

Australian Government
Department of Health and Ageing

**Review of the Existing Supply and Remuneration
Arrangements for Drugs Listed Under Section 100 of
the National Health Act 1953 (NHA 1953)**

Stakeholder Information Pack

Prepared by Australian Healthcare Associates

On behalf of
Department of Health and Ageing and
The Pharmacy Guild of Australia

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1. PURPOSE OF THIS DOCUMENT

The purpose of this document is to provide stakeholders with information about the review of supply and remuneration arrangements for drugs provided under certain Section 100 programs and delivered through community pharmacies, including the project's aim and how stakeholders can input their views about the programs at a number of points across the review process.

2. INTRODUCTION

Australian Healthcare Associates is undertaking a project to review the existing supply and remuneration arrangements relating to programs delivered through community pharmacies under Section 100 of the *National Health Act 1953*, including how these arrangements impact on community pharmacy. The review is funded by the Australian Government and forms part of the Fourth Community Pharmacy Agreement, being implemented by the Agreement Consultative Committee (ACC). The ACC comprises four members from each of the Pharmacy Guild of Australia and the Department of Health and Ageing.

3. PROJECT AIM AND ORGANISATION

The objectives of the project are to:

- Review the existing supply and remuneration arrangements for drugs listed under Section 100 of the *National Health Act 1953* programs and provided through community pharmacies;
- Assess the effectiveness and efficiency of the current arrangements as they relate to community pharmacy;
- Identify the impact of the supply and remuneration arrangements on community pharmacy; and
- Develop options to address any identified impact of the current supply and remuneration arrangements on community pharmacy.

The review includes the following programs:

- Highly Specialised Drugs (HSD) Program;
- Aboriginal Health Services Remote Access (AHSRA) Program;
- Opiate Dependence Treatment (ODT) Program;
- Special Authority (SA) Program; and
- Continuing Medication (CM) Program.

An overview of each of these five programs is provided in Appendix A.

The review will involve extensive consultation and involvement of stakeholders to identify the key issues for each program, to formulate options to address these issues and assess their feasibility. The outcome of the project will be a report, outlining the set of options to improve delivery arrangements for the five programs, which will be provided to the ACC.

The project team comprises:

- A team of six consultants from Australian Healthcare Associates, comprising Suzanne Vilé (Project Manager), Tess Lethborg, Dr Lesley McKarney, Grant McKirdy, Mark Williams and Jessica Small.
- An advisory group of four technical experts, comprising:
 - Professor Jo-anne Brien, Clinical pharmacologist and HSD/SA program advisor;
 - Dr Giselle Gallego, Pharmacist and HSD/SA program advisor;

