RACGP submission to the Pharmacy Board of Australia's draft endorsement for scheduled medicines for pharmacists

May 2026

RACGP

Contents

1. Introduction

The Royal College of General Practitioners (RACGP) thanks the Pharmacy Board of Australia for the opportunity to provide feedback on the proposal to be able to endorse the registration of suitably qualified pharmacists under section 94 of the National Law as being able to administer, obtain, possess, prescribe, sell, supply or use a scheduled medicine or class of medicines.

The RACGP is the voice of specialist general practitioners (GPs) representing more than 50,000 members in our growing cities and throughout rural and remote Australia. For more than 60 years, we have supported the backbone of Australia's health system by setting the standards for education and practice and advocating for better health and wellbeing for all Australians.

2. Executive summary

The Board would be embedding prescribing authority into registration without evidence that diagnostic risk can be safely managed or detected at system level. The model risks creating a false sense of safety and security where harm remains largely invisible until it is too late for the regulatory system to respond. The issue is not whether pharmacists can prescribe, but whether the regulatory model ensures diagnostic uncertainty is safely managed over time across the health system.

On the evidence available, this represents a shift from narrowly defined, protocol-constrained service models to a more portable prescribing qualification that may require diagnostic decision-making across settings, without a consistent mechanism to define scope, ensure ongoing clinical accountability for diagnostic decision-making or detect and respond to emerging risk at scale.

The RACGP acknowledges the intent of the Pharmacy Board of Australia to establish a principles-based ethical framework to support expanded pharmacist roles and recognises the potential benefits of improved access to care, particularly in underserved and rural settings. However, increased access must be balanced against the Board's statutory obligation under section 3 of the Health Practitioner Regulation National Law (National Law s3) to ensure that care is delivered safely and competently, and that the public is protected from foreseeable harm at a system level.

The RACGP recognises that National Law s3 requires the Board to balance the protection of the public with other objectives, including facilitating access to services, workforce mobility and the development of a responsive health workforce. However, where such trade-offs are made, they should be supported by evidence that risks to patient safety are proportionate, actively mitigated and detectable within the regulatory system.

The central issue for the RACGP is whether the proposed registration-level endorsement ensures that system-level safeguards are consistently present across the diverse practice settings in which endorsed prescribing may occur.

Within this balancing framework, the RACGP's central concern is not whether individual pharmacists can provide safe care within defined protocols, but whether the proposed registration-level endorsement embeds prescribing authority without ensuring the presence of system-level safeguards required to manage diagnostic uncertainty over time. In practice, the endorsement creates a portable qualification that enables prescribing across diverse and unconstrained practice settings, including those that lack shared clinical records, care continuity (systematic follow-up) and clear accountability for diagnostic decision-making and its downstream consequences.

While framed as prescribing within scope, the model functionally requires diagnostic decision-making in presentations where symptoms are overlapping, non-specific or evolving. Some presentations that appear minor or protocol-compatible at first contact may in fact reflect underlying mental health conditions such as anxiety, depression or eating disorders, particularly where symptoms are non-specific or only become clinically meaningful over time. Without longitudinal clinical context, opportunities for reassessment, and sufficient continuity to support disclosure, these conditions may be missed or

misclassified within episodic prescribing models. This is not simply a question of individual competence, but whether the regulatory model embeds the safeguards needed to detect complexity and emerging risk over time.

The proposal assumes that risks can be managed through individual practitioner competence and protocol adherence; however, these mechanisms do not substitute for system-level safeguards that enable reassessment over time. In many episodic care models, prescribing decisions are made in the absence of comprehensive clinical information, including prior history, comorbidities and diagnostic context, increasing reliance on symptom-based assessment rather than integrated clinical reasoning.

A central concern is that the proposed model may create a false sense of safety. The absence of reported adverse events in existing pharmacist prescribing pilots does not provide assurance of safety at system scale in the absence of processes to clearly document such adverse events. Moreover, diagnostic harm is characteristically delayed, diffuse and frequently attributed outside the original prescribing encounter. As such, it is often not captured by complaints-based regulatory systems and is unlikely to generate timely warning signals. Reliance on the absence of detected harm as evidence of safety risks systematically underestimating true risk.

Clinical risk in these contexts does not arise solely from incorrect individual decisions, but from the interaction between uncertainty and system design, specifically where the model:

- relies on single point-of-care classification in inherently ambiguous presentations
- lacks mechanisms for structured reassessment or diagnostic review
- does not assign clear responsibility for ongoing diagnostic trajectories
- functions within episodic care environments without continuity or shared clinical records.

A related and fundamental issue is that the proposed endorsement functionally certifies independent diagnostic authority, despite this capability not having been explicitly evaluated or evidenced in the Australian community pharmacist prescribing setting. Existing studies and pilots have been conducted within tightly constrained service models in which diagnostic ambiguity is deliberately minimised through strict inclusion and exclusion criteria, structured protocols and defined clinical pathways. These evaluations have focused primarily on process and service measures – such as protocol adherence, medicine supply, access and patient satisfaction – rather than diagnostic accuracy, misclassification risk or outcomes over time.

These conditions create foreseeable scenarios in which:

- initial, protocol-consistent decisions are reasonable but incorrect
- diagnostic error persists unrecognised over time
- harm emerges cumulatively across multiple encounters
- risks are unlikely to be detected early within existing regulatory systems.

This creates a critical distinction. Service-level models test whether pharmacists can deliver defined clinical services under constrained conditions. Registration-level endorsement, by contrast, asserts that practitioners can independently assess, diagnose and prescribe across diverse and unconstrained practice environments. This represents a substantive regulatory extension from system-tested service delivery to generalised diagnostic authority, which is not directly supported by the available evidence.

No component of the current framework clearly and consistently defines or enforces the clinical scope within which diagnostic capability is to be demonstrated or applied.

These risks are not unique to any individual profession. However, they are materially amplified in care models characterised by episodic encounters across multiple providers, absence of shared clinical records, and lack of assigned responsibility for ongoing diagnostic management. These conditions are most evident in non-integrated, episodic care environments, including but not limited to retail-based models and should be considered the stress test for regulatory design.

