of good practice, how professional responsibilities may be best fulfilled, and expected outcomes. At all times, pharmacists must meet any legislative requirement and are expected to exercise professional judgement in adapting the guidance provided here to presenting circumstances.

Consider professional obligations

A Professional standard
B Privacy and consent
C Duty of care

Consider options for supply without a valid prescription

Consider:
D Patient access to prescriber
E Communication with prescriber
F Medicine requested
G Previous supply by Continued Dispensing

Assess stability of patient's therapy and prior clinical review by prescriber

Consider:
H Most recent consultation between patient and prescriber
I Change to health status since last consultation
J Dosage regimen over time
K Continuity of therapy
L Prescriber's intent

Consider the safety, appropriateness and patient understanding of the medicine

Consider:
M Reason for therapy
N Medication administration
O Health status
P Adverse effects
Q Duplication of therapy
R Interacting medicines

Supply medicine by Continued Dispensing, if appropriate, and provide counselling

S Record and dispense
T Claim
U Counsel and provide written information
V Notify prescriber
W Maintain documentation

Options when considering supply of a medicine without a valid prescription:

- Refer the patient to the prescriber (without supply).
- Dispense the medicine on receipt of an order by telephone (or other means) from the prescriber, with a written prescription to follow.
- Provide an emergency supply.
- Continued Dispensing.

Providing an 'emergency supply'or referral to prescriber (without supply) should be considered when:

- The most recent prescriber cannot be identified.
- The most recent consultation between patient and prescriber was >12 months ago.
- There has been no consultation between the patient and the prescriber subsequent to initiation of medicine, or there has been a recent change to dose and/or dosing regimen.
- The therapy has not been regular or has already been interrupted.

Referral to prescriber (without supply) should be considered when the risks associated with the issues identified outweigh the benefit of continuity of therapy.

Eligible medicines

Subject to state/territory legislation, the medicines currently eligible for supply by Continued Dispensing are standard PBS packs of the following PBS medicines:[1]

- **hmG-Coa reductase inhibitors (statins)**. The approved indication for subsidy under the PBS is as an adjunct to diet for the treatment of patients with hypercholesterolaemia, provided certain eligibility criteria are met.
- **oral contraceptives**. The approved indication for subsidy under the PBS is contraception.

Explanatory notes

This protocol supports the application of the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists*[2] according to legislation at the time of publishing.

A. Professional standards

The *Professional Practice Standards*[3] (PPS) outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in the Continued Dispensing of an eligible medicine.

B. Privacy and consent

Pharmacists must meet their obligations in relation to respecting the patient's privacy and confidentiality in the Continued Dispensing of an eligible medicine and associated counselling.[4] Pharmacists must obtain consent from the patient prior to collecting health information from other pharmacies or health professionals when such information is required.

C. Duty of care

Pharmacists have a duty of care to assist patients in ensuring continuity of care.[5] Continued Dispensing is one mechanism by which pharmacists can do this.

D. Patient access to prescriber

The supply of eligible medicines by Continued Dispensing may occur when it is not practical for the patient to obtain a prescription for the medicine from an authorised prescriber. If a consultation with the prescriber can be arranged in a timeframe that supports continuity of therapy, the patient should be referred to the prescriber.

E. Communication with prescriber

The supply of eligible medicines by Continued Dispensing may occur without a prescription and without prior communication with the prescriber under defined circumstances. If an order from the prescriber can be received by the pharmacist by telephone or other means (with a written prescription to follow), this may be preferable.

F. Medicine requested

Pharmacists can only supply eligible medicines by Continued Dispensing and these will be identifiable in pharmacy dispensing software.

Medicines that are not included in the Schedule of Pharmaceutical Benefits, or medicines that would normally be available as PBS benefits but are dispensed as private supplies, are not able to be supplied by Continued Dispensing.

Medicines requiring prior authority approval from SA-Medicare for supply as a pharmaceutical benefit cannot be supplied by Continued Dispensing.

The pharmacist should be satisfied that the medicine is subsidised under the PBS for the indication for which the medicine is being used. A previous PBS prescription indicates the prescriber has already certified that the patient satisfies any relevant eligibility criteria.

