Risk Management for Prescribing Pharmacists

Purpose

Pharmacist prescribing is an expanding area of practice that brings substantial opportunities to improve patient care. These opportunities come with a distinct set of risks that require deliberate and proactive management to ensure the best possible patient outcomes, uphold professional integrity, support efficient service delivery across prescribing and other concurrent clinical activities, as well as meeting all legal and ethical obligations.

This risk management annexure is designed to support both new and experienced prescribing pharmacists by outlining key risk considerations to forecast and mitigate the challenges associated with prescribing activities.

Scope of practice

Queensland Health (2025) states that "in the context of pharmacist prescribing, scope of practice refers to the prescribing activities and clinical responsibilities that a pharmacist is trained, authorised and competent to perform. Scope of practice must be considered at both the **service or professional level** (what pharmacists are authorised to do under the regulatory framework) and the **individual level** (what a specific pharmacist is trained, experienced, currently capable of doing safely and legally authorised to perform)."[1]

PDL supports pharmacist prescribing where practitioners are educated, competent, authorised and accountable, and where robust governance and risk management frameworks exist. Practising outside of scope can lead to patient harm and/or consequences for the pharmacist. The **PDL Risk Management Guide for Pharmacists** recommends integrating "scope of practice" checks as part of your risk identification process. As per the **PDL Scope of Practice Checklist**, the following points can assist pharmacists in deciding if an activity is currently within scope and to identify any aspects of the service that need to be addressed before a service can be safely delivered:

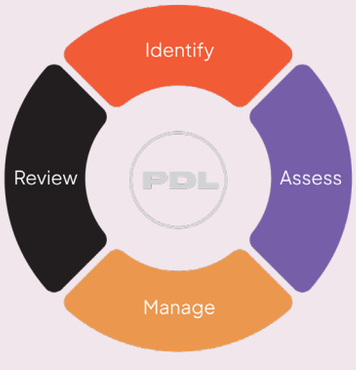
- *Have I completed the required **education**?*
- *Am I trained and **competent** to deliver this service?*
- *Am I **authorised** to deliver this service (does the service comply with state or territory regulations? Additionally, what are the premises requirements, do I need approval or endorsements from responsible authorities?)*
- *How can I demonstrate **accountability** for the service I am about to provide?*

The equation below offers a visual guide for assessing scope of practice.

Figure 1: Scope of Practice equation, from the *PDL Scope of Practice Checklist*[2]

Core risk principles for prescribing pharmacists

Pharmacist prescribing must be underpinned by proactive risk management. PDL recommends using the Risk Management Cycle:



STEP 1: IDENTIFY potential risks in this new area of practice.

STEP 2: ASSESS the severity and urgency of actions based on those risks.

STEP 3: MANAGE the risks with effective systems and processes.

STEP 4: REVIEW outcomes and adjust practices for continuous improvement.

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An absence of a thorough risk assessment for any new service could result in patient harm or trigger regulatory notifications against a pharmacist. An essential component of risk assessment is evaluating the potential impact on various stakeholders involved in any activity or service. When considering the areas of risk in pharmacist prescribing, PDL recommends pharmacists refer to the **five predominant types of risk in pharmacy practice** (Module 1, PDL Risk Management Guide for Pharmacists).

1. **Clinical Risks**

   Clinical risks encompass the possibility of pharmacists inadvertently causing harm through adverse drug reactions, misdiagnoses, or inappropriate treatments due to limited diagnostic information or time constraints. Without robust assessment protocols, there is a heightened risk of missing key clinical cues or failing to refer patients when necessary, which can lead to complications or delayed care.

2. **Regulatory & Compliance Risks**

   Pharmacists must navigate a complex regulatory landscape, ensuring every prescribing activity remains compliant with relevant national and state legislations, professional protocols and scope of authority. Failure to adhere to these requirements, or lapses in data protection and privacy standards, may result in legal repercussions and loss of prescribing privileges.

3. **Professional Risks**

   There is an expectation that pharmacists maintain high standards by adhering to established codes of conduct, professional guidelines and standard operating procedures. Risk arises when documentation is inconsistent or incomplete, or if reporting obligations are not met, potentially compromising patient safety and the pharmacist's professional standing.

