

PROGRAM RULES

COVID-19 Vaccination in Community Pharmacy (CVCP) Program

October 2021





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1. INTRODUCTION

This document outlines the Program Rules governing the COVID-19 Vaccination in Community Pharmacy (CVCP) Program. This document must be read in conjunction with the:

- Pharmacy Programs Administrator (PPA) General Terms and Conditions (General Terms)
- <u>Pharmaceutical Society of Australia (PSA) Professional Practice Standards</u> (particularly Standard 11: Vaccination Services)
- <u>PSA Practice Guidelines for Pharmacists Providing Immunisation Services</u> (collectively the Professional Standards and Guidelines)
- Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia in 2021 (ATAGI Guidelines)
- Australian Immunisation Handbook
- National Vaccine Storage Guidelines 'Strive for 5'.

Definitions in the General Terms apply in these Program Rules.

The CVCP Program is a temporary program, which aims to support and protect members of our community from novel coronavirus (COVID-19) by providing a fee for service payable to Australian pharmacies for administering the COVID-19 vaccine.

2. DEFINITIONS

Approved Pharmacist means a Registered Pharmacist.

CVCP Service means the administration of COVID-19 vaccinations to an eligible patient by an Appropriately Qualified Person including or under the supervision of an Approved Pharmacist, comprising:

- Determining patient eligibility
- Obtaining appropriate patient consent
- Administration of either the first or second vaccination where:
 - Administration of the first vaccination includes:
 - Taking a short patient history
 - Appropriate aftercare and /or referral
 - Booking the patient's second vaccination where possible and ensuring the patient is aware of the importance of the second vaccination
 - o Entry of the vaccination episode on the Australian Immunisation Register (AIR).
 - Administration of the second vaccination includes:
 - Updating the patient history
 - o Appropriate aftercare and /or referral
 - o Entry of the vaccination episode on the AIR.

Appropriately Qualified Person means a person currently holding an active AHPRA registration who is authorised in accordance with jurisdictional requirements to administer the COVID-19 vaccine in a pharmacy or off-site setting and who has undertaken the COVID-19 Vaccination Training Program.



3. PARTICIPATION REQUIREMENTS

Pharmacy Eligibility

To be eligible to become an Approved Service Provider under this temporary program, a Pharmacy must:

- Be approved to dispense pharmaceutical benefits as part of the PBS defined in Section 90 of the National Health Act 1953 (Cwlth) (Section 90 Pharmacy)
- Have received notification from the Australian Government Department of Health (or delegate)
 of their selection to participate in the national vaccine program
- Be located in a State or Territory where appropriate legislation has been enacted to allow vaccinations to be administered in pharmacies
- Agree to deliver CVCP Services in accordance with the General Terms and the CVCP Program Rules, including those related to Patient eligibility
- Agree to meet the CVAS Vaccination Site Readiness Checklist and Declaration
- Provide CVCP Services in accordance with the PSA Standards and Guidelines, ATAGI Guidelines and relevant state or territory legislation
- Have access to the Vaccination Information and Location Service. It is not mandatory to use
 the Service to manage appointments, however each pharmacy will be mandated to appear in
 the Vaccine Clinic Finder. If pharmacies have an online booking system already, they will be
 able to operate without substantial changes to their existing systems and processes
- Have registered with the Australian Immunisation Register (AIR) and undertake to report all CVCP Services within the set timeframe (within 24 hours)
- Maintain a secure facility for the appropriate storage, including cold storage, of vaccines, in accordance with the approved product information
- Undertake to obtain appropriate patient consent for the provision of a CVCP service prior to providing the service. A consent form is available online on the Department of Health's website
 - Ensure that services delivered under the CVCP Program are carried out by an Appropriately Qualified Person. Where the service is delivered in a Community Pharmacy premises, the area must meet the <u>ATAGI site requirements for COVID-19 vaccination in</u> community pharmacies.
- Agree to ensure that any person involved in providing CVCP Services through this Program
 abides by the current hygiene and isolation protocols relevant to the containment and
 management of COVID-19 within the community as issued by each State and Territory
- Ensure the Approved Pharmacist or Appropriately Qualified Person conducting the services under the Program is not responsible for dispensing or undertaking other professional duties at the time of consultation
- Register via the PPA Portal and continue to meet the above Eligibility Criteria while participating in the Program.

An Approved Service Provider must notify the PPA immediately when it becomes aware of any circumstance, event or fact that may affect the Service Provider's eligibility to participate in the Program.



Off-Site Vaccinations

Approval Process

Pharmacies must notify the PPA of their intention to deliver vaccinations off-site from the pharmacy premises. This will enable the pharmacy to administer vaccines to any eligible patient cohort in any eligible location (refer to requirements below) and notification must only be made once.

