



**Australian Government**

**Department of Health**

**Supporting pharmacist delivery of  
primary health care services  
through the  
Pharmacy Trial Program**

**Discussion paper**

**March 2016**

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## Purpose and Context

Under the Sixth Community Pharmacy Agreement (6CPA), \$50 million has been allocated for a Pharmacy Trial Program (PTP). The PTP will trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers by extending the role of pharmacists in the delivery of primary healthcare services through community pharmacy. These trial programs will be rigorously evaluated by an independent health technology assessment (HTA) committee.

The purpose of this consultation paper is to seek the views of interested stakeholders about ideas for services or programs that can be delivered to consumers by pharmacists in the pharmacy setting.

Pages 9 and 10, and **Appendix C** describe how interested individuals and organisations can respond to a call for ideas and the process once ideas are received.

## Introduction

The Australian Government recognises the important role that the pharmacy profession can play in primary health care and in improving patient health outcomes.

Primary health care plays an important role in broader population health. Primary health care providers, whether general practitioners, Aboriginal health workers, nurses, allied health professionals such as pharmacists, dieticians or physiotherapists all play an important role in health promotion, prevention of chronic disease, risk assessment and early intervention, ongoing treatment and broader management of patient health.

Effective care can offer improved health outcomes for patients, in terms of delaying complications associated with poor health status and chronic disease, avoiding hospital admissions, and meeting local needs in a way that promotes a patient centric approach to care.

### Pharmacy Trial Program

Australian Government funding for professional services delivered by pharmacists is primarily managed through the Sixth Community Pharmacy Agreement (Sixth Agreement), between the Commonwealth and the Pharmacy Guild of Australia (the Guild). The Sixth Agreement, which was signed on 23 May 2015, will deliver \$50 million for a Pharmacy Trial Program (PTP). The PTP will trial new and expanded community pharmacy programs which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary health care services through community pharmacy.

In addition to the PTP, the Sixth Agreement provides funds of \$613 million to continue a range of professional services and programs aimed at improving medication management and health outcomes for patients, which are outlined at **Appendix A**.

Further funding of \$600 million has been set aside to support recommendations by an independent health technology assessment committee (HTA) about which new programs should continue to be funded after trials conclude, and which existing programs

**(Appendix A)** should continue, again following a review of these ongoing Sixth Agreement programs by an independent HTA body.

The Australian Government has committed, through the Sixth Agreement, to an open and transparent consultation process to establish programs to be trialled through the PTP. The first step of this process was a consultation on 26 October 2015 with pharmacy, medical and consumer peak bodies and organisations where stakeholders were invited to provide input on essential principles and priority areas for funding trial programs. There have been further consultations since that date with stakeholder groups and peak bodies and a recently formed Trials Advisory Group (TAG). These consultations will continue throughout the life of the PTP.

This paper frames the current primary health care environment, the challenges that are being faced within primary health care and pharmacy and describes the processes involved in determining priority areas for trial programs and seeking ideas on programs to be funded.

This paper invites stakeholders to outline any ideas they may have for new pharmacy services and programs for consideration under the PTP by the Department of Health and the Government.

### **Primary health care environment and vision for pharmacy**

Pharmacy and pharmacists in Australia are in a transitional phase between a past focus on being compounders and dispensers of medicines and a greater involvement in directed medicines-related services and collaboration in the primary health care system.

Since 1990, successive Community Pharmacy Agreements have expanded the range, scope and locations of funded services that pharmacists can provide. This has included the introduction of funding for medication reviews, activities aimed at improving patient understanding of a medication regimen, and support for tools to assist with medication adherence and compliance such as Dose Administration Aids.

Pharmacy services have extended beyond the pharmacy as a shop front and dispensary into the homes of patients and aged care facilities. This recognises the potential value of extending pharmacy services into active medicines management interventions with the aim of improving consumer health outcomes.