G. Previous supply by Continued Dispensing

The pharmacist should identify from the patient whether they have received the requested medicine from any pharmacy by Continued Dispensing in the preceding 12 months. If supply has occurred by Continued Dispensing in the previous 12 months, a further supply is not permitted.

SA-Medicare will not allow for a further supply to be claimed through PBS Online if there has been a previous supply and claim for a Continued Dispensing supply of that PBS item within the preceding 12 months where claiming history is available.

H. Most recent consultation between patient and prescriber

The pharmacist must be able to identify the most recent prescriber of the requested medicine through the pharmacy dispensing record (their own or another pharmacy's), supported by confirmation by the patient.

If the prescriber cannot be identified, or it has been greater than 12 months since the patient has had a consultation with the prescriber (or the prescriber's medical practice), alternative supply and referral arrangements should be considered.

I. Change to health status since last consultation

A clinical review by the prescriber for the appropriateness of continuing therapy is required when the patient has experienced a significant change to their health status, e.g. as indicated by an admission to hospital and/or a significant change to their medications.

J. Dosage regimen over time

The dosage regimen over time can provide an indication of therapy stability. Information about the dosage regimen can be obtained from the pharmacy dispensing record (their own or another pharmacy's), supported by confirmation by the patient.

For supply by Continued Dispensing, the pharmacist must be satisfied that the patient has had their therapy reviewed by the prescriber following its initiation or any dose change.

K. Continuity of therapy

Continued Dispensing supports continuity of therapy when a valid prescription is not available. This may be particularly important when the effectiveness of the medicine relies heavily on adherence to the dosing regimen (e.g. oral contraceptives).

Information about adherence to the previously prescribed dosing regimen can be obtained from pharmacy dispensing records and consultation with the patient. For supply by Continued Dispensing, the pharmacist must be satisfied that the patient has been taking the medicine regularly, without interruption, prior to the request for supply. If the pharmacist has concerns about the patient's adherence or persistence with the medicine, referral to the prescriber may be appropriate.

L. Prescriber's intent

The pharmacist should be satisfied that ongoing supply is the likely intention of the prescriber. Continued Dispensing may not be appropriate if there is an indication that the prescriber intended earlier review. Some indicators include (but are not limited to):

- The most recent prescription includes fewer repeats than are usually prescribed.
- The patient reports that pathology tests have been undertaken since their last review by the prescriber.

M. Reason for therapy

The pharmacist should be satisfied that the patient is aware of the reason for therapy with the requested medicine and this is consistent with the likely intention of the prescriber.

N. Medication administration

The pharmacist should establish whether the patient is having any difficulties with medicine administration. This may include consideration of the continuing appropriateness of dose form, dose and frequency of administration.

O. Health status

The pharmacist should identify whether the patient has had any substantive changes to their health status since the medicine was last prescribed. This will help establish the presence of:

- contraindications to therapy
- precautions in the use of the therapy
- lifestyle factors that would affect response to the medicine or lead to an interaction.

Refer to credible reference sources such as Australian Medicines Handbook[6] or the approved product information for a comprehensive list of medical conditions, medications and lifestyle factors (e.g. weight gain/loss, smoking status) that may influence the response to the medicine or lead to an interaction.

P. Adverse effects

The presence of any adverse effects being experienced should be established.

Refer to credible reference sources such as Australian Medicines Handbook[6] or the approved product information for a comprehensive list of adverse effects relevant to the medicine to be dispensed.

Q. Duplication of therapy

Any duplication of therapy (medicines or medicine classes) should be established.

Generic substitution at a previous dispensing of the medicine should alert the pharmacist to consider whether the patient could be taking multiple brands of the same medicine.

R Interacting medicines

The commencement or cessation of other medicines that would affect response to the medicine or have potential for an interaction should be established.

Refer to credible reference sources such as Australian Medicines Handbook[6] or the approved product information for medicines that may interact with the medicine to be dispensed.

S. Record and dispense

The pharmacist must record in the pharmacy dispensing system the information required to support the pharmacy claim to SA-Medicare for PBS medicines, including, but not limited to, the:

- patient name, address, SA-Medicare number and any entitlement numbers
- medicine name, strength and quantity supplied
- date of supply.

