

Pharmacist Endorsement for scheduled medicines proposal - response template

The Pharmacy Board of Australia is inviting feedback on its proposal for an Endorsement for scheduled medicines for pharmacists which includes a draft:

- *Registration standard: Endorsement for scheduled medicines*, and
- *Guidelines: Endorsement for scheduled medicines*

Optional questions have been provided below and you may wish to address some or all of these in your response.

Published submissions will include the names (if provided) of the individuals and/or organisations making the submission unless confidentiality is requested.

Do you want your responses to be published after public consultation?

- Yes, I want my responses to be published after public consultation with my name and organisation visible – please note, organisation name only for publication
- Yes, I want my responses to be published after public consultation but not my name/organisation
- No, I do not want my responses to be published after public consultation

Submissions for website publication should be sent in Word format or equivalent.¹

Name: [REDACTED]

Organisation: **AMA Queensland**

Contact email (will not be published): [REDACTED]

Please note this response template contains the **same questions as the online survey**. Please choose only ONE method of responding to avoid duplicating your submission.

¹ We aim to publish documents in accessible formats (such as word files) to meet international website accessibility guidelines. Therefore, while you are welcome to supply a PDF file of your feedback, we ask that you also provide a text or word file. More information about this is available at <https://www.ahpra.gov.au/About-Ahpra/Accessibility.aspx>

	Question	Your feedback
1.	<p>The draft <i>Registration standard: Endorsement for scheduled medicines</i> at Appendix A sets out the requirements to be eligible for an endorsement for scheduled medicines.</p> <p>Is the information in the draft registration standard clear? If no, please explain why.</p>	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p>
2.	<p>Pharmacists with general registration in Australia are qualified and authorised to prescribe Schedule 2 and Schedule 3 medicines.</p> <p>Currently, some pharmacist prescribing of a range of Schedule 4 medicines for specific health conditions is occurring in some states and territories. See Appendix D and Appendix F for examples of current pharmacist prescribing and scenarios to assist with answering this question.</p> <p>The Board is consulting on the scope of the endorsement and is seeking feedback on the following two options:</p> <p>Option A: An endorsed pharmacist is qualified to administer, obtain, possess, prescribe, sell, supply and/or use Schedule 2, 3 and 4 medicines</p> <p>Option B: An endorsed pharmacist is qualified to administer, obtain, possess, prescribe, sell, supply and/or use Schedule 2, 3, 4 and 8 medicines</p> <p>Which option best describes what you think pharmacists should be qualified to administer, obtain, possess, prescribe, sell, supply and/or use? Include your reasons if possible.</p>	<p>AMA Queensland does not support the described pharmacist scenarios in relation to the following:</p> <p><u>Schedule 4 medications, not limited to:</u></p> <ul style="list-style-type: none"> ▪ Antibiotics: The decision to prescribe antibiotics must consider differential diagnoses and this must be done at the point of care. Pharmacists are not trained in complex history taking including sexual history and symptoms and signs of sexually transmitted disease or life threatening complications such as ectopic pregnancy (when patients frequently do not know that they are pregnant). Pharmacists are not trained in examination of patients. Pharmacists are not trained in the complex science of clinical reasoning which includes considering common differentials and not missing rare differentials which can be life threatening. Pharmacists are not trained the appropriate and rational requesting of pathology investigations to guide antibiotic use or refinement. GPs train for 12-15 years to be able to diagnose and treat infections safely (much of this training being done in the apprenticeship model under direct supervision of a senior doctor) and it is disingenuous to assume that a brief educational course delivered to a non-doctor can deliver equivalent safe and cost effective care. <p>As publicly outlined by Dr Maria Boulton, President of AMAQ at the time of the flawed, secretive and inadequately evaluated North Queensland Urinary Tract Infection Pilot in Queensland:</p> <p><i>[The] pilot was not conducted as a clinical trial and Queensland Health constantly resisted our requests for information about its outcomes. It also refused to provide any mechanisms for doctors or patients to report concerns. Out of frustration we surveyed Queensland doctors about the UTI trial and found hundreds of cases of women who needed further treatment, most for missed diagnoses of sexually transmitted infections, but one ectopic pregnancy and one pre-cancerous mass. When Queensland Health finally released its evaluation of the UTI pilot it found even more cases of women who needed further treatment, but claimed the trial was a success, despite being unable to follow up two-thirds of women who took part.</i></p>

