The Pharmacy Guild of Australia

Scope of Practice of Community Pharmacists in Australia

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1. CONTENTS

1. EXECUTIVE SUMMARY

1.1 Pharmacists are trusted health professionals and highly trained clinicians

Pharmacists are experts in medicines with a professional responsibility to ensure the quality use of medicines (QUM) – that is, that medicines are used safely, effectively, and judiciously. They have a unique and complex knowledge and skill base including a broad and deep knowledge of pathophysiology and pharmacotherapeutics.

Pharmacists also have comprehensive training in disease prevention, management, and treatment. There is robust evidence of the impact that pharmacists have on medication safety and adherence and the resulting savings to the health system, particularly in the case of pharmacists managing long term conditions through the quality use of medicines.[1]

Pharmacists undergo a minimum five-year training as part of their university education including a one-year intern program before being registered to practise as pharmacists. They then undertake mandatory continuing professional development (CPD) throughout their careers to maintain currency and competency in contemporary pharmacy practice and their individual scope of practice as it evolves.

The pharmacy profession and community pharmacy operate within an extensive professional and ethical quality and safety risk management framework which includes:

- The Pharmacy Board of Australia registration standards, codes, guidelines, and policies[2].
- The Australian Health Practitioner Regulation Agency (Ahpra) which supports the Pharmacy Board in its role of protecting the public and setting standards and policies that all registered health practitioners, including pharmacists, must meet.[3]
- Ahpra Shared Code of Conduct[4]
- Code of Ethics for Pharmacists[5]
- National Competency Standards Framework for Pharmacists in Australia (2016)[6]
- Professional Practice Standards[7]
- National Health (Pharmaceutical Benefits) Conditions of approval for approved pharmacists[8]
- Quality Care Pharmacy program[9] accrediting community pharmacies against Australian Standard AS 85000-2017 – quality management system for pharmacies in Australia.

A 2021 Roy Morgan survey has continued to rank pharmacists in the top three professions for ethics and honesty, despite most professions suffering from a loss of trust during the SARS CoV-2 (COVID-19) pandemic[10].

1 Ernst & Young Report *Scope of Practice Opportunity Assessment* February 2020
2 Pharmacy Board of Australia, *Codes, Guidelines and Policies*: https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx
3 Ernst & Young Report *Scope of Practice Opportunity Assessment* February 2020
4 Australian Health Practitioner Regulation Agency, *Shared Code of Conduct* https://www.ahpra.gov.au/Resources/Code-of-conduct/Shared-Code-of-conduct.aspx, June 2022
5 Pharmaceutical Society of Australia, *Code of Ethics*: https://my.psa.org.au/s/article/Code-of-Ethics-for-Pharmacists February 2017.
6 Pharmaceutical Society of Australia, *National Competency Standards*: https://www.psa.org.au/practice-support-industry/national-competency-standards/ 2016.
7 Pharmaceutical Society of Australia, *Professional Practice Standards*: https://www.psa.org.au/practice-support-industry/professional-practice-standards/ 2017.
8 Australian Government, *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists)* Determination 2017 (PB 70 of 2017): https://www.legislation.gov.au/Series/F2017L01297, 25 September 2017.
9 Quality Care Pharmacy Program: www.qcpp.com 2017.
10 Roy Morgan, *Image of Professions Survey 2021*: https://www.roymorgan.com/findings/roy-morgan-image-of-professions-survey-2021-in-a-year-dominated-by-covid-19-health-professionals-including-nurses-doctors-and-pharmacists-are-the-most-highly-regarded-but-almost-all-professions-d, 27 April 2021

1.2 Benefits of pharmacists working at full scope of practice

Australia's health system is recognised as one of the best in the world, ranking at number three for its health system, with particularly high performance in areas of Administrative Efficiency, Health Care Outcomes and Equity, but a low performance in Access to Care[11]. Australia's low performance in access to care reflects the need to improve the timeliness and convenience of primary care access in local communities.

Community pharmacy location rules mean there is equitable distribution of community pharmacies across Australia, providing the community with easy access to a healthcare professional. Community pharmacies are the most frequently accessed and most accessible health destination, making pharmacists the most visited and accessible healthcare professional in Australia[12]. Community pharmacists see patients on a regular basis without the need for an appointment. As such, community pharmacies are ideally placed to provide person-directed care to support people with their health concerns.

In 2020-2021, approximately 1 in every 18 hospitalisations in Australia was classified as potentially preventable. Measuring potentially preventable hospitalisations (PPH) can provide valuable information on the effectiveness of health care in the community. Lack of timely, accessible, and adequate primary care all contribute to higher rates of PPH[13]. Data from 2021-22 shows increasing Emergency Department (ED) wait times and a smaller portion being seen on time[14]. The quantifiable benefits of reducing PPH and improving ED efficiency, to both the economy and to the health of the community, through increased access to quality health services and improved health outcomes can be achieved by utilising community pharmacists working to full scope of practice.

The accessibility and skills that pharmacists bring to the health sector are valuable and should be optimised to improve the overall function of the health system[15]. Community pharmacists being the most accessible health professionals in the community are well placed to triage patients and either treat or refer them to other health professionals as necessary, depending on the level of care required. Community pharmacy is also a gateway for health promotion and prevention measures, boosting distribution of self-management information and resources on physical and mental health and wellbeing.

1.3 Barriers to pharmacists working at full scope of practice

The pharmacy university curriculum provides pharmacists with the required competencies; that is, the knowledge and skills, to operate as medication managers. Registration with the Pharmacy Board of Australia provides the professional authority to practise pharmacy across the full scope of pharmacy practice, which includes the prescribing, dispensing, administering, and reviewing of medicines.

1.3.1 Legislative authority

At present, pharmacists in Australia do not practise according to their full scope of practice, because they do not have the legislative authority to do so. This means that they are unable to contribute to the healthcare system at an optimum level, in accordance with their acquired and assessed competencies. Because the existing pharmacy university program facilitates the necessary competencies, the impact of legislative authority changes would quickly achieve a scale that would positively impact access to quality health services and improve health outcomes significantly.

In 2014, the Grattan Institute stated that pharmacists should be authorised *'to give repeat prescriptions and help manage chronic care. Pharmacists should also be able to administer vaccinations.'*[16]. While pharmacists are currently able to administer some vaccinations in community pharmacy dependent on jurisdiction, there is patient demand beyond what is currently accessible. For example, market research conducted in July 2022 by Orima Research[17] found that most consumers would be likely to obtain other types of vaccinations or wound care services from their local pharmacy if such services were available[18].

11 Mirror, mirror 2021: Reflecting Poorly. Health Care in the U.S. compared to other high-income countries. (2021) Mirror, Mirror 2021: Reflecting Poorly | Commonwealth Fund
12 GuildLink data
13 Australian Institute of Health and Welfare, *Disparities in potentially preventable hospitalisations across Australia*, 2012-13 to 2017-18 https://www.aihw.gov.au/reports/primary-health-care/disparities-in-potentially-preventable-hospitalisations-australia/contents/summary
14 Australian Institue of Health and Wellness, *Emergency Department Care*: https://www.aihw.gov.au/reports-data/myhospitals/sectors/emergency-department-care 2022.
15 QUT submission No 167 to the Queensland Government Inquiry into the establishment of a Pharmacy Council and pharmacy ownership in Queensland 11 July 2018
16 QUT submission No 167 to the Queensland Government Inquiry into the establishment of a Pharmacy Council and pharmacy ownership in Queensland 11 July 2018
17 The Pharmacy Guild of Australia commissioned Consumer Survey July 2022 wave (n=1,267); Orima
18 The Pharmacy Guild of Australia Commissioned *Community Pharmacy 2025*, Market Research Integrated Summary Report, Orima Research July 2022

Additional research conducted by Insightfully in September 2022 found that 88 percent of Australians *"support community pharmacists being able to provide more health services to their patients, provided they are trained and follow professional standards and guidelines"*[19]. 77 percent of respondents said they *would feel comfortable with their pharmacist monitoring their cholesterol levels and renewing relevant prescriptions*, and 81 percent were *comfortable with receiving assessment, administration and/or supply of travel-related vaccinations or preventive medicines.*

Restrictive state and territory legislation is one of the main barriers to mobilising the 31,720 strong pharmacist workforce[20] to deliver additional health services to the community. There are simple ways these restrictions can be addressed. For example, in Queensland, although prescribing is not currently included in the regulations[21] describing a pharmacist's role, the extended practice authority[22] enabled under *Queensland's Medicines and Poisons Act 2019* allows appropriately trained pharmacists to dispense Prescription Only antibiotics for uncomplicated cystitis in females without the need for a prescription.

However, to effectively utilise the Australian pharmacy workforce and empower pharmacists to reduce preventable hospitalisations and avoidable emergency department presentations, a legislative approach to facilitate the full scope of pharmacy practice across *all* patient presentations (acute conditions, chronic conditions, and preventive health matters) is required, rather than *limiting* pharmacists' scope of practice to management of discrete conditions.

1.3.2 Funding and remuneration

Another barrier to pharmacists working to full scope of practice is ensuring appropriate funding is available to support equity of access for all patients. While some community pharmacy programs exist through the 7th Community Pharmacy Agreement, which provide funding for patient medication management services, these programs are limited in scope and operate under capped budgets, meaning there is often unmet patient demand for these services.

