1 March 2019

Ms Dorothy Vicenzino Executive Director Chief Medical Officer and Healthcare Regulation Branch Level 8, 33 Charlotte Street BRISBANE QLD 4000

Via email: Dorothy.Vicenzino@health.qld.gov.au

Dear Dorothy,

Thank you for the opportunity to meet with you recently to discuss the recommendations of the Health, Communities, Disability Services and Domestic and Family Violence Prevention (HCDSDFVP) Committee report into the establishment of a pharmacy council and transfer of pharmacy ownership in Queensland.

At this meeting you asked us to provide you with further information regarding the Pharmacy Council and the proposed expanded scope of practice for pharmacists and pharmacy assistants. We have set these out below. We ask you to also refer to our Pharmacy Council submission document.

AMA Queensland is of the strong belief that in the interests of patient safety, pharmacist prescribing could only occur:

- 1. supported by core training and education meeting the standards set in the NPS Prescribing Competencies Framework;
- 2. within a medical practitioner led and delegated team environment; and
- 3. independent of any community pharmacy relationship.

Recommendation 2

Consultation with a GP utilising 13HEALTH:

Our concerns are 2 fold

- 13HEALTH employs only one general practitioner. Clearly, one GP could not address the workload coming in and could not provide the 7-day coverage required to carry out the role.
- 13HEALTH does not address our concerns about how expanding the scope of practice of pharmacists fragments patient care.

On-site testing for UTIs: If a patient presents to a pharmacist with what they or the pharmacist suspects is a UTI, it is likely that a pharmacist would prescribe antibiotics. Given the global concerns about overprescribing of antibiotics it is important that a UTI be confirmed through testing of urine cultures and catheter specimens. This involves an appropriate physical examination, taking of the patient's history and urine testing by an experienced clinician. This thorough process which cannot be achieved in a pharmacy setting, dramatically reduces the risk of misdiagnosis (including thrush, STDs, prostatitis, renal stones, or bladder cancer).

You specifically asked if it is better to have antibiotics prescribed at a pharmacy after hours rather than waiting for a full examination and diagnosis at a doctor's practice the following day. For the reasons set out about above, we do not consider a precautionary prescription of antibiotics to be better than proper and thorough diagnosis by the patient's doctor.

Requiring pharmacists to have regard to the patient's medical record via MyHealthRecord:

Although AMA Queensland believes that My Health Record is a system that can be capable of being a useful repository of health information, however, currently it is not a reliable record for doctors or pharmacists to base their prescribing decisions on.

Economic Data on Pharmacists in General Practice Model: You have also asked us to provide economic data on the AMA model for non-prescribing pharmacists working within GP clinics. The AMA has previously commissioned an



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amaq@amaq.com.au ACN: 009 660 280 ABN: 17 009 660 280 independent analysis by Deloitte Access Economics which demonstrates this measure could achieve significant savings to the Australian health system - totalling \$544.87m over four years. A copy of the paper is **attached**.

The projections cover the four years from 2015-16 to 2018-19 and take into account costs including the Pharmaceutical Benefits Scheme (PBS), Medicare Benefits Schedule (MBS), hospital and individual expenditures, as well as the cost of the PGPIP.

The analysis shows that the AMA's proposal delivers a benefit-cost ratio of 1.56, which means that for every \$1 invested in the program it generates \$1.56 in savings to the health system.

The study estimated that around 3,100 general practices would take up the PGPIP and although it would cost the Federal Government \$969.5 million over four years, this would be more than offset through broader savings to the health system in the following areas:

- Hospital savings of \$1.266 billion due to reduced number of hospital admissions following a severe adverse drug event (ADE);
- PBS savings of \$180.6 million due to the reduced number of prescriptions from improved prescribing and medication compliance;
- Individual savings of \$49.8 million from reduced co-payments for medical consultations and medicines; and
- MBS savings of \$18.1 million due to a reduced number of GP attendances following a moderate or severe ADE.

