



Guidelines for pharmacists providing staged supply services

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Contents

Executive summary	4
Acknowledgment	4
Service overview	5
Introduction	6
Terminology	7
Establishing the service	8
Policies and procedures	8
Consultation area	8
Training	8
Patient privacy	8
Providing the service	8
Identify need	8
6CPA eligibility criteria	8
Consent	9
Medication reconciliation	9
Supply	9
Dispensing	9
Storage	9
Consultation	9
Initial consultation	9
6-Month follow up consultation	9
Discontinuation	10
Transfer of services	10
Documentation	10
Communication	11
Communication with patients	11
Communication with prescribers	11
Monitoring and follow up	11
Data collection	11
Quality assurance and improvement	12
Appendix 1 Medication reconciliation	13
Appendix 2 Sample staged supply agreement	14
Appendix 3 Staged supply record (single medicine)	16
Appendix 4 Staged supply record (multiple medicines)	17
Appendix 5 Staged supply communication record	18
References	19

Executive summary

PSA Guidelines provide pharmacists with best practice guidance for the delivery of medication adherence services; Dose Administration Aids (DAA) and Staged Supply and medication management services; MedsCheck and Diabetes MedsCheck and Home Medicines Review (HMR).

These services are patient-centred clinical services delivered with the aim of improving patient health outcomes. They integrate with other patient-centred services to enhance a patient's optimal use of medicines. Pharmacists can provide these services to any patient based on their clinical need.

Services provided to eligible patients can be remunerated under the Sixth Community Pharmacy Agreement (6CPA), if pharmacists adhere to the relevant program rules. A summary of these rules can be found throughout this document in the orange boxes. Pharmacists should use these guidelines in conjunction with program rules and resources at www.6cpa.com.au

The delivery of these services encourages pharmacists to work collaboratively with the patient and their carer, their prescriber, and other relevant members of the healthcare team to enhance patient care.

Best practice for the delivery of these services includes:

- establishing patient need
- obtaining patient consent
- ensuring patient safety
- promoting quality use of medicines.

These Guidelines do not replace the need for pharmacists to exercise professional discretion and judgement when delivering these programs in their own unique practice environment. These Guidelines do not include clinical information or detailed legislative requirements. At all times, pharmacists delivering these programs must comply with all relevant Commonwealth, State and Territory legislation, as well as to the overarching and program-specific standards, codes, and rules (see Figure 1).