Professional services beyond dispensing and medication management are generally self-funded by the patient, even where there is recognition of the need to provide Government subsidisation when the equivalent service is provided in other healthcare settings. This effectively denies access to these services for vulnerable populations who may not be able to afford private service fees and restricts all patients' ability to choose the setting in which their healthcare is delivered. Where a pharmacy operates in a lower socioeconomic region, the service may not be viable at all due to limited numbers of patients able to self-fund professional pharmacy services, thereby denying access to all patients in that area.

A prime example of this is access to National Immunisation Program (NIP) funded vaccines (e.g., influenza vaccine). People eligible for NIP-funded vaccines may choose to get vaccinated at a community pharmacy due to easy access, convenience, and preference for the community pharmacy as a healthcare provider for vaccination. However, while the cost of the NIP vaccine to pharmacy is covered by the Government, pharmacies must charge patients a service fee for the administration of the vaccine, while an identical service provided by other healthcare providers such as nurse practitioners includes a Government subsidised service fee. This challenges the government's policy intent of universal access for all Australians and disadvantages those eligible patients who choose to have their NIP vaccination in a community pharmacy.

More efficient access to healthcare services can be enabled through subsidisation of community pharmacy services for vulnerable or target populations, and allow pharmacies to offer a wider range of services to patients, improving access to services for the community as a whole.

Appropriate funding mechanisms equivalent to other healthcare providers for the delivery of preventive health care would support increased and affordable access to these services and better preventive health outcomes for the community.

19 The Pharmacy Guild of Australia commissioned Full Scope of Practice, Community Pharmacists – National Opinion Research, Insightfully September 2022
20 Pharmacy Board of Australia, *Registrant data* (General registration): https://www.pharmacyboard.gov.au/About/Statistics.aspx, September 2022.
21 Queensland Government, *Medicines and Poisons (Medicines) Regulation 2021*: https://www.legislation.qld.gov.au/view/whole/html/inforce/current/sl-2021-0140 March 2023.
22 Queensland Government, *Medicines and Poisons Act 2019 - Extended Practice Authority 'Pharmacists'*: https://www.health.qld.gov.au/__data/assets/pdf_file/0027/1108944/epa-pharmacists.pdf 1 March 2023.

1.3.3 Pharmacy classification and recognition

As the most accessible primary health care profession, pharmacy should be classified as a primary health discipline like medical practice, nursing and dentistry, rather than being grouped with allied health disciplines. With this, pharmacy in general and community pharmacy in particular must be recognised as an integral part of the primary health care system and acknowledged as primary health care providers, including in health planning documents.

For the purposes of the Australian and New Zealand Standard Industrial Classification (ANZSIC, 2006), community pharmacies are currently included within Division G (Retail Trade) and within a class (4271) that *"consists of units mainly engaged in retailing prescription drugs or patent medicines, cosmetics or toiletries"*[23]. This classification of community pharmacy activities is inappropriate and misrepresentative. Community pharmacy activities should be reclassified to health care (Division Q of the ANZSIC) as the principal activity is dispensing and supply of medicines and the value added to the product by a community pharmacy enterprise is undoubtedly a health-related value. This view is shared by a number of pharmacy organisations around the world and work is underway to seek a change at a global level.

1.4 Comparison with the global pharmacist workforce

Pharmacists are among the most trusted of all professionals, are found in most communities throughout Australia and are accessible to patients without a long wait. Yet, compared to several other countries, pharmacists in Australia are still not able to practise to their full scope of practice[24]. Despite some progress in pharmacist scope of practice in various Australian states and territories, Australia continues to lag behind our international counterparts, with other countries forging ahead and utilising pharmacists practising to full scope to address healthcare access issues.

The main gaps are in areas such as the administration of injectable medicines (including vaccines), therapeutic substitution and adaptation, medication continuance, prescribing and laboratory testing. Australia lags behind countries with equivalent economies and health systems such as Canada, the UK, Ireland, the USA and New Zealand where there are examples of these practices being undertaken by pharmacists.

As stated in the International Pharmaceutical Federation (FIP) Vision statement 2020-2025, *"the COVID-19 pandemic has demonstrated the essential role of pharmacies and pharmacists in our communities and their ability to innovate healthcare solutions. We must ensure their role continues to be recognised beyond the pandemic"*[25].

23 Australian Bureau of Statistics, 1292.0 - Australian and New Zealand Standard Industrial Classification (ANZSIC), 2006 (Revision 1.0): https://www.abs.gov.au/ausstats/abs@.nsf/0/38B020E62EB7934ECA25711F00146F09 2008.

24 Grattan Institute submission No 21 to the Victorian Legislative Council, Letting pharmacists do more: https://www.parliament.vic.gov.au/images/stories/documents/council/SCLSI/Community_Pharmacy/Submissions/Sub_21_Grattan_Institute_30062014.pdf, June 2014.

25 International Pharmaceutical Federation (FIP), Vision 2020-2025 - *Pharmacists at the heart of our communities. Community Pharmacy Section*: https://www.fip.org/community-pharmacy, August 2020.

1.5 The way forward

1.5.1 The need to address gaps

Pharmacist competency training

Recently registered pharmacists in Australia who have studied under the current pharmacy curriculum already have the competencies to practise across the full scope of pharmacy practice as defined in the current Competency Standards. Additional training is only required to familiarise pharmacists with standardised professional guidelines to undertake a task, pharmacy procedures or where an individual pharmacist identifies a gap in their competency due to recency of practice or to reinforce previous knowledge.

Registered pharmacists that have been practising for many years in the community need to assess their competency in relation to any new, or additional task they undertake. They need to access appropriate education, training, or professional development to ensure they have the contemporary knowledge and skills to perform the task or additional services and meet any legislative or professional requirements. This could be considered 'retrofitting' of the workforce to ensure they have the competencies of contemporary pharmacy practice, noting the evolving nature of medicines, therapeutics, and health service delivery. This retrofitting practice is common with all health professions.

Pharmacist authorisation

Authorisation to undertake these additional tasks would need to be enabled through amendments to relevant federal, state and/or territory legislation.

These may include state and territory poisons regulations, extended practice authorities or pharmacist standards and codes, and Federal laws and legal instruments such as the *National Health Act (1953)* and its subsidiary instruments and the *Poisons Standard*.

1.5.2 Towards achieving full scope of practice in Australia

In recognition of pharmacists as the experts in medicines, they must be afforded all appropriate authorities to contribute fully to the Australian health care system by practicing at full scope of practice.

The competencies of pharmacists are being underutilised by the legislative barriers that are currently limiting their scope of practice, and therefore their value to the health system and all Australians is not being used to full advantage.

The Guild is committed to working with all levels of governments to address competency, training, professional standards, and any international or national precedents to support the required regulatory amendments as the profession of pharmacy evolves to meet health system and societal needs.

2. DEFINING SCOPE OF PRACTICE

Scope of practice is defined in the National Competency Standards Framework for Pharmacists in Australia 2016[26] (Competency Standards).

> Scope of practice is a time sensitive, dynamic aspect of practice which indicates those professional activities that a pharmacist is educated, competent and authorised to perform, and for which they are accountable

Figure 1 illustrates the components of Scope of Practice and how these are achieved.

Competency, that is, the required knowledge, skills, and attributes to prescribe, dispense, administer and review medicines demonstrated in the Medication Management Cycle (Figure 2) is initially achieved through completion of an accredited program of study that is approved by the Pharmacy Board of Australia. These programs of study include university degree programs and intern training programs. Foundational core **knowledge** is achieved through a curriculum mapped to the Competency Standards and the Australian Pharmacy Council (APC) Performance Outcomes Framework. Practical competency assessments and work integrated learning (WIL) components of degree programs, and the supervised practice requirements of provisional registration further develop knowledge and allow for demonstration of the required **skills**.

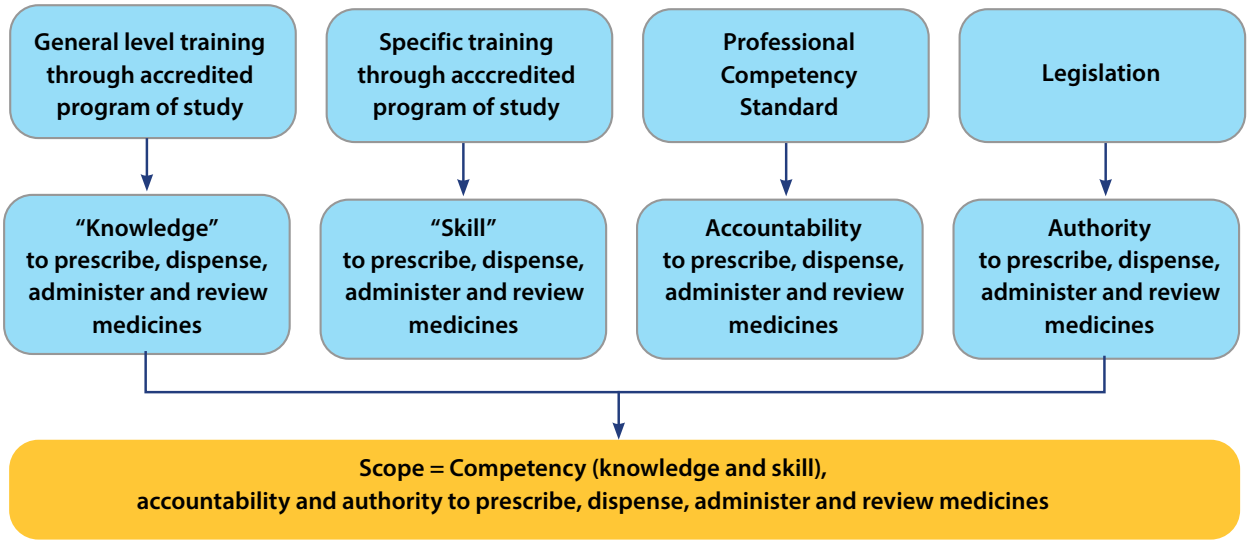

Fig 1. Understanding pharmacist scope of practice, adapted from Poudel A, Lau ETL, Campbell C, Nissen LM[27]

The Competency Standards give pharmacists the **accountability** to prescribe, dispense, administer, and review medicines as they form the basis of what is considered the acceptable standard of contemporary professional practice in Australia[28].

