



Commonwealth Department of Health

**Sixth Community Pharmacy Agreement
Pharmacy Practice Incentive Program:
Staged Supply**

Initial Evaluation – Final

17th November 2016

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Abbreviations

4CPA	Fourth Community Pharmacy Agreement
5CPA	Fifth Community Pharmacy Agreement
6CPA	Sixth Community Pharmacy Agreement
ATSI	Aboriginal and Torres Strait Islander
CI s	Clinical Interventions
DAA	Dose Administration Aid
HMR	Home Medicines Review
HTA	Health Technology Assessment
MSAC	Medical Services Advisory Committee
ODT	Opiate Dependence Treatment
PBS	Pharmaceutical Benefits Scheme
PICO	Population, Intervention, Comparator, Outcome
PPI	Pharmacy Practice Incentives
PSA	Pharmaceutical Society of Australia
PwC	PricewaterhouseCoopers
QCPP	Quality Care Pharmacy Program
QUMAX	Quality Use of Medicines Maximised (for Aboriginal and Torres Strait Islander People)
RACF	Residential Aged Care Facility
RMMR	Residential Medication Management Reviews
SS	Staged Supply

EXECUTIVE SUMMARY

On the 28th June 2016, the Department of Health engaged HealthConsult to evaluate the three Pharmacy Practice Incentives (PPI) Program initiatives: Staged Supply (SS), Dose Administration Aids (DAAs), Clinical Interventions (CIs). The initial evaluation of SS involved:

- a literature review to identify data to inform the comparative clinical and cost-effectiveness of the SS initiative and ‘like’ programs internationally; and
- an examination of Australian utilisation data from the SS initiative since its start under earlier Community Pharmacy Agreements (CPAs).

Background

The SS priority area was established under the Better Community Health Initiative of the Fourth Community Pharmacy Agreement (4CPA) and Fifth Community Pharmacy Agreement (5CPA) between the Pharmacy Guild of Australia and the Commonwealth Government. The SS initiative was continued under the Sixth Community Pharmacy Agreement (6CPA), as part of the PPI Program directed at improving medication compliance through community pharmacies in Australia.

The Pharmaceutical Society of Australia (PSA) *Standard and Guidelines for Pharmacists Providing a Staged Supply Service for Prescribed Medicines* (March 2011) defines SS to be ‘the provision of PBS medicines in instalments where requested by the prescriber or consumer’. A SS service can be initiated by the pharmacist, the prescriber, the patient or their agent, or another health professional involved in the care of the patient. Once dispensed, the medicine is held by the pharmacy and the instalments are provided to the patient according to the agreed regime (for example, daily or weekly). Medicines that may be considered for SS include antipsychotics, anxiolytics, hypnotics and sedatives, antidepressants, opioid analgesics and psychostimulants. SS services specifically exclude medicines supplied under the Section 100 Opioid Dependence Treatment Program.

The main objective of the provision of the SS service is to assist consumers who are at particular risk of medication misadventure or harm as a result of the intentional or accidental misuse of prescribed medicines, often because of mental illness or drug dependence. SS is likely to be of particular benefit where the consumer is homeless or in sheltered accommodation where the possibility of theft and lack of refrigeration must be considered.

It is important to note that the incentive payment made to pharmacies for SS services is provided as an annual payment to accredited pharmacies regardless if any or how many SS services have been provided. For the purposes of the incentive payment, in-scope SS services are those provided when requested by the prescriber (excluding the section 100 opioid dependency treatment programme).

Methodology

Literature search

A systematic literature review was undertaken in August 2016 to identify studies that provide evidence relating to the effectiveness, costs and cost-effectiveness of SS or similar programs provided by pharmacists to individuals living in the community. The grey literature was also searched, as were the reference lists of included studies. Table ES.1 presents the evidence selection criteria.

Table ES.1 Selection criteria for evidence relating to SS services provided by community pharmacies

Criteria	Description
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Criteria	Description
Population	Community patients with a mental illness, drug dependency or who are otherwise unable to manage their self-administered medicines safely. <i>Subpopulations:</i> <ul style="list-style-type: none"> • patients with confusion and/or significant disorientation • patients at risk of accidental or deliberate self-harm or harm to others • patients at risk of non-adherence to a medication regime • patients at risk of misuse or on-selling of the medication
Intervention	Supply of prescription medicines (e.g. opioid analgesics and medicines used for the treatment of mental health disorders) to a patient in periodic instalments of less than the originally prescribed quantity, at agreed time intervals (e.g. daily, weekly or as directed by the prescriber) by a community pharmacy. Note: Excludes the supply of medicines related to opioid substitution therapy.
Comparator	Community patients in the absence of the intervention.
Outcomes	<ul style="list-style-type: none"> • adherence/compliance/concordance with prescribed dose schedule • clinical outcomes (e.g. psychological symptoms in patients with mental illness) • adverse drug events/reactions and medication-related problems • mortality • health care resource use (ED attendance, hospitalisation, GP visits, specialist visits) • patient acceptance/satisfaction • health-related quality of life • costs and cost-effectiveness
Study design	Comparative studies (randomised or non-randomised controlled trials, cohort studies, case control studies) or systematic reviews of comparative studies. Applicability to the Australian context will be considered
Publication type	Full English-language publications or reports. Conference abstracts are excluded.
Search period	No year restrictions

Abbreviations: ED, emergency department; GP, general practitioner; SS, Staged Supply.

The systematic literature search did not identify any studies that fulfilled the criteria outlined in Table ES.1. The Pharmacy Guild of Australia was subsequently notified and asked whether they are aware of any relevant studies. The Guild set about searching for evidence but did not provide any studies to the review team.

The targeted search of the websites of relevant pharmacy organisations and the Commonwealth Department of Health identified two previous evaluations of the SS initiative. The findings from these reports are summarised in the main body of this initial evaluation report. Due to a lack of data, the impact of the 4CPA and 5CPA SS service on patient health outcomes was unable to be evaluated.

Utilisation analysis

Data available for the utilisation analysis included claims payment data provided by the Department of Health and de-identified patient level data by drug type of SS services provided by the Pharmacy Guild of Australia.

The claims data were analysed in the context of geographical factors that have been inferred from the postcode of each pharmacy. Those factors included remoteness; overall population and mental health issues prevalence by Primary Health Network (PHN) geographic areas. These factors were used to assess whether the growth in SS resources has occurred in line with the populations that the program is intended to target. Key metrics in the analysis are limited to the amount of claims paid to participating pharmacies in the SS program.

The data provided by the Pharmacy Guild of Australia, although it could not be reconciled to the data provided by the Department, it enabled some analysis of the types of drugs supplied as SS services which provides insight into the clinical indications of the patients requiring SS services.

Results of the literature review

The key research questions for the literature review of SS services primarily relate to the potential advantages to consumers that are outlined in the PSA Guidelines (2011).

Is there evidence that a SS service provided by community pharmacies provides benefits, compared with no SS service provided by community pharmacies, in terms of improvement in medication adherence and management; reduction in the incidence of adverse drug events; and reduction in medication-related hospitalisation.

No relevant evidence was identified.

What costs are associated with a SS service provided by community pharmacies?

No relevant evidence was identified.

Is there evidence that a SS service provided by community pharmacies is cost-effective, compared with no SS service provided by community pharmacies?

No relevant evidence was identified.

Results of the utilisation analysis

The claims data shows that the amount of claims for the provision of SS services increased substantially nationally between 2012 and 2015 due to the number of participating pharmacies in the program. But, the claims data do not contain any information regarding patients' age, frailty, mental faculties or health status; or any other patient characteristic to help determine if the program is reaching the target patient population.

To address this issue the 2015 claims data were analysed against indicators of the target population (i.e. mental health issues prevalence as an indicator of patient who might be disturbed or confused). This analysis identified no significant relationships, for example, it could not be shown that PHN areas with higher proportions of mental health issues also had a higher per capita investment in SS program resources.