Figure 1. Overarching guidance and regulation of pharmacy service delivery¹

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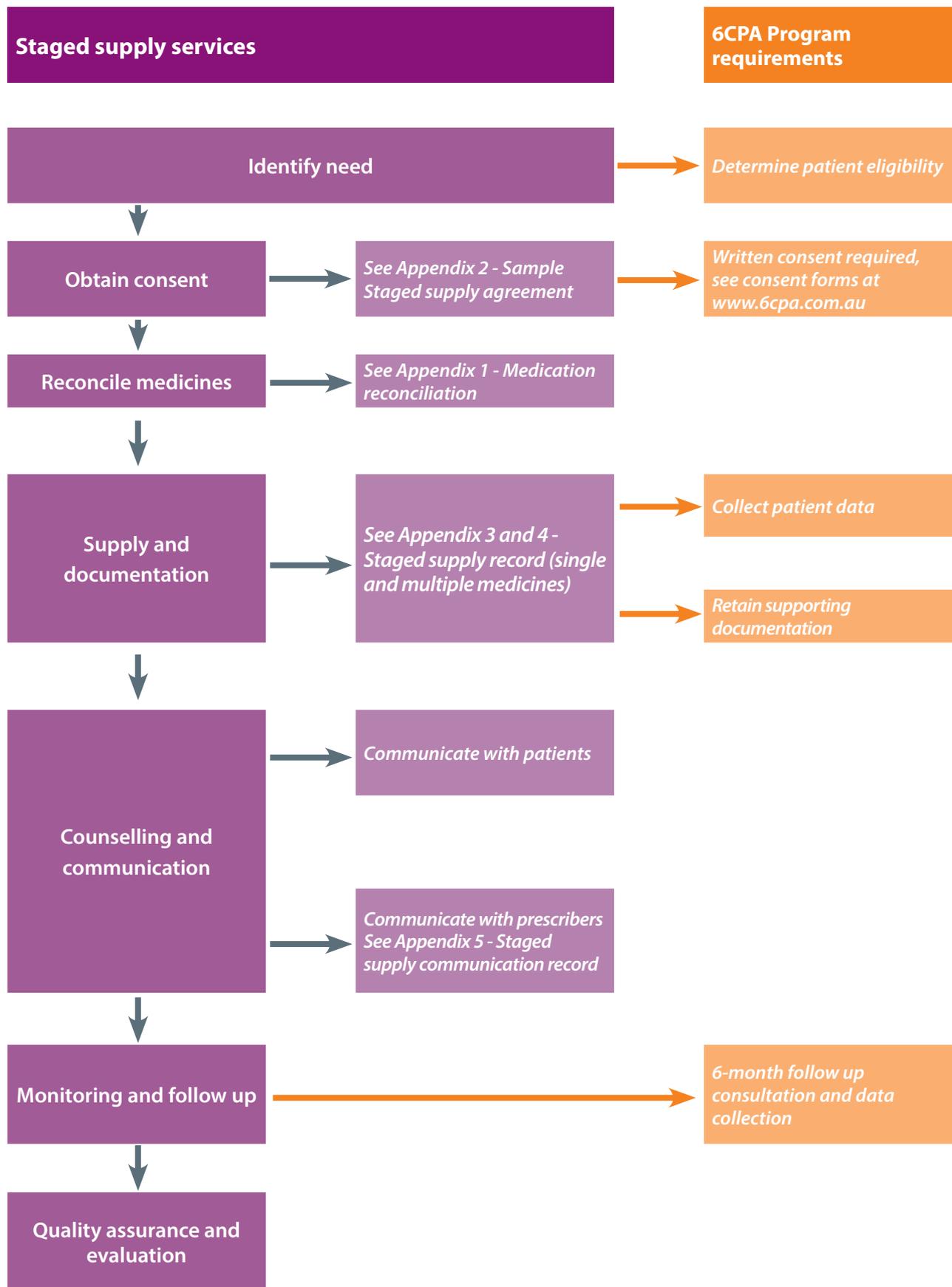
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Service overview



Introduction

Staged supply is a clinically-indicated, structured pharmacist service involving the supply of medicine to a patient in periodic instalments as requested by the prescriber or carer.

These instalments are less than the originally prescribed quantity at agreed intervals (e.g. daily or weekly). The balance of the prescribed quantity is held by the pharmacy to fulfil subsequent instalments.²

These Guidelines do not address the staged supply of methadone or buprenorphine as part of an Opiate Dependence Treatment program. Pharmacist should refer to state specific guidelines.

During this service, pharmacists should refer patients to other appropriate clinical services i.e. Dose Administration Aid (DAA), MedsCheck, Diabetes MedsCheck, Home Medicines Review (HMR), Residential Medication Management Review (RMMR), if identified as necessary for continuation of patient care (see Figure 2).