There is substantial evidence from primary care systems demonstrating that fragmentation is associated with poorer health outcomes, increased hospital utilisation and higher system costs compared with models that facilitate continuity of care.[1,2,3,4,5,6,7,8,9] Continuity is a core feature of high-performing primary care and has been shown to have a dose-response relationship with improved outcomes, including reduced acute service use and mortality[10,11,12]. Importantly, access to care should not be achieved at the expense of continuity, as both are required to ensure safe and effective patient care.[13]

These system-level risks have direct and predictable consequences for general practice as the primary provider of longitudinal care. The model shifts responsibility for diagnostic uncertainty, follow-up and complication management into GP care without corresponding mechanisms for continuity, information sharing or shared accountability. Patients are therefore more likely to present later in their illness trajectory, often with more advanced or complex conditions due to initial misclassification, symptom suppression or fragmented prescribing, increasing diagnostic difficulty and clinical risk. This results in increased GP workload related to reassessment, medication reconciliation and management of treatment failure, while reducing visibility of prior care. The model undermines continuity, weakens antimicrobial stewardship and reduces opportunities to detect vulnerability, ultimately redistributing rather than reducing system demand and introducing both workforce pressure and patient safety risk at a system level.

In practice, this model risks establishing general practice as the default point of re-presentation and correction for incomplete or episodic care, without visibility of initial decision-making or structured mechanisms for communication, thereby redistributing rather than resolving clinical risk.

Once prescribing authority is embedded in general registration, the Board assumes responsibility for monitoring and responding to harms that may be delayed, distributed across providers and difficult to detect within existing systems. In the absence of defined early-warning systems, data linkage and intervention pathways, it is unclear how the Board can meet its statutory obligation to proactively protect the public under section 3. The RACGP therefore does not support a general registration endorsement model.

Instead, the RACGP strongly supports service-level, collaborative prescribing models that:

- embed prescribing within defined clinical contexts
- ensure continuity and shared accountability
- provide mechanisms for structured review and escalation
- enable real-time governance, audit and feedback.

These models may incorporate structured clinical pathways, protocols and decision support tools, where these are implemented within systems that ensure continuity of care, integration with broader clinical records and clear accountability for patient outcomes over time. They more appropriately align prescribing authority with the systems necessary to manage diagnostic uncertainty, detect emerging harm and protect the public at scale.

On the evidence available, the RACGP considers that the proposed model does not adequately mitigate these risks. The risk is not that individual clinical decisions are incorrect, but that the model lacks mechanisms to detect and correct error over time.

Professor Barbara Starfield defines primary care not solely by access, but by the integration of access, continuity, coordination and comprehensive care; policies that prioritise access in isolation risk undermining the broader system features that protect patient safety. There is substantial evidence that continuity of care improves health outcomes, and that disrupting continuity through fragmented care models introduces measurable and avoidable system-level risk.[14,15,16,17] Access should not be at the expense of continuity.

3. Case studies illustrating system-level risk

Together, these case studies illustrate not isolated clinical errors, but predictable system-level failure modes in environments where diagnostic responsibility, continuity and follow-up are not structurally embedded. These risks are most pronounced in non-integrated settings, including community and retail environments and are less applicable to embedded models such as hospital teams where prescribing occurs within established clinical governance, shared records and defined accountability structures.

The following case studies illustrate how foreseeable patient harm may arise under the proposed endorsement model in real-world practice environments. These scenarios are not hypothetical edge cases but reflect predictable risks arising from the interaction between diagnostic uncertainty, episodic care models, and structurally conflicted retail environments. These scenarios are not intended to suggest high-frequency events, but to illustrate predictable failure modes in systems lacking continuity and diagnostic accountability, including low-frequency, high-impact risks that regulatory frameworks are expected to anticipate and mitigate. In fragmented care pathways, subsequent providers often lack access to the original clinical reasoning, assessment findings or decision-making context, limiting the ability to safely interpret, reassess or correct earlier decisions. They reflect well-recognised risks in fragmented systems, including lack of shared clinical records, ineffective clinical handover, missed opportunities for follow-up, duplication of care and reduced clinical

accountability. These factors have been associated with delayed diagnosis and suboptimal outcomes in both Australian and international primary care systems.

Under National Law s3, the Board must protect the public by ensuring safe and competent practice, while also facilitating access to services and supporting a responsive health workforce. The following case studies illustrate how the proposed endorsement model may not adequately manage foreseeable risks at a system level when these objectives intersect.

Case Study 1 – Jurisdictional implementation without defined clinical scope (Northern Territory)

At the time of implementation, all actions taken were consistent with the prevailing legislative framework and available guidance.

In May 2026, amendments to the *Medicines, Poisons and Therapeutic Goods Regulations* in the Northern Territory authorised pharmacists who had completed accredited prescribing training to prescribe and dispense unrestricted Schedule 4 and Schedule 8 medicines. This authorisation was granted at the level of medicine schedules, without defining specific clinical indications, conditions or protocol-based service models within the legislation.

Prescribing authority commenced prior to the establishment of key governance elements, including a jurisdiction-specific Code of Practice, clinical guidelines, prescribing protocols and monitoring or compliance systems.

As a result:

- there was no defined clinical scope specifying which conditions were appropriate for pharmacist-led diagnosis and prescribing
- prescribing was not constrained to protocol-based or minor ailment services
- there were no consistent mechanisms to support continuity of care, clinical follow-up, or communication with a patient's usual healthcare provider
- prescribing and dispensing occurred within the same commercial setting without structural separation
- responsibility for determining diagnostic scope and prescribing appropriateness was delegated to individual practitioner judgement

This case differs from those that follow as it illustrates a system-level risk arising from regulatory design, rather than from a single clinical encounter.

Key issues illustrated:

- Absence of defined clinical scope in law, with authorisation based on medicine classes rather than indications
- Decoupling of prescribing authority from clinical governance frameworks, resulting in a period where prescribing occurs without established system safeguards
- Reliance on individual practitioner judgement to determine diagnostic scope and prescribing boundaries, without enforceable constraints (protocols or condition definitions)
- Variability in implementation across settings, including community pharmacy, telehealth and other environments
- Limited capacity for early detection of emerging harms, where prescribing activity is not standardised and outcomes are not systematically monitored.

Alignment with National Law s3: This scenario illustrates a foreseeable risk arising from regulatory design rather than individual practitioner performance. While prescribing activity is legally authorised, the absence of defined clinical scope, governance frameworks and monitoring mechanisms limits the system's ability to ensure that care is delivered safely and competently and to identify emerging risks in a timely manner.

This case demonstrates how jurisdictional implementation can materially influence patient safety outcomes. Where prescribing authority is generalised without preserving the conditions under which safety has been demonstrated, the regulatory framework becomes dependent on retrospective detection of harm rather than proactive risk mitigation.

Case Study 2 – Diagnostic misclassification despite protocol-consistent assessment (UTI vs STI)

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 24-year-old woman presents to a community pharmacy with dysuria and urinary frequency. A structured clinical assessment is undertaken in accordance with a prescribing protocol. She denies vaginal discharge, pelvic pain and does not identify any known risk factors for sexually transmitted infection.

Based on her reported symptoms and responses to screening questions, she meets the protocol criteria for uncomplicated urinary tract infection and is supplied antibiotic treatment.

