



Community Pharmacy Roadmap Program Development Template

Program/Service	Enhanced Compounding Services
Quadrant	A – Prescribed Medicines – Services and Programs
1. Program/Service Description	
a) Background	Compounding, involving the extemporaneous preparation of a medicine by a pharmacist to accommodate the particular needs of a patient, has long been an integral part of pharmacy practice. Although compounding has declined with the introduction of mass production and the commercial marketing of pharmaceuticals, many community pharmacies still provide limited compounding services according to specific formularies when no commercial product is available. Over recent years, some pharmacies have implemented enhanced compounding services, responding to demand from consumers and prescribers by providing this more specialised, patient-focused service.
b) Brief Description	<p>With enhanced compounding services, patient's have access to a greater range of medicines than those which are commercially available. This is particularly useful for patient groups for which only a limited range of commercially available products are available, such as paediatric or veterinary patients. It is also useful for patients with specific issues such as swallowing difficulties or who are allergic to ingredients such as dyes, preservatives or fillers in commercially available products. It may include preparing products of different strengths to what is commercially available or providing an opportunity for patients to continue treatment when commercially available products are discontinued by manufacturers. Some community pharmacies are equipped to also prepare technically specialised extemporaneous products, such as sterile or cytotoxic medicines.</p> <p>Depending on the schedule classification of the medicine being compounded, a prescription may or may not be needed to access compounded products.</p>
c) Alignment with Government Policy	<p>Utilising the expertise and accessibility of community pharmacists as part of the health support team and the more efficient and cost-effective use of available health professionals are in line with recommendations from the National Health and Hospitals Reform Commission and Primary Health Care Strategy promoting team care support.</p> <p>Enhanced compounding services also align with the National Medicines Policy¹ and the National Strategy for the Quality Use of Medicines (QUM)² by addressing an individual's requirements for their medicines and promoting the wise selection and safe and effective use of medicines when they are considered necessary.</p>
d) Expected Outcomes for Government and Community Pharmacy	<p>Extending the scope for improved access to medicines for specific population groups is of benefit to the government and the community. As an example, paediatric or chemotherapy patients often need to attend public or private hospitals in order to access specialised medicines that are made up for the individual. Facilitating access to highly specialised medicines for these patients group would be a social and cost-effective benefit for the government and community, particularly for those patients in rural and regional communities. In addition, the health needs of some patients may be more cost-effectively met by facilitating access to medicines that meet their individual needs rather than having to use more costly alternative services or resources.</p> <p>From a pharmacy perspective, there will be a greater recognition for the role of community pharmacists as a member of the primary health care team. With the most comprehensive background in pharmaceuticals of any of the health professions, pharmacy is the only health</p>

¹ <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-2>

² <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm>

	<p>profession capable of providing enhanced compounding services. Community pharmacy has the opportunity to address a market need, improving its viability and reducing its dependence on the Pharmaceutical Benefits Scheme (PBS). In addition, there will be a greater capacity to effectively utilise the increased number of new pharmacy graduates in a manner that benefits both pharmacy practice and the community. Pharmacy graduates will continue to have a positive outlook for community pharmacy as a career and require ongoing training for enhanced compounding services, supporting the viability of pharmacy education providers.</p>
e) Consumer Benefits	<p>Individuals and specific population groups benefit through greater access to a wider range of medicines. This is of particular benefit to patients for which a suitable commercial product is not readily available. Some patients may be unable to use commercially available dose forms because of post-surgery impact, disease state complications, allergies to ingredients, or because they need a different strength to what is available. In such circumstances, alternative dosage forms are essential. Consumers also have an opportunity to access particular medicines if commercial products are discontinued.</p> <p>Compounding pharmacies also seek to create a collaborative relationship with the prescriber and the patient to achieve positive clinical outcomes for patients unable to take commercially available pharmaceuticals. This may also reduce the need for patients to resort to alternative interventions which may be more costly or more problematic for them.</p>
f) Who Performs the Service	<ul style="list-style-type: none"> • Pharmacists • Pharmacy assistants <p>Pharmacists perform the professional functions associated with compounding services. A trained pharmacy assistant may perform routine functions, subject to appropriate training and quality assurance checks.</p>
g) Collaboration with Other Health Care Professionals	<p><i>Will service delivery require any formal collaboration with other health care professionals?</i></p> <p>Yes. Pharmacists collaborate with prescribers to raise awareness of the service and its capacity to support individual medicine requirements as well as advising on formularies and pharmaceuticals.</p>

2. Implementation and Enablers

a) Stakeholder Consultation	<p><i>Representative bodies from the following areas will need to be consulted in order to fully develop and implement a program:</i></p> <ul style="list-style-type: none"> • Consumer organisations • Funders • Government and regulatory bodies • GP organisations and other prescriber bodies • Pharmacy organisations • Pharmacy software vendors • Professional insurers • Training bodies
b) IT Requirements	<p><i>Is pharmacy software required to deliver this program?</i></p> <p>No. While most dispensary software systems have some capacity to record and dispense extemporaneous prescriptions there may be scope for this capacity to be improved and streamlined.</p> <p>Pharmacies that provide enhanced compounding services, particularly on a large scale, may benefit from specific software systems that enable them to more efficiently meet quality assurance requirements.</p>
c) Infrastructure and Staffing	<p><i>Is a private consultation area required to deliver this program?</i></p> <p>No. However, the pharmacy will need a suitably equipped preparation area in line with relevant national standards. Community pharmacies providing technically specialised compounding services will need appropriate specialised equipment.</p> <p><i>Is the program within the pharmacist's/pharmacy assistant's normal scope of practice?</i></p>

