# Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1678 – Integrating Pharmacists within Aboriginal Community Controlled Health Services to Improve Chronic Disease Management (IPAC Project)

Applicant: Pharmaceutical Society of Australia in partnership

with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook

University

Date of MSAC consideration: 30–31 March 2023

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, <u>visit the MSAC website</u>

# 1. Purpose of application

An application requesting public funding for Integrating Pharmacists within Aboriginal Community Controlled Health Services (IPAC) for chronic disease management was received from the Pharmaceutical Society of Australia (PSA) in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University by the Department of Health and Aged Care.

#### 2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported public funding for integrating non-dispensing pharmacists within the primary health care team of Aboriginal Health Services to improve chronic disease management. MSAC considered this model of integrated, collaborative, patient-centred care was at least as safe as usual care. MSAC considered that the totality of improvements in biomedical outcomes, prescribing quality, medication adherence, self-rated health status and positive qualitative outcomes reflected an acceptable clinical outcome, compared to usual care, in an under-served population that is known to have typically poorer health outcomes compared to the broader Australian population. MSAC considered the updated economic and financial analysis indicated the per patient cost and annual cost were comparable to existing medication review programs and acceptable in the context of providing overall better quality of care that may help improve health inequities for Aboriginal and Torres Strait Islander peoples.

#### **Consumer summary**

This is an application from the Pharmaceutical Society of Australia in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO) and James Cook University requesting funding of Integrating Pharmacists within Aboriginal Community Controlled Health Services for chronic disease management.

This application was seeking funding for Aboriginal Community Controlled Health Services (ACCHS) to be able to employ non-dispensing pharmacists as a part of their usual healthcare teams to improve the health outcomes for Aboriginal and or Torres Strait Islander peoples with chronic health conditions. Non-dispensing pharmacists are pharmacists who are allowed to make recommendations about medications, but whose role does not usually include dispensing medicines. The purpose of integrating the pharmacist in the health service is to have an in-house medicines expert who can work closely together with the rest of the team to provide culturally safe healthcare, consistent with the holistic model of care of the ACCHS. The pharmacist can act as a resource for other staff, liaise with external healthcare providers such as community pharmacists, undertake service improvement activities and provide preventive care, medicines reviews, education and advice to patients with chronic health conditions (eg diabetes), and undertake service improvement activities.

MSAC previously considered this application at the 31 March – 1 April 2022 MSAC meeting (see MSAC 1678 Public Summary Document – March 2022). At that time MSAC acknowledged the potential value of funding this program which MSAC felt had the potential to improve the health of Aboriginal and Torres Strait Islander peoples. However, at the March-April 2022 meeting, MSAC deferred its decision on the application as MSAC considered that more information was needed about the improvements in health markers (e.g., diabetes control, cholesterol levels) to decide whether the program improved the health of patients.

After considering the additional information presented at the March 2023 MSAC meeting, MSAC considered that this model of care was at least as safe as usual care. There were modest improvements in health markers such as diabetes control and cholesterol levels, and improvements in patient reported outcomes, such as helping patients to take their medications regularly and patient reported health status. Patients reported being more involved in decisions about their care, and feeling empowered to better manage their health, which highlighted the cultural safety the patient experienced when participating in the IPAC study. MSAC considered that when all of the improvements were considered together, that this reflected an acceptable clinical outcome, compared to usual care.

### MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC supported public funding for integrating non-dispensing pharmacists within the primary healthcare team of Aboriginal Health Services to help improve chronic disease management. MSAC considered that the model was safe and effective compared to usual care. MSAC considered that the estimated costs for providing this integrated, collaborative, culturally appropriate patient-centred care to improve health outcomes for Aboriginal and Torres Strait Islander peoples was good value for money.

# 3. Summary of consideration and rationale for MSAC's advice

MSAC recalled that at the 31 March – 1 April 2022 MSAC meeting, MSAC had deferred providing advice on this application which seeks public funding for Integrating Pharmacists within Aboriginal Community Controlled Health Services (IPAC) for chronic disease management. MSAC recalled it had previously considered the IPAC model of care an excellent example of integrated, collaborative, patient-centred approach to primary care that has potential to have a meaningful societal impact by improving equity of health outcomes for Aboriginal and Torres Strait Islander

peoples. However, MSAC had considered that additional information was required to interpret the clinical significance of biomedical outcomes, assess qualitative feedback, revise economic analysis, and examine financial implications in the context of other relevant funding programs (MSAC 1678 Public Summary Document – March 2022).

MSAC noted that the requested additional information was now available for MSAC's consideration and that a Stakeholder meeting had been held to seek stakeholder input on issues that were raised by MSAC at the March-April 2022 meeting (see <a href="MSAC 1678 Final Stakeholder">MSAC 1678 Final Stakeholder</a> Meeting Minutes).

Regarding safety, unchanged from the previous consideration, MSAC noted that the IPAC study did not report any safety outcomes. However, MSAC considered that it is likely that this model of care was at least as safe as usual care.

Regarding comparative effectiveness, MSAC recalled that understanding the clinical significance of the modest improvements in biomedical outcomes and evaluation of the qualitative feedback from the IPAC study were outstanding considerations for MSAC. In regards to interpreting the clinical significance of the changes in biomedical outcomes reported in the IPAC study, MSAC recalled that the data provided in the IPAC study focused on changes in biomedical markers for type 2 diabetes mellitus (T2DM) (measuring HbA1c), renal function (measuring estimated glomerular filtration rate) and lipids (measuring LDL cholesterol). MSAC noted the additional information on biomedical outcomes had been considered by the MSAC Executive. MSAC considered the improvements in individual biomedical outcomes did not represent a clinically meaningful difference compared with usual care.

MSAC noted the appraisal of the qualitative evidence from the IPAC study reported that the conduct of the qualitative research was generally consistent with best practices for qualitative research (including Indigenous health qualitative research) supporting the credibility of the qualitative findings. Overall, MSAC considered that, when the improvements in biomedical outcomes and positive qualitative outcomes were considered together in conjunction with improvements in prescribing quality, medication adherence and self-rated health status, that the totality in improvements reflected an acceptable clinical outcome, compared to usual care, in an under-served population that is known to have typically poorer health outcomes compared to the broader Australian population.

MSAC noted that, after seeking additional advice from the MSAC Executive, the revised economic evaluation was presented as a cost-consequence analysis to capture improvements across numerous outcomes (biomedical, prescribing quality, adherence and self-assessed health status), as this may better reflect the costs and outcomes of the IPAC program. MSAC also noted that cost-consequence analyses were presented for integrating pharmacists within Aboriginal Health Services (AHS) per the original model proposed in the Applicant Developed Assessment Report (ADAR) and also for three (3) model options proposed by the Department. MSAC noted the differences for the models as summarised in Table 6.

MSAC noted that the cost per patient was \$1,525 (ADAR model), \$1,703 (Department model 1), \$1,523 (Department model 2), and \$1,358 (Department model 3). MSAC noted that the current cost per patient for the four models was estimated based on the applicant's estimate that only 2.6% of patients would be eligible for the service. MSAC noted that the cost per patient may be lower in practice if the outcomes in the IPAC study were able to be achieved in a larger group of patients, with sensitivity analysis showing that increasing the eligible population to 5% and 10% resulted in a substantial decrease in the per-patient cost (see Table 12). MSAC noted the revised financial analysis estimated that, across the three Department models, the total cost over six years was estimated to range from \$61 million to \$90 million (see Table 15). MSAC also noted the estimated total financial impact was similar to the total costs for the Home Medicines Review

(HMR) program, substantially lower than the MedsCheck/Diabetes MedsCheck programs costs and also substantially lower than the total program costs announced for the Aged Care on-site pharmacists measure (although the IPAC program would have a higher per patient cost). Overall, MSAC considered the updated economic and financial analysis indicated the per patient cost and annual cost were comparable to existing medication review programs and acceptable in the context of providing overall better quality of care that may help lessen health inequities for Aboriginal and Torres Strait Islander peoples.

MSAC discussed the key differences between the original ADAR model and three Department models. MSAC noted that NACCHO affiliation was an eligibility criterion for the original ADAR model (consistent with the IPAC study) but was not an eligibility criterion for the three Department models and that removing this criterion increased the number of eligible AHSs. MSAC also noted that Department models 1 and 2 increased the ratio of pharmacist to clients attending an AHS from 1:8,295 (per ADAR model) to 1:6,000, increasing the number of pharmacists that may be funded under the program.

MSAC discussed that model 1 also differed from the ADAR model and other Department models in that model 1 did not require a health service to have at least one full-time equivalent (FTE) general practitioner (GP) and removing this requirement further increased the number of eligible health services. MSAC noted the applicant's pre-MSAC response was supportive of Department model 1 and stated that the ADAR proposal to have a minimum of 1 FTE GP was included to keep the fidelity of the application with the IPAC study conditions. The pre-MSAC response also noted smaller ACCHOs with <1 FTE GP or those unable to reliably recruit a GP that wish to participate should not be penalised, and suggested that these are the services that could most use a pharmacist, particularly to support practice level activities. The applicant stated that these locations would likely have 0.2 FTE pharmacist allocation and may need to be delivered under a hub-and-spoke model. MSAC also noted that it is a recommendation of the Strengthening Medicare Taskforce Report - December 2022¹ to ensure new funding models do not disadvantage people who live in communities with little or no access to regular GP care.

MSAC considered that it was important for the health service to be supported by a GP in order to achieve the integrated, collaborative patient centred care intended by the program. However, MSAC also considered that for small health services in remote and very remote regions that this did not necessarily require a minimum of 1 FTE GP (i.e., can be less than 1 FTE GP but must be more than 0 FTE GP) and that the support did not necessarily require face-to-face GP support (e.g. fly-in-fly out, telehealth consultation etc.).

MSAC discussed that the three Department models proposed removing the requirement for the health service to be an accredited practice in accordance with the Royal Australian College of General Practitioners (RACGP) Practice Standards. MSAC expressed concern about removing this requirement but acknowledged the requirement could create an access barrier for small health services supporting patients in very remote regions. Overall, MSAC considered that RACGP accreditation should be a requirement but that the Department could design some flexibility in the program policy that could provide the ability for small, remote or very remote health services to seek an exemption from this requirement. Table 1 summarises the model criteria supported by MSAC for implementing non-dispensing pharmacists in AHS.

<sup>&</sup>lt;sup>1</sup> Strengthening Medicare Taskforce Report: <a href="https://www.health.gov.au/committees-and-groups/strengthening-medicare-taskforce">https://www.health.gov.au/committees-and-groups/strengthening-medicare-taskforce</a>

Table 1 Summary of MSAC supported model for integrating non-dispensing pharmacists in Aboriginal Health Services

Component	MSAC supported model
Pharmacist FTE: client ratio	1:6,000
Minimum pharmacist FTE	Minimum 0.2 FTE
	Minimum 1 FTE pharmacist for clinics in remote areas (MMR 6 and 7)
	NT Govt consortium of 10 FTE across all clinics
	Option to develop consortiums
Pharmacist salary	\$112,940 a
Is funded by the Department of Health and Aged Care's First Nations Health Division for the provision of primary healthcare services to First Nations people	Yes
The health service is required to be a member of NACCHO and relevant NACCHO State/Territory Affiliate	No
Minimum GP FTE	GP-supported (i.e. >0 FTE)*
RACGP accredited practice	Yes**
Eligible for CTG PBS co-payment measure or s100 PBS supply in remote areas	Yes
Private consulting room	Yes
Eligible to claim HMRs and MedsChecksb	No
Overlap with IHSPS	Yes

Abbreviations: CTG = Closing the gap; FTE = full time equivalent; GP = general practitioner; HMR = Home Medicines Review; IHSPS = Indigenous Health Services Pharmacy Support; MMR = Modified Monash Model remoteness classification. NACCHO = National Aboriginal Community Controlled Health Organisation; NT Govt = Northern Territory Government; PBS = Pharmaceutical Benefits Scheme

# 4. Background

At its March-April 2022 meeting, MSAC deferred providing its advice on the IPAC Project. MSAC considered additional information was required to interpret the clinical significance of the biomedical outcomes, assessment of the qualitative feedback, revised economic analysis and presentation of the financial implications in the context of other relevant funding programs. MSAC considered a stakeholder meeting would be informative ahead of its further consideration.

