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AMA submission to the Medical Services Advisory Committee – 1677 Pharmacy Diabetes Screening Trial

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Introduction

The AMA welcomes the opportunity to provide feedback on the Pharmacy Diabetes Screening Trial (PDST) and welcomes an independent Health Technology Assessment to determine the effectiveness and cost-effectiveness of the trial. The AMA has previously supported that pharmacy programs should come under the same level of transparency and scrutiny as medical services when they are examined through the Medical Services Advisory Committee (MSAC) process, and also under the recent Medicare Benefits Schedule (MBS) Reviews[1]. The AMA is deeply concerned with the spread of pharmacy health services across Australia that have not been appropriately assessed at the same standard as other medical services. The AMA considers these services as outside the scope of practice for pharmacists and represents a push by pharmacies to increase their profits at the expense of evidence-based, cost-effective health care. Pharmacy programs must be subject to independent evidence-based assessment, reporting and monitoring, and adequate accountability and transparency to ensure they are in the patients' best interest and are the best use of public funds.

The AMA does not believe that the evidence provided in this MSAC application is sufficient to justify continuing Pharmacy Diabetes Screening Programs when there is already an evidence-based diabetes screening process in place in general practice.

Funding pharmacy health services

The AMA agrees there are benefits in future Community Pharmacy Agreements (CPAs) being limited to remuneration for the dispensing of Pharmaceutical Benefits Scheme (PBS) medicines and associated regulation. This would allow pharmacy programs, such as medication adherence and management services currently funded under the CPA, to be funded in ways that are more consistent with how other primary care health services are funded. Given these programs are about providing health services, rather than medicines dispensing per se, it makes sense for them to be assessed, monitored, evaluated and audited in a similar way to medical services under the

[1] Australian Medical Association (2017) *AMA submission – Pharmacy remuneration and regulation review – interim report.*

MBS. $1.26 billion (including $50 million for the Pharmacy Trial Program) was provided to pharmacies under the Sixth CPA[2] without this level of transparency and accountability. This MSAC process is the first time evaluations of pharmacy programs under the CPA have been made (relatively) public. Moving pharmacist health services outside of the CPA would also open the way for more flexible models of funding, for example, support for pharmacists working within a general practice team and other innovative, patient-focused models of care.

Assessing health services

The Review of Pharmacy Remuneration and Regulation[3] provided a set of principles for the programs offered in community pharmacy to uphold. The AMA considers this MSAC process to at least begin providing appropriate scrutiny of pharmacy services, as recommended by the Review. The first principle is that "programs should be based on evidence of clinical and cost-effectiveness and the health benefits they provide to the community".

The Department of Health's *Population Based Screening Framework*[4] highlights specific criteria that must be met when considering a screening program, including that the benefits outweigh the harms and that there is community consensus that the benefits outweigh the financial costs[5]. While the PDST does not fit the definition of a population screening program, the Framework provides appropriate guidance to refer to when determining the appropriateness of the PDST. In particular, the Framework outlines that screening programs require a high level of evidence from high quality randomised controlled trials and systematic reviews.

Any cost-benefit analysis would also need to take into account the indirect costs of delayed or missed diagnoses leading to higher cost care, that are more likely when care is fragmented by patients relying on health care provided by a pharmacist (see section on general practice).

The Pharmacy Diabetes Screening Trial

The AMA does not believe there is a high level of quality evidence for pharmacy diabetes screening programs. A meta-analysis cited[6] by the PDST researchers highlights that most studies were observational, and studies overall had significant variation in outcomes (referral to patient's practitioner and uptake of referral), with high rates of attrition between screening and follow up. High proportions of patients did not attend follow up appointments. Two of the four Australian studies included in the analysis were rated as 'poor quality'[7]. The AMA is concerned that similar poor results could occur if the screening program continues in Australia.

