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# Response to the Pharmacy Board of Australia Public Consultation - draft Endorsement for scheduled medicines for pharmacists

Royal Australasian College of Physicians submission to the Pharmacy Board of Australia

June 2026

## About The Royal Australasian College of Physicians (RACP)

The RACP trains, educates and advocates on behalf of over 21,000 physicians and 9,000 trainee physicians, across Australia and Aotearoa New Zealand.

Across 33 specialties and a wide range of practice settings, the RACP represents a broad range of physicians, supervisors and trainees including in clinical pharmacology and toxicology, addiction medicine, general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, infectious diseases medicine, palliative medicine, geriatric medicine, sexual health medicine, rehabilitation medicine and occupational and environmental medicine.

Following years of rigorous specialty medical training, RACP members become leaders in advanced prescribing, highly skilled in complex patient assessment, differential diagnosis, complex medication interactions, dosing, contraindications, and evidence-based adjunctive treatment approaches.

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*We acknowledge and pay respect to the Traditional Custodians and Elders – past, present and emerging – of the lands and waters on which RACP members and staff live, learn and work. The RACP acknowledges Māori as tangata whenua and Te Tiriti o Waitangi partners in Aotearoa New Zealand.*

## Summary – RACP position

The RACP holds strong concerns about the Pharmacy Board of Australia's (PBA) proposed Endorsement model for pharmacist prescribing of scheduled medicines.

These concerns reflect extensive input from a wide range of RACP leaders, bodies, physicians and trainees across a broad range of adult medicine and its subspecialties, paediatrics and child health and its subspecialties and specialty societies. They reflect an expansive set of issues relating to education and training, nature and context of patient interactions, diagnostic uncertainty, medicines potency, care fragmentation, clinical governance, workforce and funding impacts, and medico-legal considerations.

**The RACP's positions on the options posed by the Pharmacy Board's consultation paper are:**

- **Schedule 8 and 4D medicines should not be administered, prescribed or used by pharmacists. There are no appropriate safeguards for pharmacist prescribing of these medicines**
- **A wide range of Schedule 4 medicines should not be administered, prescribed or used by pharmacists**
- **Pharmacist prescribing of Schedule 4 medicines should be limited to:**
    - **clearly defined, low risk clinical scenarios for minor conditions**
    - **prescribing where diagnosis is clear and undifferentiated**
    - **prescribing decisions which tightly controlled.**
- **In the circumstances this limited prescribing occurs:**
    - **detailed care pathways and processes, co-designed with GPs, physicians and other specialists need to be in place**
    - **clear and timely communication with regular treatment providers must occur**
    - **use of real-time prescription monitoring systems accessible by all treatment providers must apply**
    - **ongoing audit and evaluation mechanisms must be in place.**

Safe prescribing involves detailed assessment, investigation, diagnosis, monitoring and communication in a range of different ways. Medicines knowledge alone is insufficient to support independent prescribing, particularly for patients with complex, chronic, multisystem, diagnostically challenging conditions frequently managed by physicians. These patients are referred by GPs for specialist diagnostic expertise, assessment, multidisciplinary management and ongoing oversight. By contrast, the draft endorsement model frames prescribing as a discrete, episodic transaction. This does not reflect the realities of clinical care and risk to patients.

The RACP does not see how the proposed Endorsement model would result in improved safety or quality of care for patients with complex, evolving, or undifferentiated conditions. We hold significant and unaddressed concerns about diagnostic complexity, governance, continuity of care, and system-level impacts.

There is a critical need for extensive engagement with the Medical Board of Australia in relation to the broader implications of the proposal for the national registration scheme and medical registrants. Further clarification is required regarding potential impacts on clinical accountability, cost displacement, liability frameworks and professional indemnity insurance premiums for medical practitioners.

The RACP welcomes the opportunity to engage with the Pharmacy Board on potential pharmacist prescribing roles for the scenarios of low risk, self-limiting conditions set out above, balancing patient access pressures with clinical safety.