MSAC noted the positive narrative assessments and considered a formal appraisal and synthesis of the qualitative assessments should be performed. MSAC advised that the economic evaluation needed to be revised to reflect clinically meaningful outcomes. MSAC requested updated financial implications considering programmatic funding including consideration of fixed and variable costs of the program, potential economies of scale, and needs of different geographic locations. MSAC considered the revised financial implications should present the full context of similar services, include an analysis of the extent to which the IPAC model is expected to replace

<sup>&</sup>lt;sup>a</sup> Includes on-costs. Department proposed salary rate for pharmacist grade 2 salary in 2019-2020, accounting for inflation estimated at 1.8% annually, per PPA report Community and Hospital Pharmacists Employment and Remuneration Report 2019-2020) with 17% on-costs (\$16,410).

<sup>&</sup>lt;sup>b</sup> Current HMR program rules would not exclude an IPAC salaried pharmacist from claiming under this service, the Department has advised that program rules would be amended accordingly.

<sup>\*</sup> MSAC considered that eligible health services should be supported by a GP but for small, remote and very remote health services this may mean less than 1 FTE GP (but more than 0 FTE GP) and not necessarily mean face-to-face GP support.

<sup>\*\*</sup> MSAC considered RACGP accreditation should be a requirement, but it may be reasonable for small, remote or very remote health services to seek an exemption from this requirement.

services provided by other programs (such as HMRs, Indigenous Health Services Pharmacy Support [IHSPS], Workforce Incentive Program- Practice Stream [WIP]) and where IPAC would provide a service to people not accessing existing programs. Refer to the MSAC Public Summary Document (PSD) Application No. 1678 for further information.

The <u>stakeholder meeting</u> held on 10 October 2022, included representatives of the applicant from PSA, NACCHO and James Cook University, representatives from Aboriginal Health Services (AHS), Aboriginal Community Controlled Health Services (ACCHS), Northern Territory (NT) Health Department and the Department of Health and Aged Care. The aim of the stakeholder meeting was to inform MSAC's future deliberations and advice to the Minister for Health and Aged Care by providing a better understanding of issues raised during its March-April 2022 consideration of the application.

Stakeholders were unanimous in the view that integrating pharmacists within ACCHSs would provide integrated and collaborative healthcare, improving health outcomes for First Nations peoples and suggested that the IPAC study results potentially underreported the benefits due to the short duration of the study.

Stakeholders also agreed that funding programs currently available to First Nations peoples such as the IHSPS, WIP- Practice Stream, Medical Outreach for Indigenous Chronic Disease Program (MOICDP) and Primary Health Networks – Integrated Team Care were inadequate to support continued funding for an integrated pharmacist. Most of these programs were already being used to support services from other allied health professions or for other quality use of medicine (QUM) activities, leaving little or no funds for an integrated pharmacist. Additionally, other allied health professionals were eligible to claim MBS services, often used to supplement funding for other services in these ACCHSs, while this was not possible with a pharmacist. Many ACCHSs needed to use a variety of funding sources to fund an integrated pharmacist creating a lot of administrative burden and potential income loss for the ACCHS, making the prospect of continuing service untenable.

Barriers and enablers to implementation were discussed with key issues being adequate ongoing funding, workforce and support mechanisms.

#### MSAC review of Medication Management Review (MMR) Programs

In 2017, MSAC appraised the evidence for Medication Management Review Programs: Home Medicines Review (HMRs), Residential Medication Management Review (RMMR), MedsCheck and Diabetes MedsCheck programs. MSAC advised that there was insufficient evidence to determine the clinical and cost-effectiveness of the continuing 6CPA MMR programs, and thus a weak basis upon which to recommend that funding should be supported or ceased. MSAC advised that further research would be required to make a more robust assessment of the comparative clinical and cost-effectiveness of the MMR programs. With respect to HMRs, MSAC advised that there is no clear evidence that HMRs reduce hospitalisations and mortality or improves quality of life. MSAC also advised that there is low level of evidence to suggest that HMRs increased time to next hospitalisation, although the evidence on the effect of HMRs on reduction in health care resource use is conflicting. There is also insufficient evidence to assess patient satisfaction with pharmacist led HMRs. MSAC considered that the design and value of these pharmacy service programs could be improved by including formal collaboration with GPs and other healthcare networks, by being targeted to more appropriate patient populations, and by a reduction in the unit cost of providing each type of pharmacy service coupled with an incentive to increase this unit cost if adequate new evidence can be furnished to justify an increase. Further enhancement of these programs might better justify the provision of continued funding of these services.

The Department did not implement changes to these programs as a result of MSAC's 2017 review. A number of expansions to HMR and RMMR were implemented in April 2020, but not as a result of the MSAC review.

#### **Current funded programs to improve medicines use**

The Department funds the following programs under the Seventh Community Pharmacy Agreement (7CPA) to improve medicines use. These are summarised in Table 2.

Table 2 Summary of pharmacy programs under 7CPA aimed at improving use of medicines

Co	mponent	Reimbursement
	me Medicines Review (HMR)	
	Medication review service provided at patient's home. Initial service includes HMR Interview (at patient's home) with patient and Accredited Pharmacist, HMR Report to referrer and GP (if GP not the referrer). Referral from GP Specialist in Pain Medicine, Specialist Physician, Specialist Psychiatrist or Specialist in Palliative Medicine that confirms identifiable clinical need for a HMR Service. Patient at risk of, or experiencing, medication misadventure Patient must live in a community setting May include up to two follow-up services provided within one to nine months of initial interview.	HMR service provider First service \$222.77 First follow-up: \$111.39 Second follow-up: \$55.70 Rural/remote loading up to \$125 Maximum 30 claims per month per service provider GP referrers: MBS item 900: \$163.70 benefit (once per year unless significant change in patient condition or medication regimen) Other medical practitioners: MBS item 245: \$130.95 benefit
Ме	dsCheck	
	Medication review provided at a community pharmacy (note referral required)  Patient using >= 5 prescription medicines or has had a signification medical event or taking a medication associated with a high risk of adverse events  Patient must live in a community setting  Patient has not received a similar service in previous 12 months	\$66.53 (once per 12 months)  Maximum 20 MedsCheck and Diabetes  MedsCheck Services per pharmacy per  month.
Dia	betes MedsCheck	
	Medication review focussed on management of type 2 diabetes provided at a community pharmacy (no referral required). May include aim to improve use of self-monitoring devices  Patient using >= 5 prescription medicines or has had a signification medical event or taking a medication associated with a high risk of adverse events  Patient must live in a community setting  Patient has not received a similar service in previous 12 months	\$99.97 (once per 12 months)  Maximum 20 MedsCheck and Diabetes  MedsCheck Services per pharmacy per  month.
Re	sidential Medication Management Review (RMMR)	
	Medication review provided to patient residing in a residential aged care facility. Includes initial face-to-face interview with patient. Initial services includes patient interview, assessment and report to referrer.  May include up to two follow-up services provided within one to nine months of initial interview.  Referral from GP Specialist in Pain Medicine, Specialist Physician, Specialist Psychiatrist or Specialist in Palliative Medicine that confirms identifiable clinical need for the service  Patient at risk of, or experiencing, medication misadventure.  Patient must be a resident of an aged care facility or other eligible residential facilities.	HMR service provider First service \$112.65 First follow-up: \$56.33 Second follow-up: \$28.16 Maximum 30 claims per month per service provider GP referrers: MBS item 903: \$112.05 benefit (once per year unless significant change in patient condition or medication regimen) Other medical practitioners:

Component	Reimbursement
Indigenous Health Services Pharmacy Support (IHSPS)	
<ul> <li>Supports services provided by Indigenous Health Services (IHS) and Service Providers that contribute to the improvement of Quality Use of Medicines and health outcomes for Aboriginal and Torres Strait Islander people.</li> </ul>	Not applicable.
<ul> <li>Types of support include Pharmacist Support, devices for patient's personal use to help manage medication for chronic disease (e.g. asthma spacer), education for IHS employees and clients, patient transport (IHS only)</li> </ul>	
Quality Use of Medicines (QUM) Program (for aged care facilities)	
<ul> <li>Aim to support Quality Use of Medicines services that are designed to reduce adverse events and associated hospital admissions or medical presentations. Target population is residents of approved Australian Government-funded Aged Care Facilities.</li> </ul>	Payments are provided as a base annual amount plus an additional amount per eligible aged care bed within the aged care facility.
<ul> <li>Types of funded services that can be provided under this program include (but are not limited to) medication advisory activities, education activities, continuous improvement activities.</li> <li>No set requirements on the type and frequency of services (but must be documented in service agreement with aged care facility)</li> </ul>	An external review <sup>2</sup> was commissioned by the Department to assess the effectiveness of this program. The review acknowledged the national reach of the QUM program with services being utilised by facilities of all sizes and to the full extent of socio-economic status indicating that the design and implementation has been appropriate and fit-for-purpose in relation to geography, Socio-Economic Indexes for Areas (SEIFA) and Residential Aged Care Facility (RACF) sizes  However, this review also found that the measure in its current form is not designed to capture data on program outcomes, which made quantifying the effectiveness of the program including the impact of service delivery impossible.

Source: MBS Schedule (accessed 5 February 2023), Pharmacy Programs Administrator (<u>Home Medicines Review</u>, <u>MedsCheck and Diabetes MedsCheck; Residential Medication Management Review and Quality Use of Medicines</u>; <u>Indigenous Health Services Pharmacy Support Program</u>;).

 ${\tt 2} \ \underline{\sf https://www.pbs.gov.au/general/sixth-cpa-pages/cpp-files/QUM-Evaluation-Final-Report.PDF}$ 

MMR programs are currently funded under the 7CPA in a largely similar manner to the 6CPA. The following changes were made in response to the Interim Report of the Royal Commission into Aged Care Safety and Quality:

- allowing up to two remunerated follow-up HMR or RMMR services within nine months of the initial patient interview<sup>3</sup>
- patients can be referred by other medical practitioners (not just GPs), However, only GPs are able to claim MBS Item 900/903.

Table 3 presents utilisation and expenditure data on the programs aimed at improving medicines use.