[2] Department of Health (2020) *Pharmacy Trial Program.*
[3] Department of Health (2017) *Review of pharmacy remuneration and regulation – final report.*
[4] Department of Health (2018) *Population Based Screening Framework.*
[5] See also: World Health Organization (2020) *Screening programs: a short guide.*
[6] Krass et al (2017) *Pharmacy diabetes screening trial: protocol for a pragmatic cluster-randomised controlled trial to compare three screening methods for undiagnosed type 2 diabetes in Australian community pharmacy.* BMJ Open
[7] Willis et al (2014) *The effectiveness of screening for diabetes and cardiovascular disease risk factors in a community pharmacy setting.* PLOS one.

Medical services are typically backed by several high quality studies before they even considered through the MSAC process[8] In contrast, the PDST is only one trial that does not research the effectiveness or cost-effectives in the context of wider public health or other more readily available and evidence-based medical services. Rather, it provides an analysis *between* different pharmacy diabetes screening models that is largely based on economic analysis. It is unclear whether this study has been peer-reviewed and it appears that full trial results will not be publicly available until after the HTA assessment[9]. It is unclear how researchers determined GP-based costs and how potential cost offsets were measured. It is also unclear whether the trials had acceptable follow up and referral uptake in comparison to general practice robust recall systems. Without this information, and the fact that many results have been redacted in the MSAC Executive Summary, it is difficult to determine a full view on the PDST.

The PDST itself is sponsored by the Pharmacy Guild of Australia[10], an organisation that aims to represent the interest of their members - community pharmacies (businesses). This represents a direct conflict of interest because Guild members will directly benefit from government funding and an increase in profits by expanding the program. Ideally, research should be independent.

The AMA is also concerned that pharmacies are actively recruiting and marketing unnecessary and expensive pathology tests to their customers under the cover of 'health screening'. For example, the clinical guidelines state that patients without a high risk of type 2 diabetes should only be screened using AUSDRISK every three years from when they reach 40 years of age[11]. In contrast, the PDST allows anyone aged 35-74 to be screened more regularly (the customer can participate if they have not had a recent diabetes test in the past 12 months). It is also unclear how the pharmacist plans to confirm whether the patient has had a recent diabetes test which was likely initiated by a general practitioner and not the specific pharmacy. This will be crucial to determine whether costs and services are being duplicated. The AMA believes this perfectly illustrates the push by pharmacies to increase profits at the expense of evidence-based, cost effective health care.

The AMA would also expect these services to be regularly independently audited to ensure diabetes screening offers to patients were clinically necessary and not over-serviced, and that the program was effective in ensuring patients went to their GP.

General practice

The AMA opposes proposed reforms that fragment care and provide a lower quality service than medical practitioners. It is internationally recognised that GPs are the cornerstone of a successful primary healthcare system, and countries with a strong general practice have better health outcomes[12]. The patient-centred medical home model (PCMHM) is a well-regarded system of

[8] Department of Health (2019) *Medical Services Advisory Committee – Frequently Asked Questions*.
[9] Department of Health (2020) *Pharmacy Trial Program*.
[10] National Health and Medical Research Council (2017) *Australian clinical trials – The Pharmacy Diabetes Screening Trial: a comparison of three community pharmacy based approaches to screening for type 2 diabetes on proportions of newly diagnosed type 2 diabetes cases.*
[11] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice*
[12] The World Health Organisation (2008) *The World Health Report 2008 - primary health care (now more than ever).*

integrated care that is more efficient, reduces hospital admissions and provides better support for patients[13,14]. Despite a move towards the PCMHM, fragmentation of care, such as the PDST, is becoming more common as health system pressures grow. Poorly coordinated patient care within the health system and inadequate links between health and social services results in poorer health outcomes and increased health care costs[15]. Ill-considered cost reduction strategies, like task substitution of non-medical health professionals for GP-led patient care, are increasingly proposed as a solution to these pressures. Government should be focusing on increasing funding and support for general practice instead of seeking ways to produce lower-quality care solutions that are not necessarily cheaper in the long term. For example, the AMA believes that investment into general practice pharmacists is a more valuable method of providing holistic care while improving engagement between pharmacists and GPs[16].