The RACP addresses questions posed by the Pharmacy Board's consultation below.

**Which option (Option A- S4 medicines or Option B- S8 medicines) best describes what pharmacists should be qualified to administer, obtain, possess, prescribe, sell, supply and/or use?**

**The RACP opposes administration, prescription or use of Schedule 8 medicines by pharmacists, whether independently or within a collaborative model of care.**

This position is based on patient, health service and system level risks to quality and safety, including:

- **Schedule 8 medicines are high-risk medicines associated with significant risks of misuse, diversion, overdose, tolerance, adverse events and community harm**.
- Schedule 8 medicine prescription requires **comprehensive clinical assessment, longitudinal management, monitoring of outcomes and adverse effects, and ongoing review of patient risk factors, comorbidities and functional status.** These responsibilities extend substantially beyond medicine selection.
- Across life stages, the patients of physicians prescribed Schedule 8 medicines **frequently present with undifferentiated symptoms, multimorbidity, psychosocial complexity, mental health comorbidity, substance use concerns, frailty or evolving clinical conditions**. Safe prescribing for these patients requires detailed history, investigations and comprehensive assessment.
- Schedule 8 medicine prescribing frequently requires **careful coordination across multiple treating practitioners and services**, which can span GPs, physicians (including general physicians, geriatricians, neurologists, medical oncologists, paediatricians, palliative medicine specialists, and rehabilitation medicine physicians), psychiatrists and allied health professionals. In some cases, the expertise and advice of addiction medicine specialists and / or clinical pharmacologists is also required.
- **Introducing additional prescribers into already complex care arrangements risks duplication, inconsistent management plans, unclear accountability and reduced continuity of care** with serious risks of harm for patients.
- **Physicians and their specialty skills are often critical for appropriate and safe Schedule 8 medicines prescribing for complex and evolving disease presentations** requiring consideration of differential diagnoses, extensive investigations, other assessments and longitudinal clinical management.
- There is a **lack of robust evidence of the safety of this proposal nationally or internationally.**
- Allowing pharmacists **to prescribe, dispense and sell Schedule 8 medicines removes an important layer of independent oversight and weakens existing safeguards** designed to reduce inappropriate prescribing, duplication, diversion and medicine-related harm. The proposed model does not adequately address the risk of conflict created where prescribing, dispensing, and sale of Schedule 8 medicines occur within the same interaction.
- Schedule 8 medicine **prescription in retail and community pharmacy settings poses inherent serious risks**, noting inevitably limited consultation time, inherent time pressures to dispense in parallel with prescribing and general medicines advice, limited privacy, incomplete access to records and investigations, and reduced capacity for follow-up, monitoring and escalation of care where deterioration, adverse outcomes or complications arise.
- Even **prescribing within collaborative models only would introduce a range of challenging complexities and risks** across communication, coordination, oversight and supervision involving already complex conditions.

These risks are not confined to Schedule 8 medicines. **There are comparable risks for many Schedule 4 medicines requiring detailed diagnostic assessment, investigation and ongoing monitoring**.

RACP members emphasised that the above concerns are heightened for patients with substance use disorders, chronic pain conditions, palliative care needs, complex multimorbidity, neurodevelopmental conditions, paediatric patients, and patients with acute undifferentiated presentations, elderly patients and

patients in rural, regional and remote settings without physician support structures. These concerns are detailed below.