Two weeks later, she presents to a GP with persistent symptoms and new pelvic discomfort. Further assessment and testing identify a chlamydia infection with associated pelvic inflammatory disease.

At no stage is the original prescribing clinician aware of the subsequent diagnosis or outcome. There is no structured mechanism to provide feedback on diagnostic accuracy or to support learning from misclassification, limiting both individual and system-level capacity to detect and correct diagnostic error over time.

Key issues illustrated:

- Absence of feedback mechanisms linking initial prescribing decisions to subsequent diagnostic outcomes.
- Overlapping clinical presentations where urinary and sexually transmitted conditions are indistinguishable at presentation
- Limited sensitivity of symptom-based screening questions, even when applied correctly, in detecting early or atypical STI
- Diagnostic uncertainty that cannot be resolved within a single point-of-care encounter.
- A clinically reasonable, but incorrect working diagnosis arising from protocol-consistent care.

Alignment with National Law s3: This scenario demonstrates that safe and competent practice cannot be assured solely through adherence to protocols in presentations characterised by intrinsic diagnostic uncertainty. Even when care is delivered appropriately, there remains a foreseeable risk of misclassification leading to delayed diagnosis and increased morbidity. This highlights a system-level limitation, where the model relies on point-of-care classification without mechanisms to support diagnostic verification over time. This is directly relevant to the Board's obligation under s3 to ensure that the regulatory framework proactively protects the public from foreseeable harm, rather than relying solely on individual practitioner performance.

Case Study 3 – Symptom suppression delaying recognition of serious disease (reflux pathway)

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 49-year-old patient presents to a community pharmacy with new-onset reflux symptoms. A structured protocol-based assessment is undertaken. No overt alarm features are identified at the time of assessment. The patient meets criteria for management of uncomplicated gastroesophageal reflux.

The pharmacist supplies a proton pump inhibitor and recommends adjunct over-the-counter therapies consistent with symptomatic management.

The patient continues to self-manage symptoms over several months, including repeat purchases of treatment. Symptoms are partially controlled and no escalation occurs within the episodic care model. He later presents to a GP with progressive dysphagia and unintentional weight loss and is subsequently diagnosed with oesophageal malignancy.

Key issues illustrated:

- Early-stage serious pathology presenting with non-specific symptoms consistent with benign disease.
- Symptom suppression masking progression and delaying escalation
- Lack of structured mechanisms to trigger reassessment when symptoms persist
- Absence of defined responsibility for longitudinal monitoring or diagnostic review
- There is no defined mechanism within the model to ensure review of treatment response or trigger escalation where symptoms persist, nor any assigned clinician responsible for reassessment over time.

Alignment with National Law s3: This scenario demonstrates that harm can arise even when protocols are followed appropriately, due to the interaction between symptom-based treatment and the absence of longitudinal oversight. The regulatory model relies on individuals to re-present or escalate, without mechanisms to actively detect failure of initial management or evolution of disease. This creates a foreseeable risk of delayed diagnosis of serious conditions, which is

inconsistent with the requirement under section 3 to ensure that care is delivered in a manner that is safe, effective and capable of protecting the public from avoidable harm at a system level.

Case Study 4 – Fragmentation across multiple protocol-compliant encounters

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 32-year-old woman presents to a community pharmacy with symptoms of dysuria and urinary frequency. At initial presentation her symptoms meet protocol criteria for uncomplicated urinary tract infection. Screening does not identify features suggestive of alternative diagnoses. She is supplied antibiotic treatment.

Over the following six weeks, she attends two different pharmacies with recurrent symptoms. At each encounter her symptoms again meet protocol criteria, no red flags are identified at the point of care and therefore treatment is supplied in accordance with protocol. Each presentation is managed as an isolated episode with no shared clinical record or visibility of prior care.

She later presents to a GP with persistent symptoms of pelvic pain and is diagnosed with pelvic inflammatory disease.

At no stage are the pharmacists involved in earlier encounters aware of the evolving diagnosis or cumulative pattern of presentations. There is no mechanism to aggregate or feedback information across providers, preventing recognition of diagnostic error over time and limiting system-wide learning.

Key issues illustrated:

- Individually appropriate, protocol-consistent decisions
- Lack of continuity preventing recognition of recurrence patterns
- Inability to aggregate risk across encounters and providers
- Diagnostic harm emerging cumulatively across multiple interactions
- Each clinician acted reasonably in isolation, yet the system failed to detect cumulative risk.

Alignment with National Law s3: This scenario demonstrates that safe care cannot be assured where responsibility for diagnostic trajectories is fragmented. The model enables repeated prescribing without mechanisms to detect recurrence patterns, assign clinical accountability and trigger reassessment or escalation. As a result, harm arises not from individual error, but from system design that permits risk to accumulate undetected. This is directly relevant to s3 which requires regulatory frameworks to protect the public from foreseeable and cumulative harms that emerge across care settings.

Case Study 5 – Diagnostic ambiguity within protocol scope (ear conditions)

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

An 8-year-old child presents to a community pharmacy with ear pain. Assessment identifies mild inflammation of the ear canal, no fever or systemic symptoms and no red flags requiring referral. Based on findings, the presentation is consistent with acute otitis externa and is managed according to protocol.

Symptoms partially improve but recur intermittently. The child presents to different pharmacies and receives repeat protocol-consistent management. At each presentation, symptoms remained within protocol thresholds and did not meet criteria for mandatory referral.

Subsequent medical assessment identifies otitis media requiring alternative treatment.

Key issues illustrated:

- Overlapping features between otitis externa and otitis media
- Diagnostic uncertainty based on limited examination modalities
- Episodic care without reassessment of the initial diagnosis
- Repeated appropriate decisions contributing to delayed correct diagnosis with potential long term adverse outcomes.

Alignment with National Law s3: This scenario illustrates that diagnostic ambiguity within protocol scope can still result in delayed or incorrect diagnosis, even when care is provided appropriately. The absence of mechanisms to reassess or challenge initial assumptions creates a foreseeable risk that incorrect working diagnoses persist over time, leading to suboptimal outcomes. This highlights the need for regulatory models that account for diagnosis as an evolving process, consistent with the Board's obligation to ensure safe and competent care across diverse practice settings.

Case Study 6 – Vulnerability and system invisibility (domestic violence context)

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 30-year-old woman presents to community pharmacy with dysuria and urinary frequency. At presentation symptoms meet protocol criteria for uncomplicated urinary tract infection and no red flags are identified. She does not disclose any additional concerns. She is supplied antibiotic treatment.

Over the following two months, she presents to multiple pharmacies with recurrent symptoms. At each visit her symptoms meet protocol criteria and treatment is supplied in accordance with guidelines. Each encounter occurs as a discrete, time-limited interaction without continuity, shared records, or structured follow-up.