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		<ul style="list-style-type: none"> ▪ Anti-nausea medications: Again, quoting AMAQ Past President Dr Maria Boulton in the context of the Queensland Government's expansion of pharmacy prescribing: <i>...nausea may seem straightforward, but it can be a symptom of diabetes, gastroenteritis, brain cancer, appendicitis, sepsis, meningitis and more. Treating just the symptom and not the underlying cause places the patient at risk.</i> ▪ Cardiovascular medications: The prescription, combination and adjustment of medications including but not limited to blood pressure, heart failure, lipid modification and anti-thrombotic treatments requires careful consideration of history, family history, examination and appropriate bedside tests and investigations. It is often managed by GP specialists in consultation with non-GP specialists. The complexity and clinical judgement and reasoning required is honed over many years of training in the clinical environment. Pharmacists play an important role, for example in home medicines review and in instructing patients on medication side effects. It is not appropriate for a pharmacist to be unilaterally prescribing a drug with potentially life threatening side effects who has not been trained to the standard of a medical doctor. ▪ Hormonal therapies: The prescription of hormonal therapies requires an expert history, examination, appropriate investigations, appropriate public health screening, consideration of family history and often complex decision making encompassing the balance of risks, benefits and relative contraindications with shared decision making critical for patient safety and medicolegal purposes. Again, the complexity and clinical judgement and reasoning required is honed over many years of training in the clinical environment. Our members report that pharmacists frequently comment to patients regarding their hormonal treatment, casting doubt on medical decision making and in doing so showing that they simply do not have an appropriate depth and breadth of knowledge and clinical experience to be advising patients needing these important treatments. <p><u>Schedule 8 medications</u></p> <ul style="list-style-type: none"> ▪ Given the lack of evaluation of pharmacist prescribing regarding S4 medications, it is inconceivable that expansion to S8 medications would be considered. AMA Queensland's members are extremely concerned about the grave risk of harm and death to patients if drugs of dependence could be prescribed and administered by a pharmacist.

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		<ul style="list-style-type: none"> ▪ It is approximately 8 years since Codeine, a weak opioid, was scheduled so that it required a doctor's prescription, and this was done by the Therapeutic Goods Administration to curb codeine dependency, accidental poisoning and opioid related deaths. <p>AMA Queensland submits that Ahpra consider why it is even broaching pharmacist prescription of S8 medications less than 10 years since it was objectively proven that restricting a weak opioid reduced codeine sales and codeine related overdoses by 50%. https://onlinelibrary.wiley.com/doi/full/10.1111/add.14798</p> <ul style="list-style-type: none"> ▪ Opioids are most appropriately prescribed in the setting of acute severe injury, post operatively, in cancer pain and in palliative care. None of these scenarios are remotely consistent with a pharmacist unilaterally prescribing for a patient. <p>AMA Queensland also notes that pharmacy prescribing in NSW did not reduce GP visits. In addition, GPs in Victoria advise that pharmacist prescribing of prolia for the treatment of osteoporosis has led to terrible fragmentation of care, with patients not having bone density, calcium intake and vitamin D levels reviewed which is essential for osteoporosis management (in addition to smoking status, thyroid status and more). AMA Queensland notes none of these are performed by pharmacists but are standard care for GPs.</p>
3.	<p>If considering Option B:</p> <ul style="list-style-type: none"> a. Which Schedule 8 medicines, and in what situations do you believe that pharmacist prescribing of Schedule 8 medicines could support patient care? b. What safeguards would you consider essential to support safe practice in these situations? 	<p>AMA Queensland does not support Option B – see 2 above.</p>
4.	<p>Are there any specific medicines that you believe pharmacists should not be qualified to prescribe? If yes, please list the medicines and your reasons.</p>	<p>See 2 above.</p>
5.	<p>The proposed draft registration standard sets out the eligibility requirement that an applicant must complete an education program approved by the Board (which would include course</p>	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p>

