Submission by the Australian Nursing and Midwifery Federation

Endorsement for scheduled medicines for pharmacists

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Australian Nursing & Midwifery Federation

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Key Points

1. The Australian Nursing and Midwifery Federation (ANMF) is Australia's largest national union and professional nursing and midwifery organisation. In collaboration with the ANMF's eight state and territory branches, we represent the professional, industrial and political interests of more than 356,000 nurses, midwives and personal care workers (PCWs) across the country.

2. The ANMF welcomes the opportunity to provide feedback and thanks the Pharmacy Board and Ahpra for the opportunity to provide feedback on the *Endorsement for scheduled medicines for pharmacists*. The ANMF would like to acknowledge the valuable contribution pharmacists make to the health and wellbeing of the Australian community.

3. Pharmacists provide high-quality, accessible care across a wide range of healthcare settings and play an important role in supporting the safe and effective use of medicines, improving health outcomes, and enhancing access to care for the Australian public.

4. However, there are several aspects of the proposed endorsement of concern, particularly that the proposed broad prescribing authority could contribute to fragmented care if prescribing occurs outside multidisciplinary models of care and without appropriate mechanisms for communication, coordination, and continuity of care between healthcare providers.

5. It is essential that any profession granted prescribing rights demonstrates equivalence to existing prescribers in education, regulation, clinical governance, and professional accountability. Prescribing is a significant clinical responsibility with implications for patient safety and quality of care. The extension of prescribing authority should only occur where there is clear evidence that these standards can be consistently achieved and maintained.

Introduction

6. The Australian Nursing and Midwifery Federation (ANMF) is Australia's largest national union and professional nursing and midwifery organisation. In collaboration with the ANMF's eight state and territory branches, we represent the professional, industrial and political interests of more than 356,000 nurses, midwives and care-workers across the country.

7. Our members work in the public and private health, aged care and disability sectors across a wide variety of urban, rural and remote locations. We work with them to improve their ability to deliver safe and best practice care in each and every one of these settings, fulfil their professional goals and achieve a healthy work/life balance.

8. Our strong and growing membership and integrated role as both a trade union and professional organisation provides us with a complete understanding of all aspects of the nursing and midwifery professions and see us uniquely placed to defend and advance our professions.

9. Through our work with members, we aim to strengthen the contribution of nursing and midwifery to improving Australia's health and aged care systems, and the health of our national and global communities.

Overview

Is the information in the draft registration standard clear? If no, please explain why.

10. The consultation document articulates the intent of the *Endorsement for scheduled medicines for pharmacists*. However, the proposed registration standards lack sufficient detail in relation to role clarity, clinical accountability and alignment with existing frameworks including those of designated registered nurse prescribers (DRNP) nurse practitioners (NP) and endorsed midwives (EM).

11. Further clarity is required to ensure safe and effective integration within multidisciplinary models of care. Accordingly, the draft standards would benefit from more explicit delineation of scope of practice, clinical boundaries and decision-making authority.

12. Clear governance arrangements, competency requirements and communication pathways are essential to avoid role duplication, role creep, and to maintain patient safety. Strengthening these elements will be critical to ensuring the endorsement complements, rather than further fragments, team-based care delivery.

13. The endorsement focuses on the governance for being a pharmacist (bachelor prepared) rather than the expansion of this role to an endorsement for scheduled medicines. There needs to be clarity on how this expanded role will differ from a bachelor's degree (beyond the capacity to prescribe Schedule 4 and 8 medications) and their integration into the current pharmacy workforce.

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. Option A or Option B

14. The ANMF supports Option A – retain the status quo a limited scope of prescribing for pharmacists, restricted to Schedule 2 and Schedule 3 medicines. The board has provided that the endorsement is required due partially to inconsistent Schedule 4 practices across jurisdictions and inconsistent education and training. However, the proposed endorsement does address this. The scope of endorsement should be consistent with other health practitioners who have prescribing rights. The ANMF notes that a further review is scheduled following this consultation of the accreditation standards for pharmacist prescribing education programs and an accompanying performance outcomes framework.

15. There may be narrowly defined, highly specific clinical circumstances in which certain Schedule 4 and 8 medicines could be considered within tightly governed protocols.

16. Prescribing controlled medicines requires advanced diagnostic capability, patient management, and experience in managing clinical uncertainty and risk, grounded in comprehensive clinical education, autonomous practice, and integrated clinical reasoning rather than medicines expertise alone.

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?

17. The ANMF does not support the autonomous prescribing of Schedule 4 and 8 medicines for pharmacists. The ANMF would support a supervision model for these scheduled medicines similar to the RN prescribing model of supervision. The pharmacist prescriber could prescribe medicines within their scope of practice under the supervision of an authorised prescribing health professional.