Low Risk Emergencies: In regards to your question regarding "low risk emergencies", our response is that this is a misnomer as there is no such thing as a low risk emergency. It is inappropriate to handle this potential situation without appropriate training and the ability to take a confidential full clinical history and examination of the patient.

Credentialing: Credentialing is important for quality control and doctors need to be involved. The TGA has strict guidelines for being able to prescribe and any credentialing system needs to be based on these. The separation of prescription and dispensing of medications is a fundamental tenet of the healthcare system.

Dose adjustment and medications management by pharmacists: AMA Queensland does not support this. GPs should remain at the centre of the primary care model. It is dangerous to allow a pharmacist without training in diagnostics, pathology/imaging interpretation and clinical management of patients to amend a treatment plan prescribed by a doctor. For example, while it might be assumed that blood pressure medication could be adjusted according to standard norms, this is incorrect. It is often the case that individualised targets need to be set for patients based on comorbidities, an impairment in renal or liver function, other medications, and potentially competing management goals. Clinical decision-making requires a nuanced understanding of a patient's particular needs and other medical problems which can only be provided by a doctor.

It is argued that pharmacist prescribing will meet an unmet health service need because patients do not have timely access to their doctor. Firstly, there is no evidence that people cannot access their doctor within a few days for nonurgent matters. Secondly, the prescription medicines that pharmacists are likely to seek to prescribe (e.g. lipid modifying agents, the contraceptive pill, etc), are for conditions that people can plan to visit their doctor, and make an appointment at a time that is convenient for them.

Antimicrobial stewardship: Antimicrobial stewardship is an important issue and one the medical profession is contributing actively and positively to, as evidenced by the small gains made in recent times (reference ACSQHC report)¹. Wider prescription of antibiotics by pharmacist who are not appropriately trained in diagnosing or managing pathology is clearly a retrograde step in controlling antibiotic prescription.²

 ¹ Australian Commission on Safety and Quality in Health Care. Antimicrobial Stewardship in Australian Health Care 2018. Sydney: ACSQHC; 2018
 ² http://www.pulsetoday.co.uk/clinical/clinical-specialties/infectious-diseases/chloramphenicol-use-remains-40-higher-due-to-otc-status/20002757.article

Recommendation 3

Training Requirements:

The AMA places a high value on the professional role of pharmacists working with medical practitioners and patients to: ensure medication adherence; improve medication management; and provide education about medication safety. The AMA fully supports pharmacists undertaking roles within their scope of practice. That means those activities and clinical services that are covered in their core education and training. Prescribing, however, is not within pharmacists' scope of practice.

Non-medical practitioners seeking to independently prescribe medicines must meet the standards for prescribing set out in the NPS *Prescribing Competencies Framework* (p29-69). Pharmacists' core education and training does not support pharmacists to meet these standards.

Some non-medical practitioners, such as nurse practitioners, may prescribe S4 and S8 medicines, but only under strict protocols and generally in public hospital settings. For example, nurse practitioners may prescribe within a clinical unit under protocols that list the medications that can be prescribed; specify the specific circumstances; and describe when the patient must be referred to a medical practitioner.

AMA Queensland has been asked for feedback numerous times over the last few years regarding an increased scope of practice for non-medical health practitioners (NMHP) such as nurses and midwives. AMA Queensland believes expansion of the scope of practice of NMHP should only be allowed where:

- there is evidence to support the practice is safe, appropriate and benefits patients; and
- a doctor always leads the team the allied health professional is working in and has approved and delegated the practice and is available to give advice and support;
- the expanded scope of practice does not include the medical skills of diagnosis or prescribing schedule 4 or schedule 8 medications;
- There is no conflict of interest or secondary gain in the prescription of therapies for patients. It should be emphasised
 that pharmacists have an insurmountable conflict in the profit generated from their own prescription of a drug. A
 critical component of achieving measured and appropriate use of medications is the maintenance of strict separation
 of prescribing from the dispensing of medications. Patients are less likely to receive impartial, appropriate medical
 advice if this advice can also lead to financial gain from the purchase of therapies recommended.

