

PROGRAM RULES Staged Supply

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1 INTRODUCTION

Staged Supply involves the provision of Pharmaceutical Benefits Scheme (PBS) medicines in instalments when requested by the prescriber. The Program is designed to assist Patients who are at risk of drug dependency or who are otherwise unable to manage their medicines safely.

This document outlines the Program Rules governing the Staged Supply Program. This document must be read in conjunction with the *Pharmacy Programs Administrator General Terms and Conditions* (General Terms), relevant Professional Standards and Pharmacy Board Guidelines. Definitions in the General Terms apply in these Program Rules.

2 BACKGROUND

The Staged Supply Program is funded under the Sixth Community Pharmacy Agreement (6CPA). The Program aims to improve medication adherence and reduce the risk of self-harm or harm to others through accidental or intentional misuse, abuse or diversion of prescribed medicines.

For the purposes of this Program, Staged Supply is the provision of PBS medicines in instalments where requested by the prescriber. Staged Supply instalments may be made daily, weekly or as requested by the prescriber.

The Staged Supply Program specifically excludes medicines supplied under the Section 100 Opioid Dependence Treatment Program.

Staged Supply Service Providers must also collect health outcomes data for up to four patients at Initial Patient Registration and at Six-Monthly Follow-Ups. This data must be provided to the Pharmacy Programs Administrator to assist with assessing the effectiveness of the Program.

3 ELIGIBILITY

3.1 Service Provider Eligibility Criteria

To be eligible to become an Approved Staged Supply Service Provider and participate in the Staged Supply Program, a Pharmacy must:

- Be approved to dispense pharmaceutical benefits as part of the Pharmaceutical Benefits Scheme (PBS) defined in Section 90 of the *National Health Act 1953* (Section 90 Pharmacy)
- Be accredited by an approved Pharmacy Accreditation Program or be in the process of attaining accreditation within six months of applying to participate in the Program. The Australian Government Department of Health may waive the requirement to hold or be seeking accreditation in order to ensure patients can access the Program
- Agree to publicly display and comply with the *Community Pharmacy Service Charter* and *Customer Service Statement* (available here)
- Abide by the General Terms (available <u>here</u>)
- Undertake to provide Staged Supply Services in accordance with these Program Rules, relevant Professional Standards and Pharmacy Board Guidelines



- Ensure that Initial Patient Registration and Follow Up Services, and any interviews or consultations, are carried out by a Registered Pharmacist, face-to-face with the patient and/or patient's carer, and with consideration of the patient's comfort and right to privacy
- Undertake to obtain appropriate written consent for provision of Staged Supply Services prior to providing the service. A consent form is available here and at Appendix B of this document
- Ensure that the preparation and supply of the instalment occurs in an area which accords with legislative requirements for dispensing medications
- Comply with legislative requirements in relation to storage of and staff access to medicines that
 are held in the pharmacy, including ensuring that the area where the medicines are stored is not
 accessible to the public
- Agree to accept the payment received under this Program as full payment and provide all aspects of the Staged Supply Service at no cost to participating patients.

3.2 Patient Eligibility Criteria

To be eligible for a Staged Supply Service funded under the Program, the patient must:

- Be a Medicare and/or Department of Veterans' Affairs (DVA) cardholder
- Hold a current, valid, government-issued concession card
- Live at home or in a community setting
- Have been referred for a Staged Supply Service by their prescriber
- Have been prescribed one or more of the following types of medications as a pharmaceutical benefit:
 - Opioid analgesics
 - Antipsychotics
 - Anxiolytics
 - Hypnotics and sedatives
 - Antidepressants
 - Psycho-stimulants.

Staged Supply Services funded under this Program are not available to in-patients of public or private hospitals, day hospital facilities or transitional care facilities, or residents of Aged Care Facilities or correctional facilities.

Staged Supply Services funded under this Program are not available to Patients receiving Staged Supply Services funded under other federal, state or territory government programs.