Analysis of the de-identified patient level data by drug provided by the Pharmacy Guild of Australia showed that there was a relatively steady increase in the volume of services (from 3,892 services in October 2014 with to 4,744 services in September 2016; an increase of 21.9%). Although most of the drugs have multiple indications, and it is not possible to determine which indication represents the majority use, pain was the largest 'unambiguous' indication and it accounts for 35.2% of SS services in September 2016. Analysis of the distribution of SS services by age shows a slight skew towards younger patients where the summary indications include Anxiety or ADHD, and skewed towards older patients in the cases where Pain is included in the summary indications.

Although the claims payment data shows that the number of SS participating pharmacies has seen very substantial increases between 2012 and 2015 this does not provide an indication of growth in the program as the payment arrangements are not linked to activity. However the data provided by the Pharmacy Guild supports that there has been an increased number of SS services provided over time. Growth in the program suggests it is considered effective, but the available data do not allow

a determination of the reasons for growth (e.g. motivation for take-up of the incentive payment, or favourable patient feedback on the program, or both).

Conclusions

No studies were identified that assessed the impact of SS on improving medication adherence or any other health related outcome, and thus no conclusions can be made regarding its effectiveness or cost-effectiveness.

In order to make an assessment of the clinical and cost effectiveness of SS, further research is required. Such research would best take the form of a study that included:

- a high-quality study of adequate size (number of patients) and duration that assessed who utilised the SS service delivered through community pharmacies on medication adherence, clinical outcomes, health care utilisation, patient satisfaction (through primary data collection and linkage to secondary datasets, (e.g. MBS, PBS, hospital utilisation, and so on));
- a robust costing study that measured the unit cost of delivering a SS service in a variety of settings across the community pharmacy sector (also to inform fee setting); and
- a translational study that takes the results of the unit cost and outcome measurement work and calculates cost effectiveness (no further primary data collection would be required).

1 INTRODUCTION

On the 28th June 2016, the Australian Government Department of Health engaged HealthConsult to evaluate the Sixth Community Pharmacy Agreement (6CPA) Pharmacy Practice Incentives (PPI) Program: Staged Supply. The initial evaluation of SS involved:

- a literature review to identify data to inform the comparative clinical and cost-effectiveness of the SS initiative, including a review of the international literature to determine whether results for ‘like’ programs can be extrapolated to be considered as evidence for the SS initiative in Australia;
- an examination of Australian utilisation data from the SS initiative since its start under earlier CPAs, with an emphasis on elucidating the characteristics and volumes of:
 - pharmacy services delivered via the program;
 - pharmacists and pharmacies delivering these services; and
 - individuals receiving these services.

1.1 SIXTH COMMUNITY PHARMACY AGREEMENT

In May 2015, the Australian Government and Pharmacy Guild of Australia entered into the 6CPA, which provides around \$18.9 billion in remuneration for community pharmacy, as well as support to the pharmaceutical supply chain (with a further \$372 million provided for chemotherapy compounding fees). Up to \$1.26 billion in funding is available under the 6CPA for evidence-based, patient-focused professional pharmacy programs and services. This consists of:

- \$613 million for the continuation of a number of programs and services from 5CPA;
- \$50 million for a new pharmacy trial program; and
- up to \$600 million for new and expanded community pharmacy programs.

The 6CPA includes three key funding elements:

- community pharmacy remuneration;
- ensuring that all Australians have timely access to the Pharmaceutical Benefits Scheme (PBS) medicines they require regardless of the cost of the medicine or where they live; and
- community pharmacy programs directed at improving consumer management of their medications and delivering primary healthcare services through community pharmacy.

1.2 PHARMACY PRACTICE INCENTIVES PROGRAM

The 6CPA PPI Program provides a financial incentive to pharmacists to deliver compliance initiatives. As part of the 6CPA, there are several continuing PPI Programs directed at improving medication compliance through community pharmacies in Australia. The continuing programs include:

- Medication Adherence Programs
 - Dose Administration Aids (DAAs)
 - Clinical Interventions (CIs)
 - Staged Supply (SS)
- Medication Management Programs
 - Home Medicines Reviews (HMR)
 - Residential Medication Management Reviews (RMMR)
 - MedsCheck and Diabetes MedsCheck

- Rural Support Programs
 - Rural Pharmacy Workforce Program
 - Rural Pharmacy Maintenance Allowance
- Aboriginal and Torres Strait Islander (ATSI) Programs
 - Quality Use of Medicines Maximised for ATSI People (QUMAX)
 - S100 Pharmacy Support Allowance
 - ATSI Workforce Program (Pharmacy Assistant Traineeship Scheme and Pharmacy Scholarships Scheme)
- eHealth:
 - Electronic Prescription Fee

Under 6CPA, all programs and services need to be reviewed by the Medical Services Advisory Committee (MSAC) for clinical and cost-effectiveness and the health benefits they offer to the community. This process is being used to ensure pharmacy programs and services are assessed against the same standards of evidence as for other health professions. It supports a consistent approach to informing investment that delivers the greatest benefit to consumers.

2 STAGED SUPPLY

This Section describes the SS initiative, which falls under the broader Medication Adherence Program within 6CPA.

2.1 BACKGROUND

The SS priority area was established under the Better Community Health Initiative of the Fourth Community Pharmacy Agreement (4CPA) and Fifth Community Pharmacy Agreement (5CPA) between the Pharmacy Guild of Australia and the Commonwealth Government. The SS initiative was continued under the Sixth Community Pharmacy Agreement (6CPA), as part of the PPI Program directed at improving medication compliance through community pharmacies in Australia. The Pharmaceutical Society of Australia (PSA) *Standard and Guidelines for Pharmacists Providing a Staged Supply Service for Prescribed Medicines* (March 2011) defines SS to be ‘the provision of PBS medicines in instalments where requested by the prescriber or consumer’.

A SS service can be initiated by the pharmacist, the prescriber, the patient or their agent, or another health professional involved in the care of the patient. Once dispensed, the medicine is held by the pharmacy and the instalments are provided to the patient according to the agreed regime (for example, daily or weekly). The prescriber should be informed by the pharmacist of the initiation of the service and of the arrangements that will apply.

SS services specifically exclude medicines supplied under the Section 100 Opioid Dependence Treatment Program. These constitute opioid substitution therapy (i.e. pharmacotherapy with methadone, buprenorphine and buprenorphine/naloxone combinations) and pharmacists should refer to legislation and guidelines applicable in their jurisdiction and to relevant national guidelines.

2.2 OBJECTIVES OF THE SS INITIATIVE

The main objective of the provision of the SS service is to assist consumers who are at particular risk of medication misadventure or harm as a result of the intentional or accidental misuse of prescribed medicines, often because of mental illness or drug dependence. SS is likely to be of particular benefit where the consumer is homeless or in sheltered accommodation where the possibility of theft and lack of refrigeration must be considered (PSA, 2011).

In addition, SS services may also be used in conjunction with a DAA to help improve adherence to the prescribed medication treatment regimen. This may be necessary where the consumer’s capacity to manage the prescribed medication treatment regimen is compromised by impaired cognitive function (e.g. due to mental illness, intellectual disability, or alcohol or drug ingestion).

2.3 PARTICIPATION IN THE SS INITIATIVE

To be eligible to receive incentive payments for providing a SS service, a community pharmacy must:

- be a Section 90 Pharmacy;
- be accredited by an approved Pharmacy Accreditation Program such as the Quality Care Pharmacy Program (QCPP);
- agree to publicly display and comply with the Community Pharmacy Service Charter and Customer Service Statement;
- register for the SS priority area via the 6CPA Registration and Claiming Portal;
- continue to meet the above eligibility criteria while participating in the SS priority area;

- deliver SS services in accordance with the PPI Program Specific Guidelines.

SS services are paid for by the Australian Government through the 6CPA. Eligible community pharmacies are entitled to claim an annual incentive payment for offering SS services in accordance with the PPI Program Specific Guidelines. Payment for the provision of SS services is prospective. To be eligible for payment the eligible pharmacy is:

- required to retain evidence to demonstrate the pharmacy has met the requirements; and
- lodged the PPI Declaration each year as part of the pharmacy's accreditation cycle and provided the required evidence at the eligible community pharmacy's next accreditation assessment.