Table 3 Utilisation and expenditure on medication management review programs

Component	Services	Expenditure						
Home Medicines Review Program								
2020-21	119,420	\$23,858,714						
2021-22	118,960	\$22,764,443						
2022-23 (July to December)	79,891	\$14,732,760						
Residential Medication Management	Review Program							
2020-21	129,269	\$13,189,034						
2021-22	146,430	\$14,557,878						
2022-23 (July to December)	80,010	\$7,857,906						
Quality Use of Medicines Program								
2020-21	Not applicable.	\$11,084,434						
2021-22	Approximately 191,000 aged care	\$11,483,595						
2022-23 (July to December)	residents (2021)	\$5,694,451						
MedsCheck/Diabetes MedsCheck								
2020-21	539,088	\$40,406,845						
2021-22	537,720	\$40,714,619						
2022-23 (July to December)	296,938	\$22,762,893						
Indigenous Health Services Pharmacy Support								
2021-22 to 2025-26	Not applicable. Indigenous— specific primary health care organisations provided care to 586,000 clients in 2021-222	\$20 million over 4 years (\$4,000,0000 per year)						

Source: Seventh Community Pharmacy Agreement (7CPA) – Pharmacy programs data, updated 1 February 2023. Australian Institute of Health and Welfare – People using Aged Care. Aboriginal and Torres Strait Islander specific primary health care: results from the nKPI and OSR collections (updated January 2023).

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<sup>&</sup>lt;sup>3</sup> https://www.ppaonline.com.au/hmr-rmmr-program-changes

It is important to note that the above medication management programs currently exist under the umbrella of a (time limited) Community Pharmacy Agreement (CPA). In addition to the above programs, the government has committed \$345.7 million<sup>4</sup> for the new Aged Care on-site pharmacist measure intending to embed pharmacists in residential aged care homes to improve medication management and safety.<sup>5</sup>

# 5. Prerequisites to implementation of any funding advice

Pharmacists employed within ACCHSs require experience and training consistent with those required to be a general practice pharmacist.

Pharmacists participating in the IPAC project were required to have at least 2 years post-registration experience along with a post-graduate clinical qualification or demonstration of clinical experience (e.g., hospital or HMRs). The ADAR did not specify a requirement for pharmacists to have cultural awareness training to be eligible for the proposed IPAC funding. However, cultural awareness training was provided for all pharmacists who participated in the IPAC trial.

Though not mandated by the ADAR, pharmacists intending to practice in general practice or ACCHs, needed to undertake training such as the General Practice Pharmacist Foundation Training course (see <u>General Practice Pharmacist Training</u>) in addition to training specific to working in ACCHs. An Aboriginal Health Service Pharmacist Foundation Training Course titled "Deadly Pharmacists" was co-designed by PSA and NACCHO after the completion of the IPAC study, building on learnings from the IPAC study, along with further stakeholder consultation and review of literature. The ADAR did not mandate additional qualifications such as HMR accreditation for the IPAC pharmacists, though this was considered a desirable qualification.

The Department proposes that all IPAC pharmacists undertake the PSA's Deadly Pharmacists Foundation training course. While accreditation to perform medication management reviews is ideal, inclusion of this as a prerequisite could pose a risk to engaging an NDP. The Department proposes that services that engage non-accredited NDPs should support them to complete their accreditation training.

The proposal for funding presented in the ADAR was limited to ACCHSs who met the following criteria:

- employ at least 1 FTE GP who is eligible to prescribe medicines to patients of that organisation
- participate in continuing quality improvement and reporting on the national Key
   Performance Indicators through the use of electronic data extraction tools;
- use an electronic clinical information system
- provide the integrated pharmacist access to a private consulting room on the clinic premises that has access to the clinical information system, and
- are an accredited practice in accordance with the Royal Australian College of General Practitioners Practice Standards.

<sup>&</sup>lt;sup>4</sup> <a href="https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/on-site-pharmacists-to-improve-medication-management-in-racfs">https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/on-site-pharmacists-to-improve-medication-management-in-racfs</a>

https://consultations.health.gov.au/aged-care-division/aged-care-on-site-pharmacists/supporting\_documents/Aged%20care%20onsite%20pharmacists%20consultation%20paper%20%20July%202 022.pdf

The Department's proposed funding models do not limit funding based on the aforementioned criteria, although it would be reasonable to consider that all the above criteria, with the exception of the first (relating to the level of GP engagement) are relevant. This is in keeping with the Strengthening Medicare Taskforce Report – December 2022 recommendation that new funding models developed to support increased access to primary care should not disadvantage people who live in communities with little or no access to regular GP care.

# 6. Proposal for public funding

The proposed service involves the integration of a non-dispensing pharmacist in the primary health care team of Aboriginal Community Controlled Health Services (ACCHSs) to provide care to Aboriginal and/or Torres Strait Islander patients, with chronic disease. The NDP would provide both patient- and practice- related activities, including:

- medication reviews and supporting medication adherence for patients
- delivering preventative and transitional care
- medicines information and education to both patients and healthcare teams
- collaborating with healthcare teams
- liaising with external healthcare providers such as community pharmacy, and
- undertaking quality improvement activities such as drug utilisation reviews.

The ADAR proposed a baseline block funding over five years, plus pro-rata fee-for-service public funding (depending on the health service client load and episodes of care) for a non-dispensing pharmacist (NDP) within ACCHs to provide these services in an integrated model of care.

The total funding requested by the applicant was \$13,316,142 in Year 1, decreasing to \$12,851,292 in Year 5. The proposed funding included salary of the non-dispensing pharmacist, program establishment and support/administrative costs, pharmacists support and program monitoring and evaluation. The Applicant's proposal estimates costs at approximately \$83,823 per participating ACCHS variable according to practice size. Pharmacist costs have been estimated against FTE pharmacist salaries of \$151,618 (including on-costs).

The proposed new service is not seeking MBS item funding.

The ADAR only proposed funding for NDPs for ACCHSs, therefore the ADAR has only costed for 147 services. However, there are a number of non-ACCHS AHSs that support First Nations people in accessing healthcare. e.g. the Northern Territory Department of Health operates 49 AHSs in the NT.

In keeping with Commonwealth policy regarding access to programs for First Nations people, the Department proposes that eligibility for IPAC is aligned with the eligibility for the IHSPS<sup>6</sup>.

A service would be eligible for IPAC if:

- it is funded by the Department of Health and Aged Care's First Nations Health Division for the provision of primary healthcare services to First Nations people, OR
- approved to participate in the s100 Remote Area Aboriginal Health Services (RAAHS) program.

Under the Department's proposal, the total services to be funded has increased significantly as shown in Table 4.

<sup>&</sup>lt;sup>6</sup> Program Rules: Indigenous Health Service Pharmacy Support <a href="https://www.ppaonline.com.au/wp-content/uploads/2022/04/IHSPS-Program-Rules-22-23.pdf">www.ppaonline.com.au/wp-content/uploads/2022/04/IHSPS-Program-Rules-22-23.pdf</a>

Table 4 Number of Services per Governance Model

Governance model	Number of services	Remoteness Classification (Modified Monash Model) <sup>7</sup>	Estimated services/episodes of care
ACCHSs	147	108 in MMM 3-7	3.6 million
AHS/AMS	53	52 in MMM 3-7	317,356
Non-AHS funded to provide primary care services to First Nations people*	33	18 in MMM 3-7#	184,275
Total	233§	178	

<sup>\*</sup> Includes local government, non-government health service other than an AHS, non-Government service other than a Health Service, state government health service other than an AHS

A comparison of the funding models proposed by the applicant and the Department has been provided in Table 5.

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<sup>#</sup> Service may have clinical sites situated in MMM areas ranging from 1-7

<sup>§</sup> This is inclusive of services showing zero client numbers.

<sup>&</sup>lt;sup>7</sup> MMM1 Metropolitan areas; MMM2 Regional Centres; MMM3 Large rural towns; MMM4 Medium rural towns; MMM5 Small rural towns; MMM6 Remote communities; MMM7 Very remote communities

Table 5 Comparison of Proposed Funding Models

Characteristic	Applicant's Model	Department's Proposed model
Funding	<ul> <li>Proposed full-time pharmacist salary of \$151,618 including on-costs.</li> <li>FTE – baseline 0.2 FTE pharmacist/ACCHS. Additional proportional FTE based on 1 FTE pharmacist per 8,295 clients (IPAC trial methodology).</li> <li>Model has not included non-ACCHS AHSs, such as those run by NT Government (NTG) to provide healthcare services to First Nations peoples.</li> <li>Remote loading applied as per WIP-PS model.</li> </ul>	<ul> <li>The Department proposes a salary of \$96,530 (rate for pharmacist grade 2 salary in 2019-2020, accounting for inflation estimated at 1.8% annually, per PPA report Community and Hospital Pharmacists Employment and Remuneration Report 2019-2020) with 17% oncosts (\$16,410). Therefore, the total provided per 1 FTE is \$112,940, which would be indexed annually.</li> <li>The Department proposes that a ratio of 6000 clients per 1 FTE with provisions for service providers unable to support 1 FTE as a sole provider to form a consortium to access 1 FTE pharmacist. This flexibility will support pharmacists to achieve full-time employment.</li> <li>The Department proposes that all NTG AHSs are considered as a single consortium and allocated FTE in relation to the total active population across all services. This has been discussed with NTG who have proposed a hub and spoke model based on the population, geographical location, and health needs of current NTG health centres. The hub and spoke model would enable a pharmacist to be based within a larger remote health centre but adequately provide NDP services to smaller surrounding communities. NTG have proposed an allocation of 10 FTE across all NTG services to support the proposed model.</li> <li>Remote loading applied as per WIP-PS model.</li> </ul>
Population criteria	Aboriginal and Torres Strait Islander people with chronic disease (eg: cardiovascular disease, type 2 diabetes, chronic kidney disease) who are known as 'active' or 'regular' patients receiving services within ACCHSs (at least three times in the past two years).	Regular patients of a ACCHS who are at risk of developing medication-related problems due to: <ul> <li>a chronic medical condition, or</li> <li>a complex medication regimen</li> </ul> who require review and assessment of their medication management and follow-up support.
Health service	<ul> <li>ACCHOs funded by the Department of Health and Aged Care for provision of primary healthcare services to First Nation peoples</li> <li>Member of NACCHO and relevant NACCHO State/Territory Affiliate</li> <li>Be an RACGP accredited practice employing at least 1 full time equivalent GP/clinic.</li> </ul>	A service will be eligible for IPAC if:  It is funded by the Department of Health and Aged Care's First Nations Health Division for the provision of primary healthcare services to First Nations people OR  Approved to participate in the s100 Remote Area Aboriginal Health Services (RAAHS) program.

# **Department's Proposed Model - Alternative Model Options**

Based on the Department's proposed model, three different funding options have been proposed for MSAC consideration. Model 1 proposes funding to all ACCHs as given in Table 6, without any restrictions based on GP FTE numbers.

Models 2 and 3 limit funding to those clinics with at least 1 FTE GP. Model 3 adopts the higher Pharmacist: Patient ratio proposed in the ADAR model.