She later presents to a GP after relocation and is identified as experiencing family and domestic violence with urogenital symptoms associated with physical and sexual harm.

Key issues illustrated:

- Repeated, protocol-consistent prescribing across isolated encounters
- Lack of continuity limiting opportunities for broader clinical or contextual assessment
- Absence of a single practitioner or system responsible for longitudinal care
- Reduces the probability that patterns of vulnerability, which typically emerge over repeated, continuous interactions, will be identified
- This model does not provide structured opportunities for continuity or trust-building that are often required for disclosure of sensitive issues.

Alignment with National Law s3: This scenario demonstrates that safe and ethical care includes responsiveness to patient context, vulnerability and complexity, not solely symptom-based management. While no individual encounter is inappropriate, the episodic model reduces the opportunity for continuity, trust-building and holistic assessment, which are often required for disclosure and identification of vulnerability. The resulting risk is that underlying harm remains unrecognised, contributing to ongoing morbidity. This represents a foreseeable system-level limitation that is inconsistent with the requirement under s3 to ensure that regulatory frameworks support safe, person-centred care across all populations, including those at heightened risk of harm.

Case study 7 – Escalation failure in a time-critical presentation (abdominal pain)

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 52-year-old male patient presents to a community pharmacy seeking advice for abdominal pain. The pharmacy seeks clinical input from a GP regarding appropriate next steps. Escalation to urgent medical assessment is recommended; however, escalation did not occur within the episodic care pathway. In contrast to general practice, where escalation is a defined clinical responsibility supported by documentation, follow-up and accountability, escalation in this model is advisory and not structurally ensured. There is no mechanism to confirm that escalation occurs or to identify and correct failure when it does not. The patient later presents to general practice and is referred to the emergency department where pancreatitis was diagnosed.

Key issues illustrated:

- Time-critical presentation where serious pathology may not be apparent at a single point in there and where delay materially increases risk.
- Reliance on informal escalation advice without enforceable mechanisms to ensure escalation is actioned (including clear processes, documentation and follow-up responsibilities).
- Diffuse accountability where advice is sought across providers but responsibility for ensuring timely escalation and reassessment is not clearly assigned within the model.

Alignment with National Law s3: This scenario demonstrates that system-level risk is not limited to incorrect clinical decisions. It also arises where the model lacks structured mechanism to ensure escalation occurs where serious illness is possible. Even when appropriate escalation is recommended, the absence of clear responsibility for follow-up, structured reassessment pathways and visibility across the patient journey creates foreseeable patient safety risk. This is directly relevant to the Board's obligation under National Law s3 to ensure that regulatory settings protect the public from foreseeable harm at scale, rather than relying on informal escalation and retrospective detection after harm has occurred.

Case study 8 – Symptom overlap delaying recognition of serious disease.

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A patient presents at a community pharmacy with urinary symptoms that appeared consistent with an uncomplicated urinary tract infection and receives antibiotics for UTI. The patient later presents to their GP for review, where further assessment identifies an underlying serious condition (renal cell carcinoma) that had been contributing to the urinary presentation.

Key issues illustrated:

- Overlapping symptom presentations where "UTI-like" symptoms can reflect serious underlying pathology requiring diagnostic reassessment over time.
- Symptom-based treatment and partial symptom improvement can delay escalation and definitive investigation where structured follow-up and diagnostic accountability are not embedded.
- Harm is delayed and diffuse where the eventual diagnosis and consequences emerge later, outside the initiating encounter, reducing visibility to complaints-based regulatory detection mechanisms.

Alignment with National Law s3: This scenario demonstrates that patient safety risk can arise even when initial management appear reasonable, because symptom overlap in undifferentiated presentations cannot be reliably resolved at a single point in time. Where the model lacks enforceable mechanisms for structured reassessment, continuity and escalation, serious pathology may remain undetected until later. This is directly relevant to the Board's obligation under National Law s3 to ensure that regulatory settings protect the public from foreseeable harm at scale, including delayed diagnostic harm that may not generate timely notifications or complaints.

Case study 9 – Delayed harm arising from fragmented prescribing and absence of diagnostic accountability

At the time of each presentation, management was consistent with applicable clinical protocols and was clinically reasonable based on the available information.

A 45-year-old woman in rural community presented to a community pharmacy with dysuria, urinary frequency and suprapubic discomfort. She was assessed under a pharmacist prescribing protocol and commenced on trimethoprim for presumed uncomplicated urinary tract infection.

No confirmed pathology was obtained at the time of prescribing, and although a urine sample was reportedly intended, there was no structured mechanism to ensure that the sample was collected, processed, or reviewed. Responsibility for follow-up was delegated to the patient, with advice to seek medical care if symptoms did not improve.

After initial partial improvement, the patient deteriorated over subsequent days with recurrent symptoms, fever and flank pain. Due to competing social factors, including childcare responsibilities and limited access, she delayed escalation. She re-presented to pharmacy two weeks later with persistent symptoms and was advised to seek medical review. At no stage was a single clinician responsible for reassessing the diagnosis or ensuring continuity of care.

She subsequently presented to her GP, where further antibiotics were prescribed pending investigation. Within days, she deteriorated further and required hospital admission with pyelonephritis. Urine culture later confirmed a trimethoprim-resistant organism.

The initial prescribing decision and subsequent treatment course are not linked back to earlier encounters, and there is not mechanism to provide feedback to the original prescribing clinician regarding treatment failure or antimicrobial resistance. This limits both individual learning and system-level capacity to detect emerging prescribing risks.

Key issues illustrated:

- Diagnosis inferred and acted upon without confirmation or structured review
- Absence of a closed-loop system for pathology collection, processing and interpretation
- Reliance on patient-initiated follow-up in the context of real-world barriers
- Fragmentation across multiple providers with no allocation of responsibility for diagnostic trajectory
- Repeated treatment decisions based on incomplete or evolving clinical information
- Delayed identification of treatment failure and antimicrobial resistance

Alignment with National Law s3: This case demonstrates that safe and competent prescribing requires more than appropriate decision-making at a single point in time. The National Law requires protection of the public through systems that ensure care remains safe as clinical conditions evolve.
In this scenario, the regulatory model permitted prescribing to occur without ensuring:

- clear ownership of diagnosis over time
- structured reassessment when clinical response deviates from expectations
- reliable systems for pathology review and escalation

The absence of these safeguards allowed harm to emerge progressively across multiple encounters, without a single identifiable point of failure and without early detection.
This illustrates a key limitation of episodic, protocol-based prescribing models: risk is not eliminated at the point of prescribing but accumulates over time in the absence of systems that support diagnostic accuracy, continuity and accountability.