It is through state and territory legislation, that the **authority** is given for pharmacists to prescribe, dispense, administer, and review medicines. It is this legislative authority that also currently restricts pharmacists from practicing to their full scope.

26 Pharmaceutical Society of Australia, *National Competency Standards Framework for Pharmacists in Australia*: https://www.psa.org.au/practice-support-industry/national-competency-standards/, 2016.

27 Poudel A, Lau ETL, Campbell C, Nissen LM. Unleashing Our Potential- Pharmacists' Role in Vaccination and Public Health. Sr Care Pharm. 2020 Sep 1;35(9):372-378. https://pubmed.ncbi.nlm.nih.gov/32807260/

28 Pharmaceutical Society of Australia, *National Competency Standards Framework for Pharmacists in Australia*: https://www.psa.org.au/practice-support-industry/national-competency-standards/, 2016.

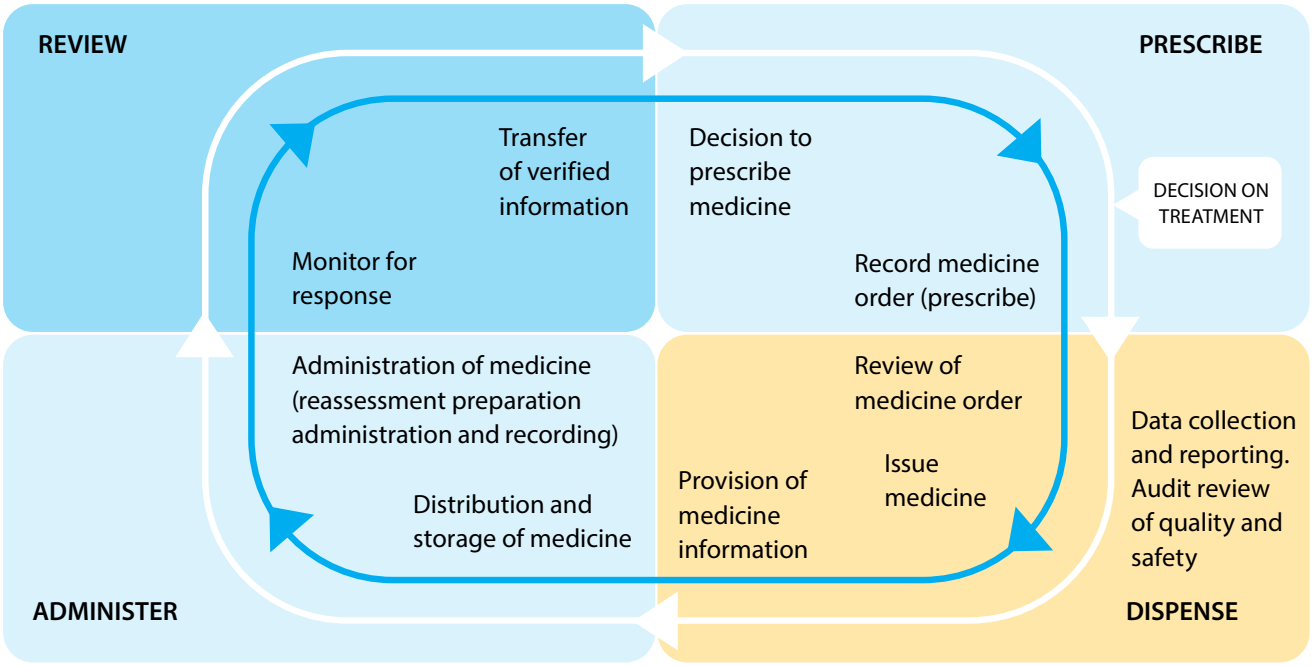

Fig 2. The medication management cycle[29]

2.1 Scope of practice – Individual versus profession

Scope of practice defines the boundaries of professional practice (Figure 3).

An individual's scope of practice is influenced by the professional roles they perform, or services they provide. Maintaining competency within one's scope of practice is achieved through ongoing education and mandatory continuing professional development requirements. This involves creating an individualised professional practice profile and selecting relevant competencies from the Competency Standards.

A pharmacist working to their full scope of practice is only limited by their individual training, experience, expertise and demonstrated competency, within the context of their place of practice, workplace policies and the health care needs of patients.

Fig 3. Scope of practice of the profession versus that of the individual, adapted from the Competency Standards

29 Adapted from Stowasser D, Understanding the Medicines Management Cycle, in The Dispensing Process (PGA)

The scope of practice for the pharmacy profession is defined within the Competency Standards. Pharmacists must register with the Pharmacy Board of Australia to practice as a pharmacist, requiring pharmacists to meet registration standards[30] that recognise and assess against the Competency Standards[31,32].

As professional practice evolves and the profession matures to meet the needs of the health care system, and society in general, so do the Competency Standards due to their dynamic nature and regular review cycle. The capacity of the Competency Standards to support and enable professional practice and growth over time is invaluable to championing full scope of practice for pharmacists now, and in the future.

Therefore, 'Full Scope of Practice' for the profession is supported by the competencies defined in the current version of the Competency Standards and explained using specific roles and activities performed by pharmacists registered with the Pharmacy Board of Australia, currently authorised or requiring authorisation under relevant legislation in each state and territory.

2.2 International benchmarking

The scope of practice for pharmacists in countries with comparable economies and health systems highlights that some countries are more advanced than Australia in the tasks they are authorised to perform.

As an example, in Canada[33], the United Kingdom[34] and New Zealand[35], community pharmacies manage common ambulatory conditions, including conditions such as urinary tract infections, back pain and eczema.

In Canada[36], Scotland[37] and New Zealand[38], pharmacists' scope of practice includes prescription renewal and the management of the ongoing supply of prescribed medicines for stable, chronic conditions without the need to necessarily return to the prescriber.

In New Zealand[39], Canada[40] and the United Kingdom[41], pharmacist prescribing programs enable pharmacists to prescribe a wide range of medicines within their clinical competence, including but not limited to antibiotics for urinary tract infections, oral contraceptives and oral COVID-19 antivirals. New Zealand and United Kingdom pharmacists can prescribe for a range of chronic long term health conditions including hypertension, cardiovascular disease, Parkinson's' Disease, epilepsy as well as mental health and respiratory conditions.

30 Pharmacy Board of Australia, *Registration Standards*: https://www.pharmacyboard.gov.au/Registration-Standards.aspx, 2016.
31 Pharmacy Board of Australia, *Registration Standard: Examinations for eligibility for general registration*: https://www.pharmacyboard.gov.au/Registration-Standards.aspx, 1 Dec 2015.
32 Pharmacy Board of Australia, *Registration Standard: Continuing Professional Developmen*t: https://www.pharmacyboard.gov.au/Registration-Standards.aspx, 1 Dec 2015.
33 Canadian Pharmacists Association, *Scope of Practice*: https://www.pharmacists.ca/advocacy/scope-of-practice/, January 2023.
34 National Health Service, NHS Inform - *NHS Pharmacy First Scotland*: https://www.nhsinform.scot/care-support-and-rights/nhs-services/pharmacy/nhs-pharmacy-first-scotland, February 2023.
35 Pharmaceutical Society of New Zealand Incorporated, *Pharmacy Healthcare Services*: https://www.psnz.org.nz/healthservices, 2023.
36 Canadian Pharmacists Association, *Scope of Practice*: https://www.pharmacists.ca/advocacy/scope-of-practice/, January 2023.
37 National Health Service, NHS Inform - *NHS Pharmacy First Scotland*: https://www.nhsinform.scot/care-support-and-rights/nhs-services/pharmacy/nhs-pharmacy-first-scotland, February 2023.
38 Pharmaceutical Society of New Zealand Incorporated, *Pharmacy Healthcare Services*: https://www.psnz.org.nz/healthservices, 2023.
39 Parliamentary Counsel Office - *New Zealand Legislation, Medicines (Designated Pharmacist Prescribers) Regulations 2013*: https://www.legislation.govt.nz/regulation/public/2013/0237/4.0/whole.html, 2013.
40 Alberta College of Pharmacy, *What drugs can pharmacists prescribe?*: https://abpharmacy.ca/what-drugs-can-pharmacists-prescribe, 2022.
41 Medscape, *How did Pharmacists Become Prescribers?*: https://www.medscape.co.uk/viewarticle/how-did-pharmacists-become-prescribers-2022a10016vc, April 2019.

3. DOMAINS OF COMPETENCY IN FULL SCOPE OF PRACTICE

The competencies and scope of practice of pharmacists are time-sensitive, dynamic, and responsive to emerging science and therapeutic trends, and the needs of the Australian health system and society in general.

