

Health Insights

Complex Compounding – How does a pharmacist prove competency?

The focus of this article is to explore how an individual pharmacist can create and maintain the documentation which may assist them in proving to the Pharmacy Board of Australia (Board) that they have met the training requirements for complex compounding.

What is compounding?

Drug compounding is the combining of individual ingredients in the exact strength and dosage form that a patient requires according to their own unique needs.¹

The Pharmacy Board of Australia (**Board**) divides compounding into two types:

- a) simple compounding; and
- b) complex compounding.

Simple compounding versus complex compounding

Pharmacists entering the profession are deemed competent to undertake simple compounding, due to the completion of an approved pharmacy program of study (for example, a Bachelor of Pharmacy), which is a prerequisite to registration as a pharmacist.

The Board has created 'Guidelines on Compounding of Medicines' (**Guidelines**)², which provides guidance on the additional requirements for complex compounding and the training required to achieve competency. According to the Guidelines:

- a) *'Subsequent to entering the profession, some pharmacists may extend their scope of practice to compound medicines of a more complex nature ('complex compounding') which requires or involves specific competencies...'*³

¹ Medisca.com.au/compounding/what-is-compounding, <https://www.medisca.com.au/compounding/what-is-compounding>.

² Pharmacy Board of Australia, Guidelines on Compounding Medicines, March 2015 (updated content issued August 2017)

³ Pharmacy Board of Australia, 'Guidelines on compounding of medicines', Issued August 2017, p 5.

- b) Examples of complex compounding include formulations containing ingredients such as cytotoxics or hormones.

Setting up and maintaining a pharmacy to undertake complex compounding requires compliance with numerous statutes to reduce the risks associated with this type of dispensing.

What are the Board's expectations regarding training to practise complex compounding?

According to the Guidelines, *'training programs may include those developed and delivered at workplaces.'* The Guidelines also state:

'When pharmacists extend their scope of practice to include complex compounding they must be able to demonstrate that they have met the requirements of the CPD registration standard by maintaining evidence of the CPD activities they have done to achieve competence to undertake complex compounding...'⁴

In March 2015, the Board developed a 'Professional Practice Profile for Pharmacists undertaking Complex Compounding' (**Profile**) which serves as a tool for pharmacists to acquire and maintain the required competence for any type of complex compounding. The Profile lists six domains, chosen by the Board from the National Competency Standards Framework, as applicable to complex compounding. The competency standards listed in the Profile are:

- a) Domain 1: Professional and ethical practice
- b) Domain 2: Communication, collaboration and self-management
- c) Domain 4: Review and supply prescribed medicines
- d) Domain 5: Prepare pharmaceutical products
- e) Domain 6: Deliver primary and preventive health care, and
- f) Domain 8: Critical analysis, research and education.

Relevantly, the Profile does not stipulate a particular training program or curriculum for complex compounding and states that the competence required to undertake complex compounding can be attained thorough training and work experience. The Profile clearly states:

'Pharmacists who wish to engage in complex compounding must acquire and build the requisite knowledge and expertise through participation in formal training programs and ongoing workplace training and experience.'⁵

The Board's publication *Frequently asked questions for pharmacists on the compounding of medicines* (dated 16 January 2020) confirms that a pharmacist has a professional obligation to:

- a) ensure that they can safely compound medication; and

⁴ Pharmacy Board of Australia, 'Guidelines on compounding of medicines', Issued August 2017, pp 5-6.

⁵ Pharmacy Board of Australia, 'Professional Practice Profile For Pharmacists Undertaking Complex Compounding', March 2015, p. 5

- b) recommend supply by another compounding pharmacist if they do not have the required competencies or equipment.

What does this mean for practitioners?

The Board's requirements for training pharmacists in complex compounding is not prescriptive, meaning that pharmacists cannot simply tick off a checklist. The onus is therefore on practitioners to determine whether or not their individual training and education meet the necessary criteria required by the Board. At first blush this may seem to be advantageous, as practitioners have the option to use different methods to extend their knowledge of complex compounding.