2.4 PATIENT GROUPS MOST LIKELY TO BENEFIT FROM A SS SERVICE

According to the current PSA guidelines for providing a SS service (PSA, 2011), the clinical need for the SS service may be identified during the delivery of other services, such as a MedsCheck (also known as Medicines Use Review) or Home Medicines Review (HMR). The decision to provide a SS service is based on performing a risk assessment by the pharmacist of the interplay between consumer and drug factors, as well as the pharmacists' professional judgement. SS may be indicated in circumstances where:

- the pharmacist or the prescriber perceive the consumer is unable to manage the prescribed medicine safely or appropriately because they are disoriented or confused;
- the pharmacist or the prescriber consider the consumer is at risk of, or there is a history of, deliberate self-harm or causing harm to others;
- there is considered to be a risk of, or there is a history of, intentional misuse or diversion of medicine;
- adherence with the intended treatment regimen is in doubt or there is a history of poor adherence; or
- regulatory requirements dictate the use of SS (e.g. jurisdictional medication supply contracts or treatment orders).

According to the PSA guidelines, SS should be considered for the following types of prescribed medicines:

- antipsychotics;
- anxiolytics;
- hypnotics and sedatives;
- antidepressants;
- opioid analgesics; and
- psychostimulants.

The most common patient groups that may access this service include those with mental illness and those with drug addiction/dependence problems.

3 REVIEW METHODOLOGY

This Section describes the methodology used to identify and assess the evidence relating to SS or similar services. The evaluation encompasses a systematic literature review of Australian and international evidence for the safety, effectiveness and cost-effectiveness of SS services provided by pharmacists to individuals living in the community, and an analysis of available data on the utilisation of the service provided under the PPI Program.

3.1 SYSTEMATIC LITERATURE REVIEW

3.1.1 Research questions and PICO criteria

The key research question for the evaluation of SS services relates to the rationale for SS, as outlined in the *Standard and Guidelines for Pharmacists Providing a Staged Supply Service for Prescribed Medicines* (PSA, March 2011).

- Is there evidence that a SS service provided by community pharmacies provides benefits, compared with no SS service provided by community pharmacies, in terms of:
 - improvement in medication adherence and management;
 - reduction in the incidence of adverse drug events; and
 - reduction in medication-related hospitalisation.

Additional research questions of relevance to the evaluation relate to the costs and cost-effectiveness of the service:

- What costs are associated with a SS service provided by community pharmacies?
- Is there evidence that a SS service provided by community pharmacies is cost-effective, compared with no SS service provided by community pharmacies?

Table 3.1 presents the selection criteria for evidence relating to SS services.

Table 3.1 Selection criteria for evidence relating to SS services provided by community pharmacies

Criteria	Description
Population	Community patients with a mental illness, drug dependency or who are otherwise unable to manage their self-administered medicines safely. <i>Subpopulations:</i> <ul style="list-style-type: none"> • patients with confusion and/or significant disorientation • patients at risk of accidental or deliberate self-harm or harm to others • patients at risk of non-adherence to a medication regime • patients at risk of misuse or on-selling of the medication
Intervention	Supply of prescription medicines (e.g. opioid analgesics and medicines used for the treatment of mental health disorders) to a patient in periodic instalments of less than the originally prescribed quantity, at agreed time intervals (e.g. daily, weekly or as directed by the prescriber) by a community pharmacy. Note: Excludes the supply of medicines related to opioid substitution therapy.
Comparator	Community patients in the absence of the intervention.

Criteria	Description
Outcomes	<ul style="list-style-type: none"> • adherence/compliance/concordance with prescribed dose schedule • clinical outcomes (e.g. psychological symptoms in patients with mental illness) • adverse drug events/reactions and medication-related problems • mortality • health care resource use (ED attendance, hospitalisation, GP visits, specialist visits) • patient acceptance/satisfaction • health-related quality of life • costs and cost-effectiveness
Study design	Comparative studies (randomised or non-randomised controlled trials, cohort studies, case control studies) or systematic reviews of comparative studies. Applicability to the Australian context will be considered.
Publication type	Full English-language publications or reports. Conference abstracts are excluded.
Search period	No year restrictions

Abbreviations: ED, emergency department; GP, general practitioner; SS, Staged Supply.

3.1.2 Search strategy

A comprehensive search of peer-reviewed scientific literature was conducted in August 2016 to identify studies that provide evidence relating to the effectiveness, costs and cost-effectiveness of SS or similar programs provided by pharmacists to individuals living in the community. Four electronic databases were searched for original research papers describing systematic reviews, meta-analyses, or comparative studies, as shown in Table 3.2. The search of Medline, Embase, International Pharmaceutical Abstracts, and the Cochrane Library was unrestricted by date and was searched up to 23rd August 2016. The specific search terms used to identify relevant literature are outlined in Appendix 3.

The Health Systems Evidence database (McMaster Health Forum) and databases maintained by Health Technology Assessment (HTA) agencies¹ were also searched to identify relevant literature.

A search of pharmacy organisations² and the grey literature was also performed to identify previous evaluations of the SS initiative in Australia, and similar community pharmacist-led programs from other jurisdictions. The reference lists of evaluation reports were examined to identify studies not otherwise found in the literature searches.

¹ Agency for Healthcare Research and Quality (AHRQ) at [AHRQ](#); Canadian Agency for Drugs and Technologies in Health (CADTH) at [CADTH Reports](#); National Institute for Health and Care Excellence (NICE) at [NICE.UK](#)

² Including Pharmacy Guild of Australia; Pharmaceutical Society of Australia; and Australian Association of Consultant Pharmacy.

Table 3.2 Databases searched

Database	Search period
Embase via Ovid	Up to 23 August 2016
Medline via Ovid	Up to 23 August 2016
International Pharmaceutical Abstracts via Ovid	Up to 23 August 2016
The Cochrane Library (includes Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Cochrane Central Register of Controlled Trials, NHS Economic Evaluation Database, Health Technology Assessment, Cochrane Methodology Register)	Up to 23 August 2016
Health Systems Evidence	Up to 14 September 2016
HTA websites and databases	Up to 14 September 2016

3.1.3 Selection of relevant evidence

The literature search outlined above identified 48 unique citations. The following a priori exclusion criteria were applied:

- Wrong population – excludes residential aged care facility (RACF) patients and hospital inpatients.
- Wrong intervention – excludes studies that did not examine a SS service or similar intervention, and studies that examined the supply of medicines related to opioid substitution therapy.
- Wrong comparator – excludes studies that compared SS with other pharmacy-led programs.
- Wrong outcomes – excludes studies that do not assess one of the outcomes outlined in Section 3.1.1.
- Not in English – excludes studies not published in English language or those that do not include at least some information (e.g. a summary) in English.

The exclusion of citations from the searches is presented in Table 3.3.

Table 3.3 Summary of the process used to identify relevant studies and reports

Description	Embase, Medline, International Pharmaceutical Abstracts, Cochrane Library	Hand searched references	Health System Evidence	Grey literature
Total number of citations	47	0	0	2
Duplicates within and across sets removed	0			
Total number of citations screened	47	0	0	2
Excluded at title/abstract review:				
Wrong population	47			
Wrong intervention				
Wrong comparator				
Wrong outcomes				
<i>Total citations excluded at title/abstract review:</i>	47	0	0	0
Citations screened at full text review	0	0	0	2
Excluded at full text review:				
Wrong population				0
Wrong intervention				
Wrong outcome				
Wrong publication type				
<i>Total citations excluded at full text review:</i>				0
Included citations from database searches	0	0	0	2
Total included studies	0			
Total included CPA reports	2			

Abbreviations: CPA, Community Pharmacy Agreement.

The systematic literature search did not identify any studies that fulfilled the PICO criteria. The Pharmacy Guild of Australia was subsequently notified and asked whether they are aware of any relevant studies. The Guild set about searching for evidence but did not provide any studies to the review team.

