



Australian Government

Department of Health and Ageing

PHARMACY LOCATION RULES

Applicant's Handbook

VERSION 1.0, 18 OCTOBER 2011

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For applications for approval to supply pharmaceutical benefits,
to be considered by the Australian Community Pharmacy Authority

VERSION 1.0

Effective date 18 October 2011

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Disclaimer

This handbook is designed as a general guide for pharmacists seeking to relocate an existing pharmacy or establish a new pharmacy approved to supply pharmaceutical benefits under section 90 of the *National Health Act 1953* (the Act). It should not be used as a basis for legal interpretations or as a definitive reference on the roles and responsibilities of all parties.

For more precise and detailed information please consult section 90 and Division 4B of the Act, the determinations made under section 99L of the Act and the explanatory statements to those determinations.

The Australian Community Pharmacy Authority and the Commonwealth Government accept no responsibility arising from use of, or reliance on, this publication.

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Introduction

The purpose of this Handbook is to provide information and guidance to pharmacists who wish to make an application to establish a new pharmacy or relocate an existing pharmacy, approved to supply pharmaceutical benefits. The requirements for approval are contained in the Pharmacy Location Rules as determined by the Minister for Health and Ageing by Ministerial Determination on 16 September 2011.

Any pharmacist wishing to make an application to establish a new pharmacy or relocate an existing pharmacy should consult this Handbook before lodging an application.

The Handbook includes information about:

- the Australian Community Pharmacy Authority (the Authority) and the Pharmacy Location Rules (the Rules);
- the application process including the types of information that must be included in an application and the requirements that must be satisfied; and
- seeking further information or assistance.

The Handbook is divided into the following sections:

Background provides general information about the Rules and the Authority.

The application process provides information about when it is necessary to seek approval, how to make an application and how an approval is granted.

The Pharmacy Location Rules sets out the requirements of each of the Rules and the types of evidence which might address the requirements.

Glossary provides definitions for terminology used within the Rules.

CONTACT INFORMATION

Australian Community Pharmacy Authority

Queries regarding the Rules and applications should be directed to:

Address: The ACPA Secretariat
Department of Health and Ageing
MDP 953, GPO Box 9848
CANBERRA ACT 2601

Phone: (02) 6289 2419
[please leave your name, contact number and a brief message and a member of the Secretariat will return your call as soon as possible]

Facsimile: (02) 6289 2365

Email: acpamail@health.gov.au

Internet: www.health.gov.au/ACPA

You can access information about the Rules and the Authority, and download electronic versions of the Rules from the above website.

Medicare

Queries regarding section 90 approvals should be directed to Medicare:

Phone: 132 290 – ask for the Pharmacy Programs Officer in your state
[please note that usual office hours apply: 9am-5pm, Mon-Fri]

Email: pbs.enq@humanservices.gov.au

Internet: www.humanservices.gov.au

Application forms and other fact sheets can be downloaded from the Human Services website by following the links for health professionals on the Medicare page.

Please note that this Handbook will be updated and revised as necessary.

BACKGROUND

Approval to supply pharmaceutical benefits

Section 90 of the *National Health Act 1953* (the Act) provides for the Secretary (of the Department of Health and Ageing) to approve a pharmacist to supply pharmaceutical benefits at particular premises. Pharmaceutical benefits are drugs or medicinal preparations for which benefits will be paid by the Commonwealth.

The Secretary's responsibilities concerning the approval of pharmacists have been conferred on the Chief Executive Medicare, who has delegated those powers to designated officers of Medicare, within the Department of Human Services. Therefore, any references in this Handbook to the Secretary mean the delegate in Medicare.

The Secretary can generally only approve a pharmacist if the Authority has recommended approval, and the pharmacist is permitted under the relevant State or Territory law to carry on business as a pharmacist.

Medicare is also responsible for other matters associated with a pharmacy approval (for example, payment for the supply of pharmaceutical benefits, changes in pharmacy ownership, monitoring compliance, etc). However, the Secretary does not require an Authority recommendation in order to make a decision to approve a change of pharmacy ownership or an expansion or contraction in the size of pharmacy premises.

The Australian Community Pharmacy Authority (the Authority)

The Authority is established under the Act to consider applications for approval to supply pharmaceutical benefits at particular premises as referred by the Secretary, and to make recommendations to the Secretary as to whether or not a pharmacist should be approved. In making its recommendations, the Authority must comply with the Rules determined by the Minister under section 99L of the Act.

Membership

The Authority consists of the following part-time members:

- (a) a Chairperson;
- (b) two pharmacists chosen from four pharmacists nominated by the Pharmacy Guild of Australia;
- (c) one pharmacist chosen from two pharmacists nominated by the Pharmaceutical Society of Australia;
- (d) an officer of the Department of Health and Ageing; and
- (e) one person who, in the Minister's opinion, is an appropriate person to represent the interests of consumers.

All members, other than the officer of the Department, are appointed by the Minister for Health and Ageing.

Secretariat support

The Department of Health and Ageing is responsible for providing secretariat services to the Authority. The Authority Secretariat serves as the liaison between pharmacists and the Authority, and its duties include:

- forwarding applications to members referred by the Secretary for the Authority's consideration;
- seeking comments from pharmacists in the vicinity of a proposed pharmacy;
- providing assistance about the Rules and the application process to any interested persons;
- communicating Authority recommendations to the Secretary.

The Pharmacy Location Rules (the Rules)

The Rules are a fundamental component of the Fifth Community Pharmacy Agreement (the Fifth Agreement) between the Commonwealth of Australia (as represented by the Australian Government Department of Health and Ageing) and the Pharmacy Guild of Australia (the Guild). This Agreement commenced on 1 July 2010 and terminates on 30 June 2015.

The Rules remain consistent with the overall objective of the National Medicines Policy¹ to improve the health outcomes of all Australians through access to, and quality use of, medicines.

A review of the Rules was undertaken in 2010 as required under the Fourth Community Pharmacy Agreement. The review considered opportunities to improve the effectiveness and efficiency of the administration of the Rules, including the application and assessment processes, the requirement for clarity regarding the Rules or their implementation, and the need for flexibility in responding to current health policy reforms and the changing policy environment for community based primary health care delivery.

The Rules as amended in October 2011 reflect the findings from the review and address other identified anomalies. They are intended to simplify the application process and encourage pharmacies to be established in areas of community need.

The Rules set out location-based criteria which must be met in order for the Authority to recommend approval of a pharmacist. The Authority cannot override the requirements of the Rules. It can only recommend that an application be approved if it is satisfied that all of the requirements of the Rule, under which the application was made, have been met. Similarly, the Authority is unable to recommend that an application be approved if it is not satisfied that each of the requirements have been met.

¹ National Medicines Policy 2000, Commonwealth of Australia 1999

THE APPLICATION PROCESS

1. When a pharmacist must seek approval

Whether simply taking on a new partner for an existing pharmacy, looking to relocate an existing pharmacy, or seeking to open a new pharmacy, a pharmacist must apply for approval under section 90 of the Act. If a pharmacist fails to obtain the necessary approval, they may not be eligible for payments from the Commonwealth Government for the supply of pharmaceutical benefits and any payments received may need to be returned.

A pharmacist **MUST** apply for approval:

- to open a new pharmacy;
- to relocate an existing pharmacy;
- to expand or contract the size of an existing pharmacy;
- to change the address of an existing pharmacy, even if the premises have simply been renumbered and the premises remain unchanged; or
- to change the ownership of an existing pharmacy, including changes resulting from the death of an owner.

A pharmacist **DOES NOT** need to apply for approval:

- to make internal changes to an existing pharmacy;
- to alter the public access points of an existing pharmacy; or
- if pharmaceutical benefits will not be supplied from the pharmacy.

The Secretary is not required to refer all applications for approval to the Authority. The only applications which must be referred to the Authority are applications for the relocation of an existing pharmacy or the establishment of a new pharmacy.

Applications relating to an expansion or a contraction in the size of a pharmacy are not required to be referred to the Authority, however in some circumstances the Secretary may consider it appropriate to do so. In this case, the application would be considered by the Authority against the relevant requirements of the Rules.

This Handbook deals only with those applications for approval that are referred to the Authority, that is, applications to establish a new pharmacy, to relocate an existing pharmacy or (if applicable) to expand or contract the size of an existing pharmacy.

All other applications for approval are dealt with by the Secretary and are not considered against the requirements of the Rules.

Please note: If a pharmacist has failed to advise Medicare of any change to their circumstances, there is a risk that the pharmacist will have to repay benefits paid to them by the Commonwealth.

If any pharmacist is in any doubt as to whether they need to obtain approval for a certain change to their pharmacy, they should contact Medicare or the Authority's Secretariat.

