

## Amendment to Pharmacy Location Rules News of September 2016

Please be advised that it has been brought to our attention that there was some incomplete information contained in the recently published *Pharmacy Location Rules News, September 2016*. This was in reference to the description of a **Medical practitioner** on page 2 of the communique.

The following description replaces that description:

The term **medical practitioner**, as it appears in the Rules, means a person registered or licensed as a medical practitioner under a State or Territory law, and does not include a person whose registration or license has been suspended or cancelled. It is distinct from the term **prescribing medical practitioner**, which is defined in the Rules to mean 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. Not all **medical practitioners** will be **prescribing medical practitioners** for the purposes of the Rules.

In calculating the number of **prescribing medical practitioners** practising at a medical centre, the hours worked by other prescribers or providers of services that are not included in the definition, such as specialists who are not providing general practice services to the community in which they practise, are not able to be included.

The Authority apologises for any confusion caused.

## Pharmacy Location Rules News

### September 2016

The following information is provided to assist applicants to prepare an application for the establishment of a new, or the relocation of an existing pharmacy approved to supply pharmaceutical benefits scheme (PBS) medicines under section 90 of the *National Health Act 1953* (the Act). In addition, it is strongly recommended that all potential applicants consult the Pharmacy Location Rules Applicant's Handbook before lodging an application.

### New pharmacy in a facility (large medical centre) applications

There continues to be some confusion regarding the evidence that is required to support an application to establish a new pharmacy in a facility (large medical centre), Rule 136. The following explains:

#### **Evidence that premises are approved for the purpose of operating a pharmacy and are accessible by the public (Item 211(c)(i) and (ii))**

One of the general requirements for all applications is that the proposed premises could be used for the operation of a pharmacy under applicable local government and State or Territory laws relating to land development, and that the premises would be accessible by the public. For large medical centre applications often there is insufficient evidence provided to demonstrate this requirement.

Large medical centre applications should provide evidence:

- a) that the land is suitably zoned to allow the operation of a pharmacy (such as 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
- b) showing 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).

When approving the development of a medical centre, it is not uncommon for the local government to approve an 'ancillary' pharmacy or dispensary. Often the local government intends that the 'ancillary' nature of the pharmacy or dispensary approval restricts the use of the pharmacy to patients of the medical centre. For this reason, it is also important for large medical centre applications to show that the local government has not placed any restrictions on who may access the pharmacy. Therefore, where evidence has been provided that identifies the pharmacy as an 'ancillary' pharmacy, details must also be provided to confirm the local government's definition of 'ancillary', and any access conditions that may restrict members of the public accessing the proposed premises.

The approval by the landlord within the lease to operate a pharmacy is not sufficient evidence to support this requirement. Neither is referring the ACPA to a website for information on local government zoning.

#### **Evidence that the proposed premises are in a large medical centre (Item 136(1))**

The ACPA must be satisfied that the proposed premises are in a large medical centre. Section 5 of the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011* (PB 65 of 2011) defines a **large medical centre** as one that: is under single management; operates for at least 70 hours each week; and has one or more prescribing medical practitioners at the centre for at least 70 hours each week.

A statutory declaration (made on a Commonwealth of Australia statutory declaration template<sup>1</sup>) from the manager or owner of the medical centre to confirm the medical centre is under single management; operates for at least 70 hours each week; and has one or more prescribing medical practitioners at the centre for at least 70 hours each week should be provided. In relation to single management, this statutory declaration should not just state that the medical centre is under single management, it should also explain why the medical centre is under single management, in line with the definition of single management defined in PB 65 of 2011.

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<sup>1</sup> As an application for pharmacy approval is made to a Commonwealth Department, statutory declarations should be made on a Commonwealth of Australia statutory declaration template, and signed in the presence of an authorised witness. Information on Commonwealth statutory declarations, including templates and information on authorised witnesses, is available at [www.ag.gov.au](http://www.ag.gov.au)

### **Evidence that supports the number of PBS prescribers at the medical centre**

Many applicants are failing to address the requirements of Item 136(4). Item 136(4) requires that the ACPA must be satisfied that, for the two months prior to the day the application is made, and for the two months prior to the day ACPA considers the application, there must be at least eight full-time PBS prescribers, of which at least seven must be prescribing medical practitioners (i.e. general practitioners) practising at the medical centre.

The Explanatory Statement to PB 65 of 2011 defines “full-time” and “the equivalent of”, “PBS prescriber” and “medical practitioner” as follows:

**Full-time PBS prescriber** (including medical practitioner) means providing the services of a PBS prescriber for at least 38 hours each week. For example, for a medical practitioner, time spent consulting with patients at their home or in hospital is included when calculating the hours that a medical practitioner practises at a medical centre. Time spent consulting at other medical centres, working at a hospital (rostered duties), attending nursing homes and undertaking administration work for the medical centre/practice, such as staff rosters, is not counted towards the time spent practising at the medical centre/practice.

The **equivalent of a full-time PBS prescriber** means any number of PBS prescribers who provide the equivalent services of one full-time PBS prescriber. For example, if one part-time PBS prescriber practises 20 hours each week and another practises 18 hours each week, then they will be considered the equivalent to one full-time PBS prescriber as their combined practice hours equal 38 hours. Similarly, if one PBS prescriber practises 57 hours each week then they are considered the equivalent to one and a half full-time PBS prescribers.

**The Rules do not require that there be eight full-time PBS prescribers practising at the one time for Item 136(4) to be met.**

**PBS prescriber** means a medical practitioner or a participating dental practitioner, or an authorised optometrist, midwife or nurse practitioner.