Such risks are foreseeable, repeatable, and unlikely to be detected through complaints-based regulatory mechanisms, and therefore require explicit consideration in the design of any registration-level prescribing framework

Harm can arise even when protocols are adhered to, because protocols cannot fully resolve diagnostic uncertainty, nor substitute for continuity, reassessment and accountability over time.

The National Law s3 test is not whether individual care can be appropriate, but whether the system reliably protects the public from foreseeable harm at scale.

RACGP's responses to the consultation questions

	Question	Your feedback
1.	The draft *Registration standard: Endorsement for scheduled medicines* at Appendix A sets out the requirements to be eligible for an endorsement for scheduled medicines. **Is the information in the draft registration standard clear? If no, please explain why.**	While the RACGP recognises that the Board must balance public protection with access and workforce objectives under National Law s3, clarity alone does not ensure that the regulatory framework provides adequate or proportionate protection against foreseeable patient-safety risks. The standard clearly establishes that: • endorsement confers qualification rather than authorisation, and • authorisation remains with states and territories. The RACGP notes that it does not oppose structured or protocol-supported prescribing where this is delivered within integrated care models with clear clinical governance, continuity and accountability. The issue is whether a registration-level endorsement ensures these system-level safeguards are consistently present across all practice settings in which prescribing may occur. However, the standard can be interpreted as conferring a level of diagnostic decision-making responsibility through a portable, profession-wide endorsement without distinguishing between: • prescribing under tightly constrained, authority-based service models, and • Independent prescribing across unconstrained practice settings. This distinction is central to patient safety and is not clearly addressed. In practice, a registration endorsement that qualifies a pharmacist to prescriber Schedule 4 medicines may function in practice as enabling independent diagnostic decision-making across settings, despite diagnostic competence never having been explicitly tested or validated in the Australian evidence base. The RACGP is particularly concerned about the creation of a regulatory ratchet effect. Once prescribing competence is embedded in national registration, future expansions of prescribing scope by states may reduce the need for reassessment of training, diagnostic risk or governance at a national level, depending on how jurisdictions implement future expansions. In effect, a general registration endorsement for prescribing signals a level of independent diagnostic decision-making capability across practice settings, despite diagnostic competence never having been explicitly or independently evaluated or validated as an outcome in Australian pharmacist prescribing evidence.

2.	Pharmacists with general registration in Australia are qualified and authorised to prescribe Schedule 2 and Schedule 3 medicines. 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. The Board is consulting on the scope of the endorsement and is seeking feedback on the following two options: Option A: An endorsed pharmacist is **qualified** to administer, obtain, possess, prescribe, sell, supply and/or use **Schedule 2, 3 and 4 medicines** Option B: An endorsed pharmacist is **qualified** to administer, obtain, possess, prescribe, sell, supply and/or use **Schedule 2, 3, 4 and 8 medicines** **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.**	**RACGP does not support general registration endorsement at all.** However, if required to nominate a position between the options presented, the **RACGP would support option A only (Schedule 2-4).** If the Board proceeds with a registration-level endorsement, additional safeguards would be required to align the model with the objectives of the National Law. RACGP does not support inclusion of Schedule 8 medicines under a general registration endorsement. Schedule 8 prescribing introduces materially higher risks relating to: • Diagnostic accuracy • Dependence, misuse and diversion • Population-level harm that is poorly captured by complaints-based regulation. The consultation materials do not present evidence demonstrating the safety or effectiveness of independent, portable pharmacist prescribing of Schedule 8 medicines. **Inclusion of Schedule 8 would represent a regulatory leap that cannot be justified by existing pilots or trials.**
3.	**If considering Option B:** **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?**	**If Option B is considered (S8)** RACGP **does not support Option B.** However, if S8 prescribing were to be introduced, RACGP's position is that it should only occur within service-level, authority-based models that include: • Explicit diagnostic accountability • Mandatory collaboration arrangements with medical practitioners • Defined settings (eg palliative care teams) • Real-time audit and antimicrobial stewardship oversight

		• Clear, rapid mechanisms for restriction or withdrawal. These system-level safeguards are inherently compatible with a general registration endorsement model, which confers broad qualifications without embedding the service-specific governance, oversight and accountability required for safe S8 prescribing. As such, the inclusion of S8 prescribing introduces risks that a general registration model cannot materially mitigate. S8 prescribing is particularly concerning in the context of chronic pain and other complex, longitudinal care needs. Safe opioid prescribing often depends on continuity of care, comprehensive knowledge of the patient's clinical and psychosocial context, and clear assignment of prescribing responsibility over time. Models that fragment prescribing across provides or settings risk undermining the principle of coordinated care.
4.	**Are there any specific medicines that you believe pharmacists should not be qualified to prescribe? If yes, please list the medicines and your reasons.**	**Yes.** RACGP considers pharmacists should not be independently qualified to prescribe: • S8 medicines • Medicines requiring complex diagnostic discrimination (e.g. presentations with overlapping symptomatology and high misclassification risk) • Medicines where delayed or missed diagnosis carries significant morbidity. These exclusions are not a judgement on pharmacists but reflect the absence of evidence demonstrating diagnostic competence transferable across settings.
5.	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 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. **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**	**No.** RACGP does not support an eligibility pathway that relies solely on completion of an approved education program, without: • Minimum post-registration clinical experience • Defined practice context or governance • Demonstrated competence in managing diagnostic uncertainty across contexts. The proposed registration standard has not set out any requirements to assess whether prescribing is appropriate when pharmacists move from supervised or team-based models into retail or other non-integrated setting. This assumes that education and credentialling are universally transferable across settings *and* jurisdictions with materially different risk profiles. Prescribing is the endpoint of a diagnostic process. Education standards alone cannot mitigate the risks introduced by diagnostic error, particularly in episodic, retail-based environments. In the absence of contextual reassessment and system-level governance, reliance on education-based eligibility requirement introduces foreseeable patient safety risks that are not adequately addressed in the proposed standard.
6.	The proposed draft registration standard states that completion of an approved program qualifies a	The RACGP supports the Board's approach of not specifying an AQF level, consistent with the approach taken by the Medical Board of Australia which bases eligibility for general registration on completion of 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. **Do you agree with this approach? Please provide an explanation for your answer and include information to support your position if possible**.	Board-approved program of study and accredited supervised training requirements, rather than an AQF-benchmark. However, aligning with this approach does not resolve RACGP's central concern that the proposal relies on education and competency frameworks without independent evaluation of diagnostic competence in the Australian pharmacy prescribing evidence base. The proposal places considerable weight on approved education, competency frameworks and additional CPD as safeguards. Education completion and credentialling does not necessarily translate into sustained diagnostic performance, safer prescribing behaviour or improved patient outcomes over time.
7.	The proposed draft registration standard has two pathways to qualify for an endorsement. These are: • 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 (*pharmacists who have completed an overseas prescribing qualification*) **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?**	The proposed endorsement pathways are clearly articulated, but **insufficiently protective.** Assessing equivalence based on educational qualification assumes that: • Diagnostic competence has been evaluated in the originating jurisdiction • Such competence is transferable across practice settings These assumptions have not been tested or substantiated. The draft standard does not provide sufficient assurance that these contextual differences have been examined or that risks associated with this have been mitigated. In the absence of explicit safeguards, supervised transition requirements, or jurisdiction-specific validation, reliance on competency equivalence alone may inadequately protect against foreseeable patient safety risks. Registration level endorsement signals to the public, employers and governments that the endorsed practitioner can independently assess, diagnose and prescribe across settings. This signal carries regulatory weight irrespective of whether diagnosis has been directly assessed.
8.	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.	**Yes.** The guidelines **operate downstream of a flawed regulatory assumption.**