Where a Patient does not meet the eligibility criteria, the Staged Supply Service Provider may offer the service at the Patient's own cost. A lack of eligibility for funding under this Program does not invalidate a Patient's (or carer's) request to provide medicines in a manner equivalent to staged supply.

3.3 Patient Consent

The Staged Supply Service Provider must obtain appropriate written consent from the Patient or the Patient's carer prior to providing a Staged Supply Service. A consent form is available online here.



4 STAGED SUPPLY PROGRAM ELEMENTS

The Staged Supply Program has two elements: the provision of a Staged Supply Services (i.e. dispensing medicines), and the collection of health outcome data. Data collection is required at Initial Patient Registration and Six Month Follow Up. Fees for each element are given at clause 5.

4.1 Staged Supply Services

A Staged Supply Service must be conducted in accordance with the Pharmacy Board Guidelines and PSA Standards, including the routine monitoring and assessment of the Patient.

Staged Supply Service Providers may claim a fee for the provision of one medication under a Staged Supply Arrangement for up to 15 eligible patients per month. Supporting documentation must be retained for each service claimed as per clause 7.3.

To be eligible to claim for Staged Supply Services under this Program, the Staged Supply Service Provider must collect information (see Appendix A) and submit it via the Pharmacy Programs Administrator Portal.

4.2 Health Outcome Data Collection

The Staged Supply Program has been redesigned to support the collection of health outcome data. Staged Supply Service Providers participating in the Program will be required to collect data at Initial Patient Registration and at each Six Month Follow Up.

Data for up to four Patients may be submitted to the Pharmacy Programs Administrator in order to monitor the Staged Supply Program's delivery of health outcomes for Patients and to assist with assessing the effectiveness of the Program. Staged Supply Service Providers claiming services for less than four patients will be required to collect and provide information for all patients.

Service Providers will receive a fee for the collection and provision of health outcome data to the Pharmacy Programs Administrator.

Initial Patient Registration

Staged Supply Service Providers will be required to collect and provide data to the Pharmacy Programs Administrator in accordance with Appendix A of these Program Rules.

Information is collected at Initial Patient Registration to ensure the eligibility requirements set out in clause 3.2 of these Program Rules are met, and must be retained as part of the Supporting Documentation outlined in clause 7.3. This includes written confirmation from the Patient's prescriber outlining the prescription medicine to be provided through a Staged Supply arrangement.

Six Month Follow Up

Staged Supply Service Providers will be required to collect and provide to the Pharmacy Programs Administrator with follow-up data on each of the patients for which Initial Patient Registration data was collected. Follow Up Services must be conducted at six-monthly and in accordance with Appendix A of these Program Rules.

If a Patient exits the Staged Supply Program prior to the Six Month Follow Up, the follow up interview should be conducted (where possible) at the time of exit.



5 FEES

Approved Service Providers can claim the following payments under the Program:

Description	Fee (per patient)
Provision of first Staged Supply Service each week (first day)	\$8.01
Each additional provision of a Staged Supply Service during the week (subsequent days)	\$4.06
Collection of data at Initial Patient Registration	\$31.90
Collection of data at Follow Up Service	\$31.90

No additional Patient charges may be levied for participating patients who are funded through the Staged Supply Program.

In order to claim the above amounts, data must be collected in accordance with Appendix A and provided to the Pharmacy Programs Administrator.

Note: Patients will still be required to pay to obtain the medicines provided through the Staged Supply Service including the PBS co-payment (if applicable).

Forms to aid with the collection of this information are available from www.ppaonline.com.au

6 FUNDING AVAILABILITY

Each pharmacy may receive funding for the provision of Staged Supply Services up to a maximum of fifteen patients per month, and up to four patients for the collection of health outcome data information.

Caps will be monitored and may be modified to ensure the funding does not exceed the allocated budget.

7 CLAIMS

To become an Approved Staged Supply Service Provider and participate in the Staged Supply Program, eligible Pharmacies must first register via the Pharmaceutical Programs Administrator Portal.