Pharmacies in the community play an important role in providing medicines information to the public and ensuring that all Australians have access to medicines in a timely and safe manner. However, medical practitioners are the only health professionals trained to fully assess a person, initiate further investigations, make a diagnosis, and understand and recommend the full range of clinically appropriate treatments for a given condition.

There is so much more to patient care than simply completing a screening tool and the AMA is concerned that patients with or at risk of type 2 diabetes will be subjected to a tick box exercise in retail pharmacies. General practitioners are already best placed in advising their patients about prevention, diagnosis, and treatment of type 2 diabetes and can help their patient achieve health goals such as improving their diet, BMI, physical activity, cigarette, and alcohol consumption[17]. Patients with, or at risk of, type 2 diabetes typically have other health conditions and concerns that are best addressed through their usual GP. Almost half of patients with type 2 diabetes have two or more additional health conditions, and more than 80 per cent will have multimorbidity within 16 years of being diagnosed[18]. In most cases, tests and/or several medications are required, and some patients may require specialist referral. Pharmacists cannot initiate or prescribe these requirements.

While the AMA understands that under the PDST pharmacists refer patients to their GP if they identify test results above a certain threshold, it is in the patient's best interest that they receive a more holistic, person-centred approach at their general practice at the beginning of their patient journey so they receive appropriate education around prevention and risk factors, and all the required referrals and tests are ordered and conducted in a more efficient manner at the medical practice and associated pathology centres. The PDST adds an unnecessary step for patients that is out of sync with holistic care.

[13] NSW Government (2021) *Navigating the health care neighbourhood – What is the patient centred medical home model?*
[14] NSW Government (2021) *Navigating the health care neighbourhood – benefits for health professionals.*
[15] Frandsen BR, et al (2015) *Care fragmentation, quality, and costs among chronically ill patients*. Am J Manag Care 2015;21:355–62
[16] Australian Medical Association (2015) *general practice pharmacists – improving patient care.*
[17] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice.*
[18] Royal Australian College of General Practitioners (2020) *Management of type 2 diabetes: A handbook for general practice*.

Scopes of practice

Current scopes of practice exist to protect patient safety and ensure patients receive best value, high quality care. The AMA considers pharmacists undertaking expanded roles, including non-medicine related tasks such as the PDST, to be expanding their scope of practice.

Under the Health Practitioner Regulation National Law Act, which governs the practice of registered health practitioners, the national boards are responsible for setting the accreditation standards for education and training for the knowledge, skills and professional attributes to practise the profession.

To ensure patient safety and cost-effectiveness for the health care system, any expanded scopes of practice by non-medical health practitioners should be underpinned by a process that ensures:

- there are no new safety risks for patients;
- the change to scope of practice is rationally related to the practice of the profession and to core qualifications and competencies of their profession;
- the change in scope of practice is consistent with the evolution of the healthcare system and the dynamics between health professionals who work in collaborative care models;
- the training opportunities for other health practitioner groups is not diminished; and
- the cost to the health care system will be lower than the current service offering, taking account of supervision costs.

In addition, processes for expanding scopes of practice should also ensure that:

- the required competencies are predetermined, and accredited training and education programs are available to deliver those competencies; and
- there are documented protocols for collaboration with other health practitioners.

The AMA is not aware of the above considerations and processes being undertaken by the Pharmacy Board prior to the Pharmacy Guild determining an expansion in pharmacists' scope of practice. The AMA recommends MSAC consults the Pharmacy Board to determine their views on the above and if necessary, conduct a consultation on expanding pharmacist scopes of practice into medical services.

Conclusion

The AMA welcomes the MSAC assessment for the PDST, so the program's effectiveness and cost-effectiveness is determined by the same process that assesses all other health services. The AMA has several concerns if pharmacy diabetes screening programs are to receive future government funding, due to the lack of high-quality evidence that these programs are in the patients' best interest, in the context of wider public health and existing primary care services. The AMA values pharmacists as experts in medicines and there are more pressing and useful models of care involving pharmacists that should be considered as part of a patient-centred medical home model rather than further fragmenting care.

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