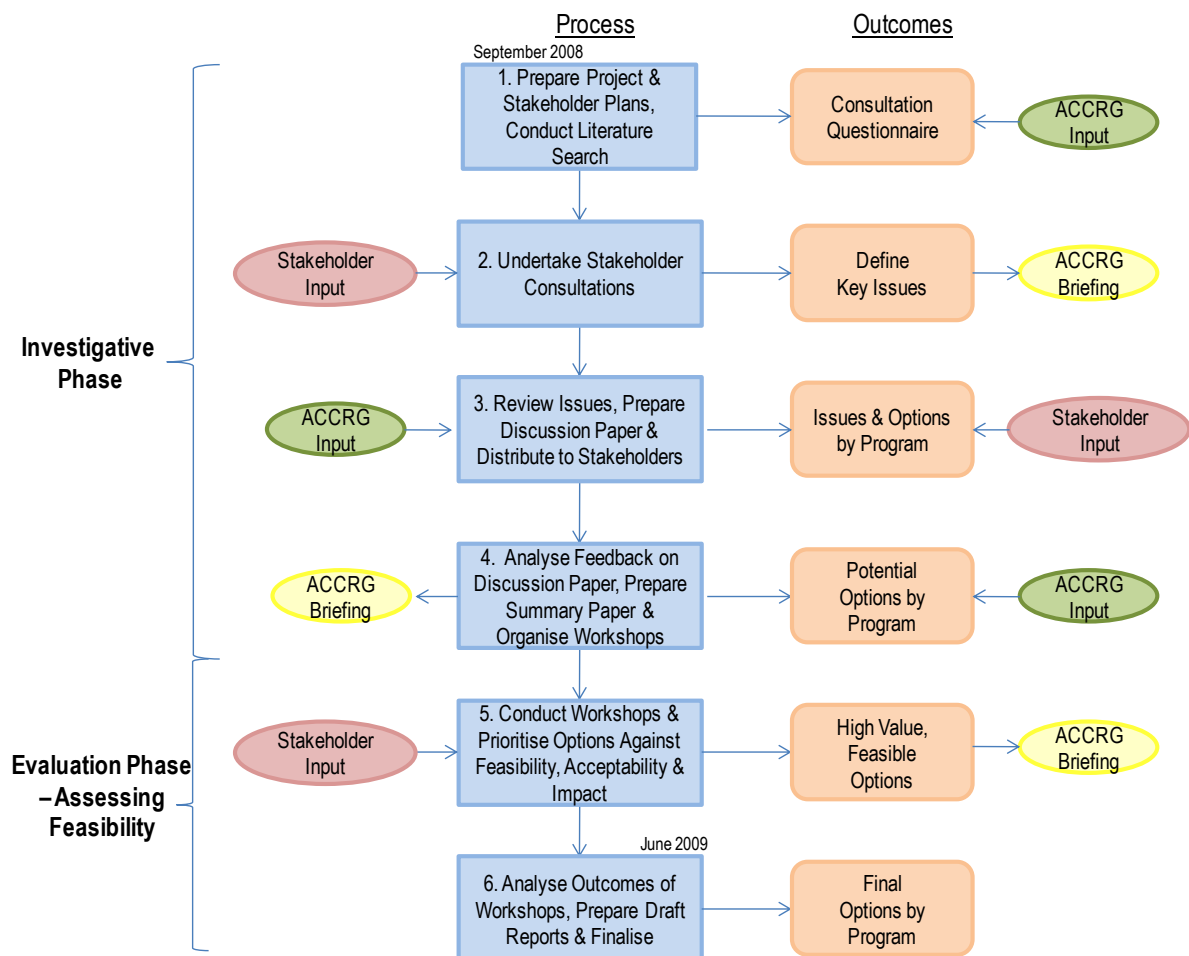
- Dr Alice Tippetts, Remote area GP and AHSRA program advisor; and
- Peter Hatswell, Pharmacist and AHSRA program advisor.

The project team reports to a sub-group of the ACC, called the ACC Review Group (ACCRG), which comprises representatives from the Department of Health and Ageing and the Pharmacy Guild of Australia. The project is expected to be complete by end June 2009.

4. YOUR INPUT TO THE PROJECT

The project team wants to hear your views about the current supply and remuneration arrangements for drugs listed under the Section 100 programs and how they may be improved. We have designed a review process that will enable you to share your views on the issues and to be actively involved in formulating the solutions. This is illustrated in Diagram 1 below.

Diagram 1: The Review Process – Inputs, Key Steps and Outcomes



The five Section 100 programs have been divided into priorities:

- Priority One: HSD and AHSRA Programs; and
- Priority Two: ODT, SA and CM Programs.

It is likely that the SA Program will be included in the review of the HSD Program as it only consists of one drug, Herceptin, for the treatment of HER2 positive breast cancer.

The following Stakeholders have been identified for initial consultation. This is a preliminary list and the stakeholders consulted will not necessarily be limited to these parties. The initial consultations will involve recognised Stakeholder representative bodies only. Individuals will be provided opportunity for input during the discussion paper and workshop phases of this review.