2. What constitutes an application

The *National Health (Pharmaceutical Benefits) Regulations 1960* provide that an application for approval must be made using the approved application form. The approved application form includes certain documents and information, and a declaration that all required documentation has been provided. **All required documentation must be provided with the application form at the time of application.**

Before an application can be registered, the application form must be completed in full and the declaration must be signed and dated by all applicants. This Handbook describes the documents to be included in an application.

It is important to note that additional documentation provided after the date of application will not be accepted. Therefore any information that an applicant wishes the Authority to consider must be provided at the time of lodging the application.

It is strongly recommended that all potential applicants consult this Handbook before lodging an application.

Please note that the Secretariat and Medicare are unable to return material provided with an application and it is therefore recommended that applicants retain a full copy of their application.

3. Providing further information

If, after lodging an application, an applicant finds that there is additional information that they would like the Authority to consider, a new application will need to be lodged with Medicare. The new application will need to include all of the information that the applicant wishes the Authority to consider. The new application does not replace the original application and the usual cut-off dates would apply for the new application.

The original application will be considered based on the information submitted with the original application. If a new application is made it will not be considered at the same meeting as the original application regardless of whether it was received by the cut-off date for that meeting.

If the applicant no longer wishes the Authority to consider the original application, a request must be made, in writing, to the Authority to request that the application be withdrawn.

4. Different types of applications

It is up to the applicant to determine the specific pharmacy location rule under which they wish to apply. Each rule sets out different requirements and it is the applicant's responsibility to select the rule which best suits their situation. In addition to the application form, an applicant will need to include evidence addressing the specific requirements of the nominated rule.

The Rules that relate to the relocation of an existing pharmacy are:

- Rule 121: Expansion or contraction (not usually referred to the Authority)
- Rule 122: Relocation within a facility (small or large shopping centre, private hospital or large medical centre)
- Rule 123: Relocation within the same town (10 km)
- Rule 124: Short distance relocation (1 km)
- Rule 125: Short distance relocation (more than 1 km)*
- Rule 126: Long distance relocation*
- Rule 127: Relocation to a population growth area*

***Note:** Applications under Rules 125, 126 and 127 must be lodged and registered by Medicare no later than 15 April 2012.

The Rules that relate to the establishment of a new pharmacy are:

- Rule 130: New pharmacy (at least 1.5 km)
- Rule 131: New pharmacy (at least 10 km)
- Rule 132: New additional pharmacy (at least 10 km)
- Rule 133: New pharmacy in a facility (small shopping centre)
- Rule 134: New pharmacy in a facility (large shopping centre)
- Rule 135: New pharmacy in a facility (private hospital)
- Rule 136: New pharmacy in a facility (large medical centre)

5. Representation

If another person, other than the applicant(s), is authorised to represent the applicant(s), the relevant section on the application form must be completed to indicate this, otherwise neither the Authority Secretariat nor Medicare will be able to discuss the application with that person.

6. Accuracy of information

It is important to ensure that any information that is provided in relation to an application is accurate and up-to-date. Giving false or misleading information is a serious offence under Division 137 of the *Criminal Code 1995*, the maximum penalty for which is imprisonment for 12 months.

7. Practicalities

Following these simple points will ensure that an application is processed as promptly as possible.

- Make sure the application form has been completed clearly and has been signed by each applicant and the representative, if applicable. If the application involves another pharmacist's existing pharmacy approval, ensure that each approved pharmacist has also signed the form.
- Make sure a particular rule has been nominated.
- Include a covering letter that clearly describes the documentation provided and any circumstances of the application that might be relevant.
- Clearly label any attachments or maps.
- In providing marked-up maps or plans, use symbols rather than colours. This ensures that the Authority Secretariat can properly duplicate the application for the purposes of Authority consideration.
- Ensure that any maps provided are clearly scaled and the source of the map is cited.
- Ensure that any survey reports are undertaken in accordance with the requirements outlined in this Handbook. The survey report should include a statement that the measurement has been undertaken in accordance with the requirements, be on the surveyor's letterhead, and be signed and dated by the surveyor.
- Ensure that any photographs include the date the photograph was taken.
- Above all, ensure that the application clearly addresses each and every one of the relevant requirements of the rule under which the application has been made.

It is **important to note** that:

- In providing evidence, it is the applicant's responsibility to summarise the material, draw conclusions from the material and clearly identify how the relevant requirements of the Rules are met by the evidence. It is not the Authority's responsibility to examine large volumes of information and identify how it satisfies the requirements.
- The Authority is unable to consider information provided by an applicant unless the information was provided at the time the application was lodged, or unless additional information has been requested by the Authority.
- Applicants are advised to keep a copy of their application (including any documentation submitted in support of the application) for their own records as applications become the property of the Commonwealth Government and will not be returned.

8. Lodging an application

Complete applications should be lodged by mail with the relevant state office of Medicare at:

Pharmacy Programs Officer
Department of Human Services
GPO Box 9826
in your capital city

9. Receipt of an application

Upon receipt of an application, a Pharmacy Program Officer in Medicare will check that the application form is complete.

If the **application form** is not complete, the application will not be registered and will not hold a place in the queue. Medicare will advise the applicant of the reasons, and will not take any further action in relation to the application unless the applicant provides the missing information.

The Pharmacy Program Officer is unable to provide advice to an applicant as to whether all of the required documentation has been provided with the application. Rather, the onus is on the applicant to ensure that each of the requirements has been addressed for the particular Rule under which the application has been made.

If the **application form** is complete, Medicare will advise the applicant, in writing, of the application's registration number. The application will then be referred to the Authority.

10. Opportunity for nearby pharmacists to provide comment

Once an application has been referred to the Authority, it is standard practice for the Authority to seek comments from other pharmacists in the vicinity of the proposed pharmacy. This practice applies to nearly all types of applications.

The Authority is not required or obliged to seek comments from nearby pharmacists, or to advise pharmacists that an application for approval has been made. However, this practice of seeking comments allows other pharmacists the opportunity to comment on whether, in their opinion, the proposed pharmacy would meet the requirements of the Rules. It is also valuable for the Authority to obtain comments from persons other than the applicant, who have specialised knowledge of a particular area. Nearby pharmacists will generally be given two weeks to respond.

The Authority cannot guarantee that it will write to all pharmacists who might be affected by an application for approval. It may be in the interest of any pharmacist that receives an

invitation for comment to make sure other pharmacists in the area are informed and have the opportunity to comment.

Any comments must be made in writing to the Authority, should be substantiated, and should relate to the relevant criteria of the Rules, as the Authority is unable to consider issues that are not within the Rules.

Pharmacists should note that giving false or misleading information is a serious offence under Division 137 of the *Criminal Code 1995*, the maximum penalty for which is imprisonment for 12 months.

Once the Authority has made a recommendation in respect of an application, the Authority will write to any pharmacist that provided comments on that application to advise the outcome. It should be noted that, if an Authority recommendation is subsequently the subject of an appeal to the Administrative Appeals Tribunal (AAT) or a Federal Court, the Authority will only advise pharmacists who provided comment on the application of the appeal.

The details of any comments, including the pharmacist that made the comments, will not be disclosed to the applicant or any other party. However, it is important to note that if the Authority's recommendation is the subject of a review by the AAT or a Federal Court, then any comments provided on that application will be released to the applicant and the AAT or court. Further, any comments provided on an application may be required to be released under the *Freedom of Information Act 1982*.

11. Length of the application process

The Authority meets once a month to consider applications. It is important to note that there are application cut-off dates in respect of each Authority meeting (approximately five weeks prior to the meeting). Each meeting deals with a large number of applications and this timeframe allows for the Authority Secretariat to process the application, invite nearby pharmacists to comment on the application, and distribute the applications to Authority members prior to the meeting to allow for pre-assessment of applications. Formal consideration of each application at the meeting will precede the decision on a recommendation.

Pharmacists should contact the Authority Secretariat to find out relevant cut-off dates, or go to the Authority website (www.health.gov.au/ACPA). The Secretariat does not have any discretion to accept a late application, or additional information, received after the cut-off date for a particular meeting.

In considering an application, the Authority might find that certain information needs to be clarified, or that additional information is necessary. In this case, the Authority may defer making a recommendation on the application until a subsequent meeting and request, in writing, that the applicant or another party provide the requested information by a specified date.

If more than one application is received in respect of a particular area, the Authority will generally consider applications in the order in which they have been received by Medicare, and not at the same meeting. Also, the Authority will only consider the next application for a particular area once it has made a recommendation in respect of the first application for that area. This means that there might be a delay before a second application for a particular area is considered.

For these reasons, it is recommended that applicants allow sufficient time between the lodgement of their application and their proposed commencement date in case of any delays.

12. Requests for additional information by the Authority

Where the Authority defers making a recommendation on an application and requests that the applicant or another party provide further information in support of an application, the Authority will specify the date by which that information needs to be provided. In such circumstances, applicants should be aware that the late provision of information may result in the Authority further deferring its consideration of the application, or recommending rejection.