Two forms will be generated by the dispensing system. The first form supports the patient's acknowledgement of receipt and the SA-Medicare claim process (see T). The second form supports the patient declaration that they understand and consent to the supply, and may also be used for written notification to the prescriber (see V and W).

T. Claim

A standard repeat authorisation form (that allows the patient to sign acknowledgement of receipt) will be generated by the pharmacy dispensing system for signing by the patient.

The pharmacist will be required to submit this signed form to SA-Medicare.

U. Counsel and provide written information

Counselling and the provision of Patient Medicine Information (CMI) should be performed to the same standards[3] expected for all services in pharmacy.

When multiple medicines have been requested in an urgent or emergency situation and different supply arrangements apply, pharmacists should attempt to minimise potential confusion about the different supply arrangements in their counselling.

The pharmacist should discuss with the patient the importance of regular review of therapy with the prescriber. They should advise the patient to organise an appointment with the prescriber immediately, highlighting that a subsequent supply of the medicine by Continued Dispensing by any pharmacy will not be possible within the next 12 months.

V. Notify prescriber

The pharmacist must send a written notification to the most recent prescriber within 24 hours of the supply of the medicine by Continued Dispensing. The notification should include the:

- patient's details (name and address)
- date the medicine was supplied
- details of the medicine dispensed (including strength, form and instructions for use)
- reason for Continued Dispensing
- declaration co-signed by the patient indicating their understanding of, and consent to, the supply.

W. Maintain documentation

The pharmacist should maintain a record of any information used to support the decision to supply the medicine by Continued Dispensing, including the:

- details of any dispensing history obtained from other pharmacies
- patient history (clinical) notes obtained during consultation with the patient/carer
- details of any communication with other health professionals/ providers and the prescriber.

The pharmacist should also file a copy of the notification sent to the prescriber which includes the declaration signed by the patient.

References

1. National Health Act 1953.
2. Pharmaceutical Society of Australia. Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists. PSA: Canberra; 2012.
3. Pharmaceutical Society of Australia. Professional Practice Standards v5. Canberra: PSA; 2017.
4. Pharmaceutical Society of Australia. Professional Practice and the Privacy Act. Canberra: PSA; 2017.
5. Pharmaceutical Society of Australia. Code of Ethics for Pharmacists. Canberra: PSA; 2017.
6. Rossi S, editor. Australian Medicines Handbook. Adelaide: Australian Medicines Handbook Pty Ltd; 2020.

Appendix 3 – Practice Tool for Continued Dispensing

Pharmaceutical Society of Australia

Medicine requested without a valid prescription

Date: .....

Pharmacist: .....

Patient details

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 • 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? • 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.

PHARMACEUTICAL SOCIETY OF AUSTRALIA LTD.
ABN 49 008 532 072

NATIONAL OFFICE
Level 1, Pharmacy House
17 Denision Street
Deakin ACT 2600
PO Box 42
Deakin West ACT 2600
P: 02 6283 4777
F: 02 6285 2869
E: psa.nat@psa.org.au

BRANCH CONTACT DETAILS
P: 1300 369 772
F: 1300 369 771

AUSTRALIAN CAPITAL TERRITORY
Level 1, Pharmacy House
17 Denision Court
Deakin ACT 2600
PO Box 42
Deakin West ACT 2600
E: act.branch@psa.org.au

NEW SOUTH WALES
32 Ridge Street
North Sydney NSW 2060
PO Box 162
St Leonards NSW 1590
E: nsw.branch@psa.org.au

QUEENSLAND
225 Montague Road
West End QLD 4101
PO Box 6120
Buranda QLD 4102
E: qld.branch@psa.org.au

SOUTH AUSTRALIA
Suite 7/102
Greenhill Road
Unley SA 5061
E: sa.branch@psa.org.au

TASMANIA
161 Campbell Street
Hobart TAS 7000
E: tas.branch@psa.org.au

VICTORIA
Level 1, 381 Royal Parade
Parkville VIC 3052
E: vic.branch@psa.org.au

WESTERN AUSTRALIA
21 Hamilton Street
Subiaco WA 6008
E: wa.branch@psa.org.au

PSA5718

Pharmaceutical Society of Australia