- Stakeholders:
 - Department of Health and Ageing (DoHA)
 - The Pharmacy Guild of Australia (PGA)
 - The Society of Hospital Pharmacists of Australia (SHPA).
 - The Pharmaceutical Society of Australia (PSA)
 - Medicare Australia
 - State/Territory Government Health Departments (6 States and 2 Territories)
 - Public and Private Hospitals
 - Medicines Australia
 - Australian Medical Association (AMA)
 - The Department of Veteran's Affairs (DVA)

Diagram 1 illustrates the review process, showing the key steps, the outcomes and where stakeholders can input into the process. Note that a new step does not necessarily have to wait until the previous step is complete.

The processes involved in each of the three stakeholder input steps (Stakeholder Consultation, Discussion Paper and the Workshops) are discussed in more detail below.

5. STAKEHOLDER CONSULTATION

The project team plans to conduct the stakeholder consultations in Review priority order, starting late October and continuing throughout November 2008. Other stakeholders will be consulted on the Programs relevant to their area of interest or expertise.

The consultation process will be highly structured: we will design a questionnaire for each program, based on a literature review and through consultation with our technical experts.

5.1 Literature Review

The literature search will be conducted using MEDLINE [OVID], PubMed, CINHALL, Google Scholar, the Cochrane Library and PsycINFO, to identify and summarise the international published literature on the supply of pharmaceutical products, and models for the dispensing of pharmaceuticals under similar programs around the world.

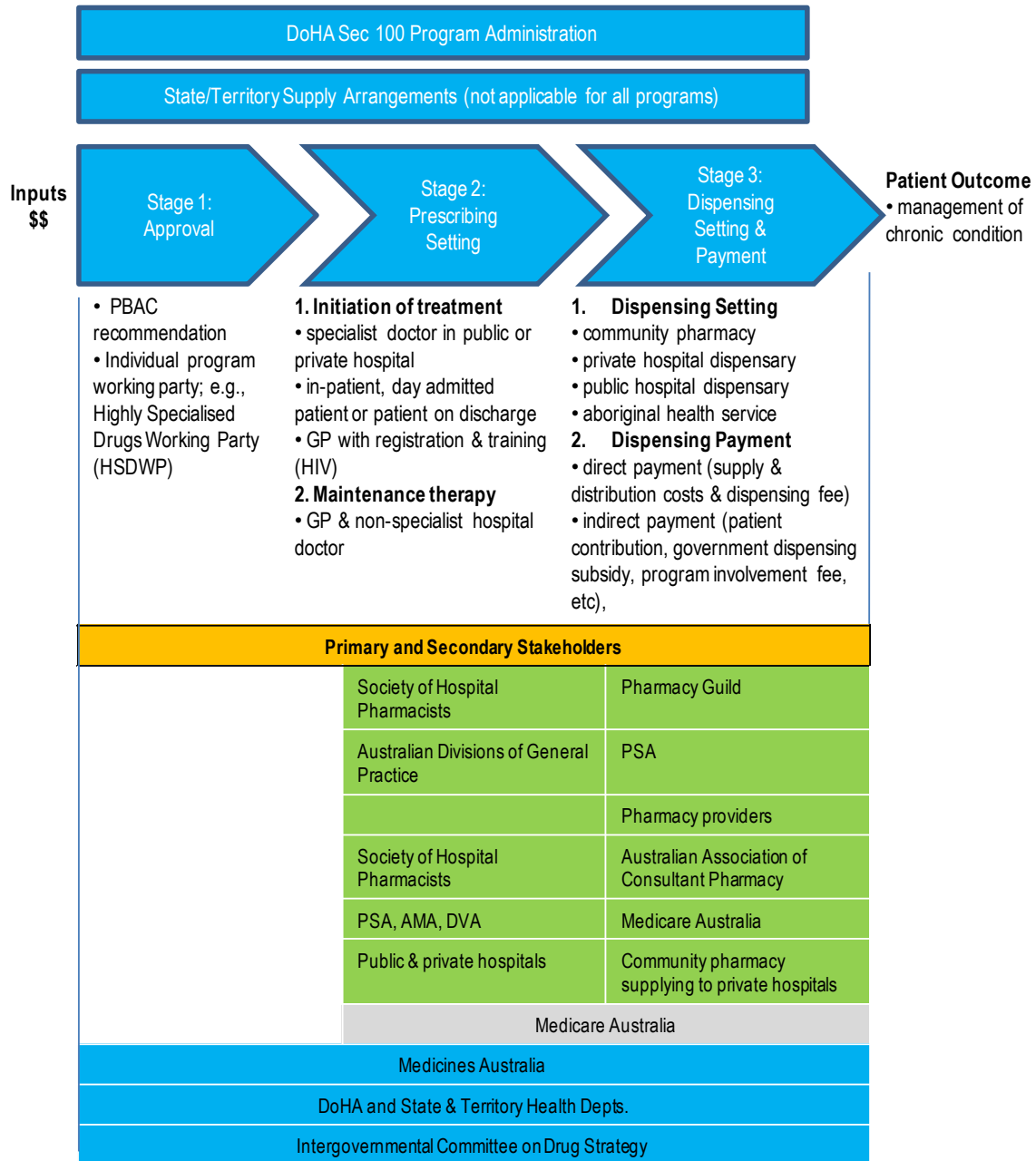
Grey literature will supplement the information gathered through the published literature review, particularly for pharmaceutical supply models to patients receiving treatment for opioid addiction. We will use an internet search to ensure the inclusion of any relevant documents, conference abstracts and proceedings, government reports and consumer group reports relating to the supply of specialised pharmaceuticals and targeted pharmaceutical supply arrangements.