| Patient group | Major risks |
|---|---|
| Patients with substance use disorders | Diversion, doctor/pharmacy shopping, escalation of dependence, and inadequate recognition of behavioural and psychosocial risk factors in potentially brief and protocolised consultations. |
| Patients with chronic pain presentations | Inadequate diagnostic assessment, symptoms masking underlying serious and complex pathologies, undetected malignancies, insufficient review of function, dependence risk and long-term benefit versus harm. |
| Patients with complex multimorbidity | Polypharmacy, interacting therapies, prescribing cascades, avoidable drug interactions, duplicated therapy, and lack of coordinated care planning. |
| Palliative care | Rapid symptom escalation, opioid titration, and inadequate management of complex symptom clusters (e.g. pain, nausea, delirium, constipation). |
| Patients with mental health conditions | Potential diagnostic oversights, comorbid anxiety/depression, risk of misuse, and potential lapses in stringent protocols for ongoing monitoring of treatment response, side effects, and impact on functional outcomes. |
| Paediatric patients | Missed developmental conditions (e.g. ADHD, ASD-related comorbidities), growth monitoring risks, behavioural assessment gaps, inadequate holistic, family-centred care. |
| Patients with acute undifferentiated conditions | Inadequate identification of early serious illness (e.g. neurological deterioration, malignancy-related complications, infection, obstruction, delayed escalation. |
| Older patients | Oversight of increased sensitivity to opioids and sedatives, renal/hepatic impairment affecting dosing inadequately screened. |
| Rural, regional and remote patients | Reduced access to physicians, multidisciplinary teams and follow-up care. |

**The RACP opposes Schedule 4D medicine administration, prescription or use by pharmacists**, whether in independent or collaborative care practice contexts. This is for similar reasons to those for Schedule 8 medicines, including the challenges of prescribing these to complex patient groups by pharmacists in pharmacy settings.

**For complex patients with a range of clinical risk factors and vulnerabilities, there can be little meaningful difference between the risks of Schedule 8 medicines and Schedule 4Ds**. Schedule 4D medicines which are habit forming, antipsychotic medicines with misuse potential, gabapentin, pregabalin, benzodiazepines, and tramadol were each pointed out explicitly for exclusion. A full list of proposed Schedule 4 exclusions is set out in our response to the next consultation question.

**Any expansion of pharmacist prescribing to Schedule 4 medicines should be limited to clearly defined, low risk clinical scenarios, focused on addressing significant challenges with access to timely care.** This must be governed by protocolised care pathways for minor conditions not requiring differentiation, and GP-led collaboration, where diagnosis is established and prescribing decisions are tightly bounded, supported by mandatory communication with regular treatment providers (including GPs and physicians where required), audit and escalation mechanisms. Any such prescribing must also be integrated into prescription monitoring programs at the state and federal levels, which would require significant systems and structural integration reform.

**Are there specific medicines you believe pharmacists should not be qualified to prescribe?**

**There are a wide range of Schedule 4 medicines used for specific clinical indications that are inappropriate for pharmacist administration, prescribing or use.** They require GP, physician and / or other specialist involvement, with careful and considered diagnosis, ongoing monitoring, and are used in clinical contexts requiring considerable care and caution.

We set these out in the table below, with clinical rationales.  For all these medications and their indications, prescribing occurs within a continuum of clinical assessment, monitoring, evaluation of treatment approaches, and ongoing risk reassessment.