18. Pharmacist prescribing education should therefore remain clearly limited in scope unless it meets this advanced practice standard and otherwise align with protocol-based care rather than autonomous diagnostic practice. Prescribing is not a discrete technical skill but is embedded within holistic patient assessment, differential diagnosis, and clinical decision-making. The proposed pathway for Endorsement Pharmacy prescribers lacks clarity and consistency with regulatory requirements for other authorised prescribers.

19. Pharmacists have an extensive knowledge of pharmacology, pharmacokinetics and pharmacodynamics, however prescribing medications is not merely a technical skill but is underpinned by assessment of a patient's history, presenting medical complaint, clinical assessment, diagnosis and clinical decision making.

20. The standalone prescribing qualification is not sufficient for autonomous prescribing authority unless it is recognised as advanced practice education at a master's level or equivalent. This level of education is currently not reflected in the proposal.

Question Your feedback b. What safeguards would you consider essential to support safe practice in these situations?

21. The ANMF supports the development of a national competency framework for pharmacists; however, competencies must be clearly defined, rigorously assessed in real-world clinical settings, and explicit about limits of practice. Competency-based models risk overestimating preparedness, if they are not matched with sufficient depth of clinical experience and exposure to complex or atypical presentations.

22. The proposal does not detail whether pharmacists will face restrictions regarding registration such as the requirement for pharmacists to have registration free from conditions before they can apply for endorsement, a requirement that is placed on nurses.

23. This omission raises questions about whether the proposal for pharmacists will be as rigorous as those for the nurses and midwives or whether the requirements will be more flexible. The criteria for an endorsed pharmacist prescriber should align with the criteria for NP or DRNP (depending on the level of education that becomes mandatory). The lack of consistency for obtaining endorsement across the professions is problematic and may pose risks to the public.

24. The ANMF will not support this endorsement unless there is a nationally consistent approach to ensure safe and effective practice. This type of role should be limited to distinct areas of employment, with a focus on supporting communities where access to healthcare is most constrained.

25. Diagnostic testing is intrinsically linked to comprehensive patient assessment, clinical reasoning, and continuity of care; extending prescribing authority without adequate clinical governance requirements or established models of care, may result in fragmented clinical reasoning, incomplete evaluation of patient presentations and poor patient outcomes.

26. NP and EM prescribing is underpinned by integrated history-taking, physical assessment, diagnostics, and prescribing and supported by established models of care and clinical governance. The proposed endorsement acknowledges clinical governance; however, fails to

include the requirement to establish a clinical governance framework regardless of the clinical context, prior to commencing as an endorsed prescriber.

27. The Board mentions on page 9 '*The Board is working with AHPRA on developing further targeted guidance to ensure pharmacists appropriately balance conflict between their clinical responsibilities and retail or commercial interests across their practice to safeguard patient care*'. This guideline must be embedded as part of a requirement for an endorsed practitioner, and essential clinical governance safeguards must be established prior to progressing to endorsed pharmacist prescribing. As currently proposed, this omission presents significant risk to the public.

28. In situations which involve vulnerable individuals, it is essential that a continuity of care plan is in place. Individuals who are at risk of medication discrepancies as they transition between healthcare providers include people with complex medication regimens, older people, those with mental health problems, people who are poor or have low literacy, and Aboriginal and Torres Strait Islander and migrant populations.[1]

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.

29. The proposed eligibility requirement for endorsement lacks sufficient detail or safeguards.

30. As stated above; The Board mentions on page 9 '*The Board is working with AHPRA on developing further targeted guidance to ensure pharmacists appropriately balance conflict between their clinical responsibilities and retail or commercial interests across their practice to safeguard patient care*'. This guideline must be embedded as an eligibility requirement of an endorsed practitioner, and essential clinical governance safeguards must be established prior to progressing to endorsed pharmacist prescribing. As currently proposed, this omission presents significant risk to the public.

[1] Wheeler AJ, Scahill S, Hopcroft D, Stapleton H. (2018). Reducing medication errors at transitions of care is everyone's business. Australian Prescriber. 41:73–7.https://doi.org/10.18773/austprescr.2018.021

31. Unlike the draft pharmacist endorsement, the regulatory framework for nurse practitioners and designated RN prescribers is clearly established within registration and endorsement arrangements administered by the Nursing and Midwifery Board of Australia (NMBA). For instance, NPs are required to complete Board approved programs of study, meet defined clinical practice requirements and demonstrate advanced practice capability prior to endorsement. The endorsement is formally recognized in the practitioner's registration and is supported by established regulatory, governance and professional standards.

32. Conversely, the proposal for endorsed pharmacist prescribing appears to focus on completion of a Board approved program of study without clearly articulating the broader endorsed framework, governance requirements, clinical practice expectations, supervision arrangements or ongoing regulatory safeguards to support it. This creates uncertainty regarding how the proposed endorsement would align with existing nationally regulated endorsement pathways.