13. Provision of advice to applicants and nearby pharmacists regarding decisions of the Authority

The Authority generally meets on the last Friday of each month to consider applications to establish a new or relocate an existing pharmacy. This is subject to change and applicants should consult the website for meeting dates and application lodgement dates.

The following timeframes have been implemented in which the Secretariat endeavours to advise Medicare, applicants and nearby pharmacists of decisions made by the Authority following a meeting.

These timeframes are intended to ensure consistency and accuracy of information and procedural fairness for all parties, and may vary depending on the number of applications considered at a meeting.

The next working day

The Secretary's delegate in Medicare will be provided with the decisions of the Authority where a recommendation to approve or not approve an application has been made.

Please note:

- If the recommendation by the Authority is to approve an application, the relevant delegate in Medicare will be responsible for granting the approval.
- The Secretariat does not write to applicants when the Authority has recommended an application be approved. Medicare will write to recommended applicants to advise of the decision and outline the requirements for obtaining approval.

Where the Authority recommends that an application not be approved, the application file will be retained by the Secretariat until the expiration of the period in which the applicant may request a statement of reasons for the Authority's decision or apply to the Administrative Appeals Tribunal for an independent review of the Authority's decision (see paragraphs 14 and 15).

Three working days after a meeting

If the Authority has deferred making a recommendation on an application, the Applicant will be advised of the additional information requested by the Authority.

Four to five working days after a meeting

If the Authority has recommended that an application not be approved, the Applicant will be advised of the decision and their rights of review.

Six working days after a meeting

Where the Authority has made a decision to either recommend or not recommend that an application be approved, any pharmacist(s) who provided comments to the Authority will be advised of the Authority's decision.

Please note:

- The Secretariat will not advise nearby pharmacists or their agents of the Authority's decisions before this time.
- Due to the secrecy provision of the *National Health Act 1953* the Secretariat is unable to provide information to a third party about the reasons for a decision, or any details relating to the applicant or the application.
- The Secretariat does not advise nearby pharmacists if a decision has been made to defer an application.

14. Reasons for decisions

The applicant may seek from the Authority a statement of reasons for a recommendation if they are adversely affected by the decision.

A request for a statement of reasons must be made, in writing, to the Authority within 28 days of the date of receiving notification of the Authority's recommendation. Upon receipt of a request, the Authority has 28 days in which to provide the statement of reasons to the person making the request.

15. Review of decisions***Administrative Appeals Tribunal***

Applicants may be entitled to seek a review by the Administrative Appeals Tribunal (AAT) in relation to an Authority recommendation.

An applicant seeking a review of an Authority recommendation has 28 days from the date of notification of the recommendation in which to seek a review of the decision.

If the applicant has requested a statement of reasons from the Authority outlining the reasons for the decision, they have 28 days from the date they receive the statement in which to seek a review of the decision.

There are fees associated with seeking a review. For further information please contact the AAT in your relevant State or Territory. It is also recommended that independent legal advice be sought before proceeding.

Federal Court

Third parties who believe that they are aggrieved by a decision of the Authority may be entitled to request a statement of reasons from the Authority outlining the reasons for the decision, and / or to seek a review of the decision by the Federal Court.

There are timeframes that apply in which a statement of reasons may be requested or a review of the decision by the Federal Court sought. There are also fees associated with seeking a review. For further information please contact the Federal Court in the relevant State or Territory. It is also recommended that independent legal advice be sought before proceeding.

Ministerial discretion to approve

Under subsection 90A(2) of the Act the Minister for Health and Ageing has a discretionary power to approve a pharmacist to supply pharmaceutical benefits at particular premises. This discretionary power is only available in certain circumstances and is intended to address any unintended consequences of the Rules.

This is not an alternative to applying for approval under section 90 of the Act, and may only be sought after an application has been considered by the Authority and rejected by the delegate in Medicare.

For information about this discretionary power, please refer to the guidelines issued by the Minister. For a copy of these guidelines, contact the Department on (02) 6289 2425 or visit the Department of Health and Ageing's website at www.health.gov.au/ministerialdiscretion-pharmacy.

16. Obtaining approval after a recommendation by the Authority

A recommendation from the Authority for approval does not constitute an approval. The applicant must still obtain final approval from the Secretary. Medicare is responsible for the issuing and cancellation of approvals, and all other matters associated with approval numbers.

THE PHARMACY LOCATION RULES

The Rules are divided into two general types – those for the relocation of an existing pharmacy and those for the establishment of a new pharmacy.

Relocating an existing pharmacy

An existing pharmacy approval is required to relocate a pharmacy under these Rules. A pharmacist will need to relocate either their own approval or, by agreement, another pharmacist's approval.

An existing pharmacy is 'relocated' by cancelling the existing approval for the purpose of having another approval granted in respect of another site. An application to relocate an existing pharmacy must, therefore, demonstrate that either the applicant or another pharmacist has requested that their approval be cancelled before the approval under consideration is granted.

There are several provisions in the Rules for relocating an existing pharmacy approval:

- Rule 121: Expansion or contraction (not usually referred to the Authority)
- Rule 122: Relocation within a facility (small or large shopping centre, private hospital or large medical centre)
- Rule 123: Relocation within the same town (10 km)
- Rule 124: Short distance relocation (1 km)
- Rule 125: Short distance relocation (more than 1 km)*
- Rule 126: Long distance relocation*
- Rule 127: Relocation to a population growth area*

***Note:** Applications under Rules 125, 126 and 127 must be lodged with and registered by Medicare no later than 15 April 2012.

A pharmacist seeking to relocate an existing pharmacy approval must decide which rule is most appropriate to their circumstances.

Establishing a new pharmacy

An existing pharmacy approval is not required in order to obtain a new approval. There are a number of provisions in the Rules for establishing a new approved pharmacy:

- Rule 130: New pharmacy (at least 1.5 km)
- Rule 131: New pharmacy (at least 10 km)
- Rule 132: New additional pharmacy (at least 10 km)
- Rule 133: New pharmacy in a facility (small shopping centre)
- Rule 134: New pharmacy in a facility (large shopping centre)
- Rule 135: New pharmacy in a facility (private hospital)
- Rule 136: New pharmacy in a facility (large medical centre)

General requirements for all applications

Schedule 2 of the Rules sets out the general requirements that every application must meet, regardless of whether the application involves the cancellation of an existing approval or not. Every application for approval, whether it is for the establishment of a new pharmacy or the relocation of an existing pharmacy, must satisfy each of the general requirements.

This section explains the general requirements which all applications must satisfy.

Identification of particular premises

The Authority is required to have a clear understanding of the location of the proposed premises. Therefore, it is important to ensure that the proposed premises are clearly identified and accurately described, including full details of specific street names, numbers and suburbs as well as any relevant shop, floor, suite or lot numbers. A floor plan of the proposed premises should be provided, clearly identifying the required details.

Evidence of legal right to occupy the proposed premises

Schedule 2, Item 211(a) of the Rules requires that the Authority be satisfied that:

The applicant had, on the day the application was made, and has, on the day the Authority makes a recommendation in relation to the application, a legal right to occupy the proposed premises on or after the day the application was made.

To support this requirement, the application must include evidence which demonstrates that the applicant has a legal right to occupy the proposed premises on the date the application is lodged, and on the date on which the Authority makes a recommendation in respect of the application. Such evidence may include a lease or agreement to lease, which includes agreed terms, a commencement date, and which has been executed (signed) and dated by both the lessor and lessee. Please note that providing a copy of an unsigned lease or agreement to lease is not sufficient to demonstrate legal right.

If more than one pharmacist is making the application, evidence must be provided to demonstrate that the legal right is applicable to all applicants, that is, that the lease or agreement to lease includes all applicants named in the application.

Leasing premises

If the proposed premises are to be leased by the applicant, the application should include a complete copy of the fully executed lease. Alternatively, other evidence may be sufficient provided that it demonstrates that agreement has been reached between the lessee and lessor on the terms and conditions of the lease and which has been signed by both parties to indicate offer and acceptance.

Sub-leasing premises

In the case of a sub-lease, evidence is also required to demonstrate that the sub-lease is permitted under the terms of the head lease.

Purchasing premises

If the proposed premises are owned or are being purchased by the applicant, the application should include a copy of the title deed and or relevant sales contract including any conditions to which it may be subject.

Leasing or purchasing premises in a company name

If the applicant is leasing or buying the proposed premises in the name of a company, evidence must be provided to link the applicant(s) to that company, for example, a copy of an Australian Securities and Investments Commission (ASIC) record that indicates that the applicant(s) is/are director(s) of that company. If there are other directors of the company who are not applicants, evidence must be provided to demonstrate that the other directors agree to the applicant making an application in the name of the company.