However, the non-prescriptive nature of complex compounding training is also an area where, in Meridian's experience, practitioners have faced Board scrutiny. Pharmacists engaging in complex compounding must complete the required training, and importantly must also be able to **prove** to the Board that their training meets the requirements. The question of proof can be a difficult obstacle. Pharmacists will be best able to fulfil this if they plan and document their complex compounding training (before commencing) along with the ongoing Continuing Professional Development (CPD) requirements.

Below is a checklist that may assist pharmacists to create and maintain the relevant documentation to provide to the Board, to show that their complex compounding training meets the Board's requirements:

- Prior to commencing training in complex compounding, ensure competence has been achieved in simple compounding. In particular, by reviewing entry level requirements in the National Framework (page 80 and the shaded sections of standards 5.1 to 5.4). Also refer to Domain 5 of the Profile.⁶
- Before commencing training, create a practice profile with reference to the Profile and assess how the six domains will be met along with the relevant listed standards. Refers to 1.8, Developing a professional practice profile of the National Competency Standards Framework (**Framework**) for Pharmacists in Australia (2010).⁷ 1.8 of the Framework provides examples of how a professional practice profile looks and the information to include. Table 1 of the Profile is an example of a professional practice profile for complex compounding.⁸
- Create a CPD plan, which is ongoing and completed contemporaneously (that is, upon completion of CPD education and training). If possible, attach certificates of completion. A professional development plan should include goals and strategies to maintain/improve professional capability.⁹
- Where possible include structured courses in the CPD plan. The Board has a tendency to prefer structured courses especially in relation to core units and extensions for compounding practice.

⁶ Pharmacy Board of Australia, 'Professional Practice Profile For Pharmacists Undertaking Complex Compounding', March 2015, p. 4.

⁷ Pharmacy Board of Australia, 'Professional Practice Profile For Pharmacists Undertaking Complex Compounding', March 2015, p. 5-6.

⁸ Pharmacy Board of Australia, 'Professional Practice Profile For Pharmacists Undertaking Complex Compounding', March 2015, p. 7.

⁹ Pharmacy Board of Australia, 'Professional Practice Profile For Pharmacists Undertaking Complex Compounding', March 2015, p. 17.

June 2022

- CPD training must show competence in complex compounding prior to commencing complex compounding practice, but should also be ongoing. Standard 1.5 of the Profile is 'Maintain and extend professional competence' and provides information on the performance criteria and evidence examples.
- Participate in a range of activities for professional development and maintain contemporaneous records of these activities.
- Show regular self-assessment and monitoring learning against goals contained in the professional development plan. It is optimal for a practitioner to demonstrate an understanding of the importance of self-assessment.
- Be aware of the limits of your professional expertise within complex compounding, so that they are not transgressed prior to obtaining the necessary competency.
- Consider engaging an expert or mentor to assist in the process of achieving competency in complex compounding. The Board encourages engagement of an expert or mentor.¹⁰
- Inform your professional indemnity insurer that you are engaging in complex compounding to ensure insurance coverage of this practise area.

The Board has provided non-prescriptive guidelines for pharmacists to train to practise complex compounding. This means that pharmacists can cater their training to their individual requirements of their unique pharmacy practice. However, it places a significant onus on pharmacists to ensure they are responsible in not only meeting the competencies, in addition to creating and maintaining the relevant documentation, so that if called upon they can prove to the Board that their complex compounding training is sufficient.

Meridian Lawyers regularly assists pharmacists with notifications to regulators such as the Office of the Health Ombudsman and AHPRA, including recently in relation to establishing the adequacy of training to undertake complex compounding. This article was written by Associate, Kristina Fox and Principal, Scott Ames. Please contact Kristina or Scott if you have any questions or for further information.



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¹⁰ Pharmacy Board of Australia, 'Guidelines on compounding of medicines', Issued August 2017, p 6.