The Fifth Agreement introduced two new medication management services within pharmacy (MedsCheck and Diabetes MedsCheck), which are designed to provide education and support for patients, and seek to improve patients understanding of their medication regimen. The Fifth Agreement also introduced support for the delivery of clinical interventions by pharmacists, recognising the important role of identification and management of drug-related problems as part of medicines dispensing activities.

These services are aimed at supporting a wider range of medication management services to meet the needs of patients without the need for an accredited pharmacist to visit a patient's home and with the aim of reducing medicines misadventure. These interventions are aimed at exploring new pathways of service delivery within pharmacy and are only a few

examples of changes to the scope of pharmacy and pharmacist services that have been facilitated through successive Community Pharmacy Agreements.

### **The changing primary health care environment**

Primary health care is also changing. There are a number of reforms in primary health care that are aimed at changing or refining the way health care is funded and managed, in response to changing demographics and an increasing burden of chronic disease.

The Government is increasingly requiring ongoing evaluation of existing services and an improved evidence base for funding future services. This is evidenced, for example, through the introduction of the PTP and the review of the Medicare Benefits Schedule. The Government is also considering new ways to manage funding, as evidenced by the work of the Primary Health Care Advisory Group (PHCAG) on potential changes to the way care is delivered and funded for consumers with chronic and complex conditions.

These initiatives are being considered in response to the changing demographics and ageing of the population, an increase in chronic disease and related healthcare needs, and funding constraints created through external financial pressures on the Australian Budget. It is vital to consider innovative ways to address health needs and improve the value and cost-effectiveness of all services, whether delivered through pharmacy or other areas of primary health care.

The implementation of Primary Health Networks, digital health reforms and a number of other initiatives reflects an increasing Government focus on the facilitation and improvement of services through improved coordination and integration of care. Examples of digital health reforms include initiatives to incentivise the uptake of electronic scripts in pharmacy, the current trial of an opt-out MyHealth record, and the introduction of the *My Aged Care* portal.

Collaboration is a key facet of both digital health and many other programs being funded by the Australian Government. These programs seek to improve consumer health outcomes by ensuring better communication and seamless care across the primary and acute health care sectors. The interface of these sectors is commonly highlighted as a point of risk for consumers where decisions about medicines, or other care, can have significant impacts on patient outcomes. For example, there are a significant number of medication related hospitalisations per year, particularly amongst the elderly. There may be further opportunities through the PTP to improve the consumer experience when transitioning between primary and acute care sectors, particularly through collaboration.

Funding for services under the PTP needs to reflect the centrality of community pharmacy within the Sixth Agreement and also as a key point of care for consumers. However, the involvement of pharmacy can potentially take a number of forms, including where the community pharmacy is a participant in a broader care model.

In future, the Government has stated its intention to fund pharmacy and pharmacist services which are high quality, evidence-based cost-effective, tailored to the needs of the person receiving them and integrated within a responsive primary health care system. These services will address the changing needs of the population and provide opportunities

to enter into partnerships between consumers, pharmacists and other health professionals with the ultimate benefit of improved health outcomes for Australians through better integration of services and the health care team.

Further information relating to current initiatives that should be considered in conjunction with the PTP is at **Appendix B**.

### **Pharmacy Trial Program principles and priorities**

Under a potential future model of pharmacy service delivery, the ability to tailor interventions to best meet patient needs is vital. However, patient needs, and how to best structure a service to address these, can differ significantly. The most effective approach will depend on a number of factors including the type and size of the problem or gap in healthcare services, the target group and the evidence supporting the proposed intervention.