Table 6 Summary of proposed models

Component	ADAR	Department model 1	Department model 2	Department model 3
Pharmacist FTE: client ratio	1:8,295	1:6,000	1:6,000	1:8,295
Minimum pharmacist FTE 0.2		Minimum 0.2 FTE Minimum 1 FTE pharmacist for clinics in remote areas (MMM 6 and 7) NT Govt consortium of 10 FTE across all clinics Option to develop consortiums a	Minimum 0.2 FTE Minimum 1 FTE for clinics in remote areas (MMM 6 and 7) NT Govt consortium of 10 FTE across all clinics Option to develop consortiums a	Minimum 0.2 FTE Minimum 1 FTE for clinics in remote areas (MMM 6 and 7) NT Govt consortium of 10 FTE across all clinics Option to develop consortiums a
Pharmacist salary	\$151,618 b	\$112,940 °	\$112,940 °	\$112,940 °
FTE pharmacists funded	77.4	130 (+10 for NT consortium)	101.3 (+10 for NT consortium)	82.9 (+10 for NT consortium)
Health services funded	140	229 d	171 <sup>d</sup>	171 d
Health service eligibi	lity			
Is funded by the Department of Health and Aged Care's First Nations Health Division for the provision of primary healthcare services to First Nations people		Yes	Yes	Yes
The health service is required to be a member of NACCHO and relevant NACCHO State/Territory Affiliate	s required to be a nember of No		No	No
Minimum GP FTE	≥1	Not applicable	≥1	≥1
RACGP accredited practice	Yes	No	No	No
Eligible for CTG PBS co-payment	Yes	Yes	Yes	Yes

measure or s100 PBS supply in remote areas				
Private consulting room	Yes	Yes	Yes	Yes
Eligible to claim HMRs and MedsCheckse	Yes	No	No	No
Overlap with IHSPS	Not Applicable	Yes	Yes	Yes
Program administration	Not specified	NACCHO (preferred) or other administrator	NACCHO (preferred) or other administrator	NACCHO (preferred) or other administrator

Source: Compiled from the ADAR and developed by the Department.

ADAR = applicant developed assessment report; FTE = full time equivalent; GP = general practitioner; HMR = Home Medicines Review; IHSPS = Indigenous Health Services Pharmacy Support; MMM = Modified Monash Model remoteness classification. NACCHO = National Aboriginal Community Controlled Health Organisation; PBS = Pharmaceutical Benefits Scheme

- <sup>a</sup> Clinics have the option to develop consortiums, therefore all clinics are included in the financial estimates for uptake.
- <sup>b</sup> The ADAR base salary was \$125,000 inclusive of oncosts, with the \$151,618 reflecting the average salary inclusive of rurality loadings.
- c Includes on-costs. Department proposed salary of rate for pharmacist grade 2 salary in 2019-2020, accounting for inflation estimated at 1.8% annually, per PPA report Community and Hospital Pharmacists Employment and Remuneration Report 2019-20202) with 17% oncosts (\$16,410).
- <sup>d</sup> Includes 49 health services funded by the Northern Territory Government.
- e Current HMR program rules would not exclude an IPAC salaried pharmacist from claiming under this service, such that program rules would be amended accordingly under the Department's proposed models

# 7. Population

The burden of disease among Aboriginal and Torres Strait Islander people is 2.3 times that of non-Indigenous Australians, with mental health and other chronic diseases being particular areas of concern<sup>8</sup>. The National Aboriginal and Torres Strait Islander Health Survey 2018-19, reported that 46% of Aboriginal and Torres Strait Islander people have at least one chronic condition that posed a significant health problem. This proportion was higher for people living in non-remote areas (48%) than in remote areas (33%). While 93% of Aboriginal and Torres Strait Islander people with chronic conditions had a GP consult in the last 12 months, more than 1 in 10 people (13%) who needed to see a GP, did not.

The ADAR estimated that 2.6% of Aboriginal and Torres Strait Islander people with chronic disease attending ACCHCs would access an integrated pharmacist for medicines management (approximately 11,000 people) based on data for the total number of regular clients accessing ACCHs available from AIHW statistics.

The integrated pharmacist intervention has core roles that include patient-related activities and staff and service-level activities. Therefore, the target population has a clinical patient component and a practice-level component.

The proposed clinical population in the ADAR is Aboriginal and Torres Strait Islander peoples with chronic disease who are 'active' or 'regular' patients of the service (at least three times in the past two years) with a diagnosis of cardiovascular disease, type 2 diabetes mellitus, chronic kidney disease or other chronic conditions and at high risk of developing medication-related problems. The IPAC participants were representative of the proposed population, and were usual

 $^8\ https://www.indigenoushpf.gov.au/getattachment/65fbaaf3-100c-4df5-941c-a8455922693c/2020-summary-ihpf-2.pdf$ 

patients accessing ACCHSs, and the intervention was tested within usual clinical settings involving the ACCHS sector.

The outcomes from the intervention were found to be generalisable to the broader Aboriginal and Torres Strait Islander patient population who are at risk of developing medication related problems and attending ACCHSs in urban, rural and remote geographical locations.

In light of these findings, the Department proposes that regular patients of a ACCHS who are at risk of developing medication-related problems due to a chronic medical condition, or a complex medication regimen, and who require review and assessment of their medication management and follow-up support, be the target clinical population for the integrated pharmacist intervention.

# 8. Comparator

Unchanged from the previous consideration, the nominated comparator is usual care. This was as usual primary healthcare service provision to Aboriginal and Torres Strait Islander peoples without the presence of an integrated pharmacist within the health service. Usual care varies across ACCHSs in the provision of medication adherence support via community pharmacy and medication management reviews via community pharmacies or directly from independent accredited pharmacists with delivery and content strictly guided by program rules.

An option to implement IPAC within the Workforce Incentive Program – Practice Stream (WIP-PS) was not provided to stakeholders for the 10 October 2022 stakeholder meeting. However, stakeholders discussed the applicability of WIP's established method for calculating rural loading. The Department is proposing to utilise this method of calculating rural loading, which was also proposed in the ADAR (Appendix 17 to the ADAR). The current WIP-PS rural loadings are 20% in MMM3, 30% in MMM4 and MMM5, 50% for MMM6 and MMM7.

The relevant Division in the Department of Health and Aged Care responsible for the WIP – Practice Stream Program has indicated that implementation of IPAC through WIP is <u>not</u> supported due to limited evidence, cost and timeframes for implementation through Services Australia, and will therefore not be recommended to MSAC as a viable option. Future changes to the WIP should be considered as a part of the Strengthening Medicare Taskforce incentives review.

# 9. Summary of public consultation input

In December 2022, further stakeholder meetings were held with the Department of Health and Aged Care to inform MSAC's future deliberations and advice to the Minister for Health and Aged Care on stakeholder views of implementation models developed for MSAC Application 1678. A summary of stakeholders' views against each option is presented below:

#### Option 1 - National Aboriginal Community Controlled Health Organisation (NACCHO)

This was the preferred option for all stakeholders.

It was agreed by participants that NACCHO is recognised as having broad superior knowledge, engagement and expertise in working with First Nations people.

NACCHO is considered to have the strongest on the ground experience and interest in progressing the health needs of this consumer group.

In addition to NACCHO's ability to leverage off existing NT Government and/or PSA for training and mentoring resources, NACCHO will be able to collaborate with regional services for

implementation, and has confirmed that it is willing to provide service delivery to non-AHS organisations

Concerns raised for the NACCHO option were a need to ensure that NACCHO has the administrative, financial and clinical capacity for reporting and evaluation activities. NACCHO advice noted that NACCHO Affiliates not recommended to form consortia in isolation as limited experience with medicines policy

#### Option 2 - Pharmacy Programs Administrator (PPA)

Stakeholders did not support the PPA option.

Stakeholders acknowledged PPA's experience in administering programs in the pharmacy sector and noted its strong capacity for managing claims disbursement and service reporting.

Concerns were raised in relation to the large administrative burden with little value-add, especially in remote areas. PPA was considered to have minimal understanding of complexities of health needs of First Nation populations, their regional needs or community-controlled practices on the ground. Stakeholders also expressed reservations about PPA's ability to conduct an evaluation of client health outcomes vs health service delivery.

#### Option 3 - Primary Health Networks

Stakeholders did not support the PHN option.

Views expressed that there are variable levels of support across PHNs nationally, with minimum value for very high administrative burden of program establishment and ongoing management

It was considered that implementation of IPAC through 31 PHNs may lead to fragmented or uneven service delivery. Although PHNs support Closing the Gap priorities, stakeholders felt there is still potential for many gaps on the ground

PPA was not considered to have capacity, knowledge or cultural expertise to run a community-controlled program or 'grow' the sector and may not have appropriate capacity to engage with relevant First Nations groups. PPA was considered to generally have a more 'urban' approach – may lead to some communities being disadvantaged

For information:

#### Option 4 - Workforce Incentive Program - Practice Incentive

This option was not provided to stakeholders for the December meetings as the relevant Division in the Department of Health and Aged Care responsible for the WIP – Practice Stream Program has indicated that implementation of IPAC through WIP is not supported.

#### 10. Characteristics of the evidence base

Unchanged from the previous MSAC consideration, the evidence base is the IPAC study, a non-randomised, prospective, pre and post quasi-experimental community-based, participatory, and pragmatic trial that integrated a registered pharmacist within an ACCHS primary healthcare team for up to a 15-month period.

MSAC previously considered further information was needed to assess the clinical significance of the magnitude of change in biomedical markers. MSAC considered a comparison of biomedical outcomes that MSAC and the Pharmaceutical Benefits Advisory Committee (PBAC) have previously considered clinically meaningful could inform this assessment. MSAC considered that changes not considered clinically significant in other contexts (such as rigorously controlled pharmaceutical trials) may be significant in this context. MSAC considered changes in HbA1c also need to be considered in the context of baseline levels in IPAC participants.

The MSAC Executive considered the Minimal Clinically Important Differences (MCIDs) of the biomedical outcomes at its September 2022 meeting.

An assessment of the qualitative assessment is presented in Section 13. Other relevant information.

# **11**. Comparative safety

Unchanged from the previous MSAC consideration, the IPAC study did not report any safety outcomes. It is likely that the intervention will be at least non-inferior to usual care.

# 12. Comparative effectiveness

Table 7 presents the glycated haemoglobin outcomes in the IPAC study. The ADAR reported the proportion of participants who attained a 0.5% reduction in HbA1c for all participants with T2DM (n=997) and participants with paired data (n=539). The study did not report the change in proportion of patients with HbA1c of  $\leq$ 6.5%, <7% or 7.0-8.0% at baseline and follow-up.