AMA Queensland values the role and specific expertise of NMHP. We acknowledge and support the collaborative arrangements between medical practitioners and other health practitioners, for example, those between general practitioners, non-prescribing pharmacists and senior nurses. However, NMHP do not have the education, training or skills to independently formulate medical diagnoses, independently interpret diagnostic tests, prescribe medication, issue repeat prescriptions, or decide on the admission of patients to, and discharge from, hospital.

AMA Queensland supports better utilising the skills and expertise of NMHP within their current scopes of practice to maximise health system capacity and efficiency. There is a current deficiency in time available by allied healthcare practitioners for direct patient care – this deficiency requires correction prior to expansion in practice. AMA Queensland believes they should be better resourced and enabled to maximise the full scope of their trained and current field of expertise, for example, utilising physiotherapists in an emergency department setting to provide better quality and more effective care to patients with fractures or soft tissue injuries.

AMA Queensland does not support independent diagnosis and treatment of medical conditions by NMHP. This encourages fragmented healthcare and presents an inherent risk to patient safety. Nor does AMA Queensland support independent prescribing by NMHP. This is in the interests of patient safety and quality of care.

Recommendation 4

In the interests of patient safety and quality in health care, AMA Queensland does not support extending the scope of pharmacists and pharmacy assistants.

Whilst we acknowledge that non-medical prescribing (NMP) has been occurring in other jurisdictions such as the United Kingdom for many years now, there is no evidence that demonstrates the safety of non-medical prescribing in that country or others. Although there have been no adverse events that can be directly attributed to NMP, tracking such adverse outcomes would be extremely difficult, if not impossible.

In our submission to the Queensland Parliament, we offered numerous examples of where a patient presenting to a GP for a prescription renewal or other minor complaint afforded the doctor an opportunity to address preventive health (e.g. overdue cervical cancer screening) and diagnose other conditions, such as skin cancers. If a patient who unknowingly had a malignant melanoma was to present to a pharmacist in the UK for a script refill, it would be highly unlikely that the pharmacist would perform the kind of examination that would allow that undiagnosed melanoma to be detected. If that patient subsequently passed away because of that cancer, this would be unlikely to be attributed to a failure of a NMP to detect it during a script refill a number of years prior.

GPs are highly trained medical professionals who, on average, have 10-14 years of training as compared to pharmacists who have only four with a completely different area of expertise.

Using their training, GPs holistically assess, examine, investigate, diagnose, refer, and coordinate multidisciplinary teams for patients in the privacy of dedicated consulting rooms. Pharmacists do not and will never be in a position to safely and appropriately do this. Any interaction that occurs between a GP and a patient is an opportunity for that GP to make the patient healthier and build rapport and understanding, not limited to the initial reason they have presented to the doctor on that particular day. Optimal chronic and complex disease management requires these enduring, mutually respectful, relationships between doctor and patient.

Any health system 'savings' through fewer GP consultations would be short-term as savings would be undermined by a reduction in the preventive health care provided by GPs and subsequent downstream costs resulting from later presentations of established illness.

This is because, while a general practitioner consultation may be prompted by the need for a prescription medicine, it is not a simple transaction for that medicine. Every GP visit includes opportunistic discussions with patients about a range of health care needs including evidence-based prevention and screening services.

Proposed changes to pharmacist scope of practice are in contrast to the best available evidence about how care should be delivered; namely, long term continuity of care with the same doctor in a therapeutic relationship based on mutual trust and respect. Whereas public opinion suggests that visiting a pharmacist may be more convenient than visiting a GP, empirical evidence from the ABS³, the BEACH data⁴, the OECD⁵, the *British Medical Journal*⁶ and numerous other sources clearly demonstrates that you are likely to live longer and achieve better health outcomes overall by seeing your GP regularly.