In order to do so, pharmacies must initially email the PPA at support@ppaonline.com.au and include:

- The pharmacy name, address and Section 90 number; and
- A written declaration indicating that the pharmacy will meet the Requirements for Off-Site Vaccinations set out in the CVCP Program Rules (outlined below).

Requirements for Off-Site Vaccinations

- Pharmacies may conduct off-site vaccinations if both the pharmacy and the off-site vaccination location are in State/s and/or Territory/s which have appropriate regulatory arrangements that allow pharmacists to vaccinate off-site. Pharmacies must ensure they are aware of and adhere to the relevant requirements of the relevant State /Territory. It is the pharmacy's responsibility to check these requirements are met before requesting approval from the PPA.
- Off-site vaccinations may be undertaken within the following distances from the pharmacy:
 - Metropolitan pharmacies located in Modified Monash (MM) 1 locations may administer vaccinations at off-site locations within a 10km radius of the pharmacy premises.
 - o Pharmacies located in MM2-7 (regional, rural and remote) locations may administer vaccinations at off-site locations within a 100km radius of the pharmacy premises.

This radius may be increased only for situations where the pharmacy has ensured there are no other participating pharmacies offering COVID-19 vaccinations (either on-site or off-site) and located within a 10km / 100km radius of the proposed vaccination site who may be impacted. Pharmacies should retain evidence of how they have substantiated this.

Where the service is delivered off-site of the Community Pharmacy premises, the pharmacy must ensure that both the <u>Taskforce requirements for conducting off-site COVID-19</u> <u>vaccinations</u> and any jurisdictional requirements are met, taking into consideration the delivery model and location of the target population.

- Pharmacies should ensure they have read and follow the <u>National Vaccine Storage Guidelines</u>
 <u>'Strive for 5'</u> for packing and monitoring vaccinations while off-site.
- Pharmacies should ensure they are not undertaking more than 50% of their total monthly vaccinations as off-site vaccinations.
- Where a service is to be delivered off-site in the patient's home, consideration should be given to the safety of the staff providing the vaccination service and whether the location is appropriate.

Patient Eligibility

This program will protect members of our community and is available to Patients meeting the eligibility criteria outlined at (https://www.health.gov.au/initiatives-and-programs/covid-19-vaccine. These criteria may change depending on the priority populations as determined by the Department.



CVCP Services delivered under this Program cannot be administered to Patients not meeting the eligibility criteria. Notification of change in priority focus will be distributed. However, Service Providers and Appropriately Qualified Persons should make themselves aware of what the priority population is at the time of booking a Patient for a CVCP Service.

Patients with no Medicare/DVA card

Patients who meet all other Commonwealth and State/Territory eligibility criteria but who either do not hold a Medicare/DVA card or are not eligible to hold a Medicare/DVA card, can receive a vaccination in a Community Pharmacy free of charge. Pharmacies must ensure they first seek confirmation from the patient that the patient does not hold, or is ineligible to hold a Medicare/DVA card and should use the 'Urgent Clinical Need' special Medicare number (25437529911) when submitting a claim in the PPA Portal for administering vaccinations to these patients.

The 'Urgent Clinical Need' Medicare number should not be used for manual reporting to the AIR. Please note some professional services software packages that integrate with both AIR and the PPA Portal may be set up in such a way that the 'Urgent Clinical Need' number must still be entered into the software for PPA claiming purposes. In these instances, the software is built to ensure the number is not then reported to AIR.

Patient Consent

The Service Provider must obtain appropriate written or verbal consent from the Patient or the Patient's carer prior to providing the Service. For further information regarding valid consent, including how to obtain consent in special populations (i.e. children or people with impaired decision-making ability), refer to the section <u>'Preparing for vaccination: Valid consent' in the Australian Immunisation Handbook.</u>

Consent forms are available on the Department of Health's website.

4. REGISTRATION, CLAIMING AND PAYMENTS

Registration into the CVCP Program

To register as a CVCP Service Provider, a Community Pharmacy must register for the CVCP Program via the PPA Portal. If a Community Pharmacy has not been notified by the PPA of their suitability and subsequent selection for the Program, the application to register for the CVCP Program will not be approved.

A user guide to assist you to register is available on the PPA CVCP Program downloads page.

Change of Circumstances

It is the responsibility of the Main Authorised Person of the Approved Service Provider to ensure that the Pharmacy's registration is up to date at all times. Approved Service Providers must notify the Pharmacy Programs Administrator within 14 days of the following changes:

- (a) Change of ownership
- (b) Change of Section 90 approval number.