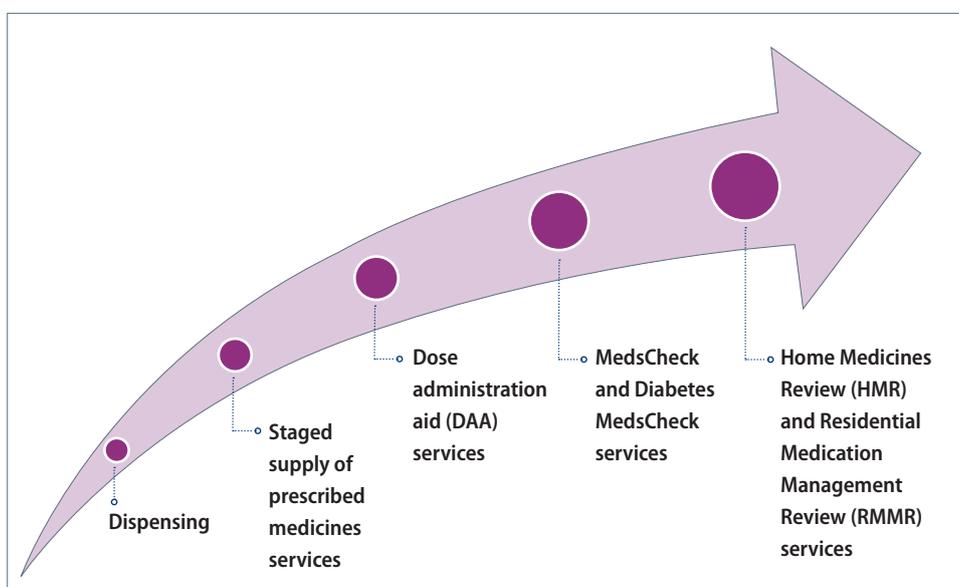


Figure 2. Medication management services across the continuum of patient care

Terminology

For a number of terms used in these guidelines, several related terms with equivalent or similar meaning may be equally appropriate in certain contexts (see Table 1).

GUIDELINE TERM	DEFINITION	EQUIVALENT OR RELATED TERMS
Adherence	A qualitative measure of the extent to which a patient's behaviour corresponds with recommendations agreed with a healthcare provider, ideally through a concordant approach ¹	Compliance, concordance
Carer	An individual who is responsible for, or taking part in, the provision of care for another person, through either a formal or informal arrangement ³	Agent, authorised representative, case worker, guardian, representative
Counselling	A two way communication process between the pharmacist and the patient or carer, in which the pharmacist ascertains the needs of the patient, and provides them with the information required to safely and effectively use medicines and therapeutic devices	Communication with patients or carers
Dose administration aid (DAA)	A tamper-evident, well-sealed device or packaging system that allows for organising doses of medicine according to the time of administration ¹	Blister pack, bubble pack, medicine sachet
Healthcare provider	A practitioner who provides services to individuals or communities to promote, maintain, monitor or restore health (such as a general practitioner, dentist, nurse practitioner, physiotherapist or case worker) ¹	Health professional, healthcare practitioner, healthcare professional
Informed patient consent	The patient agrees to a healthcare provider providing treatment and care after receiving understandable and clear information including the options, risks, benefits and purpose of the action ⁴	Consent
Medication profile	A list of medicines that a patient is currently taking including prescription, non-prescription and complementary medicines	Medication list, medication record
Medicine	A prescription, non-prescription, or complementary or alternative medicine ⁵	Drug, medication, product
MedsIndex	A score reflecting how closely patient adhere to their medication regimen	N/A
My Health Record	An electronic summary of a person's health information maintained by the Australian Government ⁵	Digital health record, eHealth record
Patient	A person who uses or is a potential user of health services, including their family and carers ¹	Client, consumer, individual, person
Pharmacist	An individual holding provisional or general registration with the Pharmacy Board of Australia, as recorded on the online Register of practitioners on the Australian Health Practitioner Regulation Agency (AHPRA) website. A pharmacist holding provisional registration must be supervised by a pharmacist holding general registration at all times in the pharmacy ⁶	Intern, registered pharmacist
Prescriber	A healthcare provider who is responsible for patient care, specifically medicines	Doctor, general practitioner (GP), nurse practitioner, other approved prescribers, specialist
Prescribed medicine	A medicine that is ordered by the patient's prescriber including Schedule 4, Schedule 8, over-the-counter and complementary medicines being used for treatment and/or prevention of chronic conditions such as paracetamol, aspirin, calcium and vitamin D ⁷	N/A

Establishing the service

Policies and procedures

Pharmacists should establish policies and procedures to govern the provision of staged supply services. They must adhere to all legislative requirements, and meet relevant professional practice standard. See *Standard 3: Dispensing and Other Supply Arrangements and Standard 16: Harm Minimisation in Professional Practice Standards, version 5*.²

Policies and procedures should be systematically reviewed and updated as required as part of quality assurance and evaluation process. See *Quality assurance and evaluation*.

Consultation area

The staged supply of medicines should be conducted in an area that protects patient privacy. This includes discussions relating to the initiation and management of the service, counselling and supervised dosing.¹

6CPA Staged Supply Program consultation area

The preparation and supply of the staged supply instalment should occur in an area which accords with legislative requirements for the dispensing of medicines

Reference: 6CPA Program Rules⁸

Training

All staff involved in providing a staged supply service must have training relevant to their role within the delivery of the service. Staff should understand their role and responsibilities as well as the policies and procedures used.¹

Training, and assessment through supervised practice, should be recorded (e.g. in a personal training record, or manual).