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	<p>work and work-integrated learning experience) to be eligible for an endorsement for scheduled medicines. The proposed draft registration standard does not set any minimum time practising as a pharmacist with general registration to be eligible to apply for an endorsement.</p> <p>Do you agree with the eligibility requirement for an endorsement as set out in the draft registration standard? If not, please describe why and include information to support your position if possible</p>	
6.	<p>The proposed draft registration standard states that completion of an approved program qualifies a pharmacist to have their registration endorsed. Approved programs need to meet the accreditation standards for pharmacist prescriber programs and providers have to show that graduates have met relevant performance outcomes and prescribing competencies. This means that the Board does not need to specify that an approved qualification needs to align with a particular level in the Australian Qualifications Framework (AQF). Appendix E provides further information on the Accreditation standards for pharmacist prescriber programs.</p> <p>Do you agree with this approach? Please provide an explanation for your answer and include information to support your position if possible.</p>	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p>
7.	<p>The proposed draft registration standard has two pathways to qualify for an endorsement. These are:</p> <ul style="list-style-type: none"> • completing an approved program of study leading to endorsement for scheduled medicines • completion of another program of study that the Board assesses as substantially equivalent to, or based on similar competencies to, an approved program of study leading to endorsement for scheduled medicines (<i>pharmacists who have completed an overseas prescribing qualification</i>) 	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p>

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	<p>Are the proposed pathways in the draft registration standard clear and do you think they are suitable to support all pharmacists who have completed appropriate prescriber education to be eligible for the proposed endorsement?</p>	
8.	<p>The draft guidelines at Appendix B provide information for pharmacists with an endorsement, including guidance on good prescribing practice managing conflicts of interest and separating prescribing and dispensing.</p> <p>Is there anything that needs to be changed, added or removed from this guideline?</p>	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p>
9.	<p>Does the guidance on managing conflicts of interest and separating prescribing and dispensing need to be changed? If so, please outline the risks that you have identified about these issues and evidence that supports the need for additional or alternative guidance.</p>	<p>AMA Queensland considers that there can be no justification for the continued restrictions on who can own a pharmacy and this needs to be acknowledged and changed, whether or not this is the remit of the Pharmacy Board.</p> <p>To avoid the appearance of impropriety, it would be appropriate for Ahpra to publish any contact the Pharmacy Board has had with lobby groups including the Pharmacy Guild and any gifts or hospitality which have been provided. Likewise, AMA Queensland considers that state and federal governments should be transparent when making announcements about pharmacy scope, including declaring the financial donations and equivalent they have received from all interested parties.</p>
10.	<p>Are there any key issues about the proposed endorsement for scheduled medicines that haven't been addressed in the guidelines? If yes, please describe and provide information if possible.</p>	<p>See 2 above.</p> <p>AMA Queensland notes that there is no mention of the very basic requirement that a pharmacist (in the context of proposed prescribing) communicate in writing with the patient's specialist general practitioner and non-GP specialists. 'Work collaboratively', and 'communicate effectively' do not in any way mandate this basic standard of patient safety and professional courtesy that all medical practitioners are taught is essential. A health professional does not reference 'access to effective systems that facilitate timely communication to the patient's other healthcare professionals'. An ethical professional health practitioner accepts that whatever the barriers they have a legal duty to keep the patient safe by communicating appropriately. There is little value in completing comprehensive patient notes in a record at the pharmacy if the patient's medical doctors do not know what is in these notes.</p>