7.1 Claim Submission

An Approved Staged Supply Service Provider may submit claims on a monthly basis for providing Staged Supply Services to eligible Patients. Claims must be submitted online via the Pharmacy Programs Administrator Portal.

Staged Supply Services and associated Follow Up Services must be claimed by the end of the next calendar month (e.g. Staged Supply Services provided in March must be claimed by 30 April). Claims submitted outside this timeframe will not be paid and cannot be resubmitted.



All information entered on the claim must be correct as any inconsistencies may result in the claim not being able to be submitted.

Claims for Follow Up Services can only be made after six months have passed from the Initial Patient Registration claim, unless the patient has exited the program in which case the patient must have been receiving Staged Supply Services for at least four months.

7.2 Claim Lodgement

The following information must be provided to the Pharmacy Programs Administrator in order to claim a payment under this Program:

- a. Section 90 number
- b. Pharmacy Accreditation ID
- c. Patient's Medicare/DVA card number
- d. Date of initial Staged Supply or Follow Up Service
- e. A declaration by the claiming Approved Staged Supply Service Provider that the patient satisfies the eligibility criteria outlined in clause 3.2 of these Program Rules
- f. All data outlined in Attachment A, where Patient consent has been obtained.

7.3 Supporting Documentation

The following information must be retained by the Staged Supply Service Provider for seven years to support any claim for payment made under these Program Rules:

- a. Section 90 number at the time of the provision of the Staged Supply Service
- b. Pharmacy Accreditation ID at the time of the provision of the Staged Supply Service
- c. Registered Pharmacist Identifier (e.g. AHPRA registration number)
- d. Copy of the patient consent form, where relevant
- e. Patient's name and address
- f. Patient's Medicare/DVA Card number
- g. Patient's concession card number
- h. How the Patient has satisfied the other eligibility criteria
- i. List of all prescription and non-prescription medicines the Patient is taking at the time the Staged Supply Service is provided
- j. Date(s) of provision of medicine instalments as a part of the Staged Supply Service.

Supporting documentation can be electronic or hard copy.

8 AUDIT REQUIREMENTS

Staged Supply Service Providers must retain all records for seven years to demonstrate that they have complied with the General Terms and these Program Rules when providing and claiming for a Staged Supply Service.

Staged Supply Service Providers may be subject to audits by the Australian Government Department of Health to ensure Staged Supply Services are provided in accordance with the General



Terms and these Program Rules. Staged Supply Service Providers that do not provide Staged Supply Services in accordance with the General Terms and these Program Rules may no longer be able to participate in the Staged Supply Program or be eligible to receive Staged Supply Program payments and repayment may be required. Under section 137.1 of the *Criminal Code Act 1995*, giving false and misleading information is a serious offence.

9 RESOURCES

Staged Supply Program resources are available for download at www.ppaonline.com.au.



CONTACT THE SUPPORT CENTRE: 1800 951 285 | support@ppaonline.com.au



APPENDIX A INFORMATION TO BE COLLECTED

As outlined in the Staged Supply Program Rules, Staged Supply Service Providers must collect and health outcomes information for four Patients that receive services, where consent has been obtained and provide this information to the Pharmacy Programs Administrator.

Please note: for Staged Supply Service Providers claiming services for less than four patients, the information must be collected and provided to the Pharmacy Programs Administrator for all patients.

This data is being collected in order to monitor the Staged Supply Program's delivery of health outcomes for Patients. Data will be required to be provided at Initial Patient Registration, and at six monthly intervals.

1. PHARMACY REGISTRATION DATA – to be provided when the Pharmacy registers for the Staged Supply Program (via Pharmacy Programs Administrator Portal):

- a. Section 90 number
- b. Pharmacy Accreditation ID
- c. Pharmacy name
- d. Pharmacy location address
- e. Pharmacy location postcode
- f. Pharmacy contact details.