Patient privacy

Pharmacists must respect and safeguard patient privacy and confidentiality at all times, particularly in relation to any information acquired when providing the service. This applies to all interactions with the patient in the pharmacy, as well as the proper handling of their healthcare records.² Pharmacists must meet the relevant *Professional Practice Standard (1.3 Privacy and Confidentiality)* in the provision of a staged supply service.¹

Providing the service

Identify need

The need for the staged supply of prescribed medicines can be identified by the prescriber, pharmacist, patient/carer, or by another healthcare provider. Prescribers usually request the staged supply of medicine by annotating the prescription.

Pharmacists may identify the need for staged supply services if signs of overuse are evident (e.g. if prescriptions are presented for dispensing more frequently than is clinically appropriate). If the need for staged supply of a medicine is identified by the pharmacist, or other healthcare provider, the patient's prescriber should be informed.

Clinical need for the service may also be identified during the delivery of other services, such as a MedsCheck and Diabetes MedsCheck and Home Medicines Review (HMR).

6CPA Patient eligibility criteria

Under 6CPA, pharmacies can receive funding for providing up to a total of four (4) Staged Supply services to eligible patients.⁸ Patients who are ineligible under these programs but who may benefit from staged supply can still be offered the service.

6CPA Staged Supply Program patient eligibility criteria

- Medicare or Department of Veterans' Affairs (DVA) Card
- Has a valid Government issued concession card
- Lives at home in a community setting
- Has been referred for a staged supply service by their prescriber
- Has been prescribed one or more of the following types of medicines:
 - ◆ opioid analgesics
 - ◆ antipsychotics
 - ◆ anxiolytics
 - ◆ hypnotics and sedatives
 - ◆ antidepressants
 - ◆ psycho-stimulants.

Note:

- A person who identifies as an Aboriginal or Torres Strait Islander person, who is eligible for a Medicare card, but who does not hold either a Medicare card or Concession card will still be eligible for this program.
- Staged supply services funded under this program are not available to in-patients of public or private hospitals, day hospital facilities, transitional care facilities, residents of an aged care facility or patients in a correctional facility.
- Staged supply services funded under this program are not available to patients receiving Staged supply services funded under other Federal or State and Territory government programs (e.g. section 100 opioid dependency treatment program).
- A patient may continue to receive this staged supply service if they no longer meet the patient eligibility criteria for a maximum of four (4) weeks.

Reference: 6CPA Program Rules⁸

Consent

Informed patient consent, including consent to disclose information relating to the service to other healthcare providers involved in the patient's care, must be obtained and documented prior to providing any staged supply service.

Consent may be included in a formal agreement between the patient and pharmacy providing the service that documents the details of the service. Where a staged supply service agreement is not used, it is recommended that a record of the service be provided to the patient and it includes all the information above.^{1,2} See *Appendix 2 – Sample agreement for staged supply service*.

Where the patient does not consent to participation in staged supply services, the pharmacist should ensure any action is consistent with patient safety.⁹

6CPA Staged Supply Program patient consent

Pharmacists must obtain written patient consent for staged supply services provided under 6CPA. See www.6cpa.com.au for patient consent forms

Reference: 6CPA Program Rules⁵

Medication reconciliation

As part of a staged supply service, pharmacists should reconcile the patient's medicines to obtain an accurate medication profile that includes all prescription, non-prescription and complementary and alternative medicines (see Box 1).¹

An HMR, RMMR, MedsCheck or other medication review services may be a valuable way to conduct this assessment.¹

See *Documentation*.

Box 1. Medication profile

- Brand name*
- Generic name*
- Form*
- Strength*
- Dose and dosage regimen*
- Indication and special instructions
- Dates started/duration
- Prescriber

*Required under 6CPA program rules

The medication profile should be confirmed with the prescriber, who should then be given a copy.

Pharmacists should use information from the patient's *My Health Record* where available, to inform the reconciliation process.¹ See *Appendix 1- Medication reconciliation*.

Supply

Dispensing

Dispensing undertaken in a staged supply service should comply with legislative requirements including, where relevant, those applicable to controlled drugs.¹ See *Professional Practice Standard – Standard 3: Dispensing and Other Supply Arrangements*.