Therefore, what may be described as 'Full Scope of Practice' today will not be the same as 'Full Scope of Practice' in the years ahead. It is for this reason that this will be a living document, updated regularly in response to evolving needs, and documenting the changes achieved.

The domains of competency for pharmacists in providing patient care include:

1. **Medication supply and dispensing**
2. **Prescribing**
3. **Medication review**
4. **Population health**
5. **Health conditions**
6. **Medicine administration**
7. **Ordering and interpreting laboratory tests**

3.1 Medication supply and dispensing

The supply of non-prescription pharmacy medicines and dispensing activities are core competencies of a pharmacist, requiring a pharmacist's expert clinical assessment regarding therapeutic appropriateness for and safety of the patient.

The terms dispensing and supply are defined as:

Dispensing – *the review of a prescription and the preparation, packaging, labelling, record keeping and transfer of the prescribed medicine including counselling to a patient, their agent, or another person who is responsible for the administration of the medicine to that patient*[42].

Supply – *to give a regulated substance without a prescription for the treatment of a condition*[43].

There are additional activities that are within a pharmacist's scope of practice that they do not currently have the authorisation to perform or for which authorisation is restricted. In the sub-domains below are some specific activities identified where action is required for pharmacist to work to full scope.

Medication continuance (prescription renewal)

Current Federal, state and territory laws allow for pharmacists to supply some Prescription Only medicines for long-term health conditions in an emergency in the absence of a prescription. These Emergency Supply and Continued Dispensing arrangements provide a one-off short supply of a person's regular prescription medicine to continue treatment until they can see an authorised

42 Pharmacy Board of Australia, *Guidelines for dispensing of medicines*: https://www.pharmacyboard.gov.au/Codes-Guidelines.aspx, September 2015.

43 Department of Health and Aged Care, Therapeutic Goods Administration: https://www.tga.gov.au/resources/resource/guidance/serious-shortage-medicine-substitution-notices#:~:text=Supply%20is%20different%20to%20dispensing,does%20not%20require%20a%20prescription. 16 February 2021.

prescriber. While state and territory laws are required to authorise both, the Continued Dispensing arrangements are a federal initiative in which the emergency supply of medicine is subsidised under the Pharmaceutical Benefits Scheme (PBS). From March 2020 to June 2022, as part of the COVID-19 management response, the Federal Continued Dispensing arrangements allowed pharmacists to use their professional judgement for urgent supply arrangements for the whole general schedule of the PBS. This was recognised in all jurisdictions with restrictions in place for Controlled Drugs. From 1 July 2022, Continued Dispensing arrangements were reduced to a much smaller list of PBS-listed medicines for the treatment of blood pressure, diabetes, asthma and HIV. These were in addition to the original 2012 Continued Dispensing list that included oral contraceptives and statins for dyslipidaemia. While an expansion on the arrangements from 2012, the reduced list of medicines failed to recognise the benefit provided by the service for patients with a wide range of chronic long term health conditions. It also failed to recognise the incidence of multimorbidity (2 or more chronic conditions at the same time), with pharmacists now only able to assist patients with urgent supply arrangements of subsidised medicines for some conditions but not others[44].

International benchmarking suggests there is opportunity for increasing authorisation for prescription renewal activities.

A change in legislation is needed to enable pharmacists to renew a prescription for a prescribed medicine on an ongoing basis. Medication continuance is used in the UK and prescription renewal is enabled across many Canadian provinces, where doctors can authorise pharmacists to continue dispensing for an agreed period. This can lead to a more efficient use of the time and expertise of a pharmacist and a General Practitioner (GP), and it reduces costs to patients[45].

An example where prescription renewal by pharmacists should be authorised is for hormonal contraceptives including oral and injectable contraceptives, and vaginal rings. Current state and territory regulations are limited to allowing Emergency Supply or Continued Dispensing of the OCP (oral contraceptive pills) in emergency situations, with the latter limited to once every twelve months. There are currently no pharmacist prescription renewal options available to those who use hormonal contraceptives as their regular contraceptive medication.

Pharmacists have been dispensing the contraceptive pill since it was initially marketed in Australia almost 60 years ago. Prescription renewal (and therapeutic adaptation) for hormonal contraceptives (for women who have been previously assessed and prescribed a hormonal contraceptive) is already within a pharmacist's scope of practice and would improve affordable access to contraception for Australian women.

Legislative enablement for pharmacists to practise to their full scope will ensure that Australians can receive timely and judicious access to their regularly prescribed medications, by allowing Continued Dispensing for the whole PBS schedule in urgent situations and enabling prescription renewal from their pharmacist for ongoing supply, including as a pharmaceutical benefit when eligible.

Therapeutic substitution

Therapeutic substitution (of equivalent medications) by pharmacists is at times necessary to ensure there is continuity of appropriate clinical care for patients, especially in situations where there is a shortage of the medicine(s) concerned.

Medicines shortages are an ongoing problem for Australians and a significant administrative burden for community pharmacies and prescribers. Australia's medicines shortages stem from the fact that we import over 90% of medicines and are at the end of an exceptionally long global supply chain, making the nation vulnerable to supply disruptions[46]. Additionally, Australia represents only 2% of the global pharmaceutical market and precedence is given to markets with the highest return on investment[47].

The Therapeutic Goods Administration (TGA), in response to extreme medicine shortages experienced at the onset of COVID-19 and recognising ongoing shortages due to various issues in the medicine supply chain, initially established the Serious Shortage Substitution Notice (SSSN) process. This allowed pharmacists to substitute specific medicines without prior approval from the prescriber during critical shortages of that medicine, however, state

44 Department of Health and Aged Care, *Pharmaceutical Benefits Scheme - PBS Continued Dispensing Arrangements*: https://www.pbs.gov.au/info/general/continued-dispensing#:~:text=Continued%20Dispensing%20complements%20other%20emergency%20supply%20provisions%20available,need%20to%20comply%20with%20state%20and%20territory%20requirements. December 2022.

45 Grattan Institute submission No 21 to the Victorian Legislative Council, *Letting pharmacists do more*: https://www.parliament.vic.gov.au/images/stories/documents/council/SCLSI/Community_Pharmacy/Submissions/Sub_21_Grattan_Institute_30062014.pdf, June 2014.

46 Institute for Integrated Economic Research, *Australia's Medicine Supply*, February 2020.

47 Felicity Nelson, *The real reasons we have drug shortages*:https://medicalrepublic.com.au/real-reasons-drug-shortages/10976, September 2017.

and territory legislation needed to be enabled for this substitution to occur[48]. The SSSN process has since been replaced by the Serious Scarcity Substitution Instrument (SSSI) process, whereby an SSSI (legislative instrument) specifying substitutable medicines is made in response to a serious scarcity being declared for a medicine. SSSI enable pharmacists to substitute medicines in accordance with the circumstances specified in the SSSI and are automatically recognised across Australia without amendment to state and territory legislation[49].

However, the current mechanisms for pharmacists to provide therapeutic substitution involve an overly complicated process which does not recognise a pharmacist's expertise and capabilities. This places patients at risk of harm, as pharmacists are limited in how they can respond and support patients when the pharmacy cannot procure the specific prescribed medicine. Additionally, therapeutic substitution via the SSSI process is not automatically covered by the PBS. The Department of Health and Ageing must separately authorise the substitution under an SSSI to be eligible for subsidisation as a pharmaceutical benefit so as not to increase patient costs for their PBS medicines. Pharmacists are medicines experts, and the straightforward dose, form and equivalency therapeutic substitutions are within the competency of every pharmacist in Australia to manage autonomously with their patients.

To optimise the current provisions, therapeutic substitution should enable pharmacists to prescribe the substitution of a medicine that contains chemically different active ingredients that are considered to be therapeutically equivalent (when required), to ensure continuity of care in times of medication shortage or other disruptions to the supply of a patient's regular medicines.

Fully enabled therapeutic substitution by a pharmacist without the need to consult a prescriber should be allowed in Australia to manage medicine shortages. It is already permitted in equivalent countries, such as the USA and Canada without compromising safety. A medicine shortage is not only inconvenient but can potentially have negative health effects for patients by interrupting treatment and affecting adherence.

Pharmacists can effectively manage continuity of care, particularly during times of medicines shortages, if legislative enablement allows pharmacists to practise to their full scope with fully enabled therapeutic substitution.

Therapeutic adaptation

Therapeutic adaptation is the process of altering an existing prescribed medication to change/adapt dosage, formulation or regimen, based on a determination of clinical need.

This is another area where state and territory legislation prohibit pharmacists from exercising their clinical judgment and positively intervening in therapy in the best interests of the patient. It may be that the pharmacist believes that a capsule rather than a tablet is going to better suit a particular patient, or that the prescribed dosage should be adjusted, to achieve the best therapeutic outcome for the patient but in neither case can such a decision be implemented unless the prescribing doctor writes a new prescription.

A common example of where a pharmacist needs to adapt the medicine dosage is in regard to prescriptions for medicine for children, in cases where the doctor has inadvertently and incorrectly prescribed a sub-therapeutic or supratherapeutic dose based on the weight of the child and the prescription needs to be amended prior to supply. Often, the prescription may be brought in after-hours when the prescriber is unavailable, and the medicine is required immediately.