Table 7: T2DM outcomes (at 284 days median follow-up)

0.1	N	Baselin	Baseline Follow-up		Mean difference		
Outcome		Mean	SD	Mean	SD	Mean (95% CI)	p-value
ΔHbA1c (%)	539	8.3%	5.5%	8.0%	5.8%	-0.3% (-0.4%, -0.1%)	0.001 a
HBA1c response (≥ 0.5% reduction)	N	n/N				Incremental difference	
	539	200				37.1%	Not
	997	200				20%	applicable

Source: Compiled from p18, Appendix 9 and Table 7, p16 of Appendix 25 (version 2, 2021) of the IPAC trial report ACCHS = Aboriginal Community Controlled Health Service; CI = confidence interval; HbA1c = glycated haemoglobin; SD = standard deviation; Δ = change in

The Department reviewed PBAC Public Summary Documents (PSDs) for medications treating T2DM from 2014 to mid-2022, including the Post-Market Review of Type 2 Diabetes Medicines9. The PBAC has typically considered a non-inferiority margin of 0.3-0.4% for HbA1c to be acceptable in the context of non-inferiority claims but has not accepted an MCID for superiority claims. In its November 2019 consideration of semaglutide for T2DM, the PBAC considered there was insufficient evidence to accept the clinical claim of superiority for semaglutide over dulaglutide based on change in HbA1c (and other outcomes) (paragraph 7.10). The PBAC also considered a 0.5% reduction in HbA1c was more relevant for the superiority claim than the 0.3% proposed by the submission (paragraph 7.5). Based on this evidence, the IPAC study may not be considered to have demonstrated a clinically meaningful improvement in the single outcome of HbA1c.The MSAC Application 1678 ADAR noted the UK Prospective Diabetes Study (UKPDS) considered any improvement in HbA1c in those with T2DM reduced the risk of diabetes complications, with little evidence of a threshold of effect. Additionally, the ADAR considered the IPAC population differed from the UKPDS population as the IPAC population had a higher body mass index, a lack of baseline glycaemic control, a higher prevalence of macroalbuminuria and cardiovascular disease at baseline. The ADAR considered that this made the IPAC population

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<sup>&</sup>lt;sup>a</sup> P-value (paired data) was derived from the cluster-adjusted (ACCHS cluster) comparison of HbA1c differences against zero

<sup>&</sup>lt;sup>9</sup> Accessible at: https://www.pbs.gov.au/info/reviews/diabetes# Final-Report-Stage-3

more similar to the participants in the ACCORD study which did not support intensive therapy to target normal HbA1c (below 6.0%).

The MSAC Executive noted the difficulty in comparing the IPAC study to other existing studies due to differences in baseline HbA1c (8.3% in the IPAC study). The MSAC Executive considered larger reductions in HbA1c could be achieved in patients with higher baseline HbA1c. The MSAC Executive considered the participants in Clifford (2005)<sup>10</sup> differed from IPAC participants as participants in the pharmaceutical care arm had baseline HbA1c of 7.5% (95% CI: 6.9, 8.1) and experienced a HbA1c change of -0.5% (95% CI: -0.7, -0.3).

The ADAR reported the change in estimated Glomerular Filtration Rate (eGFR) observed in the IPAC study as being better than the predicted change in eGFR from the eGFR Follow-Up Study – a longitudinal study of Aboriginal and/or Torres Strait Islander peoples (Table 8). The ADAR statistically compared annualised differences in eGFR against a theoretically assumed value of 3 (ml/min/1.73 m $^2$ ) – the expected mean annual e-GFR (ml/min/1.73m $^2$ ) linear decline expected without the intervention.

The subgroup of the eGFR Follow-up Study with eGFR <60 mL/min/1.73m² experienced a greater decline in eGFR. The ADAR considered this group was similar to the IPAC participants. However, increasing 'length of stay' with IPAC intervention was associated with worsening of the eGFR.

Table 8: Comparison of eGFR outcomes (mL/min/1.73m<sup>2</sup>)

Outcome measure	N	Follow up	Baseline (SD or 95% CI)		Annualised change	p-value	Crude difference (95% CI)	
IPAC	IPAC							
IPAC eGFR (all participants)	895	296 days	49.1 (159.2)	48.4 (160.4)	1.9 (0.1 to 3.7) <sup>a</sup>	<0.001	-0.8 (-2.3 to 0.8)	
IPAC eGFR (≥ 6-month follow-up)	720	317 days	49.6 (140.6)	48.1 (145.4)	-0.2 (-2.99 to 2.7) a	0.034	-1.5 (-4.0 to 1.0)	
eGFR Follow-up Study	(com	parison in IF	PAC Final report)					
eGFR Follow-up (all participants)	550	3.01yrs	83.9 (80.7, 87.3)	70.1 (66.1, 74.5)	-3.0 (-3.6 to -2.5)	NA	NA	
eGFR Follow-up (eGFR <60 group)	85	NR	<60	NR	-5.0 (-6.5, -3.6)	NA	NA	

Source: Attachment C, Appendix 9, IPAC study report

eGFR = estimated Glomerular Filtration Rate; NA = not applicable, NR = not reported; yrs = years; Δ = change in <sup>a</sup> P-value (paired data) were derived from the cluster-adjusted (ACCHS cluster) comparison of annualised differences against -3, as this is equivalent to a paired t-test. The value of -3 is the expected mean annual eGFR (ml/min/1.73m²) linear decline in Aboriginal and Torres Strait Islander adults.

The MSAC Executive considered the reduction in eGFR from baseline would be lower based on the results reported. The MSAC Executive considered the comparison should be made with caution as the IPAC and eGFR Follow-Up Study were fundamentally different in design and may differ with respect to other patient characteristics (including use of renoprotective medicines). The applicant re-affirmed that the results of the IPAC study demonstrated change in eGFR in this study, albeit small, represented a slowing of the rate of decline of eGFR in a population which

<sup>10</sup> Clifford et al. "Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes: the Fremantle Diabetes Study." Diabetes care vol. 28,4 (2005): 771-6

has been reported to experience a significantly higher eGFR decline than the non-Indigenous population.

The IPAC study reported a 0.08 mmol/L (95% CI -0.13, -0.03) reduction in low density lipoprotein cholesterol (LDL-C). The ADAR considered that as 72% of participants were prescribed statins, further reductions in LDL-C may be difficult to achieve or clinically unnecessary (mean baseline LDL-C 2.35mmol/L). The PBAC noted the results of the Cholesterol Treatment Trialists' Collaboration individual patient data meta-analyses in the 2012 Review of Statin Therapies. The analyses confirmed that for statins, the degree of treatment benefit in clinical terms is related to the degree of LDL-C lowering, with the relative risk of major vascular events and major coronary events (relative risk per 1 mmol/L LDL-C reduction) being 0.76 (95% CI: 0.73-0.79). The analyses also showed that over the ranges of baseline LDL-C and LDL-C reductions observed in the trials, this relationship was consistent in patients with and without a history of cardiovascular disease, baseline level of risk and baseline cholesterol levels.

The mean calculated absolute 5-year CVD risk was significantly reduced by 1% (95% CI: -1.8% to -0.12%, p=0.027). CVD risk as calculated using the National Vascular Disease Prevention Alliance (NVDPA) absolute cardiovascular disease risk tool which is based on the 1991 Framingham Risk Equation. Notwithstanding limitations of the Framingham risk equations, the MSAC Executive considered that this represented a very small potential benefit and could reflect the uncertainty of the clinical benefits that would be achieved from implementing the IPAC program.

The IPAC study reported a 23.9% increase in the proportion of participants with 'very good to excellent' self-assessed health status. The IPAC study also reported improvements in prescribing quality.

After considering, the changes in glycated haemoglobin (HbA1c), estimated glomerular filtration rate (eGFR), and 5-year cardiovascular risk, the MSAC Executive considered that the additional information provided on individual biomedical outcomes did not demonstrate a clinically meaningful difference compared with usual care for the purposes of performing a cost-effectiveness analysis. The MSAC Executive considered that in principle, the IPAC program would not contribute to further harm and may provide benefit, especially in what may be an underserved population that is known to have typically poorer health outcomes compared to the average Australian population.

MSAC agreed with the MSAC Executive that, after reviewing the additional information provided, the improvements in individual biomedical outcomes did not represent a clinically meaningful difference compared with usual care. Regarding comparative effectiveness overall, MSAC considered, when the improvements in biomedical outcomes and positive qualitative outcomes (Section 13) were considered together in conjunction with improvements in prescribing quality, medication adherence and self-rated health status (previously described in MSAC 1678 PSD), that the totality in improvements reflected an acceptable clinical outcome, compared to usual care, in an underserved population that is known to have typically poorer health outcomes compared to the broader Australian population.

#### 13. Economic evaluation

A cost-consequence analysis (CCA) was developed for the three models of implementation for the proposed IPAC program.

The MSAC Executive considered that the additional information provided on individual biomedical outcomes did not demonstrate a clinically meaningful difference compared with usual care for

the purposes of performing a cost-effectiveness analysis. The MSAC Executive agreed with the Department's proposal to proceed with a CCA to capture improvements across numerous outcomes which may better reflect the costs and outcomes of the IPAC program. Table 9 presents a summary of the CCA.

Table 9 Summary of the economic evaluation

Component	Description
Perspective	Health care system perspective
Population	Clients of eligible Indigenous-specific primary health organisations
Comparator	Usual care (including existing MMR programs)
Type of analysis	Cost consequence analysis
Outcomes	Biomedical outcomes: HbA1c, lipids, 5-year CVD risk, eGFR. Prescribing quality outcomes; Adherence outcomes; self-assessed health status.
Time horizon	1 year. Clinical outcomes extrapolated from 284 days (mean or median length of the follow-up of the study participants)

Abbreviations: BP = blood pressure; CVD = cardiovascular disease; eGFR = estimated glomerular filtration rate; HbA1C = glycosylated haemoglobin; LDL-C = low density lipoprotein cholesterol; MMR = Medication Management Review; TC = total cholesterol

#### The CCA made the following assumptions:

- There would be a 10% reduction in HMRs as 10% of IPAC study participants had received a HMR in the previous year based on MBS claims data for item 900 (ADAR Attachment 12, p17);
- GPs would refer all eligible patients (2.6% people accessing Indigenous-specific health services) to a medication management review and claim MBS item 900 (medication review). This would result in a net 90% increase in claims for MBS item 900 as this was only being provided to 10% of the eligible population;
- GP time spent receiving medication advice was not included in the CCA for the
  Departmental models as this should be captured by MBS item 900 which covers the full
  episode of care from referral to development of a written medication management plan
  following the medication review and discussion with the patient;
- Integrated pharmacists cannot claim reimbursement for HMRs;
- GPs save 0.94 hours per patient at cost of \$86.80 per hour. This was based on estimates used in the ADAR (Table 4, Appendix 25; Table 2, Appendix 25 of the ADAR).

The estimated proportion of patients (2.6%) is likely an underestimate of the proportion of clients of Indigenous-specific health services that may receive services from an integrated pharmacist. The 2018-19 National Aboriginal and Torres Strait Islander Health Survey estimated that 67% of Aboriginal and Torres Strait Islander people had a current long term health condition. Although not all long-term health conditions are managed using medicines, the survey estimated the proportion of persons with the following conditions that are typically managed using medicines:

- 7.9% had diabetes mellitus
- 4.5% had elevated cholesterol
- 5.2% had heart, stroke and vascular disease
- 8.3% had hypertension, and
- 15.7% had asthma.

Therefore, the applicant's estimate that only 2.6% of patients would be eligible is likely an underestimate.

Table 10 Cost of the proposed implementation models

Parameter	Department Model 1	Department Model 2	Department Model 3	ADAR (trial based)
Direct costs	Model 1	Wiodel 2	Wiodei 3	(tilai baseu)
Health services funded	229	171	171	140
Pharmacist FTE	140	111	93	77.4
Pharmacist salary	\$20,408,258	\$16,062,327	\$13,712,045	\$11,800,000 (trial based)
Eligible patients	15,594	14,227 14,227		1,456 (trial-based) 11,000 (full program)
Pharmacist allowances	Not included	Not included	Not included	\$136,658
Out-of-pocket pharmacists' payments	Not included	Not included	Not included	\$9,741
Pharmacist training	Not included	Not included	Not included	\$64,820
Cost of ACCHS support for integrated pharmacist	Not included	Not included	Not included	\$52,158
Cost per patient (direct costs)	\$1,309	\$1,129	\$964	Not calculated
Changes in health resource use				
Reduction in HMR <sup>a</sup> (10% of patients)	-\$391,600	-\$357,294	-\$357,294	\$206,559 b
Changes in GP referral for medication review (90% of patients)	\$1,837,775	\$1,676,774	\$1,676,774	-
GP time spent receiving medication advice	Not applicable	Not applicable	Not applicable	\$62,420
Increased cost of PBS medicines	\$5,925,982	\$5,406,828	\$5,406,828	\$553,849
GP time saved (0.94 hours per patient)	-\$1,269,853	-\$1,158,606	-\$1,158,606	_ c
Cost per patient	\$1,703	\$1,523	\$1,358	\$1,525

Source: Calculated for the Departmental Overview; Table 4, p28 MSAC Application 1678 Public Summary Document. Revised CCA spreadsheet.