Evidence of council approval to use the proposed premises for the purposes of operating a pharmacy

Schedule 2, Item 211(b) of the Rules requires that the Authority be satisfied that:

The proposed premises, on the day that application was made and on the day the Authority makes a recommendation in relation to the application:

- (i) could be used for the operation of a pharmacy under applicable local government and State or Territory laws relating to land development; and***
- (ii) would be accessible by members of the public at large.***

In support of this requirement, the application must include evidence to demonstrate that the proposed premises can be used for the purposes of operating a pharmacy which is accessible by members of the public at large. That is, that the relevant government authority, such as the local council, permits a pharmacy to operate at the proposed premises.

This requirement would be satisfied if planning approval for the proposed pharmacy has been obtained or, if this is not necessary in the State or Territory where the pharmacy would be located, the proposed premises are on land that is zoned to enable the operation of a pharmacy. An application to obtain building works approval or a certificate of occupancy, or similar, is not required to satisfy this requirement. However, it may be needed for compliance with requirement below (*Proposed premises will be ready to trade within six months*) depending on the operation of applicable State or Territory land development laws.

The type of evidence required will vary depending on the location of the proposed premises and the requirements of the particular local council. Some examples include:

- Evidence that planning approval for a pharmacy to operate at the proposed premises has been obtained, such as a decision notice approving a development application to vary or change the use of the proposed premises for the purpose of operating a pharmacy. (Please note that the lodgement of a development application on which a decision has not yet been made is not sufficient evidence to satisfy this Item.)
- If planning approval is not necessary, evidence that the land is suitably zoned to allow the operation of a pharmacy. This may include a letter from the local council confirming that the proposed premises are able to be used for the purpose of operating a pharmacy without the need for a development application, or print outs from the relevant council website of the Property Planning Report for the proposed premises, including all relevant schedules to the Report.
- Evidence that the relevant government authority has approved the site for a mix of retail shops and services that includes a pharmacy where the proposed premises are located within a shopping centre.

It is important that applicants ensure that the address details on the evidence being provided correspond to the address nominated as the proposed premises on the application for approval to supply pharmaceutical benefits. If the proposed premises are known as more than one address, evidence must be provided to demonstrate that this is the case.

Please note that approval by the landlord within the lease to operate a pharmacy is not sufficient evidence to support this Item.

Evidence is also required to demonstrate that the proposed premises will be accessible by members of the public at large, not just certain classes of the public. For example, the local council may approve premises for the purpose of operating a medical centre and ancillary dispensary, with a restriction that the dispensary can only be used by patients of the medical centre. This would not satisfy the requirements of the Rules as it does not support the purpose of the Pharmaceutical Benefits Scheme, which is to ensure that pharmaceutical benefits are available to the Australian community at large and not restricted to certain members of the public.

Proposed premises will be ready to trade within six months of a recommendation being made by the Authority

Schedule 2, Item 211(c) of the Rules requires that the Authority be satisfied that:

Within 6 months after the day on which the Authority makes a recommendation in relation to the application, the applicant will be able to begin operating a pharmacy at the proposed premises.

An application must demonstrate that the applicant will be ready to begin operating a pharmacy at the proposed premises within six months of the date the Authority makes its recommendation. The intention of this provision is to improve timely access to the supply of pharmaceutical benefits by ensuring that pharmaceutical benefits will be supplied to the relevant community within six months of the Authority recommending approval of an applicant. It is also intended to prevent applications being made prematurely.

Evidence addressing this requirement may include:

- plans that have already been approved by the relevant local council;
- a building or fit-out schedule that indicates works will be completed by a certain date;
- photographs demonstrating that the proposed premises are already established and need little work in order to be made ready. Please note that the date the photograph was taken should be included on the photo.

Proposed premises are not accessible from a supermarket

Schedule 2, Item 211(d) of the Rules requires that the Authority be satisfied that:

The proposed premises are not directly accessible by the public from within a supermarket.

The explanatory statement to the Rules defines a supermarket as a retail store or market, the primary business of which is the sale of a range of food, beverages, groceries and other domestic goods. Reference to a range of food, beverages, groceries and domestic goods means that it is the type of store in which a person could do their weekly shopping from fresh food (e.g. dairy, meat, bread), pantry items, cleaning products, personal care items and other household staples (e.g. laundry pegs, plastic food wrap). Reference to the primary business means that the definition would not expand to a department or variety store that has a deli or café section, nor does it include a farmer's market selling a range of produce.

Evidence to address this requirement may include a plan of the proposed premises and any adjacent or joining shops, which highlights the public access points to the proposed pharmacy and information about the type of adjacent or joining shops.

Proposed premises are not approved premises at the date of registration of application

Schedule 2, Item 212 of the Rules requires that the Authority be satisfied that:

On the day on which the application is made, the proposed premises are not approved premises.

The Authority must be satisfied that on the day the application is registered, the proposed premises are not approved premises. The meaning of approved premises includes premises:

a) in relation to which an approval granted under section 90 of the Act is in force (this, in most cases, includes deactivated approvals);

or

b) in relation to which the Authority has recommended an applicant be approved under section 90 of the Act.

APPLICATIONS INVOLVING THE RELOCATION OF AN EXISTING PHARMACY

This part of the Handbook sets out the requirements that must be met for all applications to relocate an existing pharmacy, including the types of evidence which might be provided to demonstrate that the requirements are met, and any restrictions associated with an approval granted under each rule.

Schedule 1, Part 1 of the Rules outlines the requirements that apply to each of the Rules under which an application may be made for the relocation of an existing pharmacy:

- Rule 121: Expansion or contraction (not usually referred to the Authority)
- Rule 122: Relocation within a facility (small or large shopping centre or private hospital or large medical centre)
- Rule 123: Relocation within the same town (10 km)
- Rule 124: Short distance relocation (1 km)
- Rule 125: Short distance relocation (more than 1 km)*
- Rule 126: Long distance relocation*
- Rule 127: Relocation to a population growth area*

***Note:** Applications under Rules 125, 126 and 127 must be lodged with and registered by Medicare no later than 15 April 2012.

It also outlines the requirements that apply to all applications to relocate an existing pharmacy. It provides that the Authority must be satisfied:

- That an approved pharmacist has requested that his or her approval be cancelled immediately before approval in respect of the subject application is granted;
- and
- That, on the day the application is made, one or more approvals in respect of the existing premises, have been in force continuously for at least two years immediately before the day the application is made.

Where an approval is located within a facility or in a town where the pharmacy is at least 10 km from the nearest approved premises, the approval is taken to have been in force continuously from the time it is first granted in that facility or town, regardless of any subsequent relocation within that facility or town. This means that the two year time period that normally recommences after each relocation, will continue for as long as the approval remains in that facility or town.

If the approval has been in force for a continuous period of less than two years, an application must provide evidence to demonstrate that the circumstances meets one of the exceptions specified in the Rules.

The exceptions are described below:

- The proposed premises are located within the same facility in which the existing premises are located; or

- The existing premises are the only approved premises in a particular town and the proposed premises are located within the same town as the existing premises; or
- The purpose of the application is to relocate the existing approval while the existing premises are being renovated or refurbished; or
- The proposed premises are renovated or refurbished premises that are substantially the same premises that were previously occupied by the pharmacy at the existing premises (operated by the applicant or the previous owner of the pharmacy); or
- The application is the result of exceptional circumstances caused, for example, by fire or flood; or
- The existing approval was granted following an application for an expansion or contraction of the premises and the existing and previous approvals have been in force continuously for a total of at least two years; or
- The application is for the expansion or contraction of approved premises and the application has been referred to the Authority.

Schedule 3, Part 2 of the Rules specifies the restrictions that apply to certain applications to relocate an existing approval. It is important to note that the restrictions under previous Rules continue to apply for the period specified in the restriction. For example, an approval granted as the result of an application made under Rule 113 of the previous Rules can not relocate to premises located more than 1.5 km in a straight line from the premises in respect of which the approval was originally granted, for a period of 5 years.

Rule 121: Expansion or contraction

The Secretary has the power to approve or reject applications for an expansion or contraction in the size of a pharmacy, without a recommendation by the Authority. However, the Secretary has the discretion to refer such an application to the Authority if he/she considers it should be assessed against the Rules. For example, the Secretary may refer an application to the Authority if he/she is not satisfied that the expanded or contracted premises will not be directly accessible from within a supermarket.

Requirements

An application for an expansion or contraction must meet all of the requirements listed below.

- 1. The application is for an expansion or contraction of pharmacy premises, in which the proposed premises will occupy any of the space occupied by the existing premises.**

Evidence required

A floor plan highlighting the existing premises and the premises to be occupied following the expansion or contraction of the pharmacy must be provided.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application, as well as the existing premises. Evidence must also be provided in support of each of requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- On the date of the application, the proposed premises are not approved premises. (Note: Where there is a physical difference between the proposed expanded or contracted premises and the existing approved premises, the proposed premises are not deemed to be the approved premises for the purpose of this Rule.)

The evidence required for the above is outlined under 'General Requirements for all applications' on page 14.