The balance of the dispensed staged supply must be stored securely in the pharmacy in accordance with legislative requirements.¹ Dispensed medicines must be clearly labelled with the patient's details, and stored such that patient privacy is protected.

Storage

The balance of the dispensed staged supply must be stored securely in the pharmacy in accordance with legislative requirements.¹ Dispensed medicines must be clearly labelled with the patient's details, and stored such that patient privacy is protected.

Consultation

Initial consultation

During a staged supply service, the pharmacist must conduct face-to-face consultations with the patient. Services should be delivered discreetly and in a manner that protect patient dignity.¹

Where dosing is to be supervised in the pharmacy, the medicine should be provided in a suitable container and the dose confirmed on the supply record. See *Appendix 3 - Staged supply record (single medicine)* and *Appendix 4 - Staged supply record (multiple medicines)*. Pharmacists should only supervise dosing for one patient at a time.¹

Take-away doses must be supplied in a labelled container that meets legislative requirements.

The pharmacist responsible for staged supply services should not be responsible for dispensing or undertaking other professional duties at the time of consultation.

Follow up consultation

For services funded under 6CPA, pharmacists are required to engage the patient in a follow-up consultation 6 months after the initial review.⁸ See *Monitoring and follow up*.

Discontinuation

Staged supply services may be discontinued by the prescriber, pharmacist or the patient (see Box 2).

Box 2. Reasons for discontinuing staged supply services

- Patient fails to make reasonable efforts to cooperate with the staged supply arrangements (e.g. frequent or extended breaks in participation or frequent 'loss' of instalments)
- Patient's behaviour and/or communications with pharmacy personnel and/or other clients of the pharmacy are disruptive to the normal operation of the pharmacy
- Patient/carer creates a barrier to service delivery by ongoing complaints about the service that are considered by the pharmacy personnel to be unwarranted
- Patient's dealings with the pharmacist or other pharmacy personnel are found to be dishonest
- Ongoing provision of a staged supply service is considered by any party to be futile or of no benefit to the patient
- Patient has chosen to withdraw consent and has discontinued participation in the staged supply service

Where a prescriber-initiated staged supply arrangement is in place, omission of directions for staged supply on a subsequent prescription does not constitute discontinuation of the service. Pharmacists should only discontinue the service following formal confirmation from the prescriber.

If the service is discontinued by the patient or pharmacist with patient consent, the prescriber should be notified to enable consideration of appropriate options for continuity of care.¹ See *Communication with prescribers*.

Pharmacists should use professional judgement to determine appropriate action with regard to the remaining balance of medicines with consideration of the circumstances of discontinuation, legal requirements and duty of care (see Figure 3).

6CPA Staged Supply Program service discontinuation

If the patient for which data is being collected exits the Staged Supply Program prior to the 6-month follow up, the follow-up interview should be conducted (where possible) at the time of exit. A follow-up service claim can only be made where a staged supply service has been successfully claimed continuously over at least four consecutive months.

Reference: 6CPA Program Rules⁸

Transfer of services

Patients may transfer their staged supply service to another provider on a temporary or permanent basis. Pharmacists should support this request and facilitate the change in a timely manner. Both pharmacies share responsibility for assuring continuity of care and working together with the prescriber and the patient to ensure appropriate arrangements are in place.

Patients transferring their service to another pharmacy must enter in to a new agreement with that pharmacy. Arrangements for transfer of services should be agreed upon and recorded in the service agreement with the original pharmacy. See *Appendix 2 - Sample staged supply agreement*.

Documentation

A record detailing each supply instalment should be maintained for every patient. See *Appendix 3 - Staged supply record (single medicine)* and *Appendix 4 - Staged supply record (multiple medicines)*. Pharmacists should comply with legislative requirements with regard to the specific information recorded and the period of time for which documentation is retained.

If a staged supply service is being transferred to another pharmacy or discontinued, all changes to the supply arrangements should be documented in the staged supply agreement and the staged supply record form. See *Appendix 2 - Sample staged supply agreement*, *Appendix 3 - Staged supply record (single medicines)* and *Appendix 4 - Staged supply record (multiple medicines)*.