Do you agree with this approach? Please provide an explanation for your answer and include information to support your position if possible.

33. The ANMF supports Option 1 – Retain the status quo.

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?

34. The draft registration standard lacks sufficient detail, including an overall lack of detail on potential workforce and broader service implications.

Is there anything that needs to be changed, added or removed from this guideline?

35. The current guidelines do not adequately address or provide safeguards around conflict of interest or clinical governance frameworks to ensure public safety. The endorsed prescribing is proposed as an autonomous, unsupervised role across diverse practice environments and clinical settings. A comprehensive regulatory framework to support safe practice in community pharmacy settings is required. This would need to include clearly defined scope-of-practice boundaries, condition specific protocols, and strict inclusion and exclusion criteria to prevent practice beyond competence. It would also require robust clinical governance arrangements, including external audit processes, peer review mechanisms, and defined escalation pathways to medical or nurse practitioner care. Mandatory communication with the patient's usual primary care provider, integration with shared electronic health records, and structured referral processes would be essential to prevent fragmentation of care.
36. The ANMF is concerned regarding potential unintended competition of the proposed role with registered nurse prescriber and NP roles in primary and aged care settings. Despite articulated government policy, NPs currently face challenges in primary care in securing funded, permanent positions. The clinical scenarios provided in the appendix suggest potential duplication of NP roles though without the same clinical education and experience.

Does the guidance on managing conflicts of interest and separating prescribing and dispensing need to be changed? If so, please outline the risks that you have identified about these issues and evidence that supports the need for additional or alternative guidance.

37. No, the draft guidance does not provide adequate guidance on managing conflicts of interest.
38. Given that community pharmacies operate as retail businesses within a commercial environment, strengthened safeguards addressing potential and perceived conflicts of interest are required. These should include enhanced transparency requirements, independent auditing of prescribing patterns, and clear separation of clinical decision-making from commercial incentives associated with medicine supply.

39. While regulatory and professional standards can mitigate risk, they may not fully eliminate the influence of commercial drivers on prescribing behaviour. The proposed standard does not sufficiently address these potential conflicts or provide mitigations to ensure public safety. A key concern is the need for clear delineation of roles within interdisciplinary teams. To maintain community trust and ensure patient safety, it must be clear that patients are receiving care from the most appropriate professional for their needs, in the right setting, and within each practitioner's defined scope. Without this clarity, there is a risk of role confusion or duplication.

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.

40. In relation to education and accreditation, we note that prescribing within nursing practice is supported through nationally consistent, formally accredited education pathways, with nurse practitioner and nurse prescriber programs accredited by the Australian Nursing and Midwifery Accreditation Council (ANMAC) to ensure national consistency, safety, and regulatory alignment.

41. For consistency across regulated health professions, any prescribing education pathway developed for pharmacists must be subject to formal, independent accreditation through an equivalent national accreditation authority, ensuring alignment with established standards for advanced practice education, regulatory oversight, and public safety. This is particularly important given that prescribing is an endorsed extension of professional registration and carries significant clinical and legal responsibility. As this proposed endorsement would lead to a change in national registration, therefore each program must be assessed at a consistent national level. A phased approach is recommended, beginning with limited scope prescribing and expanding only following robust evaluation of safety, quality, and patient outcomes supported by strong governance and escalation pathways.

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.

42. The ANMF supports pharmacists expanding their knowledge and scope and improving community access to health care and treatment, however the proposed endorsement lacks adequate clinical safeguards to ensure public safety. In regions where existing alternative care models such as NP or midwife-led services are already established, these should be prioritised and expanded before introducing a new clinical discipline into the same service area. A new service must complement, not duplicate, existing services. This ensures the sustainability of established models and respects the workforce planning already undertaken in many parts of the health system.

43. Another unintended effect of the proposal is that current escalation and referral policies across many health services do not account for endorsed pharmacist prescriber models of care. Without formal recognition within these clinical governance frameworks, there may be ambiguity in decision making responsibilities, scope boundaries, and patient handover processes, which could compromise patient safety.

Could the proposed draft standard and guidelines have potential negative or unintended impacts on Aboriginal and Torres Strait Islander peoples? If yes, please describe

44. Fragmented care can have a significant impact for Aboriginal and Torres Strait Islander peoples. It is essential to establish safe continuity of care practices to ensure that their PHC providers are aware of any medications/treatments they may be taking. Established engagement and communication channels to the patients' PHC providers are required to ensure the provision of culturally safe care. This includes (but is not limited to) confirming that the patient has a follow-up appointment scheduled with their PHC and ensuring that the pharmacist communicates sufficient information to the PHC about the treatment the patient received or is undertaking, to enable the continuing care of the patient. The care provided by the pharmacist also needs to be free from discrimination and bias.