Abbreviations: ACCHS – Aboriginal Community Controlled Health Service: ADAR = applicant developed assessment report; CCA = cost-consequence analysis; GP = general practitioner; HMR = Home Medicines Review

Table 11 presents the results of the revised cost consequence analysis.

<sup>&</sup>lt;sup>a</sup> Changes in HMR costs are not fully comparable between the Departmental models and the revised ADAR CCA previously considered by MSAC. The CCA for the Departmental models estimated reduced HMR costs for the 10% of the eligible population estimated to currently use HMRs at a cost of \$251.13 per patient.

<sup>&</sup>lt;sup>b</sup> This cost included costs for MBS 900 and HMR fees for pharmacists, additional costs for medication reviews where MBS 900 was not claimed, medication review follow-up (not publicly funded under the HMR program at the time of ADAR development).

c Included in the original ADAR but removed from the revised base case in the considered by MSAC.

Table 11 Cost-consequence analysis comparing mean incremental cost with changes in outcomes1

Parameter		p-value <sup>1</sup>							
Funding model	Model 1	Model 2	Model 3	ADAR					
Net cost (including cost offsets)	\$1,703	\$1,523	\$1,358	\$1,525 <sup>2</sup>	Not applicable				
Biomedical outcomes (change in mean (SD,	95% CI))				-				
HbA1c mmol/mol [% units] (n=539 in T2DM)		-2.8 (19.5,	-4.5 to -1.0)		0.001				
DBP, mmHg (n=1045)			-1.4 to -0.2)		0.008				
TC, mmol/L (n=660)		-0	0.15 22 to -0.09)		<0.001				
LDL-C mmol/L (n=575)		-0	0.08 3 to -0.03)		0.001				
TG mmol/L (n=730)		-0	0.11 20 to -0.01)		0.006				
CVD 5-year risk % units (n=38)		-1.0 (2.6, -	1.8 to -0.12)		0.027				
eGFR (no minimum follow-up time) ml/min/1.73m² (n=895)		<0.001							
Prescribing quality									
Medication appropriateness index score per participant (relative change)		0.003							
Mean number of medications per participant with ≥1 inappropriateness rating (relative change)		0.001							
Participants with any medications that met ≥1 overuse criterion		<0.001							
Mean PPOs/participant (relative change))		190	).3%		<0.001				
Medication reviews		•							
Participants with HMR (%)		-							
Participants with non-HMR		-							
Adherence to medications									
Participants adherent (NMARS, absolute change)		<0.001							
Participants adherent (SIQ, absolute change)		<0.001							
Self-assessed health status									
Participants with 'very good to excellent' self- assessed health status (absolute change)		↑23.9%							

Source: Table 29, p120 of the ADAR and calculated by the Department

Abbreviations: BP = blood pressure; CVD = cardiovascular disease; DBP = diastolic blood pressure; eGFR = estimated glomerular filtration rate; HbA1C = glycosylated haemoglobin; HMR = Home Medicines Review; LDL-C = low density lipoprotein cholesterol; NMARS = NACCHO Medication Adherence Response Scale; PPO = potential prescribing omission; SIQ = single item question; TC = total cholesterol; TG = triglycerides; T2DM = type 2 diabetes mellitus

The estimated cost per patient was \$1,703 for Model 1, \$1,523 for Model 2, \$1,358 Model 3 and \$1,525 for the ADAR model. It is likely that the cost per patient would be lower in practice if the integrated pharmacist is able to achieve similar outcomes to the IPAC study in a larger group of patients. The current cost per patient was estimated based on the applicant's estimate that only 2.6% of patients would be eligible. Increasing the eligible population to 5% and 10% results in a substantial decrease in the per-patient cost of the intervention (Table 12).

<sup>1</sup> Data pertains to biomedical indices with mean difference that was statistically significant at the 0.05 level, as sourced from clinical endpoint analysis report (Appendix 9).

<sup>2</sup> Recalculated by the commentary, but does not correct for unaccounted methodological limitations

<sup>2</sup> Calculated by the commentary

Table 12: Sensitivity analysis

Parameter	Proposed funding model									
Funding model	Model 1	Model 2	Model 3	ADAR						
Base case (2.6% of patients eligible)										
Eligible patients	15,594	14,227	14,227	11,000 (full program)						
Cost per patient (direct costs)	\$1,309	\$1,129	\$964	Not calculated						
Net cost per patient (including cost offsets)	\$1,703	\$1,523	\$1,358	\$1,525						
Sensitivity analysis 1 (5% of patients eligib	le)									
Eligible patients	29,988	27,360	27,360	-						
Cost per patient (direct costs)	\$681	\$587	\$501	-						
Net cost per patient (including cost offsets)	\$1,075	\$981	\$895	-						
Sensitivity analysis 2 (10% of patients eligil	ole)									
Eligible patients	59,975	54,721	54,721	-						
Cost per patient (direct costs)	\$340	\$294	\$251	-						
Net cost per patient (including cost offsets)	\$734	\$688	\$645	-						

Source: Table 29, p120 of the ADAR and calculated by the Department

ADAR = Applicant Developed Assessment Report.

#### Comparison with other funding programs

#### Indigenous Australians' Health Programme

The Economic Evaluation of the Indigenous Australians' Health Programme (Dalton 2018) 11 analysed the costs of ACCHSs, reviewed the economic literature relating to the economic performance of ACCHSs, and examined the relationship between ACCHS care and hospitalisations, in particular whether ACCHSs provide a 'return on investment' by reducing the rate of hospitalisations in Aboriginal and Torres Strait Islander communities. It reported a strong correlation between ACCHS episodes of care and prevented hospitalisations, suggesting that care from ACCHSs yield savings from reduced hospitalisations. The report estimated that the cost of an episode of care was higher in ACCHSs than mainstream clinics. It cautioned against the interpretation that the lower cost of mainstream services would mean that they could provide health care to Aboriginal and Torres Strait Islander communities more efficiently. It concluded that the provision of this care through mainstream services may be cheaper but is likely to be associated with worse health outcomes for multiple reasons. This included a comprehensive integrated care model being acknowledged as the most effective approach for people with chronic conditions and complex care needs compared with mainstream services potentially providing care that does not meet cultural needs and expectations, resulting in poor engagement and adherence.

Dalton (2018) also reported on studies measuring the extent to which society is willing to trade overall health benefits to promote a more equitable distribution of health. It reported on equity weights for socioeconomically disadvantaged groups derived by Lal (2017)<sup>12</sup>. Equity weights derived using epidemiological data used burden of disease and mortality data by Socio-Economic

<sup>11</sup> Dalton et al (2018). Economic Evaluation of the Indigenous Australians' Health Programme Phase I. Available from <a href="https://www.health.gov.au/sites/default/files/documents/2020/12/economic-evaluation-of-the-indigenous-australians-health-programme-phase-i.pdf">https://www.health.gov.au/sites/default/files/documents/2020/12/economic-evaluation-of-the-indigenous-australians-health-programme-phase-i.pdf</a> [Accessed 8 February 2023].

<sup>&</sup>lt;sup>12</sup> Lal A, Mohebi M, Sweeney R, Moodie M, Peeters A, Carter R. Equity Weights for Socioeconomic Position: Two Methods-Survey of Stated Preferences and Epidemiological Data. *Value Health*. 2019;22(2):247-253.

Indexes for Areas quintiles from the AIHW. Two ratios were calculated comparing quintile 1 (lowest) to the total Australian population, and comparing quintile 1 to quintile 5 (highest). Preference-based weights were derived using a discrete choice experiment survey (n = 710). Respondents chose between two programs, with varying gains in life expectancy going to a low-or a high-income group. The epidemiological weights ranged from 1.2 to 1.5, with larger weights when quintile 5 was the denominator. The preference-based weights ranged from 1.3 (95% confidence interval 1.2-1.4) to 1.8 (95% confidence interval 1.6-2.0), with a tendency for increasing weights as the gains to the low-income group increased. Dalton (2018) considered if a program is not cost-effective yet improves equity, the weights could help decision-makers decide the level of concern for equity required for the program to be considered value-for-money.

#### Aged Care on-site pharmacists

The Aged Care on-site pharmacists measure provides \$345.7 million (including administration costs) in funding over 4 years to over four years to embed pharmacists in aged care homes. Similar to the potential IPAC Program, this funding is in addition to existing funding for aged care services. The appropriate cost per resident (operational place) was estimated as \$redacted (Table 13). This was lower than the estimated cost per patient for the IPAC program.

Table 13: Aged Care on-site pharmacists cost per resident (operational place)

Parameter	Proposed funding model								
Funding model	Year 1	Year 2	Year 3	Year 4					
Uptake	30%	60%	80%	80%					
Estimated proportion of funding <sup>a</sup>	12%	24%	32%	32%					
Estimated funding per year	\$41,484,000	\$82,968,000	\$110,624,000	\$110,624,000					
Aged care residents receiving pharmacist care b	redacted	redacted	redacted	redacted					
Cost per resident	\$redacted	\$redacted	\$redacted	\$redacted					

Source: Aged Care on-site pharmacist measure Consultation Paper (July 2022)

# 14. Financial impacts

Table 14 summarises the key inputs used to calculate in the budgetary impact of the proposed IPAC program. The financial estimates were largely calculated using data reported by Indigenous-specific primary health care organisations using Online Services Report (OSR) collection for the IAHP.

<sup>&</sup>lt;sup>a</sup> Calculated as annual uptake/ sum of uptake (250%) to calculate estimated annual values.

<sup>&</sup>lt;sup>b</sup> Calculated as **redacted** operational places x uptake.

Table 14 Data sources and parameter values applied in the financial estimates

Parameter	Value	Source	Comment
Number of health services	ADAR model: 140 (limited to ACCHS) Dept model 1: 229 Dept model 2: 171 Dept model 3: 171	OSR IAHP data	Dept models include 49 NT Government clinics funded through the proposed NT Government consortium. Excludes 3 organisations without clients.
Client numbers	Total clients (range < 50 to ≈24,000)	OSR IAHP data	Data on clients who identify Aboriginal and/or Torres Strait Islander origin may be underestimated.
Remoteness classification	Based on Modified Monash Model (MMM). MMM 1: Metropolitan MMM 2: Regional centres MMM 3: Large rural towns MMM 4: Medium rural town MMM 5: Small rural town MMM 6: Remote communities MMM 7: Very remote communities	OSR IAHP data	Health services covering multiple classifications were classified according to their most urban. One health service covering MMM 1- MMM 5 regions was classified as MMM 3.
FTE GPs	Range: 0 to > 25. 68 health services reported zero FTE GPs.	OSR IAHP data	-
FTE pharmacists	ADAR model: 77.4  Dept model 1: 130 (+10 NT consortium)  Dept model 2: 103.1 (+10 NT consortium)  Dept model 3: 82.9 (+10 NT consortium)	Refer to Table 6.	-
Pharmacist salary	ADAR model: \$151,618 Dept model 1: \$112,940 Dept model 2: \$112,940 Dept model 3: \$112,940	Refer to Section 4. Proposal for public funding. Inflated at 1.8% per year.	-
Salary loading	MMM 1: 1.0 MMM 2: 1.0 MMM 3: 1.2 MMM 4: 1.3 MMM 5: 1.3 MMM 6: 1.5 MMM 7:1.5	As per Workforce Incentive Program Practice Stream.	-
Uptake	Year 1: 20% Year 2: 40% Year 3: 60% Year 4: 80% Year 5: 100% Year 6: 100%	Assumption. Calculated as a proportion of	-
Mentoring and community of practice	Years 1-3: \$529,000/year Years 4-6: \$396,750/year Community of practice: \$62,000/year	ADAR	Excludes \$30,000/year proposed in ADAR for leadership group.