5.2 The Consultation Questionnaire

Diagram 2 below shows a schematic of the supply chain for Section 100 drugs and the key stakeholders associated with each activity. The primary activities in the supply chain are drug approval, prescribing, dispensing and payment. The secondary activities are shown above the primary activities and involve the administration of the Section 100 programs by DoHA and the supply arrangements designed and

implemented by each state and territory. Note how some stakeholders, like DoHA, are associated with all activities in the supply chain.

Diagram 2: Simplified Supply Chain for Section 100 Drugs and Key Stakeholders¹



For each Section 100 program, we will develop a stakeholder questionnaire that is designed to not only address the objectives of the review, but also to target each stakeholder’s main focus of interest. The consultation questionnaire structure is illustrated in Table 1 below (note that not all questions are applicable to all stakeholders and all programs).

¹ Not all programs will have the same supply chain: for example, drugs are generally not dispensed by a community pharmacist to the client under the AHSRA program; they are supplied to the client at the time of consultation through the AHS.

Table 1: Objectives, Questions and Stakeholders

Review Objective	Key Questions	Typical Sub-Questions
1. Review existing supply arrangements	How does each program operate in broad terms in each state or territory?	How are the drugs prescribed? And who can prescribe? What is the role of the pharmacist? Does this differ to what the pharmacist does in reality? How are the drugs dispensed (or supplied under AHSRA)? Are approvals required?
	What are the costs of delivering each program in each state or territory?	What is the cost of administering each program in each state or territory? For the AHSRA program, how much funding is provided by the Australian Government? What is the cost of dispensing the drugs in private hospitals/community (Medicare) and public hospitals (State and Territory Govts.)?
	What are the dispensing payments for each program in each state or territory? - For private hospitals/community? - For public hospitals?	Direct payments -- supply & distribution costs & dispensing fee? Indirect payments -- patient contribution, government dispensing subsidy, program involvement fee, etc?
	What are the key concerns with program X from a strategic perspective ?	What are the barriers to effective program delivery and/or access? What are the enablers of improved program delivery? And what are the opportunities to improve supply arrangements for (particular) drugs in program X?
	2. Effectiveness and efficiency of the current supply arrangements	How operationally effective is the current arrangement for each program?
	How operationally efficient is the current arrangement for each program?	How much does it cost to deliver a dispensing service? - community pharmacy - private hospital dispensary - public hospital dispensary - aboriginal health service
3. Impact of the supply arrangements on community pharmacy	How does each program impact on community pharmacy and the pharmacist?	Are additional resources required to deliver the dispensing service for each program? What impact does the current delivery arrangement for drugs in each program have on the relationship between pharmacist and the client? What aspects of the arrangement should be changed?
4. Options to address the identified impact	What are the options to address these impacts?	Is the option acceptable to the wider stakeholder group? Is it feasible? And do-able? What are the costs and benefits associated with the option?