The following principles will underpin trials under the PTP:

- *Established patient need*
  - Proposals must be patient-focussed and demonstrate that there is a gap in services or a gap in accessing a particular service, i.e. it would not duplicate an existing service or create demand for a service which doesn't deliver health value.
  - Proposals should not further accentuate inequities in care (e.g. by delivering small improvements for a group of patients where the need is low).
- *Scientific rigour and accuracy*
  - The evidence base should be relevant to the Australian context and trial setting;
  - Proposals should identify measurable patient-relevant outcomes that the service will provide;
  - Total budget impact analysis (includes new costs and any savings) should be undertaken, including
    - infrastructure and implementation costs – workforce issues, including capacity, training/credentialing requirements, context in which the service will be provided (e.g. in the home, rural); and
    - consideration of utilisation estimates.
  - Appropriate data should be collected to enable evaluation of cost-effectiveness.
- *Applicability and context*
  - The proposed service must streamline the patient journey;
  - The potential for implementation on a broad scale should be examined: any factors that may impact on extrapolating the service to a wider setting, for delivery across a range of jurisdictions, locations and patient groups, should be considered, including whether the proposed participants have the capacity to implement the service;

- Any barriers to implementation should be considered, e.g. regulatory requirements, scope of practice issues.
- *Integration with existing programs, services and systems*
  - There must be demonstrated 'buy-in' from those health professionals who will be involved in/affected by the trial;
  - Trials should identify ways to facilitate communication and collaboration across professions and sectors to sustain the team approach;
  - There should be agreement on scope of practice to prevent duplication and minimise harm;
  - Interaction and alignment with other health services/systems and existing infrastructure, e.g. Primary Health Networks and digital health records, should be examined.
- *Utility and feasibility*
  - The trial must collect useful and timely information to inform decision making;
  - It should be demonstrated that the trial can be conducted at the selected sites without unduly disrupting other programs and trials.
- *Conduct*
  - Approval of trials will be needed from a human research ethics committee (this includes obtaining site specific governance approvals for conduct of the study);
  - Consumers will need to be involved at all stages of trialling.

In short, trials should make effective use of pharmacists' unique skills and knowledge in a manner that improves health outcomes and provides value for money to the individual and the wider community.

The Government has also indicated a strong commitment, through the Sixth Agreement, to funding services in the areas of Aboriginal and Torres Strait Islander health and for consumers in rural and remote areas.

These principles and priority areas should be considered in any response to the call for ideas later in this paper.

## Scope of the PTP

The PTP will:

- Benefit consumers and lead to improved health outcomes.
- Take an integrated care approach in the context of other health system priorities and reforms.
- Support innovation in community pharmacy.

- Provide funding for a range of potential services, incentives and workforce initiatives, focusing on community pharmacy but possibly involving a range of settings.
- Fund activities which facilitate changes in the roles of pharmacy or pharmacists, expand on the range of available primary health care services and which pharmacists have, or can obtain appropriate training and skills to deliver.
- Focus on activities and programs which can be rolled out to the community setting and are likely to be translatable to national programs.
- Provide opportunities for existing Sixth Agreement programs and services to be expanded or changed to either ensure a greater chance of the intervention being found to be clinically effective and cost-effective or to allow opportunities for further innovation.
- Be undertaken as an iterative process, allowing opportunities for the program itself to be improved through consultation but also for programs to be improved based on learnings throughout the trials.

The Department has overall responsibility for managing the program, but there will be significant involvement from advisory bodies such as the TAG and extensive and culturally appropriate consultation undertaken as part of the development and implementation of trials.

### **Role of the TAG**

The TAG has been established by the Department of Health as an expert advisory body to provide:

- Advice on the preferred topics to commence as trials, taking into account policy objectives under the PTP, any preferences for trial topics the Minister for Health, Aged Care and Sport, or the Government may identify, and the feasibility of proposed trials being able to deliver outcomes 'on the ground'. Recommendations on these matters will be made to the Minister through the Department;
- Advice and assistance to organisations that may be developing proposed trials, on the methodology for conducting the trial and gathering evidence throughout the trial. The National Health and Medical Research Council will be assisting with calling for future proposals (see further details on next page). The Medical Services Advisory Committee, through its Protocol Advisory Sub Committee, will also have a significant involvement in the refinement of trial methodologies, to ensure that appropriate evidence is gathered throughout trials to inform evaluations of cost-effectiveness for ongoing funding.
- Any advice required on reviews of existing 6CPA programs, which will be undertaken in parallel with the roll-out of the PTP.