Legislative enablement for pharmacists to practise to their full scope will empower pharmacists to make therapeutic adaptations to prescribed medications, to optimise therapeutic outcomes and reduce unnecessary hospitalisations or GP visits related to sub/supra-therapeutic response and/or adverse medication events.

48 Serious Shortage Medicine Substitution Notices | Therapeutic Goods Administration (TGA)
49 Substituting scarce medicines | Therapeutic Goods Administration (TGA)

3.2 Prescribing

The Guild defines prescribing as a patient-centred or patient-driven process involving the steps of information gathering, clinical decision making, communication and evaluation which results in the initiation, continuation or cessation of a medicine. The intent of prescribing is that it is a continuum of practice, a tool that can take on various forms.

There are three types of non-medical prescribing: autonomous prescribing, supervised prescribing, and via a structured prescribing arrangement. These are described as:

Autonomous prescribing – *Prescribing occurs where a prescriber undertakes prescribing within their scope of practice without the approval or supervision of another health professional. The prescriber has been educated and authorised to autonomously prescribe in a specific area of clinical practice. Although the prescriber may prescribe autonomously, they recognise the role of all members of the health care team and ensure appropriate communication occurs between team members and the person taking medicine.*[50]

Supervised prescribing – *Prescribing occurs where a prescriber undertakes prescribing within their scope of practice under the supervision of another authorised health professional. The supervised prescriber has been educated to prescribe and has a limited authorisation to prescribe medicines that is determined by legislation, requirements of the National Board and policies of the jurisdiction, employer or health service. The prescriber and supervisor recognise their role in their health care team and ensure appropriate communication occurs between team members and the person taking medicine.*[51]

Structured prescribing arrangement – *Prescribing occurs where a prescriber with a limited authorisation to prescribe medicines by legislation, requirements of the National Board and policies of the jurisdiction or health service prescribes medicines under a guideline, protocol or standing order. A structured prescribing arrangement should be documented sufficiently to describe the responsibilities of the prescriber(s) involved and the communication that occurs between team members and the person taking medicine. Health professionals may work within more than one model of prescribing in their clinical practice.*[52]

The British Pharmacological Society has developed ten prescribing principles for all health care professionals to follow which underpin safe and effective use of medicines[53]. The ten principles are:

1. Be clear about the reasons for prescribing
2. Take into account the patient's medication history before prescribing
3. Take into account other factors that might alter the benefits and risks of treatment
4. Take into account the patient's ideas, concerns, and expectations
5. Select effective, safe, and cost-effective medicines individualised for the patient
6. Adhere to national guidelines and local formularies where appropriate
7. Write unambiguous legal prescriptions using the correct documentation
8. Monitor the beneficial and adverse effects of medicines
9. Communicate and document prescribing decisions and the reasons for them
10. Prescribe within the limitations of your knowledge, skills and experience

Pharmacists practising in Australia can apply these principles when they are prescribing within their scope of practice.

Prescribing of *Schedule 4* and *Schedule 8* medicines

In Australia, in recognition of the need to increase the number of prescribers for continued equity of access to medicines, prescribing rights have already been extended to several non-medical professions but not to pharmacists, even though pharmacists have the relevant competencies.

Prescribing rights are available to doctors, dentists, nurse practitioners, midwives, optometrists and podiatrists, with all except podiatrists able to also prescribe medicines subsidised under the PBS. By international standards, pharmacists in Australia are a notable omission from the range of health professions with prescribing authority, and in this regard, Australia lags behind countries such as the UK, USA, Canada and NZ.[54]

50 Health Workforce Australia, *Health Professionals Prescribing Pathway (HPPP) Project (2013)*: https://www.aims.org.au/documents/item/400
51 Health Workforce Australia, *Health Professionals Prescribing Pathway (HPPP) Project (2013)*: https://www.aims.org.au/documents/item/400
52 Health Workforce Australia, *Health Professionals Prescribing Pathway (HPPP) Project (2013)*: https://www.aims.org.au/documents/item/400
53 British Pharmacological Society, *Ten Principles of Good Prescribing*: https://www.bps.ac.uk/education-engagement/teaching-pharmacology/ten-principles-of-good-prescribing, Accessed March 2023.
54 Pharmacy Board Commissioned Report 9 December 2015 Pharmacist Prescribing in Australia by Lisa Nissen et al of QUT

The Queensland University of Technology's (QUT) submission to the 2018 Queensland Inquiry referred to the ASPRINH Project (Cardiff L et al, 2017) led by QUT which found that pharmacists are well aligned to the National Prescribing Competencies and that universities prepare students well for roles in medicines management and for models of prescribing practice with the existing training curriculum.

However, prescribing is not currently included in legislation describing a pharmacist's role; there is only reference to the *supply* of Schedule 2 and Schedule 3 medicines, and the supply activity is not considered prescribing, even though, in order to effectively and safely supply an appropriate therapeutic intervention in the community pharmacy, the pharmacist undertakes a process that reflects the components of the prescribing process; i.e., information gathering, clinical decision making, communication and evaluation.[55]

There are several practical examples where pharmacist prescribing would enable better patient access to care, increase health system efficiency and reduce unnecessary hospitalisations, if there was enabling legislation in place to allow pharmacists to prescribe. These include:

- Effectively and appropriately managing acute pain conditions (such as dental pain) through judicious prescribing of moderate-strong pain medication for immediate, short-term relief while patients are waiting for a dental appointment.
- Prescribing an appropriate respiratory preventer medication consistent with an asthma or Chronic Obstructive Pulmonary Disease (COPD) management plan for patients experiencing worsening asthma or COPD symptoms, without needing to delay optimal symptom management while waiting to see their GP.
- Providing timely access to preventative health measures through pharmacist prescribing of both pre- and post-exposure prophylaxis for HIV (PrEP and PEP), while also providing appropriate community access to HIV screening and sexual health referrals when required.
- Prescribing medicines for diagnosed chronic health conditions (e.g. hypertension, diabetes, dyslipidaemia) consistent with the current therapeutic guidelines.

A pharmacist is the best placed health professional to effectively manage the up-and-down titration of newly prescribed medicines (e.g. antihypertensives, respiratory medicines) to ensure patients are appropriately stabilised on an optimal medicine dosage based on clinical effect and medication tolerance. Under current arrangements, patients must trial a prescribed medicine (e.g. blood-pressure medicine) and return to their GP for review and to adjust dose, add, or change to a new medicine to manage therapeutic response or an adverse reaction. This is time consuming and costly for patients and the health system, and it could efficiently be managed by community pharmacists after diagnosis. Prescribing medicines is within the scope of practice of pharmacists and included as a competency in the Competency Standards.

Legislative enablement to allow pharmacists to prescribe is needed to realise the potential patient benefits and health system savings resulting from pharmacists prescribing within their individual scope for acute conditions, chronic conditions and preventive health measures.

Enabling funding mechanisms for community pharmacy services that are equivalent to services provided by other healthcare professionals will provide effective, equitable access to services for patients.

Deprescribing

Prescribing medicines is within the scope of practice of pharmacists, therefore so too is the ability to deprescribe medicines. The World Health Organisation's *Guide to Good Prescribing* includes a step to 'Monitor (and stop?) the treatment', where it recommends using treatment monitoring to determine whether a treatment has been successful or whether additional action is needed[56]. Treatment monitoring is already within the scope of practice of a pharmacist; and using clinical knowledge and professional judgement, a pharmacist has the competency to deprescribe medicines and refer the patient for further review where appropriate.

Currently, pharmacists determine the therapeutic need of a patient when considering whether to recommend a non-prescription medicine or whether it may no longer be required. However, current legislation restricts the ability of a pharmacist to deprescribe a Prescription Only Medicine or Controlled Drug where there is no longer a therapeutic need for the medicine or due to adverse effects. As an example, pharmacists could trial cessation of long-term proton pump inhibitors and monitor and assess patient outcomes for permanent cessation.

Legislative enablement to allow pharmacists to deprescribe within their individual scope for acute conditions, chronic conditions and for preventive health measures would enable pharmacists to contribute to reducing polypharmacy, thereby providing patient and economic benefits.

55 Pharmacy Board Commissioned Report 9 December 2015 Pharmacist Prescribing in Australia by Lisa Nissen et al of QUT
56 World Health Organisation, *Guide to Good Prescribing – A practical manual.*

3.3 Medication review

Medication management review

Medication management reviews involve the review of a patient's medicines to assure quality use of medicines. Pharmacists consult with patients to ensure safe and appropriate use of their medicines and to identify and address any medicine-related problems. Noting that every pharmacist uses their clinical expertise and experience to perform a general medicine-assessment at the time of dispensing or enrolling/updating dose administration aids (DAA) for patients (e.g. assessing potential interactions, dosage or adherence issues), in-pharmacy medicines reviews, home medicines reviews (HMRs) and residential medication management reviews (RMMRs) are types of more comprehensive medication management reviews performed by pharmacists.

Patients are particularly vulnerable at any point of transfer between care providers, such as entry to or post-discharge from hospitals, residential or respite facilities. A reconciliation and review of a person's medicine at the time of transition of care is an area where community pharmacists can play a valuable role, particularly for patients at high-risk of readmission or with complex medicine-related needs. This was recognised in the final report of the Royal Commission into Aged Care Quality and Safety which recommended medicine reviews by a pharmacist on entry to a residential facility[57]. The transition between hospital and community or residential care is particularly problematic, and it is essential that there is effective communication between the hospital and primary care providers, including community pharmacy, on discharge.