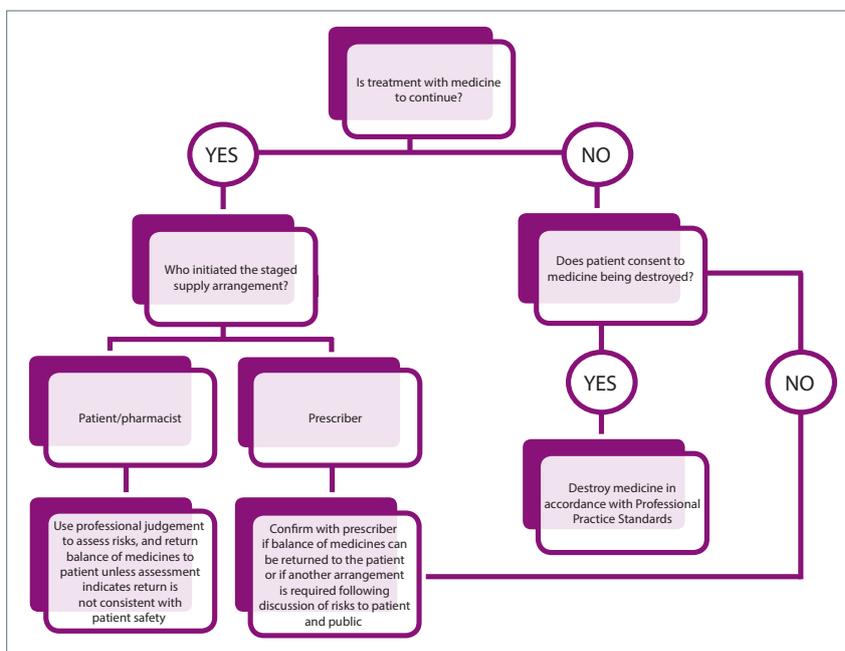


Figure 3. Management of discontinuation of staged supply services

Communication with the patient, prescriber and other relevant healthcare providers about the service should also be recorded. See *Appendix 5 - Staged supply communication record*.

If possible (i.e. software permitting), pharmacists should upload this documentation to the patient's My Health Summary as an event summary.¹ See www.digitalhealth.gov.au/using-the-my-health-record-system/how-to-use-the-my-health-record-system/uploading-an-event-summary.

For services claimed under 6CPA programs, additional documentation is required.⁸

6CPA Staged Supply Program supporting documentation

The following information must be retained for seven (7) years:

- Section 90 number at the time of the provision of the service
- Pharmacy accreditation ID at the time of the provision of the service
- Registered pharmacist identifier (e.g. AHPRA registration number)
- Copy of the patient consent form, where relevant
- Patient's name and address
- Patient's Medicare/DVA card number
- Patient's concession card number
- How the patient has satisfied the other eligibility criteria
- List of all prescription and non-prescription medicines the patient is taking at the time the service is provided
- Date(s) of provision of medicine instalments as a part of the service

Reference: 6CPA Program Rules⁸

Communication

Communication with patient

Pharmacists should communicate with patients using a staged supply service in a manner that maintains their privacy and dignity.

Patients accessing this service should receive regular counselling, and have the opportunity to freely discuss their use of medicines and any concerns they have with regard to the service (see Box 3).

Box 3. Staged supply counselling points

- Reasons for implementing the stage supply service
- Process for staged supply including what medicines are to be supplied under the arrangement, instalment frequency and arrangements for dosing (i.e. supervised dosing or takeaway doses)
- Patient responsibilities with regard to the service including obtaining prescriptions and attending the pharmacy
- Pharmacist responsibilities with regards to the service including issues requiring communication with the prescriber
- How missed instalments or lost doses will be managed
- Any side effects associated with the medicine including symptoms of withdrawal due to dose reduction

Communication with prescribers

Pharmacists should communicate all relevant issues arising from a staged supply service (see Box 4).

If the patient does not consent to the disclosure of information relating to staged supply services, the pharmacist should ensure any action is consistent with patient safety.⁹

Pharmacists should record all communication with the prescriber and patient. See *Appendix 5 - Staged supply communication record*.