Further information on the PTP and the TAG, including its Terms of Reference and membership, can be found on the Department's web site at:

[www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-program](http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-program)



## Process for identifying trials to be funded

A diagram of the process for the PTP is at **Appendix C**. As the diagram outlines, it is expected that trials will be run in several tranches or phases. The first tranche of the Trials, as described in further detail below, will involve topics identified from previous research and development work in prior Agreements or through discussions and negotiations on the Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Measure. These activities are consistent with the principles above and represent the potential to be evaluated for their cost-effectiveness.

Second and further tranches are expected to be managed through formal calls for submissions with each submission being assessed competitively for funding.

### *First tranche of the Trials*

The Government has agreed to trials in the following three topic areas:

- Improved medication management for Aboriginal and Torres Strait Islanders through pharmacist advice and culturally appropriate services;
- Pharmacy-based screening and referral for diabetes; and
- Improved continuity in the management of patients' medications when they are discharged from hospital.

These first trial topics have been provided to the TAG and the Protocol Advisory Sub Committee of the Medical Services Advisory Committee for comment on the trial protocols.

### *Second and future tranches of the Trials*

As the diagram at **Appendix C** outlines, for the second tranche of trials and moving forward, assessments by the PASC and NHMRC will be provided to the TAG for consideration and for recommendations to Government about programmes meriting funding.

These processes are still in development but it is expected, for example, that there will be some opportunity for facilitating expert assistance to organisations proposing trials, with the purpose of developing proposals to the point of being robust and researchable. This would be considered on a case-by-case basis as part of a formal call for submissions. Prior to a call for submissions, as the diagram notes, the Department is seeking high level ideas.

## Call for ideas

In addition to the above three trial topics, the Department is seeking high level ideas from stakeholders on transformative activities that could be funded through the PTP. These ideas can be in any area, including the broad areas listed above as part of the first tranche of trials.

This call for ideas will be analysed and used to develop high level themes (for example, rural and remote health) covering the range of ideas presented and indicating whether there are

particular theme areas that generated greater interest than others, have a likelihood of delivering more robust research, or that address identified gaps in services and health care for consumers.

Individuals and organisations are encouraged to put forward ideas for activities to be considered as part of this discussion paper.

This is not a call for proposals for funding or trials to commence. The information gained through this consultation process will inform setting of priorities for the next stage. It is not a requirement of any future call for submissions that a respondent must have responded to this call for ideas.

While this call for ideas is not limited to any particular type of service or intervention, a key focus of the PTP is to fund new activities that will be undertaken through community pharmacy; and the Government has identified interventions that will provide benefit to Aboriginal and Torres Strait Islanders and people living in rural and remote areas as particular focus areas for the PTP.

Ideas should take into account the principles described on pages 6-7, and comprise a high level description outlining any evidence of a gap in current services or issues with consumer health outcomes, the proposed service or intervention, a précis of a trial approach (if useful and relevant) and any other considerations or limitations that should be considered. This might include, for example, the relevance of the particular service to a particular geographical location or health sector.

Ideas should be no more than one to two pages in length and can be entered into a pro forma on a consultation page on Citizen Space or attached directly in responding (see below for details of how to access the consultation page). Stakeholders are welcome to submit more than one idea, noting that this is not a call for funding. Ideas should be put forward based on sound evidence, or demonstrated knowledge of consumer need, but do not need to include detailed accompanying data or evidence. Once themes for health areas and interventions have been considered by the Minister, there will be a formal call for submissions. The Government is committed to encouraging innovation through the PTP.

Responses to this call for ideas should be provided through Citizen Space. There is a link to the consultation page on the Pharmacy Trial Programme web page:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-trial-programme>

The consultation page can also be accessed directly at:

<https://consultations.health.gov.au/pharmaceutical-access-branch/ptp>

Responses to this call for ideas are requested by **Friday 29 April 2016**.