6. DISCUSSION PAPER

Following the phase of initial consultations with the key stakeholders, the project team is planning to provide the Discussion Paper to all interested parties for review and comment to ensure that a broad spectrum of views are reflected in the Review. The Discussion Paper will seek respondents to provide options to improve existing supply and remuneration arrangements. Respondents may also provide comments about issues identified during the consultation phase.

Response will be required in writing and need to be sent by email, fax or mail to:

The Project Manager,
Section 100 Review
c/- Australian Healthcare Associates
Locked Bag 32005
Collins Street East
Melbourne Vic 3000

Phone: 03 9663 1950
Fax: 03 9639 4459
E-mail: S100review@ahaconsulting.com.au

Alternatively, you will be able to submit your views on line through our website (just follow the links):
www.ahaconsulting.com.au

All responses will be de-identified in any document summarising stakeholders' views about issues and options.

Please feel free to contact the Project Manager, Suzanne Vilé, to discuss your submission or to clarify the intent of the Discussion Paper.

7. THE WORKSHOPS

Once we have reviewed the submissions, we will prepare a Summary Paper. The Summary Paper will outline the key issues and potential options for each program and the aim of the workshops will be to ask participants to help assess the potential of each option in terms of its feasibility (or "do-ability"), its acceptability and impact ("value for money").

The workshops will be conducted in the capital city of each state and territory as well as in some select regional centres (yet to be determined). The capital city workshops will most probably involve a Priority One workshop in the morning (HSD and AHSRA programs) and a Priority Two Workshop in the afternoon (ODT, CM and SA): sixteen workshops in total. The regional workshops may be combined Priority One and Priority Two. If you are interested in attending any of these workshops, you will need to register your interest. Registering your interest does not guarantee a place at the workshop as places will be limited.

8. THE FINAL REPORT

We will prepare two written final reports for the ACCRG: one for Priority One and one for Priority Two programs. The reports will address the objectives of the project as outlined above, including current remuneration arrangements for pharmacies as well as any special pricing arrangements. Reports will be provided to the ACC for consideration.

9. COMMUNICATION WITH THE ACCRG

Throughout the review, the project team will communicate frequently and comprehensively with the ACCRG. The ACCRG will approve all communications with the stakeholders, including who will be consulted, and the structure and content of the consultation questionnaire, the Discussion Paper and the Summary Paper.

In addition, the project team will provide a number of briefings to the ACCRG throughout the review to ensure they are fully informed of the progress of the work, including:

- The progress and findings from the consultation process;
- An analysis of the feedback from the Discussion paper;
- Preliminary recommendations coming out of the workshops for the Priority One programs and subsequently, for all five programs.

10. CONCLUSION

We consider this project provides the opportunity for stakeholders in the Section 100 programs to not only provide their views about the need for these programs and the efficiency and effectiveness of the current supply arrangements, but also to develop viable approaches to their provision. We look forward to having your active involvement.

Suzanne Vilé
Project Manager
November 2008

APPENDIX A: OVERVIEW OF SECTION 100 PROGRAMS

A.1 Highly Specialised Drugs (HSD) Program

The Australian Government provides funding for certain specialised medications under the Highly Specialised Drugs Program. Highly Specialised Drugs are medicines for the treatment of chronic conditions which, because of their clinical use or other special features, are restricted to supply through public and private hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units. A general practitioner or non-specialist hospital doctor may only prescribe Highly Specialised Drugs to provide maintenance therapy under the guidance of the treating specialist.

