



» PHARMACY LEGAL

Clinical guidelines and protocols

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Professional practice is guided by a vast array of resources in the form of protocols, clinical and practice guidelines, standards and codes.

Although practice codes and standards are broad descriptions that cover a range of practice settings, clinical guidelines and protocols are more specific and apply to specific disease conditions or patient groups. Therefore, as new information emerges, protocols and clinical guidelines need to be updated to reflect latest evidence.

This raises the question of the legal status of clinical guidelines and protocols. Medical knowledge is increasing at a tremendous rate and it is challenging for health professionals to be knowledgeable of all updated guidelines and protocols. This poses a legal risk to practise as the question is whether health professionals, including pharmacists, who deviate from guidelines, are more likely to be found negligent if patients suffer injury as a result? To answer this question we need to consider the expected level of care, referred to as the *standard of care*, of professional practice.

Guidelines and the standard of care

A breach of a pharmacist's duty of care refers to a failure on the part of the pharmacist to meet the standard of

care that the law requires. The standard of care required by law is generally defined as what a minimally competent health professional in the same field would do in the same situation, with the same resources.¹ The test to determine a breach of care is an objective one and involves determining whether a reasonable pharmacist failed to take reasonable precautions to avoid foreseeable risk. The benchmark in assessing whether the action or omission fell below the required standard is the 'reasonable man' test as defined in the British case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (at [586]):

'Where you get a situation which involves the use of some special skill or competence, then the test whether there has been negligence or not... Is the standard of the ordinary skilled man exercising and professing to have that special skill... In the case of a medical man, negligence means failure to act in accordance with the standards of reasonable competent medical men at the time... a doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art... merely because there is a body of opinion that would take a contrary view.'

Clinical guidelines would be considered in determining the standard of care if they were viewed by clinicians, the profession and other experts as the required standard of care. The guidelines therefore need to be accepted by the various role players and the credibility of the drafters and the process through which the guidelines are developed and updated are crucial in establishing their authority.² Guidelines should not be developed by a small number of individuals but by experts, approved and accepted by peers. Additionally, the guidelines need to be well known and widely distributed.

Another point to keep in mind is that patients are unique and that health professionals need to use their clinical judgement in deciding what is best for each individual patient. Although clinical guidelines and protocols provide a framework for the management of patients they do not deal with the specifics of every case as they cannot address the particular

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nature of every practice situation. Health professionals thus still need to use their professional judgement in deciding what will be the best outcome for a specific patient. Practice settings also need to be considered. For example, services available in a metropolitan setting will differ from services available in rural and remote settings.² These differences affect which guidelines will be followed and what is appropriate and possible in terms of patient care.

Of specific reference to Australian health professionals and legislation covering standard of care are the *Civil Liability Acts*.³ These Acts were introduced in all Australian jurisdictions following the Review of the Law of Negligence in 2002 and they address the required standard of care to be provided by health professionals. For example, the *Civil Liability Act 2003* (Qld) states:

S22 Standard of care for professionals

1. A professional does not breach a duty arising from the provision of a professional service if it is established that the professional acted in a way that (at the time the service was provided) was widely accepted by peer professional opinion by a significant number of respected practitioners in the field as competent professional practice.
2. However, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational or contrary to a written law.
3. The fact that there are differing peer professional opinions widely accepted by a significant number of respected practitioners in the field concerning a matter does not prevent any 1 or more (or all) of the opinions being relied on for the purposes of this section.

4. Peer professional opinion does not have to be universally accepted to be considered widely accepted.
5. This section does not apply to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information, in relation to the risk of harm to a person, that is associated with the provision by a professional of a professional service.

Guidelines that are widely accepted by the profession will be regarded as 'peer professional opinion by a significant number of respected practitioners' and could be referred to in disciplinary or court cases to lend credibility to an expert witness or defend a health professional's actions.

Professional responsibility

Pharmacists have a professional responsibility to refer to credible guidelines that have been approved and are widely accepted to guide decisions and practices. As health professionals pharmacists should also use professional judgement in deciding what is best for each individual patient, considering the unique situation, and document these decisions.

References

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2. Kluge E. Clinical practice guidelines and the law. Canadian Medical Association Journal. 1996;155(5):574-6.
3. Civil Law (Wrongs) Act 2002 (ACT); Civil Liability Act 2002 (NSW); Personal Injuries (Liabilities and Damages) Act 2003 (NT); Personal Injuries (Civil Claims) Act 2003 (NT); Civil Liability Act 2003 (Qld); Personal Injuries Proceedings Act 2002 (Qld); Volunteers Protection Act 2001 (SA); Recreational Services (Limitation of Liability) Act 2002 (SA); Civil Liability Act 1936 (SA); Civil Liability Act 2002 (Tas); Wrongs Acts 1958 (Vic); Civil Liability Act 2002 (WA).