## APPENDIX A      Continuing programs

*NOTE: there are several programs that aim to improve access to medicines that are not listed here as they are not funded through the Sixth Community Pharmacy Agreement. These include the Pharmaceutical Benefits Scheme Co-payment Measure, and the Remote Area Aboriginal Health Services Program.*

### Medication Management Services

- **Home Medicines Reviews (HMR)**, which is a GP-initiated service involving a detailed appraisal of a patient's medications by a pharmacist in the home setting (due to the home-based nature of the service, travel is involved).
- **Residential Medication Management Reviews (RMMR)**, which is a GP-initiated service involving a similar review to the HMR but in an aged care facility for permanent residents.
- **Quality Use of Medicines services**, which are funded under the RMMR program and provide for facility-wide education services targeted towards broad improvements in the quality of how medications are managed.
- **MedsChecks**, which involve an in-pharmacy review of a patient's medications with a focus on improving medication adherence and are expected to be of 15-30 minutes in duration.
- **Diabetes MedsChecks**, which involve an extended version of a MedsCheck service, specifically targeted at patients with recently diagnosed or poorly controlled Type 2 diabetes.

### Pharmacy Practice Incentive Program

Three components of this program are continuing under the Sixth Agreement. Payments are made to eligible<sup>1</sup> pharmacies and funding aims to support the quality delivery of services that improve health outcomes for patients:

- **Clinical Interventions**, provide periodic payments for a service involving a pharmacist identifying and helping a consumer about a drug related problem;
- **Dose Administration Aids**, provide periodic payments for the delivery of sealed, tamper-evident devices that allow individual medicine doses to be organised according to a patient's prescribed dosing schedule, with the aim of improving medicine adherence; and
- **Staged Supply**, provides a flat annual payment for the supply of PBS medicines in instalments where requested by the prescriber.

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<sup>1</sup> Approved Section 90 pharmacies are required to be accredited through an approved pharmacy accreditation program, display and adhere with the Community Pharmacy Service Charter and display a Customer Service Statement.

### Workforce, Access, and Quality Use of Medicines programs

The Sixth Agreement also funds a number of programs which support access to pharmacies, provide undergraduate and postgraduate scholarships and more broadly support the pharmacy workforce:

- **Rural Pharmacy Maintenance Allowance**, which provides funding to support access to pharmacies in rural and remote areas;
- **Rural Pharmacy Workforce Program**, which comprises 10 discrete initiatives that aim to support pharmacists and pharmacies in rural and remote Australia. These include rural scholarships, emergency locum support, and support to practising rural community pharmacies and pharmacy students undertaking placements in rural areas;
- **Aboriginal and Torres Strait Islander Workforce Program**, which comprises scholarships for Aboriginal and Torres Strait Islander peoples who undertake undergraduate or postgraduate studies in pharmacy, and traineeships for pharmacy assistants;
- **Section 100 Support Allowance**, which is paid to eligible approved pharmacies and approved hospital authorities for the provision of a range of Quality Use of Medicines (QUM) activities (such as education for other health professionals) and services to patients in approved remote area Aboriginal Health Services (AHSs) participating under S100 supply arrangements; and
- **Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander Peoples (QUMAX)**, which aims to improve QUM through a range of support services (such as Dose Administration Aids, cultural awareness activities and local models to support the delivery of HMR services), and which are provided by participating Aboriginal Community Controlled Health Services (ACCHSs) and pharmacies in rural and urban Australia.

### Other initiatives

In addition, the **Electronic Prescription Fee** is continuing as part of the Sixth Agreement. This supports pharmacy use of prescription exchange software, and promotes the download and dispensing of electronic prescriptions as a regular part of community pharmacy practice.

## APPENDIX B

## Relevant primary health care reforms

Following is a brief list of other Government initiatives with aspects that relate to the PTP.