The targeted search of the websites of relevant pharmacy organisations and the Commonwealth Department of Health identified two previous evaluations of the SS initiative, which are listed in Table 3.4. Section 4 provides a summary of the findings of these evaluations.

Table 3.4 Citation details for previous evaluations

Study ID	Citation
NOVA (2010)	NOVA Public Policy (2010). Review of the Staged Supply of PBS Medicines. Final Report. Retrieved from http://www.guild.org.au/docs/default-source/member-documents/news-and-events/guild-publications/other-publications/staged-supply-final-report.pdf
PwC (2015)	PricewaterhouseCoopers (2015). Combined Review of Fifth Community Pharmacy Agreement Medication Management Programmes (Final Report). Retrieved from https://www.health.gov.au/internet/main/publishing.nsf/Content/6EF022DE87761986CA257EC80013198B/\$File/combined-review-5cpa-medication-management-programmes-final-report-and-appendices.pdf

3.2 SS UTILISATION ANALYSIS

Utilisation was calculated from the SS claims payment data made by individual pharmacy, covering claims paid on dates between 4th December, 2012 and 31st May, 2016.

SS claims payment data provided by the Department of Health for 2015 have been analysed in the context of geographical factors that have been inferred from the postcode of each pharmacy. Those factors included are remoteness³ (see Table 5.2); overall population and mental health issues prevalence by Primary Health Network (PHN) geographic areas. These factors were used to assess whether the growth in SS services has occurred in line with the populations that the program is intended to target.

The claims payments administration system changed in March 2014. Before the change, payments to pharmacies were annotated with the 'Pharmacy ASN' identifier. After the change claims payments were annotated using the 'Organisation Number' identifier. Both identifying codes are used in Section 90 registers to identify individual pharmacies. These codes were used to assist in locating each pharmacy within its postcode.

Postcodes were mapped to remoteness using the Australian Bureau of Statistics (ABS) mapping table and to PHAs and PHN areas via Statistical Areas Level 2 (SA2), ABS Australian Statistical Geography Standard (ABS ASGS) 2011.

Key metrics in the analysis are limited to claims paid to participating pharmacies in the SS program in the claim period (these metrics are recorded in the claims payment administration systems pre and post the system change). Claims paid do not relate to volumes of patients receiving SS services and patient volumes are not provided in the SS claims payment data.

In addition, de-identified patient level data provided by the Pharmacy Guild of Australia included the data fields drug name, supply frequency, supply internal, start date, supply quantity and age group of each individual that had received a SS service between August 2014 and October 2016. Although the data provided by the Pharmacy Guild of Australia could not be reconciled with the data provided by the Department, it did enable analysis of the drugs being provided as SS services which provides insight into the clinical indications of the patients requiring such services.

³ ABS postcode to remoteness.xls available from <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1270.0.55.006July%202011?OpenDocument> (accessed 5th October, 2016)

4 PREVIOUS EVALUATIONS OF THE PPI PROGRAM

This Section summarises the findings of the two evaluations of the SS initiative funded by the Commonwealth under the 4CPA and 5CPA. The intention of these summaries is to provide MSAC with an understanding of the approaches taken to evaluate the SS initiative in Australia, as well as a high level overview of the findings of previous evaluations in relation to effectiveness and cost-effectiveness of the service.

4.1 4CPA REVIEW OF SS BY NOVA PUBLIC POLICY 2010

The Review of Staged Supply, which was established under the Fourth Community Pharmacy Agreement (4CPA), was undertaken by NOVA Public Policy and overseen by a Review Group nominated by the Department of Health and Ageing and the Pharmacy Guild of Australia (NOVA Final Report, February 2010). The project involved a review of legislation, regulation and procedural arrangements, construction of research instruments, and stakeholder consultations. The project did not cover the Opiate Dependence Treatment (ODT) Program or the DAA program, both of which were subject to a separate evaluation.

The Review examined the circumstances in which SS might be clinically indicated and the legislative, financial, administrative and practice implications. It included consideration of: PBS medicines used for the treatment of mental health disorders and opioid analgesics; State, Territory and Australian legislative constraints; costs to pharmacy; prescribing and dispensing practices and the patient records held by the pharmacy; implications for the PBS Safety Net Scheme; and implementation proposal for a uniform SS process.

Table 4.1 presents the main findings from the consultations conducted across Australia during August and October/November 2009. It was noted that due to the absence of uniform national procedures and the consequent lack of data on the scope of SS delivery, the potential and actual costs of a SS service, stakeholder satisfaction, and impacts on health and patient outcomes could not be tracked.

Pharmacists consulted stated that they undertake a range of significant tasks associated with SS, many of which represent a business cost to that is not remunerated. These costs may include: consultations with prescribers concerning required dispensing actions; consultation with the patient with respect to their wishes and agreed mode and frequency of supply; repackaging and additional storage of medicines; record keeping including agreements with patients in relation to the supply; multiple supply events; consultations with patients about aspects of SS including managing disputes and complaints; consultation with prescribers and/or case managers about medication adherence issues; disposal of unclaimed medications. While many of these actions may be required for standard prescribing practice, the scale and frequency of these events are increased in the case of SS. It was the general view of those consulted that these tasks represented a significant cost which was increasing as the incidence of SS increases.

Table 4.1 Main findings of the 2010 NOVA Public Policy Review of SS

Consultations	Key findings
Program regulations	<ul style="list-style-type: none"> There were no procedures to guide SS practice, although it is covered by broad guidelines, standards and State/Territory regulations for pharmacists and pharmacies.
Prevalence and participation	<ul style="list-style-type: none"> The number of patients accessing SS could not be quantified due to the absence of national data collection, and it was reported by the pharmacists consulted to be “extensive and growing”, and it may be on average up to 30 patients per pharmacy. The numbers of prescriptions delivered as SS was quantified and monitored primarily in jurisdictions where SS was provided under an “authority” or where there was tracking of specific types of medicines. The absence of uniform national procedures and the consequent lack of data on the scope of SS delivery mean that potential and actual costs, stakeholder satisfaction and impacts on health and patient outcomes could not be tracked.
Mechanism for requesting SS	<ul style="list-style-type: none"> SS is generally initiated by the prescriber, although there are no formal mechanisms for requesting it on the prescription form, and the request from a prescriber is not necessarily seen by the pharmacist as obligatory.
Applicable medicines	<ul style="list-style-type: none"> The types of medicines commonly subject, but not entirely restricted to SS included: antipsychotics, anxiolytics, hypnotics and sedatives, antidepressants, and opioid analgesics.
Participant profile	<ul style="list-style-type: none"> The patient indicators for SS that were commonly reported in the consultations included: confusion and/or significant disorientation, risk of accidental or deliberate self-harm or harm to others, risk of non-adherence to a medication regime, and risk of patient misuse or on-selling of the medication. A small number of pharmacists provided medicine in instalments, without instructions from a prescriber. This was usually where a patient’s judgment was impaired by alcohol, drugs or mental illness and providing the full supply could have contravened the professional responsibility of the pharmacist.
Reasons for offering SS	<ul style="list-style-type: none"> Reducing the rate of diverting medicines to street supply. Increase patient compliance with medication regimes, particularly where there may be resistance or a degree of confusion/incapacity to adhere to treatment regimes. Assist in monitoring patients’ medication adherence. Providing safe and suitable storage for medications for people with a mental illness who may also be homeless or in sheltered accommodation where theft or access to refrigeration is an issue. Provide a better coordinated approach to the treatment of people with a mental illness.
Prescribing, dispensing and record keeping practices	<ul style="list-style-type: none"> Variability in the frequency of SS (ranging from daily, weekly to twice a month). Variability in pharmacy approaches to (re)packaging and storage of dispensed medicines. Variability in record keeping (ranging from informal notations, daily dosage sheets to ledgers and electronic records). Variability in approaches by community pharmacies to engaging with patients. Variability in procedures for non-collection of medicines.
Costs and remuneration	<ul style="list-style-type: none"> Community Pharmacies are not currently remunerated by the Australian Government for providing services related to the SS. Current PBS arrangements define a single dispensing event with a single fee paid by the Australian Government with no capacity within the existing regulatory framework to accommodate paying for supplying a number of instalments of a dispensed medicine. A Service Fee of around \$5 is generally charged by the pharmacy to cover any costs related to preparing, labelling, packaging, recording, storing and handling of staged doses of the medicines. This fee is not a PBS patient co-payment, and thus does not count towards the PBS Safety Net threshold. There are no additional payments to community pharmacies for counselling and advice provided to patients who access SS.
Future research needs	<ul style="list-style-type: none"> Defined program parameters, outcomes or processes are required for proper evaluation of the effectiveness of this service/program.
Feasible models of remuneration suggested by stakeholders	<ul style="list-style-type: none"> Creating a special handling fee for SS. Creating an additional PBS item for the management of SS. Creating a separate program payment for Community Pharmacies engaged in SS.