2. INITIAL PATIENT REGISTRATION DATA – To be collected from the Patient on commencement of participation in the Staged Supply Program:

- a. Patient's Medicare Number or DVA file number
- b. Patient's Name
- c. Patient's Date of Birth
- d. Is the patient a Concession Card Holder?
- e. Referring GP prescriber number
- f. Patient's postcode of residence
- g. Patient's gender
- h. Is English the Patient's primary language at home?
- i. Does the Patient identify as Aboriginal and/or Torres Strait Islander?
- j. What health conditions/co-morbidities is the patient taking medications for?
- k. Reason for Staged Supply Service
- I. How frequently is the medication to be provided to the Patient under the Staged Supply Service?
- m. Actions to be undertaken by pharmacists as a result of the Staged Supply Service;
- n. What is the Patient's average MedsIndex score?
- o. In the last six months, did the Patient go to the GP or hospital because of problems with their medicine?
- p. Has the patient had any problems over the past month with their medicine/s?



- q. On a scale of 1 (not helpful) to 10 (extremely helpful), how helpful does the Patient think the Staged Supply Service will be in managing their medicines?
- r. On a scale of 1 (no impact) to 10 (had an extremely positive impact), what impact does the Patient feel that participating in the Staged Supply service will have on preventing a medicine-related problem for them?

3. To be collected at FOLLOW-UP CONTACT with PATIENT (or at ceasing of Staged Supply Service):

- a. Date of Follow Up Service
- b. Actions taken by Pharmacist/s to support the Staged Supply Service
- c. Is continuation of the Staged Supply Service recommended for this Patient?
- d. If continuation of the Staged Supply Service is not recommended, what is the reason?
- e. What is the Patient's average MedsIndex score?
- f. In the last six months, did the Patient go to the GP or hospital because of problems with their medicine?
- g. Has the Patient had any problems over the past month with his/her medicine/s?
- h. Who is participating in the follow-up/review?
- i. On a scale of 1 (not helpful) to 10 (extremely helpful), how helpful has the Patient found the Staged Supply Service in managing their medicines?
- j. On a scale of 1 (no impact) to 10 (extremely positive impact), what impact does the Patient feel that receiving the Staged Supply Service has had on preventing a medicine-related problem for them?
- k. On a scale of 1 (not met expectations at all) to 10 (met all expectations and more), how well has the Staged Supply Service met the Patient's expectations?

4. Medication Profile for medication being provided to the Patient under the Staged Supply Service:

- a. Brand name
- b. Drug name
- c. Form
- d. Strength
- e. Dose and dosage regimen.
- 5. In order to claim the fees outlined in clause 5 of the Staged Supply Program Rules, all data collected at paragraphs 1, 2, 3 and 4 above must be provided to the Pharmacy Programs Administrator.



APPENDIX B STAGED SUPPLY SERVICE INFORMATION STATEMENT

Your doctor has requested that one or more of the Pharmaceutical Benefits Scheme (PBS) medicines you are taking should be provided to you in instalments. Another name for providing medicines in instalments is the Staged Supply of medicines. This could mean you get your medicines from your pharmacy daily or weekly, as directed by your doctor. The service aims to help to improve medicine use with the goal of improved health outcomes.

Under this program, the medicine provided through Staged Supply needs to be one or more of the following types: opioid analgesics; antipsychotics; anxiolytics; hypnotics and sedatives; antidepressants or psycho-stimulants.

In order to receive this service, you need to be a Medicare and/or Department of Veterans' Affairs (DVA) cardholder, hold a current Australian Government issued concession card, live at home in a community setting and have a referral to the service from your doctor.

Under this service the pharmacist will:

- Assess your eligibility to receive the service
- Obtain informed consent from you to receive the service
- Provide certain PBS medicines to you in instalments
- Store your remaining medicines
- Monitor your progress
- Collect personal and sensitive information from you to enable the pharmacy to claim a payment for delivery of this service.