Eligibility criteria for Federal funded HMR and RMMR programs require pharmacists to be an 'accredited pharmacist'[58] – an additional training and accreditation process.

Pharmacy degree programs now include a substantial component in their curriculum of the necessary knowledge, skills and competencies to undertake comprehensive medication management reviews, indicating that the additional training is not required for recent graduates. Additional education would only be required where a pharmacist has identified gaps in their competency to complete a HMR or RMMR.

This is an example of how, as the profession evolves to meet the needs of the health system and society, so should the relevant authorisations, reducing the barriers to all pharmacists working to their full scope of practice.

Pharmacists have the necessary medicines knowledge, skills and resources to undertake and remain competent to complete a medicine review such as a HMR or RMMR. However, program requirements restrict providers to accredited pharmacists, therefore limiting many pharmacists from working to their full scope of practice and limiting patient access to medicine review services.

Removing requirements for additional accreditation for medication management services would enable pharmacists to work to full scope of practice and ensure patients are able to access these medication management services without delay.

57 Aged Care Royal Commission Final Report: Recommendations; Recommendation 64
58 Medication Management Programs – Pharmacy Programs Administrator (ppaonline.com.au); January 2023

3.4 Population health

Community pharmacy offers a highly accessible network of primary health care delivering quality advice and services, and as such is poised for effective and agile preventive health activities. Pharmacies exist in well dispersed and accessible locations, and often operate over extended hours, seven days a week in urban, rural and remote areas.

Services that community pharmacy offers that contribute to the health outcomes of their community include, but are not limited to:

- provision of up-to-date and locally relevant information on other health care and support services and resources.
- participation in community health, preventive health and other public health services.
- distribution of public health information and educational materials.
- health promotion activities and group education programs.
- screening and risk assessments
- harm minimisation programs such as needle and syringe programs and opioid replacement therapy.

Preventive health

Pharmacists already conduct preventive health programs that contribute to the health system action of preventive health. Such programs include immunisation programs (discussed specifically under section 3.5.1), smoking cessation programs, weight management programs, harm minimisation programs and general health checks. However, as with all professional services beyond dispensing and medication management, current self-funding arrangements for all patients seeking preventive health services through community pharmacy limit access for vulnerable populations, and the wider population where the service is not viable due to self-funding as a limiting factor.

Where there are funded programs available at the state level, such as harm minimisation, there is significant variability between available remuneration and patient access criteria, including quotas and patient co-payments. This affects both the level of community pharmacy participation and the extent to which patients can be supported by their preferred community pharmacy.

Screening

Community pharmacies provide health screening services for acute conditions, chronic conditions and preventive health including chronic obstructive pulmonary disease (COPD), sleep apnoea, diabetes risk, cardiovascular risk, anaemia, cholesterol and sexually transmitted infections. Some community pharmacies provide influenza-screening services using point-of-care devices[59] in addition to providing similar in-store and supervised outreach services during the COVID-19 pandemic. Pharmacists perform screening using screening tools (questionnaire or device) and provide education and referral for patients at risk where appropriate. Health screening in community pharmacy is an important measure in identifying patients who potentially require intervention for a health condition they may be unaware they have. This could be enhanced by ensuring that screening services offered by all health providers can be readily uploaded to a shared patient record with means of notifying the patient's GP or other members of their health care team.

Health screening services are recognised within the scope of practice for pharmacists, with the main barrier to pharmacists working to full scope again being lack of funding mechanisms for these services as a coordinated program, meaning vulnerable and target populations are required to self-fund access to these services. This is in stark contrast to government funded screening programs delivered through other health providers where patient costs are subsidised, particularly for vulnerable and target populations.

59 Rapid tests for the diagnosis of influenza – Australian Prescriber (nps.org.au)

3.5 Health conditions

Community pharmacists provide a range of services which extend well beyond the provision of prescription medicines and, as such, pharmacies are often the first contact point of the primary health care system for many people. Sometimes these services can be provided without the need for an appointment where they may not be time-consuming and when the pharmacy is suitably staffed.

Services that community pharmacy offer for everyday health conditions and chronic health conditions include, but are not limited to:

- assessment, treatment, and provision of information about medicines and health conditions.
- referral to and collaboration with a GP or Hospital Emergency Services; and
- referral to and collaboration with other appropriate health professionals where required; e.g. community health nurses, mental health services, physiotherapists, drug and alcohol rehabilitation facilities etc.
- monitoring of health conditions and biomarkers such as blood pressure, blood glucose levels, INR and cholesterol levels.

Everyday health conditions

The management of everyday health conditions is a core component of pharmacy practice. Pharmacists provide management, both pharmacological and non-pharmacological, for common conditions including wounds, pain (e.g. migraine, dental pain, arthritic pain), urinary tract infections, acne, constipation, diarrhoea, hay fever, common colds, head lice, mouth ulcers, gastro-oesophageal reflux, vaginal thrush and tinea. For the management of everyday health conditions pharmacists across all jurisdictions can recommend and supply medicines that are unscheduled, schedule 2 and schedule 3 medicines. Pharmacists can also provide patient education and advice on lifestyle modifications.

Pharmacist management of everyday health conditions is an under-recognised activity that adds significant value to the health system. Research conducted by Orima in 2022 showed that all pharmacies surveyed reported providing patient consultation on common conditions daily, with over half of pharmacies surveyed reporting over 20 such consultations occurring daily, and 65% of these patients indicating they would otherwise have attended their local Emergency Department or GP[60]. Pharmacists can assess and triage these common conditions, and either treat patients within their scope, or refer them to another health professional. This assessment, triaging and referral process can help to reduce the burden on emergency departments, and allow GPs to focus on more complex and chronic conditions.

The main barrier to provision of these services is a lack of adequate funding mechanisms that recognise the role pharmacists play in delivering primary healthcare services for patients. In fact, a pharmacist may spend time assessing and advising a patient and not receive any remuneration for their time as they may have determined that a treatment option is not required, or that referral is necessary. The Orima research indicates that unpaid pharmacy consultations last on average between 5 and 10 minutes, which is a significant use of pharmacist time.

Community pharmacies must be remunerated for service consultations, including recognition of the time differential that can be involved according to a patient's needs. Pharmacist health and medicine consultations can be used to manage less complex everyday health conditions as well as to triage and refer situations requiring more expert oversight. Such an arrangement would cost-effectively re-distribute the workload to enable GPs and emergency departments to prioritise and manage the more complex and/or serious conditions.

60 Orima, 2022. Framework for Change Survey of Guild Members, unpublished.

Chronic health conditions

Chronic health conditions are long-lasting conditions which might be preventable or delayed through lifestyle measures, and which can be managed on an ongoing basis to control or prevent worsening of symptoms and avoid hospitalisation or excessive health care. They include conditions such as diabetes, COPD, cardiovascular disease, mental health conditions, epilepsy, glaucoma, Parkinson's Disease and asthma. Pharmacists contribute to the management of chronic health conditions by way of ongoing treatment monitoring, therapeutic medicine monitoring, education, lifestyle interventions and advice.

The Australian Institute of Health and Welfare found that chronic conditions are becoming increasingly common, with many patients experiencing multimorbidity (2 or more chronic conditions at the same time)[61].

The role that pharmacists can play in the management of chronic conditions is evolving, and this is reflected in pharmacists becoming credentialed diabetes educators, certified asthma educators and mental health first aiders. These roles are restricted to pharmacists who have completed additional training in these specific areas, despite recent pharmacy graduates having many of the competencies required for these roles. Multimorbidity brings a greater risk of polypharmacy and as discussed previously, pharmacists can provide medicine review and adherence services to assist people with understanding and managing their medicines and addressing medicine-related problems.

Greater recognition of the role that pharmacists can play in the management of chronic health conditions will allow pharmacists to practice to full scope and provide patients with chronic conditions better access to healthcare services.

61 Australian Institute of Health and Welfare, *Chronic disease overview*, Updated 10 November 2020. https://www.aihw.gov.au/reports-data/health-conditions-disability-deaths/chronic-disease/overview

3.6 Medicine administration

Pharmacists support patients in the administration of all their medicines by ensuring appropriate counselling and advice, or provision of devices that assist effective use, such as spacers for asthma.

Pharmacists can support patients further especially for vaccine and non-vaccine injections if given the authority through legislative amendments, which will have benefits to the patient and the health system.

However, while pharmacists are trained to administer medications by injection, legislation currently restricts pharmacists to administering a limited range of injectable medicines determined at a state or territory level with significant variability between jurisdictions.

Vaccines

Pharmacists have only been involved in the supply and dispensing of vaccines or hosting a nurse immuniser vaccination service in the pharmacy until more recently where pharmacists have broadened this role to become immunisers in their own right (vaccine administrators) as well as educators and facilitators.[62]

Prior to 2014, community pharmacists in Australia were not authorised to administer influenza vaccinations, however since then, community pharmacies are now contributing to public health and herd immunity by vaccinating millions of Australians, including as part of the National Immunisation Program (NIP) for some vaccinations. Community pharmacies are becoming a preferred choice of vaccination provider for many Australians.