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11.	Could there be unintended impacts from the proposed endorsement for scheduled medicines that haven't been addressed in the guidelines? If yes, please describe and provide information if possible.	See 2 above.
12.	Could the proposed draft standard and guidelines have potential negative or unintended impacts on Aboriginal and Torres Strait Islander peoples? If yes, please describe	This is a vulnerable group of patients who are often socio-economically disadvantaged and may have health literacy vulnerabilities and complex comorbidities. They may therefore be more likely to take up the offer of pharmacy consultation and prescription and may be less likely to understand the difference between a doctor and pharmacist. They are at higher risk, due to comorbidities, of inadvertent iatrogenic harm, particularly if a comprehensive history, examination, family history and investigation results are not available or cannot be interpreted with the benefit of high level clinical reasoning. Their care requires a level of education, training and practiced skills which pharmacists have not proven that they can obtain or maintain.
13.	Could the proposed draft standard and guidelines result in any adverse cost implications for consumers, practitioners or other stakeholders? If yes, please describe.	There is a clear conflict of interest in a pharmacist being able to prescribe and sell a product – while the document advises that a different pharmacist should prescribe and dispense, it immediately allows the same pharmacist to do so if there are 'extenuating circumstances' and the examples given are so broad as to allow this to occur justifiably under most circumstances ('patient needs medicine urgently'). It is in a pharmacist's interest to sell pharmacy stock, because they own the pharmacy or their employer (who controls their conditions of employment) does. There is no financial advantage to a doctor based on whether they prescribe a medication or do not. Further, it is not possible for a doctor to own a pharmacy yet it is possible for a pharmacist to own a doctor's surgery. There are clear conflicts of interest.
14.	Could the proposed draft standard and guidelines result in any potential negative or unintended impacts for people vulnerable to harm in the community, such as culturally and linguistically diverse, LGBTQI+ peoples, children, the aged, those living with disability, and people who are the potential targets of family and domestic violence? If yes, please describe.	This is a vulnerable group of patients who may be socio-economically disadvantaged and may have health literacy vulnerabilities and complex comorbidities. They may therefore be more likely to take up the offer of pharmacy consultation and prescription, as it may be offered by the pharmacist as a 'convenient' option to them. Many, particularly those who are culturally and linguistically diverse and those who are intellectually impaired, may be less likely to understand the difference between a doctor and pharmacist. They are at higher risk, due to comorbidities, of inadvertent iatrogenic harm, particularly if a comprehensive history, examination, family history and investigation results are not available or cannot be interpreted with the benefit of high level clinical reasoning. Their care requires a level of education, training and practiced skills which pharmacists have not proven that they can obtain or maintain.

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15.	Can you identify any other potential regulatory impacts that the Board needs to consider?	<p>AMA Queensland considers that there can be no justification for the continued restrictions on who can own a pharmacy and this needs to be acknowledged and changed.</p> <p>To avoid the appearance of impropriety, it would be appropriate for Ahpra to publish any contact the Pharmacy Board has had with lobby groups including the Pharmacy Guild and any gifts or hospitality which have been provided. Likewise, AMA Queensland considers that state and federal governments should be transparent when making announcements about pharmacy scope, including declaring the financial donations and equivalent they have received from all interested parties.</p>
16.	Are there alternative or additional options not presented that could address the problems identified? If yes, what are they and what are the benefits and costs associated with the other option(s) you have identified?	See 17 below.
17.	Do you have any other comments or feedback?	<p>If AMA Queensland has not provided input on a specific point in this survey this does not constitute agreement or endorsement of that point/topic.</p> <p>AMA Queensland continues to offer to conduct a joint PhD research project with Queensland Health (and would consider other appropriate research partners) to analyse doctors' scope of practice to identify which tasks can be safely performed by other health professionals. It is essential that any such study is done in an academically rigorous process where bias is transparently stated and mitigated.</p>