Source: NOVA Public Policy (2010). Review of the Staged Supply of PBS Medicines
Abbreviations: PBS, Pharmaceutical Benefits Scheme; SS, Staged Supply.

The stakeholder consultations strongly supported the development and implementation of a more uniform national SS process, including:

- support the development of uniform national procedures that address the prescribing and dispensing variability;
- support for the implementation of accountable records at the pharmacy level that could also contribute to a national minimum data set to assist in monitoring and evaluating SS and its impacts;
- support for the development of a payment system that minimises administrative overheads, is clear and transparent, remunerates pharmacies for the business costs and the professional inputs required, and limits the financial impost on patients; and
- support for a competency mapping process to ascertain the knowledge, skills and attitudes required for the range of actions undertaken by in relation to SS services.

The Review proposed five remuneration models intended to replace the Service Fee that was in place at the time.

4.2 5CPA PROGRAM COMBINED REVIEW BY PRICEWATERHOUSECOOPERS 2015

The SS initiative was evaluated as part of the Review of the PPI Program performed by PricewaterhouseCoopers (PwC) in 2015. The overall aim of the Review was to better inform how the 5CPA Medication Management programs and services (including PPI Program and Medication Management Program) contribute to improving consumer health outcomes, in order to better inform future investment by the Australian Government in pharmacy programs and services. PwC evaluated the three priority areas in the PPI Program: CIs, DAAs and SS. The Review methodology involved an analysis of full program data in order to assess the uptake and volume of services delivered over the duration of the 5CPA (between 2011 and 2014), stakeholder consultations, consumer focus groups, practitioner focus groups, a practitioner survey and a consumer survey.

Table 4.2 summarises the main findings of the evaluation in relation to the SS priority area of the PPI Program. A total of 767 primary health care practitioners, with the majority being pharmacists (94%), responded to the practitioner survey. More than half (52%) were involved in the SS program. Results of consumer surveys are not discussed as none of the responders participated in the SS program, and thus results from the consumer surveys do not reflect consumers' satisfaction with the SS service.

SS services were viewed to assist with managing intentional misuse and to fulfil a particular need in the community, particularly for managing the medicines of vulnerable consumers who are drug dependent or living in a dangerous environment.

Overall, practitioners reported being reasonably satisfied with their involvement in the Medication Management programs and services. They also reported being satisfied with the benefit their consumers received through Medication Management programs and services, and they saw clear benefit in the suite of Medication Management programs and services as contributing towards improving the health outcomes of consumers.

However, stakeholders and practitioners indicated that 5CPA programs were difficult to access for consumers due to low consumer awareness, information on programs not being readily available to consumers, and low GP engagement and awareness to refer consumers to the relevant programs, particularly for Aboriginal and Torres Strait Islander and culturally and linguistically diverse peoples.

Table 4.2 Main findings of the 2015 5CPA combined review, 2011-2014

Measure/domain	Key findings
Program results	
PPI participating pharmacies	A total of 6,216 pharmacies (with unique registration numbers) submitted claims for PPI services overall.
SS participating pharmacies	5,577 pharmacies received payments for being accredited to provide SS services.
Total expenditure on PPI	\$126,507,909
Total expenditure on SS initiative	\$11,231,152 (9% of total funds allocated)
Practitioner focus group themes raised	
Addressing consumer need	All participants involved in SS commented that this program fulfils a need in the community and was a valuable service for managing medicines of vulnerable consumers, e.g. those that are drug dependent or living in a dangerous environment.
Eligibility criteria and targeting	There were no specific marketing strategies or recruitment activities directed at those most in need of the 5CPA programs.
Program implementation	A multidisciplinary, collaborative approach to programs/services would aid in the implementation of the programs and benefit the impacts and outcomes for consumers. It was also suggested that funding should be allocated to support implementation to prevent inconsistencies in the way that programs are delivered.
Policy and strategy	Participants agreed that generally the 5CPA programs/services added value and should be part of the overall preventative strategy for consumers.
Practitioners/providers survey results	
Interaction between programs	Less than half (42%) of total survey respondents agreed or strongly agreed that the linkages/pathways between the programs/services were clearly identified. More than half (60%) agreed that there were gaps in the services provided, resulting in unmet needs of the consumer.
Factors influencing decision making	The majority of providers agreed that the consumer needs assistance with their medicines (75%) and educating about medicines/health conditions (78%). The majority of pharmacists reported that the point at which they make the clinical decision to provide a particular service/intervention was: when a referral for service is received from a GP (76%), or during interaction with the consumer during the dispensing process (63%). None of the responding pharmacists reported making clinical decisions about service provision through delivery of SS service.
Screening/diagnostic/intervention tools	SS services were viewed as being purpose specific, with the risk of intentional misuse as the main reason for recommending consumers receive SS (67%), followed by high-risk medicines (35%).
Provider satisfaction	More than half of providers (55%) reported being satisfied with their involvement in SS programs/services. Almost two thirds reported being satisfied with the benefit their consumers receive through the SS program.
Collaboration	There was very little collaboration between GPs and pharmacists for SS services, apart from brief phone calls or faxes to confirm a prescription or dosage.

Source: PricewaterhouseCoopers Combined Review of 5CPA Medication Management Programmes (2015)

Abbreviations: 5CPA, Fifth Community Pharmacy Agreement; GP, general practitioner; PPI, Pharmacy Practice Incentives; SS, Staged Supply.

There were a number of limitations relevant to program data analysis. These included:

- Data collected as part of the claims process provided limited insight on uptake and volume of programs and services since multiple services could be submitted under one claim. The authors presented service level data where possible, merging accepted, rejected and claims datasets to conduct more accurate analyses.
- Consumer level data was de-identified and not linked to other data sources (e.g. Medicare and hospital data); therefore, it was not possible to determine the impact of participating in specific programs on consumer outcomes, outside of that particular episode of care.
- Consumer demographic data, such as age and gender, was not available for any of the PPI Program initiatives. Postcode was not captured at the consumer level within any

program/service dataset, therefore analysis of the data could not be performed for socioeconomic indicator or remoteness.

- The number of medicines and health conditions of consumers was not captured in the PPI Program dataset, resulting in the inability to analyse trends over time and potential investment value, including impact, for other programs and services.
- Analysis of program data beyond 28th February 2014 was not performed, resulting in failure to capture the effects of administrative changes to programs and services implemented on 1st March 2014 on the uptake and volume of programs and services.

A cost-benefit analysis was not performed in this Review, thus direct and indirect benefits resulting from delivering medication management programs, such as the PPI Program, could not be inferred. The authors recommended that a baseline benefits analysis be conducted in a future review of the Program to inform the health, social and economic benefits that result from these program implemented as part of the 6CPA and evaluate the cost-benefits as a result of the 6CPA investment. A reliable cost-benefit analysis would require a more sophisticated approach towards collection of data, linking program data (multiple datasets, including at consumer level) combined with regular auditing and reporting requirements to enable consumer health outcomes to be more effectively monitored and measured over time.