	Is there anything that needs to be changed, added or removed from this guideline?	While the proposal includes accreditation standards, CPD requirements and guidelines intended to support safe practice, these mechanisms primarily operate at the level of individual competence and compliance, rather than embedding system-level safeguards to detect and correct diagnostic error over time. Taken together, the proposed standard and guidelines represent structural limitations in the current regulatory model. They place primary emphasis on individual-level safeguards and retrospective mechanisms, rather than embedding enforceable system-level protections. This shift from prevention to enforcement is poorly matched to diagnostic harm, which is characteristically delayed, diffuse and rarely complaint-generating. The guidelines rely on assumptions that are problematic at a regulatory level, namely: • That diagnostic uncertainty can be safely managed through individual competence and judgement alone • that scope limitation will be consistently self-regulated in the absence of structural constraints • That individual risk management can compensate for the absence of enforceable system-level safeguards. While individual competence and professionalism are necessary, they are not sufficient to manage risk at a population level. The guidelines place primary responsibility on individual judgment, rather than embedding organisational or regulatory mechanisms that anticipate foreseeable diagnostic error and support its detection and correction over time. This requirement applies to any prescriber exercising independent diagnostic authority and is not unique to pharmacy practice. This conflates individual responsibility with system responsibility for patient safety. In regulatory terms, guidelines can articulate expectations of good practice but cannot substitute for the absence of structural safeguards once prescribing authority is embedded in general registration. The prescribing scenarios set out in Appendix F illustrate this limitation. They depict a model of care in which pharmacists undertake independent diagnostic assessment and threshold setting in circumstances where diagnostic uncertainty is managed largely at the point of care, without embedded mechanisms for structured review, escalation, or ongoing accountability for diagnostic trajectories. Reliance on patient-initiated follow-up is presented as routine, rather than as a managed risk with an identifiable owner. These scenarios therefore highlight a central weakness of the proposal – embedding prescribing authority within registration assumes that risk can be safely managed through professional judgement and guidance alone, without enforceable system-level arrangements to support continuity, detect deterioration or prevent harm when initial assumptions prove incorrect.
9.	**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**	**Yes.** While the guidance is conceptually sound and acknowledges conflicts of interest, it relies on individual judgement restraint rather than enforceable safeguards.

	supports the need for additional or alternative guidance.	Where prescribing, supply and product recommendation occur within the same commercial interaction, there is no structural separation between clinical decision-making and financial gain. In such environments, particularly in presentations characterised by diagnostic uncertainty, the default may shift toward treatment rather than referral or deferral. This creates a predictable risk of decision bias that is structural in nature and cannot be adequately mitigated through disclosure, documentation or reliance on individual professional judgement alone. In practice, closed-loop prescribing risk increases in retail environments because commercial incentives are structural rather than necessarily arising from independent practitioner behaviours. Where diagnosis, prescribing and supply occur within the same commercial setting, the potential for conflicted decision-making is structural and predictable, irrespective of professional intent or ethical standards. A related concern is vertical integration at an organisational level, where the same commercial entity controls prescribing pathways, dispensing and supply across multiple sites or channels. This is distinct from an individual conflict of interest, because the incentive structure may be embedded in the design of the service itself. In such circumstances, professional judgement and disclosure requirements alone may not be sufficient to mitigate risk. If the Board is to rely on a nationally portable endorsement operating across commercial settings, it should address whether enforceable safeguards are needed to manage organisational, as well as individual conflicts. These risks cannot be adequate mitigated through documentation, disclosure or reliance in professional judgement alone. Documentation requirements operate retrospectively, recording decisions that have already been made and harms that may have already occurred and therefore do not prevent inappropriate prescribing, diagnostic error or delayed escalation. RACGP considers that prescribing undertaken within non-integrated, episodic care environments characterised by limited continuity, lack of shared clinical resources and overlapping commercial and clinical functions may present elevated diagnostic risk. These risks are not unique to pharmacy and may also arise in other episodic care models, including urgent care and telehealth. However, they are materially amplified where prescribing, supply and product recommendation occur within the same encounter and where responsibility for ongoing diagnostic trajectories is not clearly assigned. Regulators are therefore expected to structurally eliminate conflicts of interest, or where elimination is not possible, to materially constrain risk through enforceable structural controls. Failure to do so exposes the regulatory system to avoidable patient harm and undermines public trust in health practitioner regulation.
10.	**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.**	**Yes. Critically, the following key issues have not been adequately addressed in the guidelines:** • Diagnostic uncertainty and misclassification risk • Delayed and unreported diagnostic harm • Lack of mechanism for early detection of system-level prescribing risk • Lack of clear clinical accountability • Absence of service-level audit and feedback systems post-endorsement. • Entry thresholds and experience requirements.

		The asymmetry between the consultation paper and the consumer guide may limit the extent to which consumer feedback fully reflects the complexity of the safety considerations relevant to the Board's statutory obligations. Consumers are invited to comment on a proposal with material safety implications but are not provided with clear information about diagnostic uncertainty, delayed harm or the structural consequences of registration-level endorsement. This raises concerns about whether consumer feedback can meaningfully inform the Board's statutory obligation to protect the public. Consumers are not informed that a registration endorsement: • Embeds prescribing as a portable professional entitlement • Reduces national oversight of future scope expansions • Relies on complaints systems that are poorly suited to detecting delayed diagnostic harm. **Early detection and intervention** The RACGP has been unable to identify a clearly defined, proactive and system-level mechanism by which the Board would detect, aggregate, respond and intervene in delayed diagnostic harm that: • Presents outside the original prescribing encounter • Does not generate a complaint • And emerges across multiple practice settings. Many forms of diagnostic harm are characteristically delayed, diffuse and manifest outside the original prescribing encounter, often presenting to other clinicians weeks or months later and rarely generating practitioner-specific complaints. In these circumstances, reliance on notifications or complaints systems is unlikely to provide timely or reliable early-warning signals. This limitation is particularly significant in models where care is delivered episodically across multiple providers without shared records, reducing the likelihood that emerging patterns of harm are detected in a timely manner. These considerations are consistent with established safety and quality frameworks, including the NSQHS Standards, which emphasise continuity of care, clinical handover and clear accountability for ongoing patient management. Given the nature of diagnostic harm, which is often delayed, diffuse and not captured through complaints processes, clarity on these mechanisms is essential to demonstrating how the model meets the Board's proactive public protection obligations under section 3 of the National Law. The RACGP therefore respectfully ask the Board to clarify: • The early-warning indicators or data sources will it rely on to identify emerging diagnostic or prescribing-related harm that does not generate complaints • How such harm will be attributed back to endorsed prescribing across multiple settings and providers

		• What clear thresholds and intervention powers will be available to the Board to rapidly constrain, recalibrate or suspend the endorsement should systemic risks emerge once endorsement is embedded in registration. In the absence of an articulate early-detection and intervention framework, it is unclear how the Board can be assured that a registration-level endorsement is capable of preventing harm before it occurs, rather than responding only after harm has become established. The proposed endorsement does not merely introduce potential patient risk; it creates an ongoing regulatory exposure for the Board. Once prescribing competence is embedded in national registration, the Board assumes responsibility for monitoring, detecting and responding to population-level diagnostic harm that is delayed, diffuse and frequently invisible to complaints systems. In the absence of a defined early-warning and intervention mechanism, the Board's ability to meet its statutory duty becomes dependent on harm accruing to a detectable threshold. This shifts regulatory risk from a prospective design choice to a retrospective defence posture, increasing the likelihood of delayed corrective action and external scrutiny. **High-risk settings and vulnerable cohorts (including residential aged care)** The guidelines do not sufficiently address how the endorsement would operate in foreseeable high-risk settings and for high-vulnerability cohorts, where diagnostic uncertainty, polypharmacy and delayed harm are amplified and where safe prescribing is highly dependent on system design rather than individual competence. In a setting such as resident aged care, clinical deterioration is often subtle, harms emerge over time and accountability is frequently distributed across multiple health professionals. In this context, safe prescribing depends not only on multidisciplinary input but on clear assignment of responsibility for ongoing diagnostic and prescribing decisions over time. A generalise, portable prescribing endorsement introduces decision-making authority into this environment without ensuring that responsibility for ongoing diagnostic trajectories is clearly assigned or structurally supported. In this setting, safe prescribing depends on system prerequisites (shared records, structured review timeframes, escalation pathways and explicit assignment of accountability) and facility-level governance that are materially different from episodic retail-based care models. This risk is consistent with the jurisdictional example outlined in Case Study 1, where prescribing authority was implemented without defined clinical scope or supporting governance frameworks, illustrating how once prescribing is generalised, system-level safeguards may not be consistently maintained across high-risk settings. **Medico-legal cover/liability** The guidelines do not specify medico-legal accountability and professional indemnity expectations for endorsed pharmacist prescribers across the full range of practice contexts in which prescribing may occur. By comparison, the Medical Board of Australia requires practitioners to be insured or indemnified for every context in which they practise and makes clear that if a practitioner is specifically precluded from cover for any aspect of practice, they must not practice in that area.

		In general practice, medico-legal accountability is closely linked to ongoing clinical responsibility, including requirements for appropriate follow-up, safety-netting and continuity of care. These expectations are supported by practice systems such as recalls, reminders and structured review processes, which function as critical safeguards against missed or evolving diagnoses. In episodic care models where prescribing occurs without assigned responsibility for follow-up, these system-level protections may not be present, increasing the risk that clinical deterioration or diagnostic error is not identified or acted upon in a timely manner. Consistent with this principle, the Pharmacy Board guidelines should more explicitly address how liability and accountability will operate where prescribing, follow-up and escalation occur across fragmented pathways, including clearer expectations for: • the scope of indemnity coverage required for endorsed prescribing across settings • minimum documentation and handover requirements • who holds responsibility for follow-up when clinical risk evolves after the initial prescribing encounter.
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.**	**Yes.** National Boards are required to regulate for population-level safety, including median and worst-case practice environments, not only for highly motivated practitioners also operating under ideal conditions. Episodic, point-of-care environments, including retail pharmacy settings, represent a foreseeable worst-case environment for independent prescribing. These environments are structurally limited in their ability to support continuity, reassessment over time and accountability for diagnostic trajectories, and should therefore be used as the stress-test for regulatory design, rather than treated as a benchmark of suitability. Key foreseeable impacts include: • Increased misdiagnosis in presentations with overlapping symptoms or non-specific symptoms (eg UTI vs STI or pelvic pathology) • Fragmentation of care and loss of continuity, particularly where prescribing decisions are detached from longitudinal clinical responsibility • Population-level harms such as antimicrobial resistance that are difficult to detect through complaints-based mechanisms • Transfer of risk from systems to individuals, reducing preventability of harm • Reduced regulatory visibility of delayed or diffuse diagnostic harm These impacts are not primarily the result of individual practitioner behaviour. Rather, they arise from regulatory models that normalise episodic decision-making without embedding accountability for diagnostic evolution over time. Evidence from primary care systems indicates that episodic care delivered across multiple providers without continuity or shared records is associated with duplication of care, reduced coordination, increased hospital utilisation and higher overall costs, supporting the conclusion that fragmentation is a system-level risk rather than a function of individual practitioner performance.