| Medication type | Clinical indications/contexts of use | Clinical rationale |
|---|---|---|
| Antibiotics | Undifferentiated infection; community infections; paediatric infections | Requires accurate diagnosis (bacterial vs viral), culture collection, and stewardship oversight; risk of antimicrobial resistance and missed serious illness; lack of diagnostic testing and follow up pathways. |
| Antihypertensives | Hypertension and cardiovascular risk management | Requires full clinical assessment, identification of secondary causes, comorbidities, and ongoing monitoring; risk of inappropriate initiation. |
| Anticoagulants (e.g. warfarin, DOACs) | Thromboembolic disease prevention | Requires bleeding risk assessment, renal function monitoring, and dose adjustment; high risk of serious harm if mismanaged. |
| Bronchodilators/relievers | Asthma presentations | Requires differential diagnosis and ongoing clinical assessment of complications which can mimic and complicate other respiratory and cardiovascular conditions, requiring differential diagnosis; oversight risks for prevention opportunities and complex exacerbations may not be appreciated. |
| Insulin and complex diabetes therapies (including GLP-1s) | Diabetes management | Requires metabolic assessment, monitoring for hypoglycaemia, and ongoing titration; complex chronic disease requiring longitudinal care and complex ongoing monitoring. |
| Thyroid and endocrine therapies (e.g. thyroxine, HRT) | Endocrine disorders | Requires biochemical monitoring and nuanced dose adjustments; dependent on interpretation of pathology and clinical state. |
| Corticosteroids (systemic) | Inflammatory/autoimmune conditions | Can mask underlying disease; significant systemic adverse effects; requires close monitoring and clinical oversight. |
| Cardiovascular drugs (including antiarrhythmics, heart failure medicines) | Cardiac disease, arrhythmias, heart failure | Requires investigation (ECG, laboratory monitoring), ongoing review and dose adjustment; risk of arrhythmia, electrolyte disturbance, hypotension, or organ toxicity. |
| Immunosuppressants and biologics | Autoimmune disease, transplant, inflammatory conditions | Requires specialist diagnosis, infection risk management, pathology monitoring, and ongoing surveillance for serious adverse effects and multisystem treatment impacts. |
| Chemotherapy / oncology therapies | Cancer treatment | Highly specialised regimens requiring diagnosis, staging, toxicity monitoring, and multidisciplinary oversight; not appropriate outside specialist care pathways. |
| Anti-epileptic medicines/anticonvulsants | Seizure disorders | Requires specialist diagnosis, careful titration, and complex monitoring of neurological and systemic adverse effects. |
| Psychotropic medicines (e.g. antidepressants, antipsychotics, mood stabilisers) | Mental health disorders | Require complex diagnostic assessment, monitoring for adverse effects and suicidality, and integration with non-pharmacological care and longitudinal review. |
| Hormonal therapies (e.g. reproductive and endocrine medicines) | Reproductive, metabolic, endocrine conditions | Requires differential investigations, ongoing cardiovascular and thrombotic risk assessment, and longitudinal follow-up. |

| Medication type | Clinical indications/contexts of use | Clinical rationale |
|---|---|---|
| Polypharmacy / renal-adjusted medicines | Multimorbidity; chronic kidney disease | Requires holistic patient assessment, interpretation of pathology, medication reconciliation, and dose adjustment across multiple interacting therapies. |
| Paediatric medicines | Children and adolescents | Requires weight-based dosing, developmental assessment, safeguarding considerations, and recognition of atypical or evolving presentations. |
| Medicines requiring investigation interpretation | Broad range of acute and chronic conditions | Safe prescribing depends on interpretation of pathology, imaging, ECGs or other investigations not routinely available or interpretable within pharmacy settings. |
| Medicines requiring ongoing monitoring and follow-up | Chronic disease management | Requires longitudinal care, treatment titration, adverse event monitoring, and management of complications beyond episodic encounters. |
| Medicines requiring specialist shared-care arrangements | Complex chronic disease and specialist-managed conditions | Safe prescribing dependent on coordinated multidisciplinary management, specialist review, and integrated communication across care teams. |

**Jurisdictional pilots of pharmacist prescribing to date have not demonstrated consistent diagnostic accuracy or adequately addressed diagnostic uncertainty, escalation pathways, or system impacts.**

**Robust national evaluations of safety and efficacy remain limited**. Emerging evidence from implementation models, including interstate trials and audit processes, suggests variability in clinical outcomes and reinforces the need for caution in extending prescribing authority beyond tightly defined protocols.

**Investment in the medical workforce, across physicians, GPs and other specialists, represents the most appropriate and evidence-informed response to workforce and access challenges for the complex patients for whom these medicines may be indicated.** Further consideration should also be given to the involvement of nurse practitioners in collaboration with GPs.