5 SS UTILISATION ANALYSIS

This section presents utilisation analysis using data provided by the Department (Sections 5.1 and 5.3) and by the Pharmacy Guild of Australia (Section 5.2).

5.1 SS INITIATIVE PARTICIPATING PHARMACIES AND CLAIMS MADE

Between 2012 and 2016, 7,738 pharmacies have participated in the SS incentive program, peaking in 2015 at 4,897 pharmacies⁴. The variability in number of pharmacy claims suggests that the provided data was likely missing 2013 and the first quarter of 2014. Additionally, 2016 is a part year, it is under-represented in the data and it, along with 2013 are largely excluded in the analysis (Table 5.1).

Table 5.1 Summary of pharmacy SS claims 2012 – 2016

Claim year	No of pharmacies with claims	Value of claims	Average claim per participating pharmacy
2012	2,456	\$2,577,634	\$1,050
2014	4,791	\$4,825,000	\$1,007
2015	4,897	\$5,566,100	\$1,137
2016	1,352	\$1,769,100	\$1,309
Total	7,738	\$14,737,834	\$1,905

Source: Claims payment data supplied in PPI Total Data Compilation_Copy.xls

Table 5.1 shows that number of participating pharmacies has grown from 2,456 in 2012 to 4,897 in 2015, an increase of 99.4%. It also shows that the average amount earned by pharmacies' annual SS claim has increased by 8.3%, going from \$1,050 per pharmacy in 2012 to \$1,309 in 2015. The variations in the per pharmacy annual claim values are due to a combination of changes in claim rates, for example, from 19th November, 2015 the rate at which claims were paid increased from \$1,000 per pharmacy to \$1,300 per pharmacy, and part payments being made to pharmacies especially in the 2012 claim year.

Table 5.2 deconstructs the same data by Australian Bureau of Statistics (ABS) remoteness. There is very little difference in average claim values in any given year with the highest variation between highest and lowest values being 5.7% in 2015. This small variation arises as a result of timing variations in the submission of claims at the end of 2015 where the claim rate increases from \$1,000 to \$1,300.

⁴ Pharmacies are counted according to unique S90 and /or Organisation Number identifiers.

Table 5.2 Summary of pharmacy SS claims 2012 – 2016 by ABS Remoteness

ABF Remoteness	Claim year	No of pharmacies with claims	Value of claims	Average claim per participating pharmacy
Inner Regional Australia	2012	495	\$518,626	1,048
	2014	915	\$919,000	1,004
	2015	923	\$1,058,700	1,147
	2016	270	\$354,550	1,313
	Total	1,506	\$2,850,876	1,893
Major Cities of Australia	2012	1,676	\$1,761,900	1,051
	2014	3,288	\$3,313,000	1,008
	2015	3,366	\$3,802,500	1,130
	2016	915	\$1,197,450	1,309
	Total	5,343	\$10,074,850	1,886
Outer Regional Australia	2012	243	\$254,339	1,047
	2014	479	\$484,000	1,010
	2015	493	\$572,300	1,161
	2016	136	\$176,800	1,300
	Total	766	\$1,487,439	1,942
Remote Australia	2012	31	\$31,536	1,017
	2014	72	\$72,000	1,000
	2015	73	\$85,900	1,177
	2016	22	\$28,600	1,300
	Total	115	\$218,036	1,896
Very Remote Australia	2012	11	\$11,233	1,021
	2014	37	\$37,000	1,000
	2015	42	\$46,700	1,112
	2016	9	\$11,700	1,300
	Total	64	\$106,633	1,666
Total		7,738	\$14,737,834	1,905

Source: Claims payment data supplied in PPI Total Data Compilation_Copy.xls in conjunction with ABS postcode to remoteness.xls available from <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/1270.0.55.006July%202011?OpenDocument> (accessed 5th October, 2016)

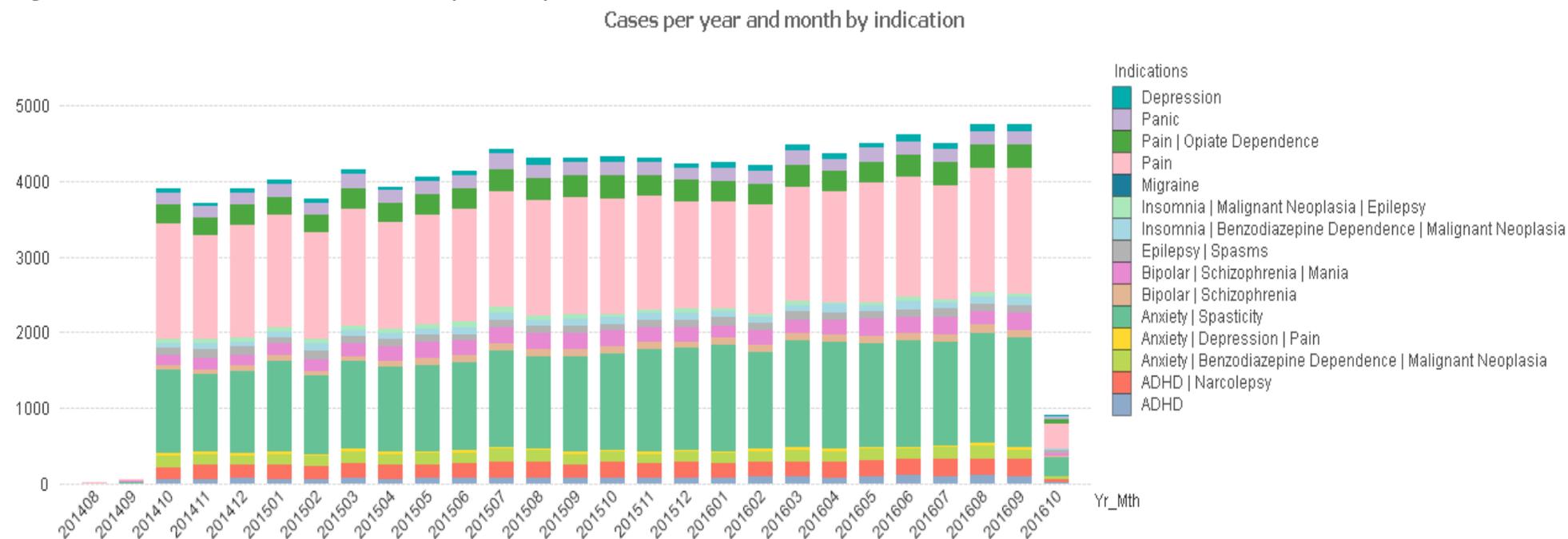
Abbreviations: ABS, Australian Bureau of Statistics; SS, Staged Supply

In contrast to the low levels of variation in per pharmacy annual claim payments, the rate of pharmacy participation in the scheme has increased significantly. The Very Remote Australia regions experienced the highest relative increase in participating pharmacies, with numbers growing 282% (from 11 to 42) between 2012 and 2015, but in absolute terms, the Major Cities of Australia regions added 1,690 pharmacies over the same period (101%).

5.2 SUMMARY INDICATIONS OF PATIENTS RECEIVING SS SERVICES

Figure 5.1 shows the SS services provided at individual patient level by drug, between August 2014 and October 2016, according to data held by the Pharmacy Guild of Australia. Only the 20 most common drugs are included in the analysis, however these accounted for greater than 80% of all the patient level services provided. Although the data was not reconcilable to the claims data provided by the Department, it does enable some descriptive data to be presented on the clinical indications (based on the medication being supplied) of the individuals accessing the SS services.

Figure 5.1 Count of SS services 2014 – 2016 by summary indication

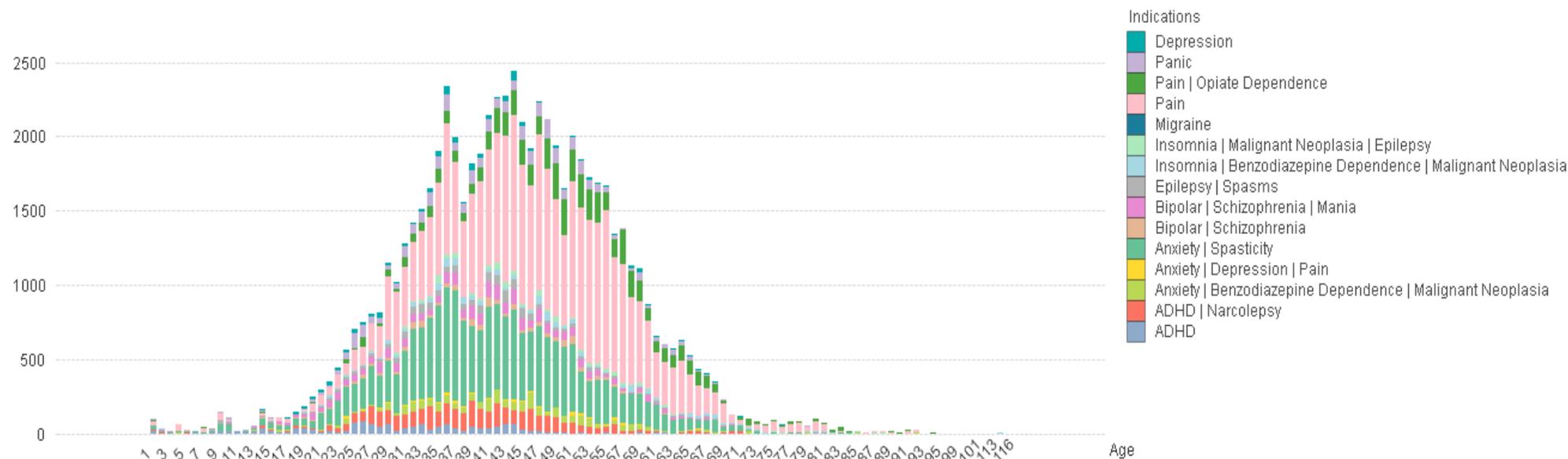


Source: Staged Supply Guild Data Provided 07_10_2016.xlsx in conjunction with amt2_20161001.csv, RestrictionExtract_20161001.txt and LinkExtract_20161001.txt available from <https://www.pbs.gov.au/downloads/2016/10/2016-10-01-xml.zip> (accessed 30th October, 2016)

A relatively steady increase in the volume of services can be observed between October 2014 with 3,892 services provided and September 2016 with 4,744 services provided (an increase of 21.9%). Most of the drugs have multiple indications so it is not feasible to determine which indication represents the majority use. However, Pain is the largest ‘unambiguous’ indication and it accounts for 35.2% of SS services in September 2016.

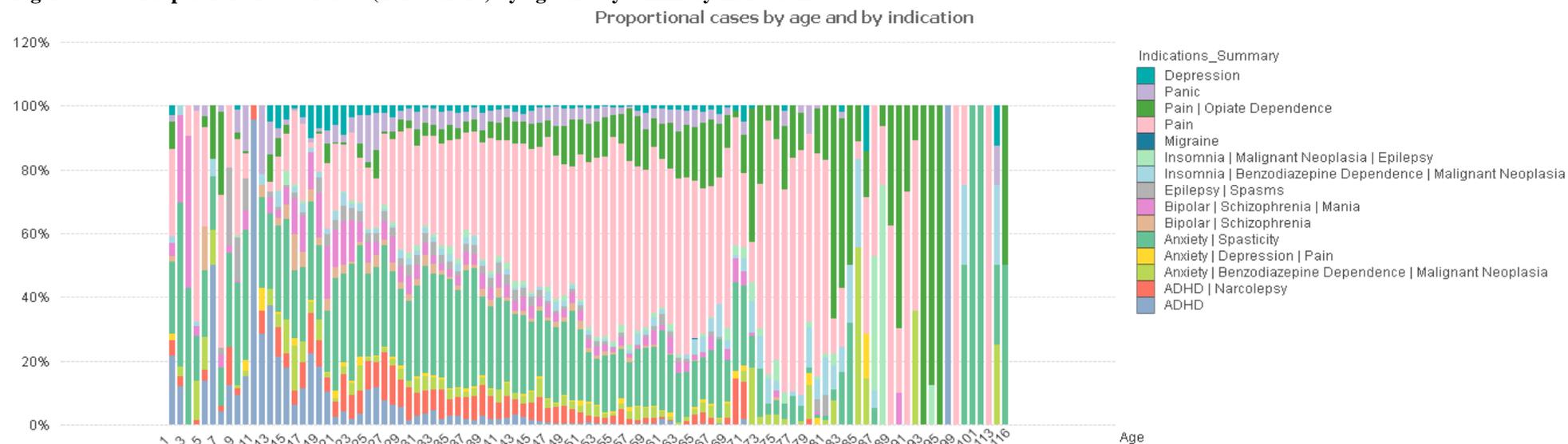
Figure 5.2 shows the distribution of SS services by age. The distributions show a slight skew towards younger patients where the summary indications include Anxiety or ADHD, and skewed towards older patients in the cases where Pain is included in the summary indications.

Figure 5.2 Count of SS services (2014 – 2016) by age and by summary indication
Number of Cases by Major Indication



Source: Staged Supply Guild Data Provided 07_10_2016.xlsx in conjunction with amt2_20161001.csv, RestrictionExtract_20161001.txt and LinkExtract_20161001.txt available from <https://www.pbs.gov.au/downloads/2016/10/2016-10-01-xml.zip> (accessed 30th October, 2016)

Figure 5.3 shows the proportional spread of patients by summary indication within each patient age. Visual examination reinforces the relationships identified in Figure 5.2, younger patients have a higher proportion of indications that include Anxiety and ADHD, and this steadily gives way to indications that include Pain between the ages of 13 and 80.

Figure 5.3 Proportion of SS services (2014 – 2016) by age and by summary indication

Source: Staged Supply Guild Data Provided 07_10_2016.xlsx in conjunction with amt2_20161001.csv, RestrictionExtract_20161001.txt and LinkExtract_20161001.txt available from <https://www.pbs.gov.au/downloads/2016/10/2016-10-01-xml.zip> (accessed 30th October, 2016)

The claims payment data shows that the numbers of SS participating pharmacies has seen very substantial increases between 2012 and 2015 nationally. However due to the payment arrangements, which are not linked to activity, the claims data are not able to provide information on whether the SS services have increased. However the data provided by the Pharmacy Guild supports that there has been an increased number of SS services provided. Growth in the program suggests it is considered effective, but the available data do not allow a determination of the reasons for growth (e.g. motivation for take-up of the incentive payment, or favourable patient feedback on the program, or both).

5.3 SS INITIATIVE REACH TO TARGET POPULATIONS

The claims data do not include any information on the characteristics of the patients receiving the SS service such as age, or indicators of frailty, mental faculties or health status; or indeed any other data that would assist in determining whether the patient population reached by the SS program is consistent with what is intended (PSA Guidelines) and/or whether the program is effective.

The provided Pharmacy Guild data on the SS program, does provide some insight into patient service provision and key indications for the most common (top 80%) of drugs prescribed to participating patients in the program, but there is no definitive relationship between often multiple indications (per PBS restrictions) and the disease they may be prescribed to treat and how many unique patients are receiving services.

Nonetheless, assuming that the program is reaching the intended target groups, it should be possible to observe a relationship between, for example, mental health issues prevalence and the investment in participating pharmacies per-capita at geographic area level (i.e. it might be expected that areas with high mental health issues prevalence would also have a high per capita incidence of participating pharmacies in the SS scheme and thus higher claims).

To illustrate, Table 5.3 looks at the distribution across PHNs areas for SS claims paid against estimated mental health issues (as an indicator of patients who might be disturbed or confused) prevalence (i.e. proportion of the population in the PHN area with mental health issues). Note that the high, medium and low groupings in Table 5.3 are calculated by dividing the values for each of the metrics into three even segments between the highest and lowest values for all PHNs. Microsoft Excel is used to apply heat map colour coding to show where the range of values for each metric fall.

