

Pharmacy Insights

Pharmacy Location Rules - understanding the process for PBS approval in large medical centres

Seeking to establish a new PBS approved pharmacy in a large medical centre is made less complex by partnering with an experienced pharmacy lawyer. The PBS approval process is multifaceted and requires a number of key requirements to be met to satisfy *Pharmacy Location Rules*.

In this article we explore the process of obtaining PBS approval and outline the important factors pharmacists need to consider.

PBS Approval

Section 90 of the National Health Act 1953 (Cth) (**Section 90**) provides the basis for a pharmacist to apply for an approval to supply pharmaceutical benefits from particular premises (**PBS Approval**).

The PBS Approval is attributed to the particular pharmacist at those particular premises, and cannot be transferred or relocated without further approvals being given.

The Pharmacy Location Rules (Location Rules) set out precise requirements that must be satisfied before a pharmacy can be approved for the first time under *Section 90*. The body tasked with considering applications for new PBS approvals is the Australian Community Pharmacy Authority (**ACPA**).

Item 136 of the Location Rules governs the requirements for the approval of a new PBS pharmacy in a large medical centre.

Specific requirements of *Item 136* include:

- (a) the proposed premises are in a large medical centre
- (b) there are no approved premises already in the large medical centre
- (c) the ACPA be satisfied that, during the two months before the day on which the application is made and until the day the application is considered by the Authority, the number of PBS prescribers at the medical centre is equivalent to at least eight full-time PBS prescribers, of which at least seven PBS prescribers must be prescribing medical practitioners; and
- (d) the ACPA be 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

There are also requirements regarding the distance between the proposed premises and the nearest existing PBS approved pharmacy.

There are a range of other, detailed requirements which must be met before the ACPA can approve an application. These include the requirement that the applicant must already have a legal right to occupy the proposed premises on the day the application is lodged, and on the date on which the ACPA makes a recommendation in the application.

Leasing

The lease, sublease or agreement to lease must contain agreed terms, contain a commencement date, and must be signed and dated by the lessor and the lessee.

Some pharmacists take a lease or sublease of the proposed premises in a new medical centre and open a private pharmacy while the medical centre builds up the number of PBS prescribers in the centre.

Others choose not to open a private pharmacy, but hold the lease (or agreement to lease) on low or no rent terms until such time as the number of PBS prescribers builds up to the numbers required to make the application.

Consideration should be given as to whether the lease should contain a right for the parties to terminate in the event that the necessary approvals to open the new PBS pharmacy are not granted by an agreed longstop date.

Rigorous attention to detail

The very high level of detail in the *Location Rules*, and the fact that nearby PBS approved pharmacists will be given an opportunity to provide comment on the application, means that it is no small task to apply successfully for a new PBS approval under *Item 136*.

It is essential that the evidence provided to the ACPA is of the highest quality, and that it complies with their requirements in all respects. