

# Review of the National Prescribing Competencies Framework

Royal Australasian College of Physicians submission to the Australian Health Practitioner Regulation Agency May 2025

### **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.

The RACP represents a broad range of medical specialties including clinical pharmacology and toxicology, general medicine, paediatrics and child health, cardiology, respiratory medicine, neurology, oncology, public health medicine, infectious diseases medicine, occupational and environmental medicine, palliative medicine, sexual health medicine, rehabilitation medicine, geriatric medicine, and addiction medicine.

Beyond the drive for medical excellence, the RACP is committed to developing health and social policies which bring vital improvements to the wellbeing of patients and the community.

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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.



### Introduction

The Royal Australasian College of Physicians (RACP) thanks the Australian Health Practitioner Regulation Agency (Ahpra) for seeking the views of Australia's physicians and trainee physicians for the Review of the National Prescribing Competencies Framework (the framework).

As the national training body for physicians, we bring unique expertise in shaping how advanced prescribers are educated, assessed, and supported across the continuum of their careers — from trainees to senior physicians. Our physicians and trainees see emergent practice issues in prescribing within complex and quickly evolving healthcare environments. This is enhanced through our recent policy and advocacy work on medicines shortages, medicines surveillance, supply chains, and related practice pressures.

Our submission provides feedback on the consultation questions outlined in Ahpra's public consultation paper. It reflects the input of a wide range of RACP specialties and practice contexts, including clinical pharmacology and toxicology, paediatrics, thoracic medicine, endocrinology, neurology, public health medicine, occupational and environmental medicine, gastroenterology, addiction medicine, general and acute medicine, sexual health medicine, clinical immunology, and sleep medicine.

Our national role in curriculum design, professional standards, workforce development and related policy reform gives us a system-wide view of the requirements for safe, sustainable prescribing — and how to implement those competencies in challenging practice environments.

We look forward to engaging with Ahpra further on the formulation of the framework as a continuing expert advisor throughout the reform process.

### 1. Should the existing framework be updated?

Most respondent members agreed the framework should be updated, noting the proliferation of medicines prescribing privileges and need to maintain safety and Quality Use of Medicines (QUM).

There was a divide in the extent to which our members believed it needed to be updated to align with current practice requirements and promote safety. Most suggested it needed only minor augmentation rather than a significant review and revision.

Overall, our members expressed cautious support for an update of the framework, with consideration to its existing balance of benefits, current alignment with prescribing practice, prescribing contexts, cultural, language and other barriers to patient inclusion in prescribing decisions.

## 2. Will the revised framework empower the person receiving care to actively participate in shared decision-making with a prescriber?

Feedback to this question was divided amongst members.

Just over half suggested that the revised framework would empower the person receiving care to actively participate in shared decision-making with a prescriber; the other half was either neutral or disagreed that the revisions would serve to empower the person receiving care.

It is important that competencies in patient-centred involvement and empowerment ultimately be applicable and appropriate to a range of specialty disciplines and the various worksite contexts in which they practice.

#### Reasons for

Members who suggested the framework would empower the person receiving care identified that it was underpinned by driving principles of patient autonomy and ensuring individuals receiving care are central to treatment decisions. Rationales included that it clearly reinforces the requirement for patient inclusion, understanding and consent, information exchange and communication, making it clear that patients should be informed participants in decisions about medications, extending to off-label prescribing as a new framework competency area. The recognition that not all side effects can be fully explained was appreciated as realistic, and the framework was thought to encourage practical and respectful shared decision making.

One member specifically noted that the framework offers greater nuance around the four stages of prescribing, including thoughtful commentary on issues such as the use of administration aids and continuity during transitions of care. However, it was emphasised that medicines prescribing is not always the best strategy and recommend the clause "recognising that medicines may not be the most appropriate management strategy" be reinserted from the 2021 framework. This reinsertion would be aligned with the intent of QUM principles and encourage consideration of non-pharmacotherapies as a first line approach where possible.

Other feedback specifically complimented the additional emphasis placed around the social aspects of patients in prescribing considerations, including financial, cultural, and cultural safety principles, particularly for Aboriginal and Torres Strait Islander peoples. This was appreciated for acknowledging that prescriber to patient relationships and historical relationships, including bias, can influence medication administration and use. These practical additions were seen as directly supporting safer, more patient-aligned prescribing, and better supporting patient adherence to prescribed medicines.

### Reasons against

Reasons given for why the framework would have limited or negligible impacts on empowering the person receiving care included that it is a regulatory document for medical colleges and practitioners which is generally unknown to patients. This suggests the need for improved communication with patients about their role in prescribing, as well as the development of life-stage appropriate health literacy tools for patients of all ages—from children to adults. For complex patients in particular, these supports are essential and should be delivered as a separate project in addition to the framework.

Some members also indicated that the framework would risk raising patient expectations and concurrently cause practice challenges for prescribers, given prescribing is ultimately the responsibility of the practitioner. This was considered especially important for restricted or scheduled medicines, and in situations where factors such as the type of disease, duration of medication use, level of patient choice, patient personality, and the degree of established trust in the consultation all influence shared decision-making. Prescriber interface with priority patient groups with potential barriers, including the elderly, children, rural, regional and remote populations, need to be considered.

Other members also commented on the practical limitations of facilitating patient empowerment in busy, time poor practice settings, within the limits of various types of physician consultations. They emphasised the framework needed to have implementable thresholds for involvement and empowerment of the person.

# 3. One new competency around "off-label" prescribing has been added. Do you have any feedback or suggestions regarding this new competency, including supporting examples?

While members generally supported the addition of a competency on off-label prescribing in principle, there was clear member feedback that broader support is needed to manage the practical challenges of off-label prescribing, and the competency needs greater nuance, clarity, and proportionality.

To reduce medico-legal risk, it was suggested that the term "adequate information" in the off-label competency be expanded upon with some examples for off-label medications in the competency. Whether this would, for example, encompass expert recommendation, trial data, guideline-based advice, peak body guideline/recommendations, or liaison with an expert committee should be defined, referring to patient groups for whom off-label prescribing is common and routine.

It may also be helpful to consider what constitutes 'adequate information' in the context of two types of off-label prescribing: long-established off-label uses that are widely practiced, and more recent or less commonly used off-label applications.

Some members felt that appropriate and safe off-label prescribing would be more broadly supported beyond the framework through expanded resources and education, including enhanced coordination by Ahpra and the Medical Board of Australia with the RACP on education resources and learning offerings. This could enhance awareness of best practice in off-label prescribing, monitoring and medicines transitions, clinical record keeping and evaluation, risk assessment, appraisal of the evidence to support clinician judgement and shared decision making.

Another theme that emerged is that the framework should acknowledge other regulatory mechanisms for maintaining safe and off-label prescribing via the TGA, PBS and SAS/AP schemes. In particular, there is need to reduce duplication and unnecessary regulatory barriers wherever possible. Practitioners would benefit from streamlined off label prescribing support, including assurance for overseas products, medico-legal risks, incident reporting, balancing existing regulatory mechanisms.

## 4. Will the revised framework result in any potential negative or unintended effects for people requiring healthcare?

A significant proportion members indicated the revised framework could result in potentially negative or unintended effects for people requiring healthcare. A smaller share of members was undecided. Combined this made up approximately half of all member feedback. The other half foresaw no such effects.

- Framework compliance could add to the work of prescribing which would come at the expense of practitioner time, increasing burnout risk with effects for patient safety.
- At any given time, Australia is facing hundreds of medicines shortages, being reliant on imported medicines for 98% of our domestic supply. This adds administrative burden on prescribers seeking substitutes which could be exacerbated without domestically manufactured alternatives and carefully streamlined regulatory approval requirements.
- Compliance could also absorb an inordinate amount of the consultation time, impacting
  frequency and turn-around of patient consultations. Some members highlighted the risk that
  compliance activities could disincentivise prescribers from managing particularly complex
  patients.
- The framework could discourage practitioners from prescribing evidence-based, effective offlabel medicines—particularly when no suitable alternatives exist—unless it is aligned with existing regulatory mechanisms that ensure safety and quality in such prescribing.

Several members who considered the framework would have no negative effects for patients did indicate that compliance with it would have negative effects for the operational flow of practice and their practice time. While they did not deem this a 'patient specific effect', it aligns with the feedback detailed above.

Given the spread and range of compliance burden concerns, this clearly needs further consideration as a driver for unanticipated, adverse impacts on patient care.

Members who believed the framework would have no potential negative effects for the person requiring healthcare emphasised its centring of cultural competence, and the potential of the framework to raise awareness of shared decision-making among prescribers. Awareness can however be raised through various additional methods, including dedicated education on the concepts and requirements of the framework (as outlined earlier in this submission).

## 5. Will the revised framework result in any potential negative or unintended effects for Aboriginal and/or Torres Strait Islander people?

Members overwhelmingly felt the framework would not pose specific harms to Aboriginal and Torres Strait Islander people given its centring of cultural competence and cultural safety in competent prescribing.

Nonetheless, we recommend (if not already underway) Ahpra seeks the views of Aboriginal and Torres Strait Islander peoples directly, including through the National Aboriginal Community Controlled Organisation (NACCHO).

## 6. Is the content of the proposed framework clear and reflective of safe, contemporary and ethical prescribing practice?

Members indicated that, in general, the framework is clear and reflects good practice.

The framework may however need to differentiate competencies for prescribers and dispensers to recognise the shared risk context in which medicine prescribing occurs.

Several members who considered the revised framework unclear identified its extensive length and the reduced use of dot point summaries in the new draft, which were considered a helpful element in the existing framework for quick reference.

Some feedback doubted the capacity of the framework to guide safe and ethical prescribing practice without practical tools for shared decision making and better educational linkages with the RACP and other medical colleges to proactively reduce regulatory risk.

## 7. Other prescriber and appropriate prescribing-related issues Ahpra should be aware of relating to the framework

It is imperative to consider that medicines shortages, of which there are hundreds at any given time in Australia, pose independent risks to optimal levels of practitioner compliance with the framework, including framework clauses concerning most evidence- based and safest medicines. This uncontrollable factor requires nuance and flexibility in the way regulatory scenarios are interpreted.

Compliance barriers to electronic documentation may exist in busy practice settings for patients who have opted out of My Health Record. Additionally, one member identified that pharmacovigilance measures, including TGA adverse events reporting, needs to be optimised to support framework implementation.

More broadly, the obligations placed on practitioners cannot be excessively onerous, impede other components of good patient care, or duplicate requirements.

We also highlight for consideration the implications of prescribing in vertically integrated businesses, where there is financial interest in a medicine being prescribed.

It would be useful to clarify resources beyond this framework to support appropriate social prescribing as a separate domain of prescription and healthcare.

#### Conclusion

We welcome Ahpra's review of the National Prescribing Competencies Framework and offer cautious support for the proposed revisions.

The diversity of member feedback highlights the need for further consultation with the RACP and prescribers. This will help ensure the framework is fit-for-purpose, relevant, clearly understood, and practical to implement.

The final framework must be fit for purpose in busy clinical environments, account for the contextual challenges of health service delivery—such as patient demand and ongoing medicines shortages—and avoid any unintended negative impacts on patients.

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