4. **Ethical Risks**

   Ethical risks become prominent when there are conflicts of interest, such as personal or commercial gains conflicting with patient welfare, or when patients' autonomy is not fully respected. Pharmacists must ensure informed consent is always obtained, with patients given comprehensive information to make voluntary choices about their care.

5. **Operational Risks**

   Integrating prescribing into pharmacy workflow introduces operational risks related to staff training, supervision and resource allocation. Without clear standard operating procedures tailored to the site and adequate support for staff, there is a risk of inefficiencies, errors or gaps in service delivery. To address operational risk, pharmacists should implement a Continuous Quality Improvement (CQI) framework. CQI helps identify workflow gaps, improve processes, and ensure safe, efficient integration of prescribing into pharmacy practice.

Understanding the relationship between different aspects of practice enables pharmacists to adopt a holistic approach to risk management. Figure 2 illustrates the interconnected nature of three common aspects of practice.

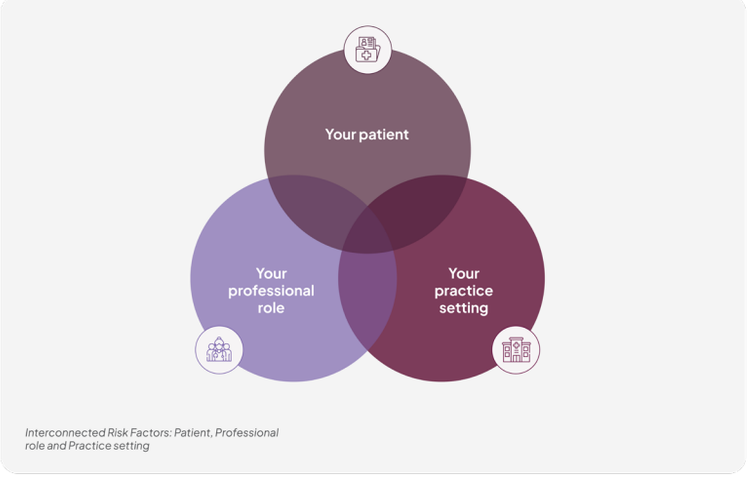

Figure 2: Interconnected Risk Factors, from Module 2 of the *PDL Risk Management Guide for Pharmacists*

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For instance, from a **patient perspective**, considerations extend beyond the individual to include carers and other healthcare providers (GPs, specialists, etc.). Additionally, if a patient transitions to another provider, what happens to their records? From a **professional perspective**, pharmacists may need to shift their mindset to address conflicts of interest and meet documentation requirements. From a **practice setting perspective**, factors such as consultation space, privacy, staffing allocation, delegation and workload distribution must be carefully assessed.

By recognising the interplay between these risk factors, pharmacists can better anticipate potential issues, understand the broader implications for patients and pharmacists, and make more informed decisions when assessing and managing risk.

Effective risk mitigation strategies should be integrated across all aspects of practice to ensure patient safety, regulatory compliance and professional integrity remain balanced and upheld.

For further guidance, refer to Module 2 of the PDL Risk Management Guide for Pharmacists.

Key risk areas in prescribing practice

Prescribing pharmacists work within a complex clinical environment where many factors can increase the likelihood of errors or adverse outcomes. Understanding these key risk areas can help pharmacists take a proactive approach to prevention, and these considerations are relevant to all practitioners providing patient care in this field.

PDL strongly encourages pharmacists to establish and maintain robust protocols, ensure compliance with legislative and regulatory requirements, keep their credentialing and training up to date, and understand their responsibilities in documentation, reporting and overall service oversight.

The following points are provided to raise awareness of foreseeable risks that may arise, and to support thoughtful consideration of how they can be mitigated.