Since 2016, the AHPRA Prescribing Working Group has been developing a clear national pathway for other health practitioners to prescribe but there must be clear steps to determine community need, a comprehensive survey of

³ Australian Bureau of Statistics, Patient Experiences in Australia: Summary of Findings 2016-17, Canberra

⁴ Lyndal J Trevena, Christopher Harrison and Helena C Britt, Med J Aust 2018; 208 (3): 114-118. || doi:

^{10.5694/}mja17.00225 Published online: 19 February 2018

⁵ OECD (2017), *Health at a Glance 2017: OECD Indicators*, OECD Publishing, Paris

⁶ Pereira Gray DJ, Sidaway-Lee K, White E, *et al*, Continuity of care with doctors—a matter of life and death? A systematic review of continuity of care and mortality, *BMJ Open* 2018;8:e021161. doi: 10.1136/bmjopen-2017-021161

training/standards/accreditation, and a requirement to gain approval at various levels including the AHPRA Scheduled Medicines Expert Committee and then AHMAC before looking at state-level approval.

If pharmacists were given approval to prescribe in Queensland, this would be in opposition to nationally agreed and developed processes which take into account fundamental issues of patient safety and would be more akin to the Optometrists who in 2015 just decided they could prescribe by changing their policies with no regard to patient safety or proper processes.

If Queensland goes it alone, the AMA Queensland believes that this process contravenes a Council of Australian Government's agreement that any prescribing by non-medical practitioners MUST go through a proscribed, national process, overseen by AHPRA, and ultimately approved by Health Ministers.

Conflict of Interest: It is noted that the Pharmacy Guild states that the "separation of prescribing and dispensing of medicines provides a safety mechanism as it ensures independent review of a prescription occurs prior to the commencement of treatment."⁷ If the scope of practice for pharmacists and pharmacy assistants was to be extended to allow them to become both a prescriber and a dispenser, this safety mechanism is put at risk and creates a clear conflict of interest.

Doctors are careful to consider whether or not they have a conflict of interest in providing advice. In this, doctors in Australia are guided by two documents. The first is the Medical Board of Australia's (MBA) *Good Medical Practice: A Code of Conduct for doctors in Australia.* The second is the AMA Code of Ethics.

As defined by the MBA, a conflict of interest is what arises when a doctor, entrusted with acting in the best interests of patients, also has financial, professional or personal interests, or relationships, which may affect their care of the patient⁸. Doctors may also be influenced by interests that extend to other persons connected to the provider. The *AMA Code of Ethics* states in section 3.5.1 that doctors must ensure their financial or other interests are secondary to their primary duty of serving patients interests⁹.

Doctors avoid the conflict of providing advice and prescribing with the associated financial gain of selling medications, by avoiding the latter entirely and concentrating solely on providing high-quality healthcare and advice to the patient. The measured and appropriate use of medications depends on this separation of responsibility. The additional aspect of the pharmacist's conflict of interest as a prescriber and dispenser is the opportunity within a pharmacy setting to upsell to patients. Upselling often involves the selling of products that have few, if any, proven health benefits. Often profit margins in retail pharmacies are greater on 'front of shop' complementary medicine that has no evidence basis, as opposed to evidence-based PBS subsidised medications.

It is hugely problematic therefore for patients to be receiving advice outside of a medical therapeutic relationship in a retail shop that leads them to purchase non evidence-based medications that provide greater profit for the pharmacist providing the advice. Our general practitioner (GP) members have offered many examples of upselling experienced by their patients, such as pharmacists recommending probiotics when dispensing antibiotics or glucosamine when the patient has their arthritis medication dispensed. Neither have a credible evidence basis in published literature. Other members have provided examples of when pharmacists have persuaded patients not to fill a script because they've misunderstood the reason for the prescription and/or to use an over the counter medicine instead, without input from the original prescribing doctor.

This was already a concern noted by the Federal Government's Pharmacy Review in 2016 which noted in its discussion paper that the Panel had "heard that some consumers are concerned that pharmacists may compromise on the level of

⁷ Pharmacy Guild of Australia, *Dispensing your prescription medicine: more than sticking a label on a bottle*, <u>https://www.guild.org.au/__data/assets/pdf_file/0020/5366/the-dispensing-process.pdf</u>

⁸ Medical Board of Australia, *Good Medical Practice: A Code of Conduct for doctors in Australia*, Online. URL:

http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx

⁹ AMA (2016), Code of Ethics, Online. URL: https://ama.com.au/position-statement/code-ethics-2004-editorially-revised-2006-revised-2016

professional advice provided to patients on the quality use of medicines and feel financial pressure to 'up-sell' to consumers, for example by recommending medicines or products that may not be necessary for the patient."¹⁰ It's also worth noting that without national approval, there is no chance of the Commonwealth agreeing to pharmacist prescriptions being subsidised under the PBS. Unless the prescribed medicines cost less than the PBS patient co-payment, patients will end up paying more for their medicines. Pharmacists would also not be eligible to claim a dispensing fee for non-PBS medicines.