Abbreviations: ACCHS = Aboriginal Community Controlled Health Service; ADAR = Applicant Developed Assessment Report; Dept = Department; FTE = full time equivalent; GP = general practitioner; IAHP = Indigenous Australian Health Program; MMM = Modified Monash Model; NT = North Territory

The estimated budget impact of the IPAC program is summarised in Table 15. The budget impact for each year was estimated as the proportion of 100% uptake. In practice, uptake is likely to differ from the estimates. In practice, uptake will depend on the ability of each health service to recruit a suitable pharmacist. Health services in metropolitan areas and regionals areas with a larger pharmacist workforce may be able to recruit a suitable pharmacist more easily. The estimated budget impact does not consider grandfathering as several health services already have integrated pharmacists.

Table 15: Financial implications of the proposed IPAC Program

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	
Department Model 1							
Total FTE pharmacists	140	140	140	140	140	140	
FTE pharmacists (100% uptake)	130	130	130	130	130 130		
NT consortium FTE pharmacists	10	10	10	10	10	10	
Salary costs							
Pharmacist salaries (100% uptake, excluding NT consortium)	\$18,714,158	\$19,051,013	\$19,393,931	\$19,743,022	\$20,098,396	\$20,460,167	
Pharmacist salaries (NT consortium)	\$1,694,100	\$1,724,594	\$1,755,636	\$1,787,238	\$1,819,408	\$1,852,158	
Uptake	20%	40%	60%	80%	100%	100%	
Total pharmacist salaries	\$4,081,652	\$8,310,243	\$12,689,741	\$17,224,208	\$21,917,804	\$22,312,325	
Program costs							
Mentoring and community of practice	\$591,000	\$591,000	\$591,000	\$458,750	\$458,750	\$458,750	
Total cost	\$4,672,652	\$8,901,243	\$13,280,741	\$17,682,958	\$22,376,554	\$22,771,075	
Department Model 2							
Total FTE pharmacists	111	111	111	111	111	111	
FTE pharmacists (100% uptake)	101	101	101	101	101	101	
NT consortium FTE pharmacists	10	10	10	10	10 10		
Salary costs							
Pharmacist salaries (100% uptake, excluding NT consortium)	\$14,368,227	\$14,626,855	\$14,890,138	\$15,158,161	\$15,431,008	\$15,708,766	
Pharmacist salaries (NT consortium)	\$1,694,100	\$1,724,594	\$1,755,636	\$1,787,238	\$1,819,408	\$1,852,158	
Uptake	20%	40%	60%	80%	100%	100%	
Total pharmacist salaries	\$3,212,465	\$6,540,579	\$9,987,465	\$13,556,319	\$17,250,416	\$17,560,923	
Program costs							
Mentoring and community of practice	\$591,000	\$591,000	\$591,000	\$458,750	\$458,750	\$458,750	
Total cost	\$3,803,465	\$7,131,579	\$10,578,465	\$14,015,069	\$17,709,166	\$18,019,673	

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Department Model 3						
Total FTE pharmacists	93	93	93	93	93	93
FTE pharmacists (100% uptake)	83	83	83	83	83	83
NT consortium FTE pharmacists	10	10	10	10	10 10	
Salary costs						
Pharmacist salaries (100% uptake, excluding NT consortium)	\$12,017,945	\$12,234,268	\$12,454,485	\$12,678,666	\$12,906,882	\$13,139,206
Pharmacist salaries (NT consortium)	\$1,694,100	\$1,724,594	\$1,755,636	\$1,787,238	\$1,787,238 \$1,819,408	
Uptake	20%	40%	60%	80%	100%	100%
Total pharmacist salaries	\$2,742,409	\$5,583,545	\$8,526,073	\$11,572,723	\$14,726,290	\$14,991,363
Program costs						
Mentoring and community of practice	\$591,000	\$591,000	\$591,000	\$458,750	\$458,750	\$458,750
Total cost	\$3,333,409	\$6,174,545	\$9,117,073	\$12,031,473	\$15,185,040	\$15,450,113

Source: Calculated by the Department.

Abbreviations: FTE = full time equivalent; NT = Northern Territory

The total cost of the proposed IPAC Program over six years was \$90 million for Department Model 1, \$71 million for Department Model 2 and \$61 million for Department Model 3. The direct cost of the IPAC Program would be higher if uptake is higher than forecast.

The annual cost of the IPAC program would be similar to the annual cost of the HMR Program (approximately \$22 million per year) and substantially lower than the MedsCheck/Diabetes MedsCheck Programs (approximately \$40 million per year).

The annual cost of the IPAC program will be substantially lower than the Aged Care on-site pharmacists program that is expected to cost \$345.7 million over 4 years.

The IPAC Program may increase MBS costs for MBS items 900 and 245 for a medical practitioner's involvement in a medication review. If the IPAC program results in overall greater utilisation of medicines, there may be additional costs of the PBS. These costs may increase net costs to government but may result in patients receiving overall better quality of care.

#### 15. Other relevant information

#### **Qualitative Evidence**

At its March 2022 meeting, MSAC noted the positive qualitative assessments by participants, GPs, IPAC pharmacists, health service staff and managers and community pharmacists. MSAC noted the qualitative outcomes were positive. In particular, MSAC noted that nearly all the GPs provided positive feedback. While MSAC noted the positive narrative assessments, MSAC considered a formal appraisal and synthesis of the qualitative assessments should be performed.

The IPAC qualitative assessment was informed by 104 participants, including 24 IPAC pharmacists, 13 general practitioners, 12 service managers, ten community pharmacists, 17 health service staff, and 17 patients. Data from 24 IPAC pharmacists was collected using multiple methods including semi-structured interviews. ACCHS staff, patients and pharmacists identified many benefits to having a pharmacist integrated within the ACCHS. These were briefly summarised in MSAC 1678 Public Summary Document and remain unchanged.

The Commentary on the IPAC qualitative evidence (presented in MSAC application 1678 ADAR), in appraising and synthesising the qualitative evidence, aimed to answer the following questions:

- 1. Did the proposed aim and methodology applied in the qualitative research align with the research activities conducted?
- 2. Was the research approach consistent with best practice?
- 3. Were the conclusions and recommendations consistent with the evidence presented?

To facilitate consideration of these questions, the appraisal applied the Joanna-Briggs Inventory (JBI)<sup>13</sup> for qualitative evidence to the overall evidence package, as well as the 32-item consolidated criteria for reporting qualitative research (COREQ)<sup>14</sup> checklist for assessing the quality of reporting in the qualitative evidence report and potential risk of bias with each of the individual sources (as described above) used in accessing qualitative data.

In addition, given the explicit focus of the IPAC project on Aboriginal and Torres Strait Islander health, the 14-item Aboriginal and Torres Strait Islander Quality Appraisal Tool (QAT)<sup>15</sup> has also been applied in assessing whether the qualitative evidence report followed best practice for culturally safe research in an Indigenous health context.

#### Results of the Commentary appraisal of the qualitative evidence

The Commentary considered that in general, the IPAC qualitative methods were appropriate qualitative research methods to capture participants' perceptions and experiences of the IPAC program. The use of several methods and sources of data collection, and multiple researchers to analyse the data supports the credibility of the findings. The conduct of interviews and focus groups aligns with the stated aims of the research. However, it was not clear from the information provided whether the online (GP) surveys fulfilled the stated research aims, largely because the capacity for open text responses within fields was, by nature, more restrictive (than could have occurred via an interview, for example).

The Commentary considered that the conduct of the qualitative research was generally consistent with good research practice. However, there appear to have been some deviations from best practice, including:

The applicant's claim that the qualitative research component of the IPAC study adhered to a
community-based participatory research (CBPR) model was not well substantiated. The
details of the community groups involved and their roles throughout the various stages of the
qualitative research process were not clearly articulated.

<sup>&</sup>lt;sup>13</sup> JBI. (2017). Checklist for qualitative research. Adelaide: The Joanna Briggs Institute.

<sup>&</sup>lt;sup>14</sup> Tong, A., Sainsbury, P. & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care, 19(6), 349-357

<sup>&</sup>lt;sup>15</sup> Harfield, S., Pearson, O., Morey, K., et al. (2020). Assessing the quality of health research from an Indigenous perspective: the Aboriginal and Torres Strait Islander quality appraisal tool. BMC Medical Research Methodology, 20(79)

- Although the pre-planned documentation indicated that a thematic analysis would be applied, the findings reported in the IPAC qualitative evidence report were based on a narrative synthesis of results by prompt/question presented in each of the study approaches.
- Survey questions and instruments were piloted among members of the research team rather than potential research participants.
- Multiple methods for sourcing qualitative evidence (e.g., online surveys, site-visit interviews)
  were combined within one research group (e.g., GPs) without clear explication of how the
  data from those sources were combined and weighted.
- There was an over-reliance on single quotes to justify recommendations arising from the research (rather than such instances being used as indicative of areas for further exploration).

The IPAC qualitative evidence report's recommendations arising from the qualitative evidence to enhance future implementation are enumerated, Congruence of conclusions and recommendations with the evidence presented in Table 16. The Commentary noted that 12 of the 23 recommendations presented in the qualitative evidence report were well supported by evidence—drawn from respondents representing two (seven recommendations) or three (five recommendations) of the five identified stakeholder groups (i.e., IPAC pharmacists, clinical staff, health service managers, community pharmacists and patients). However, 11 of the 23 recommendations were poorly supported (i.e., were drawn from responses of only one stakeholder group (8 recommendations) and/or were supported by a single quote or were not clearly substantiated (3 recommendations) by the evidence presented—either directly (in the form of quotes or excerpts) or indirectly (through a synthesis of qualitative findings). This was particularly the case for recommendations focusing on payments for IPAC services.

The applicant response to the Commentary on the IPAC qualitative evidence reiterated that the IPAC study adopted the CBPR criteria modelled on World Health Organisation (WHO) guiding principles for CBPR and that for pragmatic reasons, deductive analysis was first undertaken but for pragmatic reasons inductive thematic analysis using the constant comparison approach was then used.