Note:

An expansion or contraction of pharmacy premises is described in subsection 90(3AE) of the Act. It applies where an existing pharmacy is expanding or contracting its premises, and the expanded or contracted premises occupy any of the space occupied by the existing pharmacy premises. This does not include proposed and existing premises that share only a common wall - this would constitute a relocation (see Rule 122 or 124).

Rule 122: Relocation within a facility

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

- 1. The existing premises are situated within a facility* and the proposed premises are in the same facility as the existing premises.**

** Please refer to the Glossary for the definition of 'facility'.*

Evidence required

Evidence is required to demonstrate that both premises are located within a facility. Such evidence could include a floor plan of the facility, clearly marking the location of the existing and the proposed premises, and a statutory declaration from the centre management of the shopping centre, or manager of the private hospital or large medical centre, confirming that the facility meets the definition of a facility.

If the existing and proposed premises are located within a private hospital and an applicant is unsure as to whether the private hospital meets the required definition, they should contact the governing Authority of the hospital for advice.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Rule 123: Relocation within the same town (10 km)

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

- 1. The proposed premises are situated in the same town as the existing premises.**

Evidence required

A map highlighting the location of the existing premises and the proposed premises is required to demonstrate that both premises are located within the same town.

- 2. The proposed premises are at least 10 km, by shortest lawful access route, from the nearest approved pharmacy, other than the existing premises.**

Evidence required

The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by average persons travelling that route. It can be by car, walking, or other legal means of travel, or a combination of these. The route can include walking through public land such as parks and reserves, however the route must be one available to most members of the public rather than one catering to persons or groups with specialised needs.

The route must take into consideration relevant factors such as traffic conditions, safety, proximity to solid objects and general common sense, for example, whether the route is prone to flooding.

The measurement of the shortest lawful access route must follow the shortest lawful access route between the two premises, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 10 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate shortest lawful access route distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the shortest lawful access route distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the shortest lawful access route distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and

- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for applications*' on page 14.

Rule 124: Short distance relocation (1 km)

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

1. The proposed premises are no more than 1 km, by straight line, from the existing premises.

Evidence required

The Rules specify that the straight line distance must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door of either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the existing premises and the proposed premises is substantially less than 1 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the existing premises and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

2. Either:

a) The existing premises are not in a facility;

or

b) The existing premises are in a facility and the proposed premises are at least 500m, in a straight line, from all approved premises not located in the facility.

Evidence required

- a) If the existing premises are not in a facility (see glossary for definition of 'facility') evidence must be provided to demonstrate that this is the case.

This may include a photograph of the existing and adjoining premises, or a letter from the manager / owner of the building in which the premises are located, confirming that the premises are not located within a facility as defined in the Rules.

- b) If the existing premises are within a facility, evidence that the proposed premises are at least 500m, by straight line, from all other approved pharmacies other than those located within that facility.

Please refer to the evidence required for requirement 1 (above). If the distance separating the approved premises not located within the facility, and the proposed premises is substantially more than 500m, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis, or using web based map and measuring tools. However, if the distance is near to 500m, a surveyor's report should be provided (see 1 above).

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket;
- An approval has been in force at the existing premises continuously for at least two years or the application is of the type set out in the prescribed exceptions; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

Applicants wishing to relocate an existing approval that was originally granted under a Rule associated with a new rural approval under the previous Rules, or a new pharmacy (at least 10 km) under the current Rules must demonstrate that the proposed premises are within the same town in which the approval was originally granted.

Applicants wishing to relocate an existing approval that was originally granted under a current Rule associated with a small shopping centre, large shopping centre, private hospital or large medical centre, must satisfy the Authority that there are exceptional circumstances if the proposed premises are not located within the same facility in which the approval was originally granted.

Restrictions also apply to an existing approved pharmacy in a small shopping centre, large shopping centre, private hospital or large medical centre if the approval was originally granted as the result of an application under Rule 109, 110, 111 or 112 of previous Rules in place from 1 July 2006 to 17 October 2011.

Applicants wishing to relocate an existing approval that was originally granted under the previous Rules associated with a new approval (urban locality) or new approval (general) within the five years prior to the date of application, may only relocate to proposed premises that are not more than 1.5 km, by straight line, from those original premises.

Rule 125: Short distance relocation (more than 1 km)

The provisions of this Rule will expire on 16 April 2012. Therefore applicants wishing to lodge an application under this Rule must do so before this date. Please refer to page 8 for information on 'Receipt of an application'.

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

1. The application was lodged with and registered by Medicare no later than 15 April 2012.

Evidence required

The date the application is registered by Medicare as a complete application is the date that the Authority considers the application to be made.

2. The proposed premises are more than 1 km but not more than 1.5 km, in a straight line, from the existing premises.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the existing premises and the proposed premises is substantially less than 1.5 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the existing premises and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

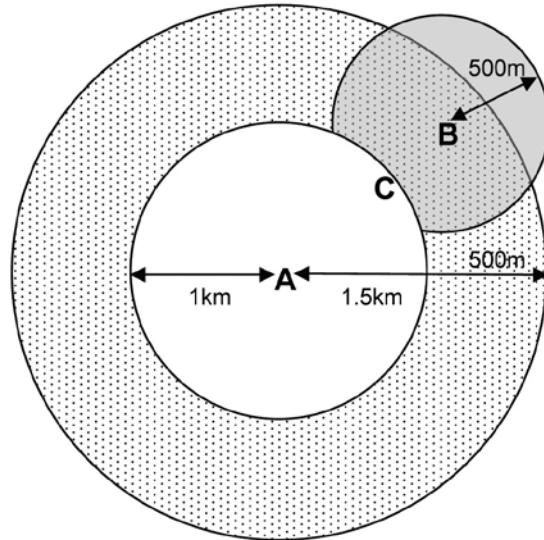
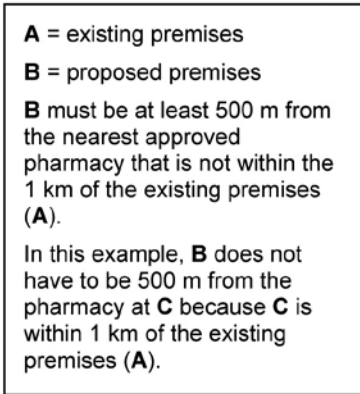
3. Either

- a) **If the existing premises are not in a private hospital or large shopping centre, then the proposed premises must be at least 500m, by straight line, from all other approved pharmacies other than approved premises that are no more than 1 km, in a straight line, from the existing premises (see figure 1).**

or

- b) If the existing premises are in a private hospital or large shopping centre, then the proposed premises must be at least 500m, in a straight line, from all approved premises other than approved premises in the private hospital or large shopping centre.

Figure 1



Evidence required

Please refer to the evidence required for requirement 2 (above).

4. The Authority is satisfied that, before 18 October 2011, the applicant had a legal right to occupy the proposed premises on or after 18 October 2011.

Evidence required

Refer to the 'General Requirements for all applications' section on page 14 for information on the types of evidence that may demonstrate an applicant's legal right to proposed premises.

In addition to providing evidence to demonstrate an applicant's legal right to the proposed premises, an applicant must provide evidence to demonstrate that the legal right was established before 18 October 2011.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket;

- An approval has been in force at the existing premises continuously for at least two years or the application is of the type set out in the prescribed exceptions; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Rule 126: Long distance relocation

The provisions of this Rule will expire on 16 April 2012. Therefore applicants wishing to lodge an application under this Rule must do so before this date. Please refer to page 8 for information on 'Receipt of an application'.

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

1. The application was lodged with and registered by Medicare no later than 15 April 2012.

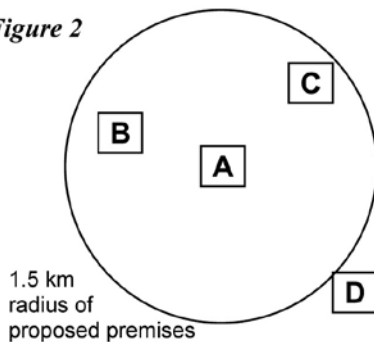
Evidence required

The date the application is registered by Medicare as a complete application is the date that the Authority considers the application to be made.

2. The proposed premises are:

- a) at least 1.5 km, in a straight line, from the nearest approved pharmacy;
- or
- b) If paragraph a) does not apply, at least 2 km, by the shortest lawful access route, from each approved pharmacy that is within 1.5 km, in a straight line, from the proposed premises (see Figure 2).

Figure 2



In this diagram, **A** is the proposed premises.

B, **C** and **D** are other approved pharmacies in the area.

B and **C** are within 1.5 km (straight line) of **A**, and must therefore be at least 2 km (by shortest lawful access route) of **A**.

D is already more than 1.5 km (straight line) from **A**.

Evidence required

Straight line measurement

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 1.5 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

Shortest lawful access route measurement

The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by average persons travelling that route. It can be by car, walking, or other legal means of travel, or a combination of these. The route can include walking through public land such as parks and reserves, however the route must be one available to most members of the public rather than one catering to persons or groups with specialised needs.