### Do you agree with the eligibility requirement for an endorsement as set out in the draft registration standard?

**The RACP does not support the eligibility requirements for endorsement.**

The consultation documents describe an endorsement model and eligibility criteria that appear to be at an early stage of development. **There is no clarity on critical details of education, training and experience**, including necessary years of post-registration experience, core professional competencies, minimum years of clinical supervision or supervisory assessment pre-endorsement, formal recredentialling requirements, or outcomes monitoring for continuous improvement. There is also **no detail on endorsed courses, content, design, course governance and accreditation arrangements.**

Self-assessment and theoretical course knowledge alone do not support safe prescribing.

We consider that the eligibility proposal introduces additional substantial risk, uncertainty and variability in giving power to the Pharmacy Board to determine 'substantially equivalent' international courses from vastly different regulatory environments.

**The draft provision for 10 hours of CPD on prescribing practice post-endorsement is inadequate for maintaining competence without existing skill base, expertise and experience in prescribing, the identification and screening of red flags, basic clinical diagnostic skills, and integrated multidisciplinary practice.**

The eligibility requirements signal an absence of criteria to identify, prevent and divert harms to patients in potential scenarios of conflict where a sole registrant is a prescriber, dispenser, seller and owner of a pharmacy.

### Are the proposed two pathways in the draft registration standard clear and do you think they are suitable to support all pharmacists who have completed prescriber education to be eligible to prescribe?

**The RACP considers the two pathways described are inadequate and lack critical detail. We cannot be confident that they would enable safe prescribing practice to a minimum standard**.

The registration standard leaves unaddressed safety, governance, quality and consistency concerns in both pathways.

Both pathways rely on completion of unspecified educational programs, domestically or an 'international equivalent', introducing serious risks of variability.

Neither pathway addresses the absence of minimum training and minimum years of supervised practice in diagnosis, clinical assessment and pathophysiology. Both would confer eligibility without clarity on the level of capability required for safe prescribing practice.

Safe prescribing in physician, GP and other specialist care relies on comprehensive assessment, access to investigations and continuity of care. Multidisciplinary input is often required. By contrast both pathways treat prescribing as a single theoretical step rather than part of an integrated clinical process over time.

The pathways may generate misplaced perception of competence without the necessary clinical depth, increasing the risk of inappropriate and risky prescribing. They introduce serious risk of pharmacists with very different levels of clinical preparation being treated as equivalent.

**Neither pathway sets out how prescribing practice will be monitored, how adverse outcomes will be identified, or how clinical variation will be managed**. Given that prescribing risk often emerges over time, this is a significant gap and creates a risk of expansion into high-risk clinical contexts.

We reiterate need for further engagement of the RACP and other medical colleges to identify low risk Schedule 4 prescribing functions suitable to the training and experience levels of pharmacists and how pathways can be appropriately designed to mitigate patient and public safety risk.

### Is the information in the draft registration standard clear?

**The RACP considers the draft standard is at a very early stage, with critical oversights, offering a self-regulated approach to implementation, an absence of sufficient guardrails and lack of clarity.**

RACP members consistently highlighted that these oversights offer significant risks of amplifying ambiguity for patients in an already complex and layered health care system, causing confusion on when and where to seek care, potentially delaying diagnosis and diverting patient demand across the health system.

Members frequently cited the absence of information on how prescribing decisions are to be made in practice, by whom, and within what clinical and governance frameworks. This reduces our capacity to draw inferences about how the proposed pathways are to be understood in clinical practice settings.

Members also frequently pointed out that standard does not discuss regulatory expectations for diagnoses, expectations regarding overall responsibility for clinical judgement, clinical monitoring and outcomes. Ambiguity in roles and accountabilities must be avoided, given their relationship with quality, efficacy and efficiency of patient care.

### Is there anything that needs to be changed, added or removed from the draft guidelines for Endorsement?

A point of emphasis from RACP members is that **the draft guidelines do not articulate medico-legal accountability for prescribing decisions, diagnosis, follow-up, and the management of adverse outcomes**, nor how complaints regarding pharmacist prescribing would work in practice. This offers significant uncertainty for pharmacists, GPs, physicians and other health professionals.