Box 4. Issues to communicate to prescribers

- Details of the service (if not initiated by the prescriber)
- Details of service transfers (if not requested by the prescriber)
- Details of service discontinuation (if not discontinued by prescriber)
- Issues with patient behaviour including missed or non-regular dose collections and requests for replacement of lost instalments
- Patient request to amend prescriber initiated staged supply arrangement
- Patient request for additional supply (e.g. weekend away or holidays)
- Omission of staged supply directions on prescription
- Presentation of prescriptions from an alternate prescriber (unless otherwise approved by initiating prescriber)
- Evidence of patient obtaining additional medicine from another pharmacy
- Any other issues or concerns for patient safety

Monitoring and follow up

Pharmacists should regularly review patient staged supply records to ensure that the arrangement remains effective and in accordance with the agreement.² Any issues identified should be discussed with the patient and prescriber, as appropriate. See *Communication*.

Services funded under 6CPA Staged Supply Program include a formal 6-month follow-up consultation to enable pharmacists to monitor patient health outcomes.⁸ See *Data collection*.

Data collection

Staged supply services that are funded under 6CPA programs require patient data to be collected at both the commencement of the service and at the 6-month follow up consultation to evaluate the impact of the Staged Supply Program on patient health outcomes.⁸

Pharmacists should consider collecting data for all patients using a staged supply service to inform quality assurance and service evaluation. See *Quality assurance and evaluation*.

Note: If a patient withdraws from the 6CPA Staged Supply Program prior to six months, a follow-up interview should be conducted at the time of patient withdrawal from the program, where possible.

6CPA Staged Supply Program data collection

After obtaining patient consent, the following data must be collected for all 6CPA-funded Staged Supply Program patients

At initial staged supply consultation

- Patient's Medicare Number or Department of Veterans' Affairs file number
- Is the patient a concession card holder?
- Referring GP prescriber number
- Patient's date of birth
- Patient's postcode of residence
- Patient's gender
- Is English the patient's primary language at home?
- Does the patient identify as Aboriginal and/or Torres Strait Islander?
- What health conditions/co-morbidities is the patient taking medicines for?
- Reason for staged supply service
- How frequently is the medication to be provided to the patient under the staged supply service?
- Actions to be undertaken by pharmacists as a result of the Staged Supply service
- What is the patient's average MedsIndex score?
- In the last six months, did the patient go to the GP, or hospital, because of problems with his/her medicine?
- Has the patient had any problems over the past month with his/her medicine?
- On a scale of 1 to 10 how helpful does the patient think the Staged Supply service will be in managing his/her medicine?
- On a scale of 1 (no impact) to 10 (had an extremely positive impact) does the patient feel that participating in the Staged Supply service will have an impact on preventing a medicine related problem for him/her?

At 6-month follow up consultation

- Date of follow-up service
- Actions taken by pharmacists to support the Staged Supply service
- Is continuation of the Staged Supply service recommended for this patient?
- If the staged supply service is not recommended for continuation, what is the reason?
- What is the patient's MedsIndex score?
- In the last six months, did the patient go to the GP, or hospital, because of problems with his/her medicine?
- Has the patient had any problems over the past month with his/her medicine?
- Who is participating in the follow-up/ review?
- On a scale of 1 to 10 how helpful has the patient found the Staged Supply service in managing his/her medicine?
- On a scale of 1 (no impact) to 10 (had an extremely positive impact), does the patient feel that receiving the Staged Supply service has prevented a medicine-related problem for him/her?
- On a scale of 1 (not met expectations at all) to 10 (met all expectations and more), has the Staged Supply service met the patient's expectations?

Reference: : 6CPA Program Rules⁸

Quality assurance and evaluation

To ensure that a staged supply service meets the safety and quality requirements of professional practice, pharmacists should introduce procedures for quality control, quality assurance and monitoring of service provision.¹

Audits should be carried out prior to the commencement of a staged supply service and at 6-monthly intervals. *Professional Practice Standard 3: Dispensing and Other Supply Arrangements* and *Standard 16: Harm Minimisation* should be used as tools for self-assessment. The performance and results should be recorded together with any actions taken, and the resulting outcomes. Any changes should be reflected in updated policies and procedures.¹

Health outcome data collected from patients receiving staged supply services can be used to inform quality assurance and service evaluation. It can also help identify patients suitable for additional services and enhance overall patient care.