The route must take into consideration relevant factors such as traffic conditions, safety, proximity to solid objects and general common sense, for example, whether the route is prone to flooding.

The measurement of the shortest lawful access route must follow the shortest lawful access route between the two premises, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 2 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate shortest lawful access route distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the shortest lawful access route distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the shortest lawful access route distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

3. The Authority is satisfied that, before 18 October 2011, the applicant had a legal right to occupy the proposed premises on or after 18 October 2011.

Evidence required

Refer to the '*General Requirements for all applications*' section on page 14 for information on the types of evidence that may demonstrate an applicant's legal right to proposed premises.

In addition to providing evidence to demonstrate an applicant's legal right to the proposed premises, an applicant must provide evidence to demonstrate that the legal right was established before 18 October 2011.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket;
- An approval has been in force at the existing premises continuously for at least two years or the application is of the type set out in the prescribed exceptions; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Rule 127: Relocation to a population growth area

The provisions of this Rule will expire on 16 April 2012. Therefore applicants wishing to lodge an application under this Rule must do so before this date. Please refer to page 8 for information on 'Receipt of an application'.

Requirements

An application made under this Rule must meet all of the requirements, including all of the general requirements, listed below.

1. The application was lodged with and registered by Medicare no later than 15 April 2012.

Evidence required

The date the application is registered by Medicare as a complete application is the date that the Authority considers the application to be made.

2. The proposed premises are at least 500m, in a straight line, from the nearest approved pharmacy.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 500m, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

3(a)(i). The Authority is satisfied that the resident population of the catchment area for the proposed premises is, for most of the year, at least 8,000.

Evidence required

In determining a catchment area, the Authority must be satisfied that it is likely that a

significant number of residents from within the claimed catchment area will naturally and reasonably gravitate or flow to the proposed premises.

In considering a catchment area, the Authority will take into account matters such as traffic flows, proximity to other services, attractions and existing pharmacies, geographical features, and any natural barriers.

It is important to note that the Authority must be satisfied that features claimed as part of the catchment area are present, rather than features that are proposed for the future, for example, new housing developments not yet built or a proposed new shopping centre or medical centre.

Evidence provided in support of a claimed catchment area should include:

- a single scaled A3 map of the proposed catchment area, clearly showing the road networks and which has superimposed the ABS Census Collection Districts (CCDs) or ABS Mesh Blocks and associated population figures. In addition, the proposed premises, existing pharmacies including those not within the claimed catchment area, medical practitioner(s), and other relevant services, facilities and attractions such as shopping facilities, should be clearly marked and labelled on the map; and
- a discussion as to why a significant number of residents within the claimed catchment area would naturally and reasonably gravitate or flow towards the proposed premises, taking into account the following factors:
 - natural flow of the population and any natural barriers which may influence this;
 - distribution of the population and any unique characteristics of the population;
 - the location of services, attractions, medical practitioners and other pharmacies in the catchment area which might target the population from a larger region; and
 - access to existing pharmacies and to the proposed premises, including road networks and public transport.

All maps provided should be of a sufficient scale to enable clear identification of any relevant features. The source of the map must also be cited.

The population of the catchment area must be residential as opposed to workforce, and must be present for most of the year.

In considering whether population is present for 'most of the year' the Authority may consider a range of factors. For example, increases in population during holiday seasons and periods of the year where annual shows or festivals are held, would not be considered residential population.

Data provided in relation to resident population must be from an objective and reliable source, such as the Australian Bureau of Statistics, government or local council reports or publications, or market research reports prepared by professional accredited persons.

3(a)(ii). The Authority is satisfied that the population of the catchment area for the proposed premises has grown by at least 5% in each of the 2 years before the day on which the application was made.

Evidence required

The Authority must be satisfied that the population of the relevant catchment area has grown at least 5% over each of the past two years immediately preceding the date of the application. This requirement is not limited to a financial or calendar year, but rather applies to any two consecutive 12 month periods.

The growth rate is not be used as an average and the population must have grown by at least 5% for both years. For example, if an application is made in January 2012, the Authority must be satisfied that the population of the relevant catchment area grew by at least 5% in 2011 and grew by at least 5% in 2010.

Any data provided relating to population growth should be from an objective source, for example, the Australian Bureau of Statistics, local or other Government reports or publications, or market research reports prepared by professionally accredited persons

3(b). The Authority is satisfied that the catchment area for the proposed premises contains only one approved pharmacy.

Evidence required

In providing the map required at 3(a) above, all existing pharmacies both within and surrounding the proposed catchment area must be clearly marked.

3(c). The Authority is satisfied that the applicant had, before 18 October 2011, a legal right to occupy the proposed premises on or after 18 October 2011.

Evidence required

Refer to the 'General Requirements for all applications' on page 14 for information on the types of evidence that may demonstrate an applicant's legal right to proposed premises.

In addition to providing evidence to demonstrate an applicant's legal right to the proposed premises, an applicant must provide evidence to demonstrate that the legal right was established before 18 October 2011.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket;
- An approval has been in force at the existing premises continuously for at least two years or the application is of the type set out in the prescribed exceptions; and
- On the date of the application, the proposed premises are not approved premises.

The evidence required for the requirements above is outlined under 'General Requirements for all applications' on page 14.

APPLICATIONS TO ESTABLISH A NEW PHARMACY

Schedule 1, Part 2 of the Rules sets out the requirements that must be met for all applications to establish a new pharmacy, including the types of evidence which might be provided to demonstrate that the requirements are met, and any restrictions associated with an approval granted under each Rule.

Schedule 2 of the Rules outlines the requirements that apply to all applications to establish a new pharmacy.

A pharmacist does not require an existing pharmacy approval in order to obtain a new approval.

There are a number of provisions in the Rules for establishing a new approval:

- Rule 130: New pharmacy (at least 1.5 km)
- Rule 131: New pharmacy (at least 10 km)
- Rule 132: New additional pharmacy (at least 10 km)
- Rule 133: New pharmacy in a facility (small shopping centre)
- Rule 134: New pharmacy in a facility (large shopping centre)
- Rule 135: New pharmacy in a facility (private hospital)
- Rule 136: New pharmacy in a facility (large medical centre)

Rule 130: New pharmacy (at least 1.5 km)

Requirements

1. The proposed premises are at least 1.5 km, by straight line, from the nearest approved pharmacy.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken. If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 1.5 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

2. The Authority is satisfied that, at all relevant times[#] there is:

- (a) Within 500m, in a straight line from the proposed premises:
 - i. at least one full time* prescribing medical practitioner; and
 - ii. a supermarket with a gross leasable area* of at least 1000m²;

or

- (b) within 500m, in a straight line, from the proposed premises a supermarket with a gross leasable area* of at least 2500m².

[#] For this item, all relevant times means:

- (a) on the day on which the application was made, being the day the application was registered by Medicare; and
- (b) on the day on which the application is considered by the Authority.

* Please refer to the Glossary for the definition of 'full-time', and 'gross leasable area'.

Evidence required

When claiming that a full-time prescribing medical practitioner and a supermarket with a gross

leasable area of at least 1000m² is within 500m, in a straight line from the proposed premises, evidence must be provided, which could include:

- a statement or statutory declaration from the relevant medical practitioner or practice manager stating the hours the medical practitioner(s) is available for appointments and for the issuing of prescriptions for pharmaceutical benefits, in addition to a practice information sheet and provider number(s) for the medical practitioner(s); and
- a clearly scaled map highlighting the location of the proposed premises and that of the medical practitioner's premises and / or supermarket and a statement of the distance between the premises using the scale on the map as the basis.

When claiming that a supermarket with a gross leasable area of at least 2500m² is within 500m, in a straight line from the proposed premises, evidence must be provided which could include:

- a floor plan of the supermarket demonstrating the gross leasable area and a statutory declaration from the manager of the supermarket confirming the gross leasable area of the supermarket based on the definition within the Rules, that is, not including loading docks.

As outlined in requirement 1 above, the Rules specify that the straight line measurement must be taken from the midpoint at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance between the proposed premises and the medical practitioner's premises and/or supermarket is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance as outlined in requirement 1 above.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

To ensure that new approvals that are granted to address community need remain in that area of need, an approval granted following an application made under Rule 130 must stay within a 1 km radius of the premises in respect of which the approval was originally granted, for a period of 5 years.

Rule 131: New pharmacy (at least 10 km)

Requirements

1. The proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved pharmacy.

Evidence required

The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by average persons travelling that route. It can be by car, walking, or other legal means of travel, or a combination of these. The route can include walking through public land such as parks and reserves, however the route must be one available to most members of the public rather than one catering to persons or groups with specialised needs.

The route must take into consideration relevant factors such as traffic conditions, safety, proximity to solid objects and general common sense, for example, whether the route is prone to flooding.