Pharmacists can develop the competency to administer vaccinations either as part of their pre-registration pharmacy education or through pharmacist-specific accredited training programs and thus establish and deliver vaccinations in community pharmacy to patients of all different age groups.[63]

The geographical spread of pharmacies throughout Australia, combined with their convenience and extended hours of operation, assists in increasing vaccination rates. The administration of vaccines by pharmacists complements the work of traditional immunisers. This increased choice and the convenience of being able to walk in and be immunised opportunistically means that a greater number of at-risk patients, particularly older adults, can access the service, including those who might not otherwise have been vaccinated, for example in the case of the annual influenza vaccine.[64]

Despite community pharmacy demonstrating a willingness and capability to administer vaccines, pharmacists are only able to administer a limited range of vaccines with significant variation between the states and territories as to which vaccines pharmacists can administer and whether or not as part of the NIP[65]; The National Centre for Immunisation Research and Surveillance maintains a resource that details these variations.

Where pharmacists can administer NIP vaccines, while the Federal Government covers the cost of the vaccine, there is no service remuneration at either Federal or state or territory level for the community pharmacy, requiring costs to be paid by the patient. This service inequity is not acceptable given that NIP patients are the most vulnerable community members, many being on aged care or disability pensions.

Legislative enablement in all states and territories for pharmacists to practise to their full scope will ensure that pharmacists are able to deliver all vaccinations to meet preventative care requirements for patients, following the guidelines set out in the *Australian Immunisation Handbook*[66].

62 Poudel A, Lau ETL, Campbell C, Nissen LM. Unleashing Our Potential- Pharmacists' Role in Vaccination and Public Health. Sr Care Pharm. 2020 Sep 1;35(9):372-378. https://pubmed.ncbi.nlm.nih.gov/32807260/

63 Ibid

64 Poudel A, Lau ETL, Campbell C, Nissen LM. Unleashing Our Potential- Pharmacists' Role in Vaccination and Public Health. Sr Care Pharm. 2020 Sep 1;35(9):372-378. https://pubmed.ncbi.nlm.nih.gov/32807260/

65 Vaccination from community pharmacy | NCIRS

66 Australian Immunisation Handbook – https://immunisationhandbook.health.gov.au/

Other injectable medicines (non-vaccine)

Pharmacists having completed first aid training and attained certification can administer adrenaline in the event of an anaphylactic reaction. Whilst this type of acute care is permitted, administration of injectable medicines for other health conditions is almost non-existent.

The ability of pharmacists to administer non-vaccine medicines, requiring the same injection techniques that pharmacists are trained and competent in, are currently not enabled through legislation. Medicines such as Vitamin B12 injections, depot medroxyprogesterone as a long-acting contraceptive or the osteoporosis medication Prolia® (Denosumab) injections are not able to be administered to patients by a pharmacist when requested, or when they are due. This latter example has posed concerns during the pandemic, while GP surgeries have been closed, as it has left many patients deferring their 6-monthly dose of this medication, impacting its therapeutic efficacy.

Additionally, enabling pharmacists to administer non-vaccine medicines, such as injectable buprenorphine to a patient for the treatment of opioid dependence, would provide increased patient access to these services at a location and time that is convenient to the patient. Authorised pharmacists in Victoria[67] have been administering depot buprenorphine since 2020 and while other states are in the process of making changes, it has not been a consistent implementation process. Given the lack of service providers for opioid replacement therapy (ORT) programs, enabling pharmacists to monitor and prescribe ORT would enhance patient access and assist in addressing this significant community problem.

Legislative enablement for pharmacists to work to full scope of practice would ensure that patients who are prescribed injectable non-vaccine medicines could have these administered in a community pharmacy at a time and location that is convenient for the patient.

Travel medicine

Australians undertaking international travel have always needed to consider their travel health risks and requirements. Some countries mandate that travellers have to be immunised against specific conditions. Travellers also need to be cautious of infectious diseases such as malaria or travellers' diarrhoea. As Australians' travel levels continue to increase through the pandemic recovery, some restrictions are still in place across various countries, and travel health measures continue to exist to keep travellers safe on their journey and to keep Australia safe upon their return. Community pharmacies are ideally placed to provide travel health services with vaccines (see section 3.5.1) and other travel medicines. However, there are restrictions with regard to the travel medicines that a pharmacist can supply without requiring a prescription.

In the current global climate, the ability for a comprehensive travel health service to be provided through community pharmacy would provide Australians with an alternative, affordable option to receive travel medicines and tailored travel heath advice to support their safe travel overseas.

Legislative enablement for pharmacists to practise to their full scope would ensure that a comprehensive travel medicines service could be delivered through community pharmacy, to prescribe and administer appropriate travel health vaccines to patients as well as provide preventative health travel medicines such as antimalarials for chemoprophylaxis and antibiotics for travellers' diarrhoea.

67 Victorian Pharmacist-Administered Vaccination Program Guidelines (health.vic.gov.au)

3.7 Ordering and interpreting laboratory tests

Ordering and interpreting laboratory tests

Not all pharmacists in Australia are able to order laboratory tests (relevant to pharmacist care) on behalf of a patient, despite having the clinical knowledge and competencies to undertake this role and despite this role being within their scope of practice. Therapeutic drug monitoring (TDM) is the *"interpreting and monitoring of measured drug concentrations in body fluids to optimise medicine efficacy and minimise toxicity. TDM applies to the disciplines of pharmacology, pharmacokinetics, pathology and clinical medicine"*[68]

If authorised to take on this function, pharmacists would be able to ascertain whether further medical treatment should be sought or whether pharmacist care interventions would be appropriate for the patient's clinical need, thus saving time and expediting appropriate treatment/management approaches. Additionally, further TDM or other pathology testing could be ordered and interpreted as part of a medicine review, such as those funded under the Seventh Community Pharmacy Agreement (7CPA)[69].

In jurisdictions within Australia where legislation enables pharmacists to order laboratory tests for patients, the major barrier to this occurring is patient cost due to lack of appropriate remuneration and subsidisation for pharmacists providing the consultation. As pharmacist-ordered laboratory tests are not subsidised, patients must cover both pathology costs and pharmacy service costs. Appropriate funding for a standardised service through a government funded program would lead to increased patient access where appropriate.

Pharmacists in equivalent overseas countries are already authorised to order and interpret laboratory tests, with US pharmacists accessing and/or ordering laboratory tests dependently within collaborative practice agreements, and pharmacists in Canada able to access and/or order laboratory tests depending on the province in which they practice. The United Kingdom allows for laboratory testing to be performed by independent prescribing pharmacists or dependently by supplementary prescribing pharmacists[70], and New Zealand pharmacist prescribers can independently order laboratory tests.[71]

Legislation enabling pharmacists in all jurisdictions to order and interpret laboratory tests would ensure patients could access testing and receive appropriate treatment with minimal delay.

Point of care and diagnostic testing

Pharmacists are able to provide point of care testing and diagnostic testing, within the scope of practice of pharmacists, for many acute and chronic health conditions; including blood glucose testing, HbA1c testing, INR testing, cholesterol testing, blood pressure testing, pulmonary function testing, anaemia testing and genetic testing.

Section 3.4.2 highlighted how some pharmacists provide point-of-care testing for communicable conditions such as influenza or COVID-19. Pharmacies are also involved in facilitating diagnostic testing and screening services for health conditions including bone density testing, hearing testing, bowel cancer screening, sleep apnoea screening and COPD screening.

The main barrier to pharmacists working to full scope in this area of practice is the same as that for ordering and interpreting laboratory tests – inadequate access to funding for a standardised program to make these services affordable for patients.

68 National Competency Standards Framework for Pharmacists in Australia
69 Medication Management Programs - Pharmacy Programs Administrator (ppaonline.com.au)
70 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6739653/
71 https://pharmacycouncil.org.nz/public/pharmacist-scopes-of-practice/

4. THE VISION

Some significant advancements towards pharmacists in Australia working to full scope have been achieved, and the implementation of pharmacist full scope of practice pilots in several jurisdictions is progressing. However, the journey to pharmacists working to full scope is ongoing, with the future vision being for pharmacists to prescribing independently as autonomous prescribers.

4.1 Current state of play

The table below documents the current state of play across Australia in relation to conditions and services identified as areas of opportunity to utilise pharmacists working to full scope. It highlights government announcements about scope of practice, preparation being done for implementation, phased implementation (including pilots), and services that have become permanent practice.

Condition	ACT	NSW	QLD	NT	WA	SA	VIC	TAS
Acute cellulitis				●				
Acute nausea and vomiting		●	●	●				
Acute wound management		●	●	●				
Allergic and non-allergic rhinitis		●	●	●				
Asthma and exercise induced bronchoconstriction		●	●	●				
Atopic dermatitis		●	●	●				
COPD		●	●	●				
Depression and anxiety				●				
Dyslipidaemia		●	●	●				
ENT infections		●	●	●				
Gastro-oesophageal reflux		●	●	●				
Herpes Zoster (shingles)		●	●	●				
Hormonal contraception	●	●	●	●			●	
Hypertension		●	●	●	●			
Impetigo		●	●	●				
Influenza testing, diagnosis and treatment						●		
Mild to moderate acne		●	●	●				
Minor skin conditions							●	
Musculoskeletal pain and inflammation		●	●	●				
Oral health screening and fluoride application		●	●	●				
Other injectable medicines (non-vaccine)		●	●				●	●
Psoriasis		●	●	●				
Smoking cessation		●	●	●				
Travel medicines	●	●	●	●				
Type 2 diabetes		●	●	●				
Uncomplicated urinary tract infections	●	●	●	●	●	●	●	
Vaccination (NIP and non-NIP)	●	●	●	●	●	●	●	●
Weight management for obesity		●	●	●				

● Govt Announcement/interest ● Preparation ● Phased Implementation ● Permanent Practice

4.2 The journey to prescribing

The future vision is for pharmacists practising in Australia to be enabled to prescribe independently as autonomous prescribers. It is important to distinguish between autonomous prescribing and structured prescribing, which is the type of pharmacist prescribing being implemented through the full scope of practice pilots, where pharmacists will prescribe in accordance with the treatment protocols of the Therapeutic Guidelines.