To gain access to a Commonwealth funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge, be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a highly specialised drug at a similar rate to the Pharmaceutical Benefits Scheme. Commonwealth subsidy is not available for hospital in-patients.

Subsidy for drugs under this program commences after approval by the Australian Government and after the States and Territories agree to the administrative arrangements.

In addition to the above requirements, for Highly Specialised Drugs prescribed through private hospitals, claiming and approval of authority prescriptions is administered by Medicare Australia. Highly Specialised Drugs are authority required items. Medical practitioners must seek approval to prescribe these items as pharmaceutical benefits prior to their dispensing under the PBS.

The remuneration rates for Highly Specialised Drugs prescribed through private hospitals comprise the normal PBS ready-prepared dispensing fee plus a mark-up ascertained as follows:

- 10% for drugs with a price ex-manufacturer of less than \$40;
- \$4 for drugs with a price ex-manufacturer of between \$40 and \$100;
- 4% for drugs with a price ex-manufacturer of between \$100.01 and \$1000; and
- \$40 for drugs with a price ex-manufacturer of greater than \$1000.

For Highly Specialised Drugs prescribed through public hospitals, claiming and access to the program is administered by the States/Territories Health Departments. Prescriptions for Highly Specialised Drugs can be dispensed by public hospital pharmacies. Benefits are available for the listed clinical indications only. There is no facility for individual patient approval for indications outside those listed.

Highly Specialised Drugs Working Party (HSDWP) of the Australian Health Ministers' Advisory Council (AHMAC)

The Highly Specialised Drugs Working Party (HSDWP) is a non-statutory body established by AHMAC in 1991. It consists of representatives from the Health departments of each of the states and territories, the Australian Private Hospitals Association (APHA) and the Department of Health and Ageing as Chair. The Working Party annually reports its activities to AHMAC.

The HSDWP makes recommendations to the Pharmaceutical Benefits Advisory Committee (PBAC) on

the suitability of listing drugs under section 100 of the *National Health Act 1953* on the Highly Specialised Drugs Program.

The Minister for Health and Ageing may make a declaration under the *National Health Act 1953* that a drug will be subsidised as a special pharmaceutical product. The Minister must not make a declaration unless the PBAC has recommended to the Minister to do so.

A.2 Aboriginal Health Services Remote Access (AHSRA) Program

The AHSRA program was introduced as an initiative to improve health outcomes among Aboriginal Health Services (AHS) clients by improving access to PBS medicines and addressing cultural barriers. Under the AHSRA program, which began in 1999, 167 approved AHSs (see approval requirements below) can order bulk quantities of general schedule PBS medicines (i.e. Section 85 (S85) drugs with the exception of Schedule 8 (S8) drugs – drugs of dependence, Doctor's Bag supplies and extemporaneous items) and supply them onsite at the time of consultation to clients of the AHS. Patients are not required to pay the normal patient co-contribution that would usually be associated with the supply of these medicines under S85.

Under this program pharmacists supplying approved AHS are remunerated in a different way to S85 dispensing because of the bulk supply arrangements under s100. Pharmacists receive the approved price within subsection 98B (3) of the Act, which aligns with the pricing under S85 (wholesale price and retail mark-up) and a handling fee (rather than a dispensing fee, in recognition of the bulk supply arrangements). The handling fee is the difference between the dispensing fee for the supply of ready-prepared medicines and the concessional co-payment or \$1.14, whichever is greater.