45. In relation to a fee for service –the Closing the Gap (CTG) PBS Co-payment Program should apply to this system[2] to ensure Aboriginal and Torres Strait Islander people can access this service without social disadvantage.

46. The Pharmacy Board should consider exemptions for small regional or rural areas, where a pharmacist can dispense medication that they have prescribed, consistent with other health practitioners who have both prescribing and dispensing rights, within these communities.

47. Deploying or integrating an endorsed pharmacist prescriber into vulnerable or isolated communities without establishing clinical governance frameworks including clinical escalation pathways, could have significant negative impacts. Including requirement for culturally safe care and meaningful partnerships with Aboriginal and Torres Strait Islander communities is essential.

Could the proposed draft standard and guidelines result in any adverse cost implications for consumers, practitioners or other stakeholders? If yes, please describe.

48. The funding model will be critical. Without access to publicly funded mechanisms there is a risk that services that are provided by the proposed endorsed pharmacist prescriber will require out of pocket payments from patients. This could create inequitable access to care particularly in low income, rural or remote communities. Regulatory design must therefore account for the need to align the role for funding pathways that support affordable universal access.

49. It is important that pharmacists do not use 'prescribing of medicines' as a business model opportunity. Pharmacists should not be able to prescribe the most expensive medication to

[2] Australian Government. (Services Australia). *Closing the Gap PBS – Prescribers*. Retrieved from https://www.servicesaustralia.gov.au/closing-gap-pbs-co-payment-for-prescribers?context=20 and Australian Government (Department of Health, Disability and Ageing). First Nations. Retrieved from https://www.health.gov.au/cheaper-medicines/first-nations

patients. Signed, written informed consent should be documented. Informed consent must also include financial consent.[3]

50. Pharmacists must make a record and include documents shared with patients, which at a minimum should include Consumer Medicine Information (CMI)[4] and disclose medication costs, as well as alternative medication options. This record must be available and verifiable to ensure that patients are fully informed prior to making any financial and health decisions. Conflicts of interest must be proactively managed by Ahpra and relevant accrediting bodies.

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.

51. While expanded prescribing authority may improve access to medicines and continuity of care, it may also introduce risks related to fragmented communication, reduced holistic assessment, and inequitable care if safeguards are not robust. There is also a risk that complex medication regimens prescribed across multiple conditions may not fully account for psychosocial determinants of health, particularly if coordination with primary health care practitioners or multidisciplinary teams is inconsistent.

52. Further care provisions will be required to ensure that vulnerable members of the community receive continuity of care. This includes (but is not limited to) confirming that the patient has a follow-up appointment scheduled with their PHC and ensuring that the pharmacist communicates sufficient information to the PHC. The care provided must be free from discrimination and bias.

[3] The Pharmacy Guild of Australia. (2022, December). *Prioritising informed consent.* Retrieved from https://www.guild.org.au/news-events/news/forefront/v12v12/prioritising-informed-consent

[4] Australian Government (Department of Health, Disability and Ageing) (Therapeutic Goods Administration). (2020, August). *Consumer Medicine Information (CMI)*. Retrieved from https://www.tga.gov.au/products/regulations-all-products/about-australian-register-therapeutic-goods-artg/consumer-medicine-information-cmi

53. The proposed guidelines omit how privacy will be maintained by pharmacists in retail settings in comparison to other primary health or community settings where consultation rooms are readily available to consult with patients. There is the unintended risk that harm could occur or compromise communities' trust if systems do not adequately support comprehensive assessment, interprofessional collaboration and culturally safe trauma informed practice.

Can you identify any other potential regulatory impacts that the Board needs to consider?

54. Health records and information systems, regulatory frameworks must address pharmacists' access to shared electronic health records, privacy legislation compliance, and information-sharing agreements. Without adequate access, there is further risk of fragmented care and medication-related harm.

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?

55. The ANMF supports a nationally consistent approach to prescribing endorsements across all authorised prescribers.

Do you have any other comments or feedback?

56. Tele-health prescribing does not appear to be included. Marginalised groups may find it difficult to present to a pharmacist. This should be consistent with other health practitioners who have prescribing rights.

Conclusion

57. The ANMF will continue to support initiatives that improve timely access to safe, high-quality care. However, any expansion of prescribing must maintain a clear and inseparable link between diagnosis, clinical accountability, and prescribing authority, and should complement not duplicate existing endorsed prescriber roles.

58. Prescribing authority must remain linked to diagnostic capability, holistic assessment, and clinical accountability. Ahpra should prioritise the full utilisation of existing endorsed prescribers, including NP and EM and RN prescribers. A balanced approach that leverages the strengths of each profession within a collaborative, well-integrated system will best serve patient safety and the long-term sustainability of the health system.