The Australian Government is paying the pharmacy for the Staged Supply Service. You will not be charged an additional fee by the pharmacy for this service.

You will still be required to pay to obtain the medicines that will be provided through this Staged Supply Service.

If you provide your consent, the pharmacist will also:

- Collect personal and sensitive information from you at the first patient registration appointment to allow the Australian Department of Health (the Department) to monitor and evaluate the program's effectiveness
- Collect personal and sensitive information from you at six monthly appointments after you start using the Staged Supply Service to allow the Department to monitor and evaluate the program's effectiveness. The Australian Government will pay for the full cost of data collection at your first registration appointment and at each 6 monthly follow-up appointment. You will not be charged an additional fee by your pharmacy at these data collection appointments.



Australian Privacy Principle 5 Notification under the *Privacy Act 1988*

Your personal information is protected by law, including the Privacy Act 1988.

Collection of personal information to allow payment to your pharmacist

The Department and the Pharmacy Programs Administrator are collecting your personal information to verify your eligibility to receive the Staged Supply Service and enable the pharmacy to claim a payment for the delivery of the service to you.

Personal information, details about your eligibility for the service, the medications you are taking and other health information will be collected by your pharmacist and disclosed for this purpose.

If you consent to receive this service by completing and signing the consent form, your personal information will be collected for this purpose.

If you do not provide your consent to the collection of your information for this purpose, your pharmacist will not be able to assess your eligibility for the service and you will not be able to access a funded Staged Supply Service. In this event, you may be required to pay for the cost of the service to your pharmacist.

Collection of additional information to allow monitoring and evaluation of the service

You also have the option of consenting to the Pharmacy Programs Administrator and the Department collecting your personal information for the purposes of monitoring and evaluating the Staged Supply Service. If you consent, your personal information will be collected at an initial appointment and six monthly follow up appointments. Your personal information will also be disclosed to the Department's contracted researchers (Health Consult Pty Ltd) for this purpose.

Personal information, details about your eligibility for the service, the medications you are taking and other health information will be collected by your pharmacist and disclosed for this purpose.

Your access to the Staged Supply Service will not be affected if you do not provide consent to the collection of this additional information.

If any information is published as a result of the analysis, your information will be provided in such a way that you cannot be identified.

Further Information

The Department and the Pharmacy Programs Administrator are unlikely to disclose your personal information to overseas recipients.

The Department can be contacted by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at www.health.gov.au.

The Pharmacy Programs Administrator can be contacted by telephone on 1800 951 285 or email at help@ppaonline.com.au.

The Department has a privacy policy which you can read at www.health.gov.au/privacy

The Pharmacy Programs Administrator has a privacy policy which you can read at www.ppaonline.com.au.



You can obtain copies of these privacy policies by using the contact details set out above. The privacy policies contain information about:

- How you may access the personal information the Department or Pharmacy Programs
 Administrator holds about you and how you can seek correction of it
- How you may complain about a breach of the Australian Privacy Principles and how complaints are dealt with.

ACKNOWLEDGEMENT

I have read or had explained to me, and understand, the contents of the Staged Supply Service Information Statement.

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	I consent to receive the Staged Supply Service and in doing so I consent to the collection personal information by the Pharmacy Programs Administrator and the Australian Govern Department of Health to enable the pharmacy to claim a payment for delivery of that see							
	I consent to the collection of my personal information by the Pharmacy Programs Administrator and the Australian Government Department of Health for program monitoring and evaluation purposes.							
Si	gnature	Date						
Pr	int name							
If y	ou are signing on	behalf of the Participant, please indicate your relationship to the Participant:						
	☐ Parent or guardian of child							
	Other – Please tick applicable category below:							
	☐ Enduring Guardian, recognised by a relevant State or Territory law							
	Enduring Power of Attorney, recognised by a relevant State or Territory law							
	☐ A person recognised by a relevant State or Territory law							
	A person who capable of gi	o has been nominated in writing by the Participant while the Participant was ving consent						

This program is funded under the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia.



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