Recommendation 6

View on establishment of a Pharmacy Council: AMA Queensland does not support the establishment of a pharmacy council in Queensland. Based on the issues paper from the committee, it would appear most of its proposed functions and powers are already vested in legislation and the Pharmacy Board of Australia, thus duplicating processes that already exist for what may be very little benefit.

AMA Queensland considers that the current arrangements have been serving patients and the broader health system extremely well and that the move to an 'independent' body whose secretariat and executive could potentially be stacked with pharmacy industry representatives presents a serious threat to that stability.

Membership of council: The HCDSDFVP committee recommended that the Pharmacy Advisory Council be comprised of members appointed by the Minister with expertise in law, accounting, business management and members representing the pharmacy sector and consumers.

It is noted that this proposed membership of the committee emphasises the commercial aspects of pharmacy practice rather than patient safety and augmenting a high-quality healthcare system. AMA Queensland considers that a Pharmacy Council is established, doctors – including at least one GP – should have membership of that council. The relationship between dispensers and prescribers is a cornerstone of the health system and the input of doctors will be invaluable to the work that the Advisory Council performs. Ideally a public hospital specialist who has knowledge of the hospital pharmacy sector should also have a place on the Advisory Council.

Recommendation 10

AMA Queensland considers the current regulatory system to be working well. We note however there is no publicly available information on how the *Pharmacy Business Ownership Act is administered*. Greater transparency in this regard could improve compliance and ease of enforcement without the need for a pharmacy council. We consider the government should identify gaps such as these and amend the legislation to incorporate them. Such a move would likely remove the need for a Pharmacy Council.

Recommendation 11

Communicating to the public about Pharmacists providing vaccines and immunisations: AMA Queensland has long opposed pharmacists providing provide vaccinations and immunisations for good reasons. Pharmacists are not trained to provide care in a situation where a patient experiences anaphylactic shock or some other kind of adverse outcome.

Importantly, vaccines administered outside general practice, breakdowns the enduring therapeutic relationship between a patient and their doctor.

Furthermore, the provision of MMR or yellow fever vaccines without a full medical history of a patient is a very concerning and involves unnecessary risk. Vaccines like MMR, typhoid and yellow fever are live vaccines which means that they contain specially prepared organisms that can multiply in the vaccinated person. If that person has a compromised immune system – and they may not be aware if they do – the vaccine strain can cause serious illness or even death. Medications or illicit substances that people have taken in the past can place them at serious risk from live vaccines, so it is not a matter of simply assessing current medications and making a decision on the spot. It is therefore absolutely

"We believe all Queenslanders deserve the best healthcare.....we are all patients"

¹⁰ Aubusson, K (2016), *Pharmacist conflicts of interest and 'up-selling' patients flagged in major federal government review*, Sydney Morning Herald, Online. URL: <u>https://www.smh.com.au/healthcare/pharmacist-conflicts-of-interest-and-upselling-patients-flagged-in-major-federal-government-review-20160728-gqfptl.html</u>

critical that live vaccines are managed by GPs or specialised travel vaccine providers who are extensively trained to assess the risk/benefit ratio of such a product.

We are also concerned that with anti-vaccination groups looking for any opportunity to discredit the safety and efficacy of vaccines, even one adverse outcome delivered at a pharmacy resulting in death could undermine the Government's efforts to increase vaccination rates.

Yours sincerely,

Dr Dilip Dhupelia President AMA Queensland

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Jane Schmitt Chief Executive Officer AMA Queensland