If either of these have occurred since the EOI was submitted, a further declaration will be required to confirm the new Section 90 pharmacy approval details meet, at a minimum, the same EOI requirements that were confirmed to be met, as per the original EOI submission.



Claims

Service Providers must submit claims online via the PPA Portal.

CVCP Services delivered under the Program must be claimed by the end of the following calendar month following provision of the Service (e.g., services provided in May should be claimed by 30 June). Claims that are outside this timeframe, that are incomplete, or that do not meet Program Rules cannot be submitted and will not be paid.

All information entered in the Claim must be correct as any inconsistencies may prevent claim submission.

Claim Lodgement

The following information must be provided to the PPA in order to lodge a claim:

- Section 90 number
- Confirmation of patient consent
- Name and AHPRA number of person administering vaccination
- Patient's Medicare/DVA Card number (or special Medicare number (25437529911) if the Patient does not hold a Medicare/DVA card or is not eligible to hold a Medicare/DVA card)
- Patient's full name
- Patient's date of birth
- Whether the vaccination is the first or second in a course of an eligible vaccine
- Date of vaccination/administration
- A declaration that the vaccination has been recorded in the AIR.

If the Patient is presenting for the second vaccination and has received the first vaccination elsewhere, this must also be noted.

Supporting Documentation

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

- Section 90 number at the time of the provision of the CVCP Service
- Details of the Appropriately Qualified Person administering the vaccination including their AHPRA registration number
- Patient's name and address
- Patient's Medicare/DVA Card number (if applicable)
- How the Patient has satisfied Eligibility Criteria
- Whether the vaccination was administered off-site and if so, the location of the vaccination.



Payments

Approved Service Providers can claim the following payments under the Program These fees are GST Exempt. [* Modified Monash (MM)]

Description	MM1* Fee	MM2 - 7* Fee
First Administration	\$16	\$19
Second Administration (where the first administration was undertaken by the same Service Provider)	\$26	\$29
Second Administration (where the first administration was undertaken by a different Service Provider)	\$16	\$19
Third Administration (for severely immunocompromised patients)*	\$16/\$26	\$19/\$29

^{*} The PPA Portal is currently being updated to accommodate third dose claiming via the inclusion of an 'Additional Dose' option. The below table provides guidance on interim claiming arrangements which will require you to take different approaches based upon your pharmacy's claiming history for each patient.

Pharmacies may also choose to wait until the 'additional dose' type is available to claim all third doses (an extended claiming deadline will be provided to allow for submission of October and November third dose claims).

Existing claims in PPA Portal for Patient	How to submit a 3rd Dose claim in the PPA Portal (until 14 December 2021)
No 1st Dose or 2nd Dose claimed by your pharmacy	Manually submit as 1st Dose (paid \$16/\$19 fee based on MM as per table above)
 No 1st Dose claimed 2nd Dose (Other Provider) already claimed by your pharmacy 	You will need to wait until the 'additional dose' type option is available in the PPA Portal from 14 December to claim
 1st Dose already claimed by your pharmacy No 2nd Dose (Same Provider) claimed by your pharmacy 	Manually submit as 2nd Dose (Same Provider) (paid \$26/\$29 fee based on MM as per table above)
Both 1st Dose and 2nd Dose (Same Provider) already claimed by your pharmacy	You will need to wait until the 'additional dose' type option is available in the PPA Portal from 14 December to claim

Service Providers cannot charge any Patient for a COVID-19 vaccination service. This includes Patients who do not hold or are ineligible to hold a Medicare card.

Additionally, fees cannot be charged for providing off-site vaccinations.



5. AUDIT AND COMPLIANCE REQUIREMENTS

Service Providers must retain full and true records (including all patient consent forms) in relation to the provision of services for not less than seven years after the claim for payment. Such records must be kept in a manner that permits them to be conveniently and properly audited, and enables the amounts claimed as well as the services provided under the General Terms and these Program Rules to be determined. Service Providers may be subject to audits by the Australian Government Department of Health (or its representative) to ensure that the General Terms and these Program Rules have been complied with, and must provide all and any records requested as part of such audit(s).

Service Providers must also ensure that they are using current documents when obtaining information or consent from patients. Service Providers that wrongfully or incorrectly receive support and/or do not meet the requirements set out in the General Terms and these Program Rules may be subject to compliance action (as determined by the Australian Government Department of Health or Pharmacy Programs Administrator) and repayment may be required.

Under section 137.1 of the Criminal Code, giving false and misleading information is a serious offence.

If an audit/compliance action is to be conducted, Service Providers will be required to produce documentation within a specified time frame.





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