Appendix 1 – Medication reconciliation

Medication reconciliation is a formal process of verifying a patient's medicines to obtain a complete and accurate list of their current medicines.¹⁰ Medication reconciliation can identify medication errors occurring from incomplete or miscommunicated information, especially at points of transition of care¹¹; more than 50% of medication errors occur at transitions of care.¹² Errors that can occur include transcription, omission, duplication of therapy, and drug-drug and drug-disease interactions.¹¹

Reconciling a patient's medicines is essential to ensure a patient's medication profile contains accurate information; a vital component of medication adherence and management.

As part of the reconciliation process, pharmacists should take the best possible medication history by¹³:

- reviewing relevant patient information such as age, and cognitive state and considering what impact these may have on obtaining reliable information and if a carer or family member should be present
- asking the patient about any previous adverse medication events or allergies
- asking the patient to bring all current medicines including prescription, non-prescription and complementary and alternative products to the consultation
- asking the patient to bring all their prescriptions and repeat prescriptions, if not already retained by the pharmacy to the consultation
- assessing the patient's understanding of rationale for treatment, attitude and adherence to prescribed treatment.

Pharmacists should try to confirm the accuracy of the medication history with the prescriber or a recent hospital discharge summary.¹⁴ Pharmacists should access the patient's My Health Record, if available for information such as the shared health summary, dispense records and discharge summaries to help in developing the medication profile.

After reconciling a patient's medicines, an accurate medication profile can be prepared including name of medicine, dose (strength, dose form, frequency and route) and details of allergies and adverse reactions.

Pharmacists should inform the GP of any discrepancies in the list, discuss and document any changes.

If possible (i.e. software permitting), pharmacists should upload this documentation to the patient's *My Health Record* as an event summary. See www.digitalhealth.gov.au/using-the-my-health-record-system/how-to-use-the-my-health-record-system/uploading-an-event-summary

Appendix 2 – Sample staged supply agreement

Patient			
Name	Date of birth		
Address	Phone number		
	Medicare number		
Email	Concession card details		
Carer			
Name	Phone number		
Emergency contact details			
Pharmacy providing the service			
Name	Phone number		
Address	Email		
	Name of pharmacist		
Prescriber			
Name	Phone number		
Address	Email		
Medicine			
Drug name/brand name	Dosage (and time if required)	Collection frequency	
		Daily	Alt days
		Weekly	Fortnightly
		Other (specify)	
		Daily	Alt days
		Weekly	Fortnightly
		Other (specify)	
Service			
Description			
Supply arrangements			
New prescription requirements			
Missed or lost doses			
Procedure to be followed in the event of missed doses			
If you miss _____ days' supply, the pharmacy will:			
Other arrangements for missed doses:			

Supply during extended public holiday periods i.e. take away doses	
Transfer to another service provider or discontinuation of the service	
Fee for service	
Name of payment source	Phone number
A fee of _____ will be charged (frequency)	
Other payment details	
Storage	
Your medicines will be kept separate from other people's medicines. If you don't collect your medicines for a period of _____ the medicines will be deemed unwanted and disposed of	
Termination	
The pharmacy reserves the right to terminate the delivery of the service to the patient/carer where the terms of this agreement have not been met. If the service has been initiated by the prescriber, the prescriber will be contacted to discuss continuity of care and arrangements for the balance of supply of medicine	
Pharmacy responsibility	Patient/carer responsibility
<p>The pharmacy will:</p> <ul style="list-style-type: none"> • communicate with the prescriber when required • ensure that all records are accessed only by authorised personnel • retain the dispensed medicines in the pharmacy in a secure location • sign the staged supply record each time a supply is collected • advise you when the dispensed quantity is running out • let you know if the terms of the service change • advise you if the service is to be discontinued 	<p>You will be required to:</p> <ul style="list-style-type: none"> • consent to the pharmacist communicating with the prescriber when required • provide information to the pharmacy when requested (e.g. medication history, allergies) • agree to leave dispensed medicines in the care of the pharmacy • ensure that a valid prescription is available for subsequent dispensing of medicines • sign the staged supply record each time a supply is collected • advise the pharmacy in a timely manner if third party payment arrangements change • advise the pharmacy as early as possible if travel or transfer arrangements need to be made • advise the pharmacy in a timely manner if the service is to be discontinued
The prescriber has been notified about the service: Yes No Date: ____/____/____	
Signature	
By signing this form I consent to participate in the staged supply service according to the terms outlined above	
Patient	Date
Pharmacist	Date

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