### The Primary Health Care Advisory Group (PHCAG)

Chaired by Dr Steve Hambleton, the PHCAG has been established to develop advice to Government on short, medium and long term opportunities to reform the primary health care system, with a particular focus on:

- The interface between primary and acute health care, including the proposed and potential roles of PHNs;
- Innovative care models for target groups such as those with complex, chronic diseases;
- Funding models that best support proposed service improvements;
- Potential revised roles for existing players in the health system that support proposed service improvements; and
- Better recognition and treatment of mental illness.

### Primary Health Networks (PHNs)

PHNs have been established to increase the efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes and to improve coordination of care to ensure patients receive the right care, in the right place, and at the right time. PHNs will achieve these objectives by working directly with general practitioners, other primary health care providers including pharmacists, secondary care providers and hospitals to facilitate improved outcomes for patients.

PHNs will be informed at a regional level by GP-led Clinical Councils and consumer involvement in Community Advisory Committees. These governance structures will provide a direct link between the PHN Board, clinicians and community representatives to ensure decision making is focused on the health needs of communities within PHN boundaries.

### Digital health initiatives

As part of the Government's National Digital Economy Strategy, primary health care providers and organisations are being encouraged to make use of digital technology such as My Health Record – Australia's national digital health record system - and tele-health to improve the delivery, safety and quality of health services. For example:

- A pharmacy connected to the *My Health Record* system is able to view a patient's health information, like current medications, prescriptions or adverse reactions. *My Health Record* can be useful in supporting pharmacists to conduct effective, accurate and timely medication reconciliation, which can decrease medication errors and adverse events. In the 2015-16 Budget, the Government announced funding for the

redevelopment and continued operation of the My Health Record system; for trials of new participation arrangements for individuals, including an opt-out system; and for strengthened national digital health governance arrangements. The opt-out trials commenced in mid-March in North Queensland and the Nepean Blue Mountains region of New South Wales and are expected to lead to around one million new records being created across both regions by mid-June. These records will be accessible by the healthcare providers involved in the patient's care, including pharmacists, by mid-July.

- Medicare funded telehealth is used to overcome some of the geographic barriers faced by Australians living in regional, rural and remote areas in accessing specialist services. Medicare rebates are available for video consultations with medical specialists for patients in telehealth-eligible areas. Rebates are available for clients of Aboriginal Medical Services and residents of aged care facilities in all areas, including inner metropolitan.

### The Medicare Review Taskforce

The roles and responsibilities of the Taskforce, chaired by Professor Bruce Robinson, include the following:

- Undertake a high level review of the Medicare Benefits Schedule (MBS) as a whole to identify priority areas, taking account of factors including concerns about safety, clinically unnecessary service provision and accepted clinical guidelines;
- From this high level review, identify Review topics and assign priority to nominated topics;
- Commission evidence-based reviews that rely on assessment of literature and data by Working Groups; and
- Analyse the advice from the Working Groups and, in turn, provide advice to the Minister, including advice on the evidence for services, appropriateness, best practice options, levels and frequency of support through Medicare.

### The Review of Pharmacy Remuneration and Regulation

This Review, chaired by Professor Stephen King, will provide recommendations on future pharmacy remuneration, regulation including pharmacy location rules, and other arrangements that apply to pharmacy and wholesalers for the dispensing of medicines and other services.

The Review's recommendations will be directed toward achieving arrangements which are transparently cost-effective for Government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines, in the context of Australia's National Medicines Policy and the broader Australian health sector.

The Review will provide a report to the Minister for Health by 1 March 2017.

### The Expert Review of Medicines and Medical Devices Regulation

Emeritus Professor Lloyd Sansom AO chaired this Review, which examined Australia's medicines and medical devices regulatory framework and processes with a view to identifying:

- Areas of unnecessary, duplicative, or ineffective regulation that could be removed or streamlined without undermining the safety or quality of therapeutic goods available in Australia; and
- Opportunities to enhance the regulatory framework so that Australia continues to be well positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods.

The Panel has provided the Government with its reports, which make a total of 58 recommendations. It does not make recommendations regarding reimbursement schemes.

# Process for Trials