The measurement of the shortest lawful access route must follow the shortest lawful access route between the two premises, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 10 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate shortest lawful access route distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the shortest lawful access route distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the shortest lawful access route distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;

- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the requirements above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 131 can not under any circumstances relocate from the town in which the approval was originally granted. It may only be relocated within the same town.

Rule 132: New additional pharmacy (at least 10 km)

Requirements

1(a). The proposed premises are located in the same town as an approved pharmacy.

Evidence required

A map highlighting the location of the existing premises and the proposed premises is required to demonstrate that both premises are located within the same town.

1(b). The proposed premises are located at least 200m, in a straight line, from the nearest approved pharmacy.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 200m, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

1(c). The proposed premises are at least 10 km, by the shortest lawful access route, from the second nearest approved pharmacy.

Evidence required

The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by average persons travelling that route. It can be by car, walking, or other legal means of travel, or a combination of these. The route can include walking through public land such as parks and reserves, however, the route must be one available to most members of the public rather than one catering to persons or groups with specialised needs.

The route must take into consideration relevant factors such as traffic conditions, safety, proximity to solid objects and general common sense, for example, whether the route is prone to flooding.

The measurement of the shortest lawful access route must follow the shortest lawful access route between the two premises, from the centre, at ground level, of the public entrance of the first premises to the centre, at ground level, of the public entrance of the second premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 10 km, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate shortest lawful access route distance using the scale on the map as the basis, or using web based map and measuring tools.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the shortest lawful access route distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the shortest lawful access route distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

2. The Authority is satisfied that, at all relevant times[#], within the same town as the existing approved premises and the proposed premises, there are at least the equivalent of four full time* prescribing medical practitioners* practising and one, or a maximum of two, supermarkets with a combined total gross leasable area* of at least 2,500m².

For this item, all relevant times means:

(a) on the day on which the application was made, being the day the application was registered by Medicare; and

(b) the day on which the application is considered by the Authority.

** Please refer to the Glossary for the definition of 'full-time', 'prescribing medical practitioner' and 'gross leasable area'.*

Evidence required

Evidence must be provided to demonstrate that at least the equivalent of four full-time prescribing medical practitioners are practising within the same town as the proposed premises. This could include:

- a statutory declaration from the relevant medical practitioners or practice manager regarding the hours the medical practitioners are available for appointments and for the issuing of prescriptions for pharmaceutical benefits, in addition to a practice information sheet and provider numbers for the medical practitioners;
- a floor plan of the supermarket demonstrating the gross leasable area and a statutory

declaration from the manager of the supermarket confirming the gross leasable area of the supermarket based on the definition within the Rules, that is, not including loading docks; and

- a clearly scaled map highlighting the location of the proposed premises and that of the medical practitioner's premises and / or supermarket(s) and a statement of the distance between the premises using the scale on the map as the basis.

The Authority will not be satisfied if a medical practitioner lives in the relevant town but operates their medical practice outside that town. The medical practitioner must be practising in the same town as the proposed premises.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the requirements above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 132 must stay within the same town in which the approval was originally granted.

Rule 133: New pharmacy in a facility (small shopping centre)

Requirements

1. The proposed premises are in a small shopping centre*.

* Please refer to the Glossary for the definition of 'small shopping centre'.

Evidence required

A floor plan of the shopping centre should be provided in addition to a statutory declaration from the shopping centre manager to confirm that the centre meets the definition of a small shopping centre and the numbers and types of commercial establishments within the centre, including the leasing status of each commercial establishment.

In considering an application to establish a pharmacy in a small shopping centre, the Authority need not be satisfied that the requisite number of commercial establishments are operating within that centre. Rather, the Authority must be satisfied that the centre is, or is likely to be, occupied by the requisite number of commercial establishments. In considering this, the Authority will have some discretion and may consider matters such as, how much progress has been made on fitting out the relevant premises and how soon the commercial establishments will begin operating.

2. The proposed premises are at least 500m, in a straight line, from the nearest approved pharmacy.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 500m, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

3. There are no approved pharmacies in the small shopping centre.

Evidence required

The statutory declaration from the shopping centre manager should include information to confirm whether there are any other pharmacies within the centre.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 133 must stay within the same shopping centre for a period of 10 years, unless there are exceptional circumstances. The pharmacy can move within the same shopping centre at any time (please note that an application is still required to be made to the Authority – see Rule 122).

Rule 134: New pharmacy in a facility (large shopping centre)

Requirements

An application made under this Rule must meet all of the requirements listed below.

1. The proposed premises are in a large shopping centre*.

- * Please refer to the Glossary for the definition of 'large shopping centre', 'gross leasable area', 'single management' and 'commercial establishment'.

Evidence required

A floor plan of the shopping centre should be provided in addition to a statutory declaration from the shopping centre manager to confirm that the centre meets the definition of a large shopping centre and the numbers and types of commercial establishments within the centre, including the leasing status of each commercial establishment.

In considering an application to establish a pharmacy in a large shopping centre, the Authority need not be satisfied that the requisite number of commercial establishments are operating within that centre. Rather, the Authority must be satisfied that the centre is, or is likely to be, occupied by the requisite number of commercial establishments. In considering this, the Authority will have some discretion and may consider matters such as, how much progress has been made on fitting out the relevant premises and how soon the commercial establishments will begin operating.

2. There are:

- (a) for a shopping centre that contains at least 50, but less than 100, commercial establishments – no approved pharmacies in the shopping centre; or
- (b) for a shopping centre that contains at least 100, but fewer than 200, commercial establishments – no more than one approved pharmacy in the shopping centre; or
- (c) for a shopping centre that contains at least 200 commercial establishments – no more than two approved pharmacies in the shopping centre.

- * Please refer to the Glossary for definition of 'commercial establishment'.

Evidence required

Depending on whether the application is for the 1st, 2nd or 3rd pharmacy in a large shopping centre, an application must demonstrate one of the following:

- (a) the centre does not contain an approved pharmacy; or
- (b) if the centre contains no more than one approved pharmacy, there are at least 100 other commercial establishments in the centre (including the proposed premises); or
- (c) if the centre contains no more than two approved pharmacies, there are at least 200 other commercial establishments in the centre (including the proposed premises).

The statutory declaration from the shopping centre manager should include information to confirm the number of pharmacies within the centre.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the requirements above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 134 must stay within the same shopping centre for a period of 10 years, unless there are exceptional circumstances. The pharmacy can move within the same shopping centre at any time (please note that an application is still required to be made to the Authority – see Rule 122).

Rule 135: New pharmacy in a facility (private hospital)

Requirements

An application made under this rule must meet all of the requirements listed below.

1. The proposed premises are in a private hospital*.

* Please refer to the Glossary for the definition of 'private hospital'.

Evidence required

Applicants should provide a letter from the management of the private hospital to confirm that it meets the definition of 'private hospital' as defined in the glossary. A floor plan of the private hospital clearly identifying the location of the proposed premises should be provided.

2. There are no approved pharmacies in the private hospital.

Evidence required

The letter from the management of the private hospital should also confirm whether there is a pharmacy currently located within the private hospital.

3. The hospital authority for the private hospital is not approved under section 94 of the Act.

Evidence required

The letter from the management of the private hospital should confirm whether the private hospital contains a pharmacy approved under section 94 of the Act.

4. The private hospital is registered or licenced, under the law of the State or Territory in which the private hospital is located:

- (a) to contain at least 150 beds to provide health services to patients;
- or
- (b) to treat, accommodate or lodge at least 150 patients at any one time.

Evidence required

The letter from the management of the private hospital should confirm:

- the number of beds that the hospital is registered or licenced to contain to provide health services to patients;
- or
- the number of patients that the hospital is registered or licenced to treat, accommodate or lodge at any one time.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 135 must stay within the same private hospital, unless there are exceptional circumstances. The pharmacy can move within the same private hospital at any time (please note that an application is still required to be made to the Authority – see Rule 122).

Rule 136: New pharmacy in a facility (large medical centre)

Requirements

An application made under this rule must meet all of the requirements listed below.

1. The proposed premises are in a large medical centre.

* Please refer to the Glossary for the definition of 'large medical centre'.

Evidence required

Applicants should provide a letter from the practice manager of the medical centre to confirm that it meets the definition of 'large medical centre' as defined in the glossary. A floor plan of the medical centre clearly identifying the location of the proposed premises should be provided.

2. There are no approved pharmacies in the large medical centre.

Evidence required

The letter from the practice manager should also confirm whether there is a pharmacy currently located within the medical centre.

3. The proposed premises are at least 500m, in a straight line, from the nearest approved pharmacy other than an approved pharmacy in a small shopping centre, a large shopping centre or a private hospital.

Evidence required

The Rules specify that the straight line measurement must be taken from the mid point at ground level of the public access door of each of the premises. If there is more than one public access door for either or both of the premises, the measurement must be taken from the public access door nearest to the other premises, that is, the shortest measurement that can be taken.