Table 16 Congruence of conclusions and recommendations with the evidence presented

Recommended potential pathways to implementation		Stakeholder				Evaluator's Comment
	IPAC Pharmacist	Clinical staff	HSM	СР	Patient	
1. Support policy to integrate the role of non-dispensing pha	armaci	st with	in AC	CHSs		
1.1 Participants in the qualitative evidence report suggested options to support ACCHSs implement an ongoing integrated pharmacist model of care:	<b>✓</b>				<b>✓</b>	
1.1.1. Core services funding be increased to enable ACCHSs to implement the role.			<b>V</b>	<b>√</b>		In the community pharmacy surveys, one respondent supported large ACCHS to employ a pharmacist and implement the role.
1.1.2. In remote settings explore increasing the section 100 pharmacy support allowance to fund integrated pharmacist time onsite within the clinic to deliver patient-related services.				>		One respondent in the community pharmacy survey supported the increase in funding to the section 100 pharmacist allowance to allow the Community pharmacy providing services to the ACCHS, to employ a pharmacist in an ACCHS clinical role.

Recommended potential pathways to implementation		Sta	akehol	der		Evaluator's Comment
	PAC Pharmacist	Clinical staff	HSM	CP	Patient	
1.1.3. Consideration for other Federal Government	쁘	√ V	エ	ပ	Δ.	
sources of financial support for an integrated pharmacist within ACCHSs such as the creation of an MBS item for integrated pharmacist patient-related services (time based).		·				
1.2 Participants in the qualitative evidence report suggested that the cap on the number of funded HMRs should be removed to enable ACCHSs to facilitate as many HMRs as is needed by their patients. Current HMR Program Rules as defined by the Sixth Community Pharmacy Agreement limits HMRs which can be conducted by an accredited pharmacist to 20 per month			<b>✓</b>			A comment from one manager
2. Advocacy and support to ACCHSs to facilitate processes	s for in	tegratı	ng pha	armacı	sts	
2.1 NACCHO and Affiliates support the development of processes and resources for pharmacists to be integrated in the primary health care teams of ACCHSs. Processes and resources should support ACCHS staff to be informed on the value of having a pharmacist in the team, to implement change management processes to introduce and embed the pharmacist and develop referral processes.	<b>√</b>	<b>√</b>	<b>√</b>			Pharmacists identified integration was facilitated by education of the pharmacist role.  Pharmacists identified several formal and informal referral processes, some of which were developed in collaboration with ACCHS staff for patient referral.
2.2 Resources to guide preparation should consider the IMPACT Framework and assist ACCHSs for the pharmacist role.						
2.3 ACCHSs that will be most ready to establish an integrated pharmacist role are those with systems established for quality improvement (e.g. Referral, CIS).	<b>√</b>	<b>√</b>	<b>√</b>			
2.4 Develop the capacity of Aboriginal Health Workers/ Practitioners and Outreach Workers to facilitate referral for patients needing support from the integrated pharmacist.	<b>✓</b>	<b>✓</b>	<b>✓</b>			The pharmacists identified that AHW were a source of referrals for patients (particularly when the GPs were not referring patients). However, the pharmacists did not comment on how to develop the capacity of AHW to facilitate these referrals.
3. Co-design of the pharmacist role with the ACCHS to ens	ure it r	neets	their n	eeds		
3.1 Policy guiding the implementation of the pharmacist role should allow flexibility for ACCHSs to use the role to best meet the needs of the health service and promote self-determination.	<b>√</b>		<b>✓</b>			Two quotes directly supported the ACCHS to utilise the skillset of the pharmacist to align with the ACCHS's needs.
3.2 ACCHSs should be actively involved in the co-design of the integrated pharmacist role to ensure it suits their needs and seek support from NACCHO and their Affiliate where necessary.	<b>~</b>		<b>✓</b>			
3.3 The recruitment of pharmacists to be integrated within ACCHSs should be flexible and be led by ACCHSs, so that pharmacists have the 'right organisational fit' and are skilled in key areas (character, clinical skills, communicator, collaborator and culturally responsive).		<b>✓</b>	✓			
3.4 Future projects to assess outcomes from integrated pharmacists within ACCHSs or alternate new models, need to allow a lead-in time to allow pharmacists to	<b>√</b>	<b>√</b>				One quote directly supported lead-in time, as patient recruitment couldn't

Recommended potential pathways to implementation		Sta	akehol	der		Evaluator's Comment	
	PAC Pharmacist	Clinical staff	HSM	CP	Patient		
develop relationships with staff and patients and develop a deeper understanding of the local community and health service culture.	=			0	<u> </u>	happen until the pharmacist was well embedded in the service.	
4. Training and support to prepare pharmacists for a non-d	ispens	ing, int	egrate	ed role	within	ACCHSs	
4.1 Support pharmacists to develop career pathways for integrated pharmacist roles.			_				
4.2 Prepare pharmacists for integrative roles within ACCHSs through the development of a training program that includes the conduct of medication reviews, working with internal and external stakeholders, team-based collaboration, patient counselling, preventive health care, transitional care arrangements, medication adherence assessment of Aboriginal and Torres Strait Islander patients, the provision of education and training and medicines information to staff and patients, and undertaking drug utilisation reviews. The program should also include comprehensive training on clinical information systems including all basic functionality, how to generate quality improvement reports and how to set up patient recalls.	<b>✓</b>	<b>✓</b>	<b>√</b>			Pharmacists commented on the usefulness of the PSA training, though still identifying that its limited.  Pharmacists identified additional areas where training would be useful e.g., use of clinical information system and guidance around communicating findings.	
4.3 Ensure opportunities for pharmacists to undertake cultural safety training responsive to their place of practice prior to commencing activity within ACCHSs.	•	•				Several pharmacists undertook general cultural awareness training before commencing the role. Some pharmacists received local cultural induction. Local cultural induction generally happened after the pharmacist started the role and feedback was generally positive.	
4.4 ACCHSs to provide pharmacists with induction to the service and the local community including introduction to staff members in key roles and cultural orientation to the local population.	<b>√</b>					One pharmacist commented on the value of ACCHS induction.	
4.5 Facilitate a community of practice network to enable knowledge sharing and peer support. Mentors can assist with clinical and/or cultural aspects of integrated practice and development of career pathways	<b>✓</b>					Pharmacists commented on the usefulness of having a peer network for clinical support, mentors for clinical/cultural support. The pharmacists did not identify the peer network for the development of career pathways.	
5. Facilitate continuous improvement through further resea	rch an	d evalu	uation				
5.1 Funding should be made available for further research and evaluation of integrative pharmacist programs to facilitate continuous quality improvement.							
5.2 Research involving patients receiving services from pharmacists should use simplified information sheets and consent forms for patients and consider formal translation into local languages.	<b>√</b>					Two pharmacists reported the difficult consent process.	
5.3 Future research projects may consider the use of the pharmacist logbook in order to facilitate data collection about the activity of integrated pharmacists. Some design improvements to simplify data entry, and comprehensive training, are suggested.	<b>✓</b>					The pharmacists recommended further training for the logbook and reported it was a time-consuming task.	

Recommended potential pathways to implementation		Sta	akehol	der		Evaluator's Comment
	IPAC Pharmacist	Clinical staff	HSM	СР	Patient	
5.4 In the design of future research projects consider the time required for data entry and ensure this element is adequately factored into the allocation of working hours.	<b>√</b>					Some pharmacists completed data entry outside of allocated hours.
5.5 Mechanisms need to be established to support the continuation of trials, beyond the trial period, if they have been found to be successful. Short term projects have detrimental impact on Australian Aboriginal peoples and Torres Strait Islanders who have historically been over researched, and on ACCHSs work processes.	<b>√</b>	<b>√</b>			<b>√</b>	

Source: Adapted from Table 6, pg 34 of MSAC 1678 – Commentary on the IPAC Qualitative Evidence Abbreviations: ACCHS = Aboriginal community controlled health service, AHW = Aboriginal health worker, CIS = clinical information system, CP = community pharmacist, HSM = health service manager, NACCHO = National Aboriginal Community Controlled Health Organisation PSA = pharmaceutical society of Australia.

# Results of the Commentary appraisal of the cultural appropriateness of the qualitative evidence

The Commentary considered the conduct of the qualitative research was generally consistent with best practices for culturally safe Indigenous health research. However, in some instances, the qualitative evidence report did not reflect best practice in the design and conduct of holistic, participatory health research with Aboriginal and Torres Strait Islander people, including:

- While the broader IPAC study was clearly co-designed with a broad group of stakeholders to address priorities determined by community, it is not clear that the specific aims of the qualitative evidence report itself reflect local community priorities (i.e., to evaluate the perceptions of health service staff, patients and local community pharmacists on having an IPAC pharmacist integrated within ACCHSs and explore perceptions regarding the effectiveness of the intervention through an in-depth assessment of implementation in an urban, regional and remote setting).
- The IPAC qualitative evidence report stated that the qualitative research was co-designed with input from the project operational team, steering committee and evaluation team. However, the report did not indicate which key cultural and other community bodies may have been consulted in the development and carriage of the qualitative evaluation.
- While the IPAC qualitative evidence report indicated the involvement of two Indigenous
  researchers, it did not sufficiently explicate the community background, role and credentials
  of Indigenous and non-Indigenous researchers engaged in particular research activities (i.e.,
  research design; data collection; synthesis and interpretation of findings; write-up; and
  dissemination of findings to community-based stakeholders and external audiences).
- The qualitative evaluation was not clearly guided by an identified Indigenous research paradigm.

The Commentary noted that more Indigenous research frameworks have now been published that could be used by future applicants when developing qualitative research with First Nations people and to aid the subsequent assessment of that qualitative evidence.

The applicant response to the Commentary on the IPAC qualitative evidence highlighted that the OAT was published after completion of the IPAC study. The response also reiterated that the IPAC

study was undertaken as a direct result of the workforce reform priorities identified by the ACCHSs sector and highlighted the informed consent and research agreements that aimed to secure cultural safety for all participants. Equity and Societal Considerations

The existing programs for medication review services limit the number of services that are funded by the Government on a per provider per month basis. This approach may create barriers timely to access where demand for medication review services exceed the per-provider limits to reimbursement. The Department does not collect data on Indigenous identification of people receiving existing MMR services.

# 16. Applicant comments on MSAC's Public Summary Document

Aboriginal and Torres Strait Islander peoples continue to experience a higher burden of chronic disease due to cardiovascular, diabetes and other health problems than other Australians. To compound this, AIHW data show significant ongoing disparity in medicines access between Aboriginal and Torres Strait Islander peoples and other Australians. Through the IPAC Trial and broader consultation, the Pharmaceutical Society of Australia (PSA) and the National Aboriginal Community Controlled Health Organisation (NACCHO) have observed how adverse health outcomes can be minimised when prescribing quality is improved, and patients and the healthcare team are supported with medicines use and management. Integrating pharmacists within Aboriginal and Torres Strait Islander primary health care services, where their medicines expertise can be applied in a culturally safe environment, is critical to building equitable access to quality use of medicines support and to optimising health outcomes for Aboriginal and Torres Strait Islander Australians. PSA and NACCHO recognise the valuable role undertaken by MSAC in its appraisal of the IPAC Trial and welcome its support for public funding for integrating nondispensing pharmacists within the primary health care team of Aboriginal Health Services to improve chronic disease management. We look forward to working with the Department to further consider and develop an implementation model which meets the needs of the Aboriginal and Torres Strait Islander health and pharmacy sectors and is consistent with the Australian governments' commitment to the Priority Reforms of the National Closing the Gap Agreement.

## 17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: <u>visit the MSAC website</u>