	<p>While all pharmacists are capable of providing basic compounding services, the provision of enhanced compounding services requires additional training in pharmaceuticals, particularly for pharmacists involved in the preparation of technically specialised products.</p> <p><i>Is an additional pharmacist likely to be needed?</i></p> <p>When planning to develop enhanced compounding services as part of the pharmacy's business plan, owners and/or managers must be prepared to engage additional personnel to ensure the pharmacy continues to meet all of its professional obligations whilst effectively providing the new services. As the scale of the enhanced compounding business increases, there will be a greater need to engage additional pharmacists and/ or pharmacy assistants with the appropriate competencies.</p>
<p>d) Training</p>	<p><i>What additional formal training is likely?</i></p> <ul style="list-style-type: none"> • under-graduate pharmacist • post-graduate pharmacist • pharmacy assistant <p>Pharmacy graduates should be trained to a level where they can confidently provide routine compounding services upon registration and are aware of the fundamentals for enhanced services.</p> <p>Pharmacists providing enhanced compounding services must meet specific professional competencies. Additional training in pharmaceuticals is essential for pharmacists wishing to specialise in compounding, along with an understanding of relevant regulatory and policy requirements</p> <p>Refresher training should be available for registered pharmacists to ensure compounding services (both routine and enhanced) remain aligned with current clinical guidelines and relevant standards.</p> <p>If a pharmacy assistant has any significant role apart from that of general administration, appropriate training would need to be determined and provided in a suitable format.</p> <p><i>Does any suitable training exist?</i></p> <p>Limited training in compounding is available through bodies such as the Professional Compounding Chemists of Australia (PCCA), however, there is a need for more specialised training within an Australian context than that which is currently available.</p>
<p>e) Supporting Standards, Procedures and Templates / Checklists</p>	<p><i>Will a QCPP standard be required?</i></p> <p>Strict adherence by pharmacists to professional protocols set out in an auditable standard should ensure the public receives a standardised, quality-assured professional compounding service. These standards should give consideration to the requirements for personnel competency and the necessary infrastructure and equipment as well as the quality of ingredients used. Generic standards for professional support services are available as part of QCPP 2nd edition. As specific services are developed, the need for supporting templates and procedures can be assessed and where not available, the development of new ones should be part of any program structure.</p> <p><i>Will professional guidelines and/or standards be required?</i></p> <p>Supporting professional standards are an essential part of professional services. The newly revised Professional Practice Standards³, provided by the Pharmaceutical Society of Australia (PSA), includes one standard for compounding (Standard 10), and one for the compounding of sterile preparations (Standard 11).</p> <p><i>Will a service protocol be required?</i></p> <p>Minimal additional service protocols should be needed to existing dispensing protocols.</p> <p><i>Are there any national guidelines which need to be taken into account in developing the program to ensure consistency with best practice?</i></p> <p>The Australian Pharmaceutical Formulary and Handbook (APF) is a mandatory text for all</p>

³ Professional Practice Standards Version 4 2010; PSA; www.psa.org.au

	<p>community pharmacies in Australia and includes a section dedicated to ‘extemporaneous dispensing’, providing general guidance to compounding practice with a limited number of commonly used formula.</p> <p>The government’s ‘Guiding principles for medication management in the community’⁴ provides general guidance on medication management with limited application to compounding services. With the greater availability of enhanced compounding services, it is reasonable to anticipate that future adaptation of this and other relevant government guidelines will provide greater reference to compounding services.</p>
f) Legislation / Regulation Implications	<p>The Therapeutic Goods Administration (TGA), a division of the Commonwealth Department of Health and Ageing, is responsible for administering the provisions of the Therapeutic Goods Act⁵ as the overall regulatory control for the supply of therapeutic goods in Australia, with States and Territories introducing complementary legislation.</p> <p>While the preparation and supply of compounded medicines by pharmacies have been exempt from aspects of therapeutic goods regulations, the TGA has been concerned that there are sufficient quality assurance processes in place with pharmacies providing enhanced compounding services, particularly pharmacies providing technically specialised compounded products or those providing compounding services on a very large scale. The TGA has been conducting a number of consultations as part of its continuing review of the therapeutic goods regulations with regards to the practice of compounding and is considering implementing licensing arrangements to resolve these issues.</p>
3. Funding	
Funding Options	<p>Possible funding options include:</p> <ul style="list-style-type: none"> • Commonwealth Government – through the PBS • User-pays • Private health insurers <p><i>Has any funding for this program been secured?</i></p> <p>No. The provision of enhanced compounding services is primarily a business decision for the community pharmacy proprietor and/or manager. There are no incentives currently available to assist the pharmacy in establishing the service, with infrastructure, equipment, training and licensing costs needing to be covered by the pharmacy. With only limited extemporaneous products covered by the PBS, costs for enhanced compounding services are predominantly met by the end-user patient. The pharmacy must have or be confident of developing adequate custom to cover business costs.</p> <p>There may be an opportunity to extend the PBS coverage for products for particular population groups (e.g. paediatrics) to facilitate access when commercially available products are unavailable. This would be particularly advantageous to concessional patients and those who are socio-economically disadvantaged as well as those living in rural or remote locations.</p>
4. Timelines	
Timelines	<p><input checked="" type="checkbox"/> Established community pharmacy practice</p> <p><input checked="" type="checkbox"/> Immediate to short-term implementation (< 30 June 2015) – for regulatory reform</p> <p><input type="checkbox"/> Medium-term implementation(1 July 2016 to 30 June 2020)</p> <p><input type="checkbox"/> Longer-term implementation (> 1 July 2020)</p>

⁴ <http://www.health.gov.au/internet/main/publishing.nsf/Content/apac-publications-guiding>

⁵ <http://www.tga.gov.au/legis/index.htm>