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**	**Yes.** Fragmented, episodic prescribing models risk: • Erosion of culturally safe, longitudinal care • Reduced coordination with Aboriginal Community Controlled Health Organisations (ACCHOs) • Reinforcement of access-over-quality trade-offs. Pharmacist prescribing may improve access in some rural, remote and Aboriginal-controlled settings, but access benefits can only be realised where it is embedded within culturally safe care models and integrated with ACCHOs, Aboriginal and Torres Strait Islander health practitioners, local GPs and families/kinship carers. The guidelines do not adequately address cultural safety risks associated with delivering diagnostic and prescribing services in retail/time-limited settings, where trust, culturally safe communication and holistic assessments are critical.
13.	**Could the proposed draft standard and guidelines result in any adverse cost implications for consumers, practitioners or other stakeholders? If yes, please describe.**	**Yes.** Consumers may face: • Duplicate consultations and repeat assessments • Out-of-pocket diagnostic testing • Increased expenditure from inappropriate or repeated prescribing. Practitioners may face: • Indirect cost and workload impacts for general practitioners and other providers, including follow up of incomplete assessments, management of complications and reconciliation of fragmented care Health systems and other stakeholders may face: • Increased risk of cost-shifting, where short-term access gains are offset by downstream costs from delayed diagnosis and escalation of care. • Increased administrative and coordination costs arising from fragmented, non-integrated models of care.
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.**	**Yes.** Populations particularly at risk include: • Children/older people – higher risks of diagnostic error where presentations are atypical and symptoms overlap. • Adolescents – increased risks of missed diagnosis where symptoms may relate to sexual health, mental health, eating disorders or substance use. • People with underlying mental health conditions – anxiety, depression and eating disorders may present with somatic, non-specific or fluctuating symptoms that appear compatible with minor illness at first contact. • People experiencing family and domestic violence – increased safety risks where episodic prescribing occurs without continuity and privacy safeguards. • Culturally and linguistically diverse communities – increased risk of miscommunication, misdiagnosis and reduced informed consent in retail settings where access to interpreters, culturally appropriate communication and longitudinal care is limited. • People living with disability or complex health needs – greater vulnerability to fragmented care, duplicated treatments and medication-related harm where prescribing occurs outside coordinated, GP-led care models.

		• LGBTQIA+ peoples – increased risks of stigma, discrimination which results in lower quality care and delayed diagnosis.
15.	**Can you identify any other potential regulatory impacts that the Board needs to consider?**	Taken together, the proposed standard and guidelines represent structural limitations in the current regulatory model. They place primary emphasis on individual-level safeguards and retrospective mechanisms, rather than embedding enforceable system-level protections. This shift from prevention to enforcement is poorly matched to diagnostic harm, which is delayed, diffuse and rarely complaint-generating. The endorsement model lacks structural mechanisms to assign and retain accountability for diagnostic trajectories over time, relying instead on post-event detection through complaints, notifications and audits after harm has occurred, and on individual practitioner discretion once harm has materialised. Rather than embedded continuity or escalation frameworks. The endorsement model: • Shifts regulation from prevention to enforcement – reliance on post-event standards rather than embedding structural safeguards that reduce the likelihood of unsafe prescribing before harm occurs. • Relies on complaints systems poorly suited to diagnostic harm, where error is often delayed and difficult to attribute to a single encounter, reducing likelihood that emerging risks are detected early through existing regulatory mechanisms. • Makes rapid restriction, recalibration or reversal difficult once risks emerge, because regulatory response becomes dependent on accumulated evidence of harm rather than proactive risk controls. • Erodes clarity of regulatory accountability, where diffuse responsibility across professions, settings and encounters complicates investigation and learning from adverse events (including incident attribution and complaint pathways when adverse outcomes occur). This limitation is not unique to pharmacy practice but becomes more consequential where prescribing authority is embedded in general registration and decoupled from continuity-based care models that allocate responsibility for diagnostic trajectories. As prescribing authority expands across multiple professional groups and settings, governance complexity increases. In practice, this makes incident attribution, complaint pathways and clinical accountability harder to manage when adverse outcomes occur, particularly where responsibility is distributed between the prescriber, the system and subsequent or referring clinicians. Cross-jurisdictional implementation variability further compounds these risks. Differences in scope, safeguards and enforcement settings across states and territories may create inconsistent prescribing standards and escalation expectation, undermining national coherence in medicines governance and limiting system-wide learning. Telehealth prescribing warrants separate consideration in this context, as remote prescribing may further weaken safeguards and compound risks, particularly where shared records, follow-up responsibility and clear escalation pathways are not well embedded.

		The endorsement model introduces a regulatory ratchet effect, lowering the threshold for future scope expansion while simultaneously reducing the Board's ability to re-impose safeguards once risks emerge. Finally, the asymmetry between the consultation paper and the consumer guide may limit the extent to which consumer feedback fully reflects the complexity of the safety considerations relevant to the Board's statutory obligations. Consumers are invited to comment on a proposal with material safety implications but are not provided with clear information about diagnostic uncertainty, delayed harm or the structural consequences of registration-level endorsement. Without clear information on these risks, consumer input may systematically under-weight safety concerns in favour of convenience, limiting its utility for regulatory risk assessment and limiting its utility in supporting the Board's statutory obligation to protect the public.
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?**	**Yes.** RACGP strongly supports: • Collaborative prescribing models • Practice-embedded or co-located arrangements • Service-level authorisation with defined governance • Models analogous to designated RN prescribing These approaches are more proportionate, evidence-aligned and protective. The endorsement model introduces a regulatory ratchet effect, lowering the threshold for future scope expansion while simultaneously reducing the Board's ability to re-impose safeguards once risks emerge. These models may include structured clinical pathways and protocol-supported prescribing where they are embedded within systems that ensure continuity of care, shared clinical records and clear clinical accountability. If the Board is seeking alternative options that better address underlying problems identified, greater policy attention should be directed to strengthening evidence base rather than broadening registration level-prescribing authority. This includes supporting non-pharmacological management and de-prescribing where appropriate.
17.	**Do you have any other comments or feedback?**	**Early detection and intervention** The RACGP has been unable to identify a clearly defined, proactive and system-level mechanism by which the Board would detect, aggregate, respond and intervene in delayed diagnostic harm that: • Presents outside the original prescribing encounter • Does not generate a complaint • And emerges across multiple practice settings. As outlined above, many forms of diagnostic harm do not generate timely or identifiable signals within complaints-based systems. In these circumstances, reliance on notifications or complaints systems is unlikely to provide timely or reliable early-warning signals.

		This limitation is particularly significant in models where care is delivered episodically across multiple providers without shared records, reducing the likelihood that emerging patterns of harm are detected in a timely manner. The RACGP therefore respectfully ask the Board to clarify: • The early-warning indicators or data sources will it rely on to identify emerging diagnostic or prescribing-related harm that does not generate complaints • How such harm will be attributed back to endorsed prescribing across multiple settings and providers • What clear thresholds and intervention powers will be available to the Board to rapidly constrain, recalibrate or suspend the endorsement should systemic risks emerge once endorsement is embedded in registration. In the absence of an articulate early-detection and intervention framework, it is unclear how the Board can be assured that a registration-level endorsement is capable of preventing harm before it occurs, rather than responding only after harm has become established. Medical registration does not 'add' prescribing to an otherwise non-diagnostic role. Pharmacist endorsement does. RACGP urges the Board to distinguish between: • Enabling access to services, and • Certifying safety at population scale. While the proposed endorsement may address an administrative and consistency challenge, it does so at the cost of introducing foreseeable patient-safety risk. In this context, the question for the Board is not whether prescribing can be performed safely within isolated encounters, but whether the regulatory model ensures that diagnostic uncertainty is systematically identified, reassessed and managed over time across the health system.

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