**Medical practitioner** means a person registered or licensed as a medical practitioner under a State or Territory law, and does not include a person whose registration or license has been suspended or cancelled. For the purposes of the Rules, the requirements associated with a medical practitioner require that the medical practitioner provides general practice services in the relevant community and issues prescriptions for pharmaceutical benefits.

In calculating the number of PBS prescribers practising at a medical centre, the hours worked by other prescribers or providers of services that are not included in the definition of “PBS prescriber”, such as specialists, are not able to be included.

To address this requirement, the following evidence is required at the time the section 90 application is made:

- a) a statutory declaration (made on a Commonwealth of Australia statutory declaration template) from the owner or practice manager of the medical centre confirming the hours the medical centre operates and the hours that each PBS prescriber practices;
- b) copies of any advertisements regarding the hours the medical centre operates;
- c) a practice information sheet; and
- d) rosters from the medical centre for the two months prior to the day the application is made.

In addition, the ACPA also requests that evidence be provided to demonstrate the Australian Health Practitioner Regulation Agency registration status of the PBS prescribers at the medical centre. That is whether the PBS prescribers are general practitioners or specialists, and any restrictions such as supervision requirements.

If supervision requirements exist, details also should be provided on what type of supervision is required and by whom this supervision is being undertaken. Depending on the level of supervision required, and if the supervision is undertaken by another PBS prescriber at the medical centre, the hours spent supervising may not be able to be attributed to the supervising medical practitioners hours.

In addition to the evidence that is required when submitting an application for a new pharmacy in a medical centre, prior to the ACPA meeting in which the application will be considered, the ACPA Secretariat will contact the medical centre requesting rosters that cover the period from the day the application was made until the day the application is to be considered by the ACPA. At this time, the medical centre should only provide the requested rosters and not any additional information to support the application. If any additional information is provided by the medical centre it will not be reviewed by the ACPA when it considers the application.

When providing medical centre rosters, the actual times (start and finish times) and total number of hours worked by each PBS prescriber for each and every week must be provided. Rosters must also factor in any breaks the PBS prescriber has and must not include time spent consulting at other medical centres, working at a hospital (rostered duties), attending nursing homes and undertaking administration work for the medical centre/practice, such as staff rosters, as they do not count towards the time spent practising at the medical centre/practice.

## Short distance relocation (1 km) applications

One of the requirements of the short distance relocation Rule 124 is that the ACPA be satisfied that either the existing (current) premises are not in a facility (Item 124(2)(a)) or that if the existing (current) premises are in a facility, that the proposed (new) premises are at least 500 m, by straight line, from all approved premises not located in that same facility (Item 124(2)(b)).

Many applicants are failing to address this requirement, or are instead providing evidence of whether the proposed (new) premises are located in a facility or not.

A facility is defined as a small shopping centre, a large shopping centre, a large medical centre or a large private hospital, definitions of which are also included in PB 65 of 2011.

Please refer to the Handbook for further information on these requirements.

## Presentation of scaled map in support of distance requirements

The ACPA has observed that many of the scaled maps that are being provided as evidence in support of distance requirements do not have scales that are in proportion to the size of the map and therefore the distance shown on the map. This is predominantly evident in maps that have been generated from web based mapping tools such as Google Maps and Google Earth.

Please be aware that the ACPA will generally not rely on evidence of measurements provided by web based mapping tools only. It is preferable that a clearly scaled map, highlighting the location and addresses of the relevant premises is provided. The scaled map should clearly identify and label the relevant premises, and include a statement of the distance between all of the relevant premises. The scale should also be clearly shown on the map and correctly reflect the scale of the map. It is preferable that symbols be used to identify locations rather than colour.

If the distance between the relevant premises is near to the required distance, applicants should provide a report from a licensed or registered surveyor. 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 or each of the premises.

## Provision of additional information

Many applicants are submitting additional information in support of their application after the application has been lodged and referred to the ACPA.

PB 65 of 2011 allows that the ACPA may only consider information provided by an applicant if:

- a) the information was given at the time the application was made; or
- b) the ACPA requested the information.

Where an applicant provides additional information and the information was not requested by the ACPA, it will not be considered by the ACPA when assessing the application.

## Meeting dates for 2017

The ACPA meeting dates for 2017 and the corresponding application lodgement timeframes for complete applications to be received by the Department of Human Services are outlined in the table below. Please note these dates are subject to change and any updates will be published on the website at [www.health.gov.au/acpa](http://www.health.gov.au/acpa).

ACPA Meeting date	Timeframe to lodge an Application with the Department of Human Services	
	From	To
Friday		
20 January 2017	Tuesday 8 November 2016	Monday 12 December 2016
24 February 2017	Tuesday 13 December 2016	Monday 23 January 2017
31 March 2017	Tuesday 24 January 2017	Monday 27 February 2017
5 May 2017	Tuesday 28 February 2017	Monday 3 April 2017
9 June 2017	Tuesday 4 April 2017	Monday 8 May 2017
14 July 2017	Tuesday 9 May 2017	Tuesday 13 June 2017
18 August 2017	Wednesday 14 June 2017	Monday 17 July 2017
22 September 2017	Tuesday 18 July 2017	Monday 21 August 2017
27 October 2017	Tuesday 22 August 2017	Tuesday 26 September 2017
8 December 2017	Wednesday 27 September 2017	Monday 6 November 2017
19 January 2018	Tuesday 7 November 2017	Monday 11 December 2017

Note: Application lodgement timeframes are to ensure that the Department of Human Services and the ACPA Secretariat have sufficient time to process and register applications, undertake consultation with third parties and for the ACPA to give proper consideration of applications.