Incorrectly defining or using interchangeable terms such as dispensing, supply and prescribing, and not distinguishing between different types of prescribing, is doing an injustice to our current workforce, our future pharmacists and their professional practice, and confuses the public.

There are many benefits to pharmacists having the ability to independently prescribe. In the United Kingdom, pharmacist independent prescribing was introduced in 2006, with research reporting benefits including decreased workloads for general practitioners, increased patient safety, improved job satisfaction for pharmacists, improved patient relationships, and enhanced cost savings.[72]

Using the checklist for change will help identify and address changes that need to be made to enable pharmacist to independently prescribe as autonomous prescribers.

72 General practice pharmacists in England: Integration, mediation and professional dynamics - ScienceDirect

5. CHECKLIST FOR CHANGE

In order for pharmacists to work to full scope of practice, now and into the future, the following are key considerations that will need to be worked through on each occasion to provide evidence and assurance for governments that pharmacists are indeed competent and accountable to undertake the task and therefore should be afforded the appropriate authority.

Competency	• Are the competencies required to perform the task included in the Competency Standards? • Are the competencies covered in university programs, ITPs, or existing training for pharmacists?
Training	• Is training required for all pharmacists (new skill), OR • Is training required for pharmacists that need to 'retrofit' a competency that is now in the degree programs? • Does training need to be developed, and accredited?
Qualification or Endorsment	• Is an additional qualification required? For example, vaccination certificate, CDE • Is a professional endorsement required by the Pharmacy Board, as required by AHMAC? For example, autonomous presecribing
Funding Mechanism	• What is the proposed funding mechanism - private, government funded? • What are the eligibility requirements for government funding?
Professional Standards / Guidelines	• Do professional practice guidelines, or standards need to be developed?
Legislative Authority	• What are the legislative or regulatory changes required? • What is the relevant legislation/regulation that needs amending? • Is there a precedent in another jurisdictions

6. GLOSSARY

Accountability	Responsibility of a heath professional, such as a pharmacist, to uphold professional standards of practice
Acute conditions	Conditions which usually have a sudden onset
Administer a medicine	To give a patient a single treatment of the dose of a medicine by the prescribed route e.g. injection of a vaccine
Ahpra	Australian Health Practitioner Regulation Agency
APC	Australian Pharmacy Council
Authority	Legislative authority to undertake practice components
Chronic conditions	Conditions which are long-lasting and/or ongoing
Competency Standards	See National Competency Standards Framework for Pharmacists in Australia 2016
Continued Dispensing versus Prescription Renewal	Continued Dispensing is the one-off emergency supply of a prescription medicine in the absence of a prescription to ensure continuity of therapy whereas Prescription Renewal is the ongoing authorisation for dispensing a prescription medicine for a chronic condition
Controlled drugs	Substances listed in Schedule 8 of the Poisons Standard
COPD	Chronic Obstructive Pulmonary Disease
CPD	Continuing Professional Development
CVR	Combined Hormonal Vaginal Ring
Dispense	To supply a medication on prescription
Drug versus medicine or medication	Australian Federal, state and territory regulations use the terms poisons and drugs, with drugs being defined as a poison for therapeutic use (e.g. Poisons Standard). For this document, the term medicine or medication is preferentially used being the formulated form of a drug intended for therapeutic effect in humans or animals.
Drug Schedules in Australia	See Medicine Schedules in Australia
Drug Schedules in other countries	The Drug Schedules for the comparator OECD countries (Appendix 1) do not directly match the scheduling in Australia, however there are broad similarities in medications provided 'over-the-counter' by pharmacists, on prescription only and classified as controlled (or narcotic) drugs.
Extended Practice Authority	A certified document published by the Department stating circumstances in which, and conditions under which, a person who may act under the protocol may use a stated controlled or restricted drug or poison for stated purposes (Queensland)
Emergency Supply	Limited supply of restricted drug (S4 medication), to a patient who does not have a script, but who has an urgent need for that medication (See continued dispensing)
ENT infections	Ear nose and throat infections
FIP	International Pharmaceutical Federation (Federation Internationale Pharmaceutique)
Generic/Biosimilar Substitution	Substitution by pharmacist of a bioequivalent medicine for the prescribed medicine, where the patient has provided consent
HPPP	Health Professionals Prescribing Pathway (published Health Workforce Australia in 2013)
IHC	Injectable Hormonal Contraception

Immunisation program	An immunisation program carried out by the department, local government or Hospital and Health Service; a certified program
Laboratory tests	A procedure in which a sample of blood, urine, other bodily fluid or tissues, is examined to get information about a person's health. E.g. INR test to monitor blood thinning medicines/ anticoagulants
MBS	Medical Benefits Scheme
Medication adherence	Patient compliance with prescribed medicine regimen
Medication adherence counselling/management	Pharmacist intervention to ensure there is patient compliance with medicine regimen
Medication continuance	See Continued dispensing
Medication Management Review	Review of a patient's medicine regimen by a pharmacist to ensure that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken and able to be taken by the patient as intended
Medicine Schedules in Australia	• Schedule 2 of the Poisons Standard: Pharmacy Medicine – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person • Schedule 3 of the Poisons Standard: Pharmacist Only Medicine – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription. • Schedule 4 of the Poisons Standard: Prescription Only Medicine – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription. • Schedule 8 of the Poisons Standard: Controlled Drug – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.
National Competency Standards Framework for Pharmacists in Australia 2016	A framework describing the knowledge, skills and attributes that are central to pharmacists performing effectively to an acceptable standard in contemporary professional practice in Australia
NIP	National Immunisation Program
Non-vaccine Injectable medications	Medicines, other than vaccines, that are administered by injection. E.g. Denosumab (Prolia) to treat osteoporosis
NPS	National Prescribing Service
Nurse	A registered nurse or enrolled nurse
Nurse practitioner	A registered nurse whose registration is endorsed under the Heath Practitioner Regulation National Law as being qualified to practise as a nurse practitioner
OCP	Oral Contraceptive Pill
ORT	Opioid Replacement Therapy
OTC	Over the counter medicines, such as Schedule 2 and Schedule 3 medicines, sold in pharmacies without a prescription
PBA	Pharmacy Board of Australia
PBS	Pharmaceutical Benefits Scheme
PCF	Prescribing Competency Framework: NPS Medicine Wise Competencies required to prescribe medicines; 2nd edition April 2021

Point of care testing	A form of testing in which the analysis is performed outside of a laboratory setting e.g. Blood Glucose (BG) levels via a *glucometer* (testing device)
Prescribe	Make a written direction (other than a purchase order or written instruction) authorising a dispenser to dispense a stated controlled or restricted medicine or poison
Prescriber	A person who is endorsed by regulation to prescribe a controlled or restricted medicine
Prescribing	• A patient-centred or patient-driven process involving the steps of information gathering, clinical decision making, communication and evaluation which results in the initiation, continuation or cessation of a medicine • Autonomous Prescribing - the prescriber acts with independent accountability, without the supervision of another heath professional (but still in collaboration with other health professionals) • Collaborative prescribing – the prescriber is supervised by, or acts collaboratively with, another authorised heath professional • Structural Prescribing - the prescriber has limited authorisation to prescribe medicines under a guideline, protocol or standing order
Prescription	A prescriber's direction (other than a purchase order or written instruction) to dispense a stated controlled or restricted medicine for an identified patient, with details of medicine form, quantity and dosage and whether supply can be repeated
QCPP	Quality Care Pharmacy Program – quality assurance program for community pharmacies
QPIP	Queensland Pharmacist Immunisation Pilot
QUM	Quality Use of Medicines
Registered nurse	A person registered under the Health Practitioner Regulation National Law to practise in the nursing profession
Registered pharmacist	A person registered under the Health Practitioner Regulation National Law to practise in the pharmacy profession
Repeat prescription	A prescription on which there is a direction to repeat the supply of a stated controlled or restricted medicine for a specified number of times
Restricted medicines	Schedule 4 substances
Scope of pharmacy practice	Those professional activities that a pharmacist is educated, competent and authorised to perform, and for which they are accountable
Supply	To issue one or more doses of a medicine as treatment for a diagnosed condition for a patient
TGA	Therapeutic Goods Administration
Therapeutic Substitution	Issue to a patient of an equivalent prescribed medication at the same dosage to ensure continuity of care (for example, during medicine shortages)
Therapeutic Adaptation	Change or adaptation of prescribed medicine dosage, formulation, regimen, based on determination of clinical need and in response to control of patient's condition or experience of adverse effects
Travel medicine	Medicines and/or vaccines required to prevent or manage health problems for international travellers
UTI	Urinary tract infection, also known as cystitis
Vaccine	A biological preparation that provides active acquired immunity to an infectious disease. A restricted medicine that is identified as a vaccine in the current Poisons Standard
Vaccine preventable conditions	Diseases that can be prevented by vaccine, such as influenza, measles, whooping cough

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