To be eligible for access to the AHSRA program, the following criteria need to be met:

1. The Health Service must have a primary function of meeting the health care needs of Aboriginal and Torres Strait Islander peoples.
2. The clinic, or other health care facility, operated by the AHS from which pharmaceuticals are supplied to patients, must be in a remote zone as defined in the Rural, Remote and Metropolitan Areas Classification 1991 Census Edition.
3. The AHS must not be a party to an arrangement, such as a coordinated care trial, for which funds from the Pharmaceutical Benefits Scheme have already been provided.
4. The AHS must employ or be in a contractual relationship with health professionals who are suitably qualified under relevant State/Territory legislation to supply all medications covered by the Section 100 arrangements and undertake that all supply of benefit items will be under the direction of such qualified persons.
5. The clinic or other health care facility operated by the AHS from which pharmaceuticals are supplied must have storage facilities that will:
 - prevent access by unauthorised persons;
 - maintain the quality (eg chemical and biological stability and sterility) of the pharmaceutical; and
 - comply with any special conditions specified by the manufacturer of the pharmaceutical.

A.3 Opiate Dependency Treatment (OPT) Program

Opioid withdrawal and replacement therapy is the use of legal and controlled opioid products such as methadone replacement for heroin addiction. Opioid replacement therapy has been identified as one of the most cost effective treatment interventions for people with problematic illicit drug use, and is an important harm minimisation strategy, a key focus of the National Drug Strategic Framework.

Most opioid replacement therapy is provided by community pharmacies, with 1,872 community pharmacies across Australia providing this service in 2006. A minority of patients however still receive their treatment via hospital clinics, particularly in NSW.

At present, the opioid replacements in the OD program (methadone, buprenorphine and buprenorphine with naloxone) are provided to community pharmacies at no cost. Community pharmacies do not receive a dispensing fee for the provision of opioid replacement therapy to patients, as they would for general schedule items. Patients receiving opioid replacement therapy pay a patient contribution, which varies between pharmacies, but is on average \$5 per day (as the program usually requires daily dosing). There is significant variation in this patient contribution, and in some cases State/Territory governments provide fully or partially subsidised treatment to patients, by paying their contribution.

A.4 Special Authority (SA) Program

Currently, only one drug is listed on the SA program, Herceptin (Trastuzumab), for the treatment of HER2 positive breast cancer. This program is very similar to the HSD program, however due to additional considerations (such as the nature of restrictions, the potential for use outside the restriction and the cost involved) this additional program was created.

A.5 Continuing Medication (CM) Program

The Continuing Medication Program was established in 1990 by the Department of Health and Ageing. The objectives of the programs are to:

- Assist people, who are homeless and are considered incapable of managing their own affairs, to continue their PBS medication where non-medication could lead to undesirable medical or social consequences.
- Reimburse organisations where they have met the General Schedule of the PBS concessional patient co-payment for prescribing items on behalf of their clients, where it is reasonable to conclude that the client is eligible for concessional benefits of managing his or her own affairs and is homeless.

The following eligibility requirements exist for organisations, pharmacies and homeless people:

Organisation – to access the program organisations must:

- be not-for-profit.
- be providers of care to homeless people.
- not be receiving other funding for pharmaceutical services from the Australian Government.
- establish an account with a pharmacy.
- ensure medication supplied under the program is only to their clients who meet the eligibility requirements of homelessness.

Pharmacy - to access the program pharmacies must:

- operate an account that provides an invoice/receipt for each PBS item dispensed to eligible clients of the organisation, which includes the following details:
 - patient name
 - prescription number
 - drug name
 - date of dispensing
 - eligibility number (where possible)
- maintain safety net records for clients whose payments are charged to this account.
- ensure the account only attracts entries that comply with eligibility requirements of homelessness.
- provide service to the organisation in urgent situations.

Clients – to be eligible for the program, clients must fit into one or other of the following definitions of Primary and Secondary Homelessness:

- *Primary homelessness*
People without conventional accommodation, such as people living on the streets, sleeping in parks, squatting in derelict buildings, or using cars or railway carriages for temporary shelter.
- *Secondary homelessness*
People who move frequently from one form of temporary shelter to another and covers: people using emergency accommodation (such as hostels for the homeless or night shelters); teenagers staying in youth refuges; and women and children escaping domestic violence (staying in women's refuges).