There is **limited contextualisation of the draft guidelines within broader health system governance and health record infrastructure that support prescribing decisions** and how they would function in relation to an endorsed pharmacist. This includes consideration of access to comprehensive clinical information, assessments and records, initiating and maintaining communication with regular treatment providers, defined arrangements for audit and surveillance, and adverse events reporting and outcomes. Significant risks of delayed or missed diagnosis, inappropriate treatment, and escalating need in emergency and other clinical settings cannot be excluded and must be addressed.

Where prescribing authority is determined at a state and territory levels, greater consideration of how to manage potential inconsistency in scope, implementation, and oversight across jurisdictions is required.

### Does the guidance on managing conflicts of interest and separating prescribing and dispensing need to be changed?

Below are a range of scenarios not covered by the draft guidance where pharmacists could inadvertently become conflicted between the principles of appropriate prescribing and dispensing incentives.

***Retail / commercial chain pharmacy conflicts***

- The guidance does not address the influence of retail and commercial pharmacy environments and the potential pressure to sell on prescribing behaviour.

- There can be a fundamental mismatch between quality care and its delivery within a setting where medicines are marketed, sold, and promoted, creating an unmitigated link between clinical decision making and commercial processes. Such environments can introduce subtle but persistent pressures and perverse incentives that may influence prescribing decisions.
- These pressures will not be addressed through disclosure requirements alone as the standard infers and would therefore not be subject to appropriate National Scheme regulation.
- This would represent a move toward market driven prescribing rather than safe and effective use of medicines. Patients may receive medicines more readily, including in circumstances where risk–benefit considerations would support a more cautious approach.

***Care model and prescribing interface conflicts***

- The guidance does not address the potential conflict created when prescribing occurs outside established care teams, communication pathways, without clinical records, thorough patient clinical information and the resulting pressures to prescribe instead of referring care elsewhere in these instances.

***Role/professional conflicts***

- The guidance does not address the potential conflict between prescribing, supply, and sale of medicines within the same interaction, namely the issue of independent clinical checks where prescribing and dispensing are undertaken by the same practitioner.
- Dispensing functions as a secondary verification point that can identify prescribing errors, inappropriate treatment and / or safety concerns. Collapsing these functions into a single role function means the pharmacist is effectively self-reviewing their own prescribing decisions.
- The guidance does not address how the proposed collapsing of roles could create a conflict between prescribing and referring, namely a disincentive to refer to other health professionals to prescribe and dispense. There are no provisions to ensure referral decisions are independent of prescribing interests.
- The guidance does not address potential conflicts involving ensuring provision of quality care in busy pharmacy settings. This can give rise to clinical errors. This cannot be mitigated through self- reporting.
- The guidance does not recognise that when prescribing occurs without clearly defined diagnostic accountabilities, a conflict arises between scope of practice and the requirements for safe care.

**Are there any key issues about the proposed endorsement for scheduled medicines that have not been addressed in the guidelines?**

As detailed above, the draft materials have not addressed:

- Patient groups and clinical situations unsuitable for pharmacist prescribing. Clinical safety requires clear limitations set for children, pregnancy, frail older people, cognitively impaired patients, palliative patients, people with multimorbidity, renal or hepatic impairment, polypharmacy, immunosuppression, diagnostic uncertainty, complex pain, rehabilitation needs, mental health presentations, and any presentation requiring differential examination, investigation and comprehensive monitoring.
- Risks of diagnostic uncertainty, delayed diagnosis and escalation, and duplicated treatment.
- Managing adverse events, including effects of prescribed medications on other patient comorbidities.
- Expectations regarding clinical escalation, follow up care, monitoring, clinical deterioration recognition, record keeping, referral thresholds, deprescribing indicators, integration of care and communication with usual treating practitioners.
- Informed financial consent. For instance, whether an endorsed pharmacist would be required to disclose to the patient in the consent process any financial motives or incentives for prescribing.
- The extent of potential medico-legal risks and how they can be appropriately addressed.