Table 5.3 Mental health prevalence and SS dollars claimed per capita, 2015

Primary Health Network	Mental health prevalence	Mental health prevalence range	Average SS claim per capita	SS claim /capita range
Northern Territory	7.9%	Low	0.190	Low
Western Queensland	8.2%	Low	0.210	Low
Western Sydney	10.8%	Mid	0.230	Low
North Western Melbourne	11.1%	Mid	0.220	Low
Northern Queensland	11.1%	Mid	0.240	Low
Country WA	11.3%	Mid	0.270	Mid
Eastern Melbourne	11.4%	Mid	0.200	Low
Northern Sydney	11.4%	Mid	0.260	Mid
South Western Sydney	11.5%	Mid	0.250	Mid
South Eastern Melbourne	11.7%	Mid	0.220	Low
Central and Eastern Sydney	11.8%	Mid	0.280	Mid
Perth North	11.8%	Mid	0.240	Low
Nepean Blue Mountains	11.9%	Mid	0.240	Low
Perth South	12.4%	Mid	0.200	Low
Western NSW	12.7%	Mid	0.340	High
Brisbane South	12.8%	Mid	0.230	Low
Murrumbidgee	12.8%	Mid	0.370	High
Brisbane North	13.3%	High	0.220	Low

Primary Health Network	Mental health prevalence	Mental health prevalence range	Average SS claim per capita	SS claim /capita range
South Eastern NSW	13.3%	High	0.250	Low
Western Victoria	13.3%	High	0.270	Mid
Murray	13.4%	High	0.280	Mid
Darling Downs and West Moreton	13.7%	High	0.250	Low
Gold Coast	13.7%	High	0.240	Low
Hunter New England and Central Coast	13.7%	High	0.270	Mid
Adelaide	14.0%	High	0.260	Mid
Australian Capital Territory	14.0%	High	0.210	Low
Country SA	14.0%	High	0.340	High
Gippsland	14.2%	High	0.240	Low
Central Queensland, Wide Bay, Sunshine Coast	14.5%	High	0.280	Mid
Tasmania	14.5%	High	0.280	Mid
North Coast	15.3%	High	0.270	Mid
Total	12.5%		0.230	

Source: Claims payment data supplied in PPI Total Data Compilation_Copy.xls in conjunction with Phidu_data_pha_aust.xls available from <http://www.phidu.torrens.edu.au/social-health-atlases/indicators-and-notes-on-the-data/social-health-atlases-of-australia-contents#population-projections> (accessed 5th October, 2016)

Abbreviations: SS, Staged Supply.

Visual examination of Table 5.3 reveals that there is little relationship between mental health issues prevalence and SS resources applied. It shows that only 7 of 31 PHNs have the same banding for both mental health issues prevalence, and average SS resources (claims) per capita. In fact, only one of the five highest prevalence mental health issues PHNs feature as high SS resource invested PHN. The degree of similarity in the heat map coloration of each column is negligible. It is important to note that due to the SS incentive payment not being linked to volume of SS services, the interpretation of this analysis is problematic.

Overall, these results are insufficient to demonstrate a clear relationship between the factors that describe the target population according to the PSA Guidelines and the take up rates for the SS services. To shed further light on the issue, parametric statistical analysis using correlation coefficients was attempted, but this work was similarly inconclusive, and therefore is not presented here.

It is clear that to make a more robust assessment of the impact of the SS program, more comprehensive data are required. Such data should include the characteristics of patients receiving the SS services to enable funders and providers to be confident that the initiative is applying resources to the intended target populations. Ideally the additional data collected should also include measures of interim and final clinical outcomes, as well as patient reported measures of experience with the program, to enable an assessment of clinical and cost effectiveness. It is acknowledged that this type of data could probably only be collected in the context of a structured trial of the SS program.

APPENDIX 1

REFERENCES

NOVA Public Policy Pty Ltd. Review of the Staged Supply of PBS Medicines. Final Report. 2 February 2010. Retrieved from <http://www.guild.org.au/docs/default-source/member-documents/news-and-events/guild-publications/other-publications/staged-supply-final-report.pdf>

Pharmaceutical Society of Australia (PSA). Standard and guidelines for pharmacists providing a staged supply service for prescribed medicines. March 2011. Retrieved from <http://www.psa.org.au/downloads/practice-guidelines/staged-supply-guideline.pdf>

PricewaterhouseCoopers (2015). Combined Review of Fifth Community Pharmacy Agreement Medication Management Programmes (Final Report). Retrieved from [https://www.health.gov.au/internet/main/publishing.nsf/Content/6EF022DE87761986CA257EC80013198B/\\$File/combined-review-5cpa-medication-management-programmes-final-report-and-appendices.pdf](https://www.health.gov.au/internet/main/publishing.nsf/Content/6EF022DE87761986CA257EC80013198B/$File/combined-review-5cpa-medication-management-programmes-final-report-and-appendices.pdf)

APPENDIX 2

WORKING GROUP MEMBERS

The Department of Health established a Working Group of nominated representatives to provide advice to the Department and the Assessment Group on the research questions and PICO criteria for the literature review, the literature search terms, utilisation data and analysis.

Table A-2.1 Members of the Working Group for the evaluation of the medication adherence PPIPs

Name	Representing

APPENDIX 3

SEARCH STRATEGY

The SS search strategies for each database are outlined below.

Table A-3.1 Embase search strategy (23rd August 2016)

#	Search term	Number of citations
1	pharmac*.mp.	1199299
2	community pharmac*.mp.	9142
3	1 or 2	1199299
4	staged supply.mp.	0
5	(staged adj2 supply).mp.	6
6	staged dispensing.mp.	0
7	periodic dispensing.mp.	0
8	periodic instal\$ment.mp.	0
9	staged instal\$ment.mp.	0
10	((periodic or staged) adj2 (installment or instalment or dispensing)).mp.	1
11	4 or 5 or 6 or 7 or 8 or 9	7
12	3 and 10	1
13	limit 11 to (human and english language)	0

mp = title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword

Table A-3.2 Medline search strategy (23rd August 2016)

#	Search term	Number of citations
1	pharmac*.mp.	694696
2	community pharmac*.mp.	4989
3	1 or 2	694696
4	staged supply.mp.	0
5	(staged adj2 supply).mp.	3
6	staged dispensing.mp.	0
7	periodic dispensing.mp.	0
8	periodic instal\$ment.mp.	0
9	staged instal\$ment.mp.	0
10	((periodic or staged) adj2 (installment or instalment or dispensing)).mp.	0
11	4 or 5 or 6 or 7 or 8 or 9	3
12	3 and 10	0

mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier

Table A-3.3 International Pharmaceutical Abstracts (IPA) search strategy (23rd August 2016)

#	Search term	Number of citations
1	pharmac*.mp.	195014
2	community pharmac*.mp.	9583
3	1 or 2	195014
4	staged supply.mp.	0
5	(staged adj2 supply).mp.	0

#	Search term	Number of citations
6	staged dispensing.mp.	0
7	periodic dispensing.mp.	0
8	periodic instal\$ment.mp.	0
9	staged instal\$ment.mp.	0
10	((periodic or staged) adj2 (installment or instalment or dispensing)).mp.	1
11	4 or 5 or 6 or 7 or 8 or 9	1
12	3 and 10	1

mp = title, subject heading word, registry word, abstract, trade name/generic name.

Table A-3.4 Cochrane Library search strategy (23rd August 2016)

#	Search term	Number of citations
1	pharmac*	164972
2	community pharmac*	4807
3	#1 or #2	164972
4	staged supply.	47
5	(staged adj2 supply).	47
6	staged dispensing.	3
7	periodic dispensing.	24
8	periodic instal\$ment.	0
9	staged instal\$ment.	0
10	((periodic or staged) adj2 (installment or instalment or dispensing)).	0
11	#4 or #5 or #6 or #7 or #8 or #9 or #10	74
12	#3 and #11	46