If the distance separating the nearest approved pharmacy and the proposed premises is substantially greater than 500m, it may be sufficient to provide a scaled map, highlighting the two premises and the approximate straight line distance using the scale on the map as the basis.

If the distance between the nearest approved pharmacy and the proposed premises is very near to the required distance, applicants should provide a surveyor's report of the measurement of the straight line distance. Any surveyor's report should include:

- a clearly scaled map;
- a description of the methodology and equipment used in the measurement;
- the straight line distance measured;
- the margin for error in the measurement;
- detailed information about the public access doors to each of the premises; and
- confirmation that the measurement has been undertaken from the mid point at ground level of the public access door of each of the premises.

- 4. The Authority is satisfied that at all relevant times[#] the number of PBS prescribers* at the medical centre is equivalent to at least 8 full-time* PBS prescribers, of which at least 7 PBS prescribers must be prescribing medical practitioners*.**

For this item, all relevant times means:

- (c) on the day on which the application was made, being the day the application was registered by Medicare; and*
- (d) at all times during the 2 months before the day on which the application was made; and*
- (c) at all times during the 2 months before the day on which the application is considered by the Authority.*

** Please refer to the Glossary for the definition of 'full-time', 'PBS prescriber', and 'prescribing medical practitioner'.*

Evidence required

Evidence to be provided could include a statutory declaration from the practice manager of the medical centre confirming the hours the medical centre operates and the hours that each PBS prescriber practises, copies of any advertisements regarding the hours the medical centre operates, and a practice information sheet.

- 5. The Authority is satisfied that the applicant will make all reasonable attempts to ensure that the operating hours of the proposed premises will meet the needs of the patients of the medical centre.**

Evidence required

Evidence addressing this requirement might include evidence of an agreement between the applicant and the management of the medical centre which indicates that the proposed pharmacy's hours will largely reflect those of the medical centre, or that the applicant will endeavour to open the pharmacy outside of normal hours if there is sufficient need.

General requirements

Please note that it is important to clearly identify the proposed premises that are the subject of an application. Evidence must also be provided in support of each of the requirements below:

- The applicant has a legal right to occupy the proposed premises;
- The proposed premises can be used for the purpose of operating a pharmacy which would be accessible by members of the public at large;
- The applicant will be ready to operate a pharmacy at the proposed premises within six months;
- The proposed premises are not directly accessible by the public from within a supermarket; and
- The proposed premises are not approved premises on the date of the application.

The evidence required for the above is outlined under '*General Requirements for all applications*' on page 14.

Restrictions

New approvals that are granted following an application made under Rule 136 must stay within the same large medical centre, unless there are exceptional circumstances. The pharmacy can move within the same large medical centre at any time (please note that an application is still required to be made to the Authority – see Rule 122).

GLOSSARY

Act	<i>National Health Act 1953</i>
approved premises	<ul style="list-style-type: none"> (a) premises in relation to which an approval granted under section 90 of the Act is in force, and which are not redundant (see redundant premises); or (b) premises in relation to which the Authority has recommended an applicant be approved under section 90 of the Act
Authority	Australian Community Pharmacy Authority
commercial establishment	<p>premises:</p> <ul style="list-style-type: none"> (a) in a shopping centre; and (b) occupied or likely to be occupied by: <ul style="list-style-type: none"> (i) a shop where goods, food or beverages are sold retail; or (ii) a bar, café, restaurant or takeaway; or (iii) a business that provides services to customers (1) commercial establishment does not include: <ul style="list-style-type: none"> (a) commercial office space; or (b) premises occupied by an accountant, analyst, architect, engineer, lawyer, planner, stockbroker or surveyor, unless the premises are occupied by a shopfront; or (c) premises occupied by a real estate agent or an insurance company, agent or broker, unless the premises are occupied as a shopfront for the real estate agent or insurance company; or (d) a council office or government or statutory corporation office or shopfront, other than an Australia Post shopfront, an Australian Broadcasting Corporation shop or a Medicare or Centrelink shopfront; or (e) a car wash or car parking facilities; or (f) a library; or (g) a kindergarten or preschool; or (h) a child care centre or child minding facility, unless the centre or facility is regularly available for use by customers of the shopping centre while the customers are shopping at the centre; or

	<ul style="list-style-type: none"> (i) a storeroom or storage area; or (j) a temporary selling point; or (k) an automatic teller machine or automatic dispensing machine <p>In working out the number of commercial establishments in a shopping centre:</p> <ul style="list-style-type: none"> (a) 2 or more commercial establishments occupied by, or likely to be occupied by, one business are counted as one commercial establishment; and (b) the maximum number of shopfronts for accountants, analysts, architects, engineers, lawyers, planners, stockbrokers or surveyors that can be counted towards the total number of commercial establishments in a shopping centre is: <ul style="list-style-type: none"> (i) for a small shopping centre – one; or (ii) for a large shopping centre – two
facility	a small or large shopping centre, a large medical centre, or a private hospital
full-time	<ul style="list-style-type: none"> (a) for a prescribing medical practitioner, providing the service of a prescribing medical practitioner for at least 38 hours each week (b) for a PBS prescriber, providing the services of a PBS prescriber for at least 38 hours each week
gross leasable area	for a shopping centre – the total floor area of the shopping centre excluding loading docks and car parks; and for a supermarket – the total floor area of the supermarket excluding loading docks
large medical centre	a medical centre that: <ul style="list-style-type: none"> (a) is under single management; and (b) operates for at least 70 hours a week; and (c) has one or more prescribing medical practitioners at the centre for at least 70 hours per week
large shopping centre	a shopping centre that: <ul style="list-style-type: none"> (a) has a gross leasable area of at least 5000m²; and (b) contains a supermarket occupying a gross leasable area of at least 1000m²; and (c) contains at least 50 other commercial establishments; and (d) has customer parking facilities
PBS prescriber	a medical practitioner, or a participating dental practitioner, or an authorised optometrist, or an authorised midwife, or an authorised nurse practitioner

pharmacy	has the meaning given by subsection 90 (3AB) of the Act – a business in the course of the carrying on of which pharmaceutical benefits are supplied
Pharmacy Location Rules	<i>National Health (Australian Community Pharmacy Authority Rules) Determination 2011</i>
prescribing medical practitioner	a medical practitioner who provides general practice services to the community in which he or she practises, including the issuing of prescriptions for pharmaceutical benefits
private hospital	has the same meaning as in the <i>Health Insurance Act 1973</i> : “(a) premises that were, immediately before 1 October 1986, a private hospital (within the meaning of this section as in force at that time), other than premises in respect of which a declaration under subsection 23EA(2) is in force; and (b) premises in respect of which a declaration under subsection 23EA(1) is in force.”
proposed premises	the premises at which an applicant proposes to supply pharmaceutical benefits
redundant premises	Premises to which all of the following apply: (a) the premises are existing premises in relation to an application; (b) the Authority has recommended that the applicant who made the application be approved under section 90 of the Act in relation to the proposed premises; (c) the pharmacist approved in relation to the existing premises has requested, in writing, that if the applicant is to be approved in relation to the proposed premises, the existing approval will be cancelled immediately before the approval in relation to the proposed premises is granted; (d) the pharmacist approved in relation to the existing premises has ceased to carry on business as a pharmacist at the approved premises; (e) the Secretary; i. is aware of the cessation and of the reason for it; ii. has agreed to cancel the existing approval only in accordance with a request of the kind mentioned in paragraph (c)
same town	proposed premises are taken to be in the same town as approved or existing premises if they are located in the same town and postcode as the approved or existing premises

<p>single management</p>	<p>for a shopping centre or medical centre:</p> <ul style="list-style-type: none"> (a) means the management of the centre as a whole: <ul style="list-style-type: none"> (i) by one manager, or by two or more managers working cooperatively under an agreement; and (ii) to encourage use of the centre as a single integrated facility; and (iii) including management of the following matters for the centre: <ul style="list-style-type: none"> (A) security; (B) pedestrian and vehicular access; (C) cleaning; (D) signage; (E) trading hours; (F) marketing; (G) maintenance of buildings, common areas and utilities; and (b) does not include independent owners or tenants of premises of a building or centre that cooperate: <ul style="list-style-type: none"> (i) on particular occasions; or (ii) in relation to some but not all of the matters mentioned in subparagraph (a) (iii) in relation to the building or centre
<p>small shopping centre</p>	<p>a shopping centre that:</p> <ul style="list-style-type: none"> (a) has a gross leasable area of at least 5000m²; and (b) contains a supermarket occupying a gross leasable area of at least 2500m²; and (c) contains at least 15 other commercial establishments; and (d) has customer parking facilities
<p>supermarket</p>	<p>a retail store or market, the primary business of which is the sale of a range of food, beverages, groceries and other domestic goods</p>

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All information in this publication is correct as of September 2011