- How the standard and guidelines would interact and intersect with existing TGA, PBS and MBS frameworks.

**Could there be unintended impacts from the proposed endorsement for scheduled medicines that have not been addressed in the guidelines?**

Possible unmitigated patient impacts include potential for misdiagnosis, delayed diagnosis, inadequate follow up and access to appropriate care, fragmentation of care, unclear professional responsibilities, harmful medication interactions and advice, symptom exacerbation, morbidity, mortality and antimicrobial resistance.

Harmful, low value prescribing cascades are possible, given the proposal and standard encourages access to prescribing outside of medical care. The RACP and its Specialty Societies have collaborated on the Evolve program and recommendations on medicines use in the specialties of geriatric medicine, infectious diseases, nephrology, neurology, general paediatrics , palliative medicine and pharmacology in particular, illustrate the complex considerations involved in the use of a wide range of medicines.

The proposal could encourage misplaced clinical confidence, conflicting advice for patients who need clear care plans, and may lead to patients incorrectly attributing GP, physician and other specialist medical practitioner responsibilities to pharmacists. Absent clear guidance on appropriate representations pharmacists can make to patients, it could also increase 'holding out' notifications under the National Law. Patients with lower health literacy, economic pressures, for whom medical care is most indicated, could stand to be disproportionately impacted.

We hold serious concerns the endorsement seeks to ease patient demand, while risking later escalation into secondary and tertiary care settings, which are already pressured. System costs and medico-legal issues could be significant.

Patients consulting pharmacists may also have reduced privacy and confidentiality. The physical space and design of many pharmacies are not conducive to history taking or physical examination.

RACP members expressed particular concern for the impacts of the endorsement on the continued viability of General Practice and patients' continued access to the holistic skills of GPs to reduce and prevent unnecessary escalation to physician care or hospital admission. There are risks of delayed demand for GP care for follow up, adverse reactions and potential for delayed symptom recognition. This would have flow on impacts for physician capacity and caseloads.

Access to medical care is crucial in rural, regional and remote communities for equitable healthcare outcomes. We are concerned that the proposal could reduce the much-needed distribution of GPs in rural, regional and remote areas in the short term and generate unsustainable demand pressures over the medium and longer term from escalating need and unaddressed health issues. This again would produce follow-on pressures for access to physician care.

The Pharmacy Board must also consider the overall potential for increased cost to the PBS from increased prescribing and dispensing, and the implications for medicines supplies. As a member of the TGA's Medicine Shortage Stakeholder Forum, the RACP is aware of significant and regular medicines shortages impacting the most vulnerable priority groups, the challenges of rapid international importation and sourcing during public health crises, and underdeveloped domestic manufacturing capabilities. This makes our supply of medicines more precarious than other global markets with far larger populations. This proposal may exacerbate existing medicines supply issues for patients for whom ongoing access is vital.

**Could the proposed draft standard and guidelines have potential negative or unintended impacts on:**

**a) Aboriginal and Torres Strait Islander peoples**

The range of risks explored above are heightened for Aboriginal and Torres Strait Islander communities, who face higher overall rates of comorbid complex conditions.

The proposals risk fragmenting prescribing episodes from Medicare general health checks and multidisciplinary care offered by Aboriginal Community Controlled Health Organisations (ACCHOs), which are

crucial for early detection and ongoing management of complex conditions including diabetes, kidney disease and related conditions. ACCHOs are also crucial for providing culturally safe care for Aboriginal and Torres Strait Islander communities.

### b) People vulnerable to harm within the community

For the diverse patient groups at increased vulnerability to harm, the draft standard and guidelines do not recognise the often complex care needs of these groups beyond prescribing medicines. This requires a holistic understanding of the patient, their environment and services they may need.

There are significant risks that trauma, coercion, violence, abuse or harm related issues could go undetected and be inappropriately managed in transactional prescribing encounters outside the context of ongoing relationships with treating practitioners like GPs, physicians and other specialists. Lower levels of health literacy for some people could have further compounding effects.