1. **Fragmentation of care**

   - Limited access to clinical records by pharmacists
   - Substandard communication between pharmacist prescribers and other health practitioners
   - No clinical handover or escalation when appropriate
   - Non-contemporaneous or incomplete documentation

2. **Pharmacists not appropriately trained**

   - Pharmacists working outside of their scope of practice
   - Prescribing activities limited to approved indications for medicines (not off-label requests)
   - Risk assessments not conducted prior to commencing prescribing activities
   - Competency not met, even if education requirements are fulfilled (see Scope of Practice equation)

3. **Informed consent (clinical and financial)**

   - Inability to confirm the patient's capacity to consent, receive full disclosure and make voluntary decisions
     Note: clinical consent should encompass treatment, referral and follow-up
   - Insufficient conversation to confirm the patient has given financial consent
     Note: this conversation must clarify fees, expectations and outcomes
   - Insufficient clarity of communication to manage patient expectations and reduce the likelihood of complaints

4. **Privacy, confidentiality and consent**

   - Failure to maintain strict confidentiality of patient records
   - Consultation areas not adequately equipped for privacy
   - Proceeding without properly obtaining consent (refer to *3. Informed consent*)
   - Unauthorised staff accessing clinical information
   - Professional boundaries not upheld
   - Insufficient privacy during consultations
   - Outdated or poorly implemented privacy policies

5. **Conflicts of interest and managing expectations**

- Blurred boundaries between prescribing and dispensing services, creating real or perceived conflicts of interest
- Allowing workflow, commercial or patient pressure to influence prescribing decisions
- Failure to clearly communicate in advance that a consultation does *not* guarantee a prescription
- Lack of clear processes for follow-up or clarification (refer to *1. Fragmentation of care*)
- Issuing prescriptions that do not meet legal or jurisdictional requirements

6. **Documentation and access to records**

- Clinical documentation below professional standards
- Documentation and records that are not comprehensive, contemporaneous or consistent
- Improper storage or retrieval of records
- Insufficient time or resources allocated for documentation duties
- Staff not adequately trained in documentation policies, leading to inaccurate entries, the likelihood of errors or inconsistencies

7. **Incident management and continuous improvement**

- Failure to adopt patient-centric responses such as open disclosure and appropriate apologies
- Poor governance in reporting incidents or near misses
- Delay in seeking timely support and advice post-incident, e.g. from PDL Professional Officers
- Lack of structured, productive reflective practice for post-incident review and action planning (refer to the PDL Reflective Practice Activity for assistance)

Summary

Pharmacist prescribing offers expanded opportunities and responsibilities. Effective governance, continuous professional development and robust systems are essential for safe, high-quality care.

As there are multiple healthcare providers involved, it is essential to ensure clear communication, effective and timely integration of clinical records, and good processes for clinical handover to ensure a safe and high-quality service.[3]

To mitigate the key risk areas discussed, PDL suggests pharmacists should pay particular attention to:

- Maintaining prescribing competence and authority through recognition of own scope of practice
- Engaging in reflective practice and continuous quality improvement
- Professional communication, informed consent, documentation and record-keeping
- Maintaining appropriate governance, including data security, privacy and confidentiality
- Coordination of prescribing activities with other clinical duties and team workflows

PDL is committed to supporting members as the profession evolves, ensuring patient safety and quality remain at the forefront. For further guidance or to report incidents, contact PDL on 1300 854 838 or email info@pdl.org.au.

Useful risk management tools from PDL

- **PDL Risk Management Guide for Pharmacists** – for a clear, practical approach to risk management; helping to prevent incidents and improve systems
- **Risk Assessment Tool (RAT)** – for self-assessment and action planning
- **Scope of Practice Checklist** – to confirm readiness for new services
- **Reflective Practice Activity** – for learning from incidents and improving practice
- **Guide to Incident Management** – a step-by-step process for managing incidents and near misses
- **Guide to Good Dispensing** and **Supplement to Guide to Good Dispensing: Final Check & Supply of Medicine** – for best practice in supply and documentation

References

1. Queensland Government. Prescribing scope of practice management – prescribing in community pharmacy, July 2025. Cited 15 Dec 2025 at https://www.health.qld.gov.au/__data/assets/pdf_file/0031/1450984/guidance-prescribing-scope-practice.pdf
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