Interpreters and community liaison supports can be essential for the prevention of harm and their availability within pharmacy settings is not established.

**Could the proposed draft standard and guidelines result in any adverse cost implications for consumers, practitioners or other stakeholders?**

For patients, adverse costs could include increased medication prices, decreased use of generics and competition for diminishing medicine supplies, especially given gaps in PBS eligibility for pharmacist prescribing of subsidised medicines.

Medicare items for subsidised occasions of service with a pharmacist are unavailable. This cost would fall to the patient in a private practice community setting. For retail and commercial pharmacy environments the potential for price spikes in multiple components of service is particularly concerning.

Patients may also bear the costs of duplicated care, diversion to other care settings, and avoidable referrals.

The potential for repeat investigations, ordering of inappropriate investigations, and the financial costs to patients and the health system where care is fragmented must be addressed.

The costs of unidentified chronic disease and onset comorbidities not detected for the patient and health system are critical to consider, particularly once prevention or early intervention opportunities have ended and disease has progressed.

This proposal could inadvertently defer risk and cost across the National Scheme, particularly to the Medical Board and registered medical practitioners, particularly through lack of clarity around pharmacist responsibilities in working with medical practitioners and other health professionals, and in these professionals managing missed diagnoses and adverse events. This could put upward pressure on complaints and consequent costs to broader professions.

Increased costs may also be passed on to patients of pharmacist prescribers, arising from increased education, continuing professional development and professional indemnity costs. With assumption of responsibility for a broad range of prescribing decisions, particularly if made independently of GPs, physicians and other specialists, increases in indemnity costs could be very significant.

**Are there alternative or additional options not presented that could address the problems identified?**

We recognise that the draft proposal and endorsement aim to respond to the very significant issue of patient access barriers to appropriate care.

There is a critical need for further Government investment in medical workforce planning, training places, rural specialist training programs and rural relocation incentives to improve necessary access to medical care in communities across Australia, but particularly in regional, rural and remote areas.

There are also alternative options for additional prescribing workforces with stronger existing system integration with GPs, particularly nurse practitioner workforces. These should be explored further as a mechanism to improve access to care, particularly where GP access is limited.

Some RACP members suggested that it would be helpful for the PBS to extend the expiry timeframe and number of dispenses for some scripts used in long chronic condition management to optimise the support medical professionals can provide, alongside streamlining PBS authority approval processes for increased quantity and repeats.

Other members highlighted an important role for the Pharmacy Board in supporting pharmacists to work at the top of their existing scope and training in advanced credentialing for medication review, adherence support, medication counselling, vaccination where authorised, identifying drug interactions, and communicating medication concerns. This would better support pharmacists to reduce harmful prescribing cascades and serve to balance medicines shortage concerns within the community.

Consideration could also be given to potential Schedule 4 medicines that could appropriately and safely be down scheduled for minor conditions in non-complex patients, balancing the benefits of improving patient access, reducing pressure on primary care, and commitment to safety.

### Next steps

The proposed endorsement model does not provide a sufficient basis for safe expansion of prescribing authority to pharmacists for Schedule 4 or Schedule 8 medicines.

In place of a broad endorsement for prescribing, we see a core role for the Pharmacy Board in consultation with the Medical Board and other relevant national boards and medical colleges, in developing the clinical risk and governance frameworks for endorsement in the prescription of protocol driven medications for uncomplicated low risk conditions not requiring differential diagnosis in patient cohorts beyond complex and vulnerable patient groups.

The RACP would welcome further engagement with the Pharmacy Board, Medical Board and Ahpra to identify clearly defined, low risk prescribing scenarios involving Schedule 4 medicines that may be safely supported within protocolised models of clinical care with appropriate governance and system integration.

Please email Peter Lalli, Acting Manager - Policy & Advocacy, for inquiries related to this submission via policy@racp.edu.au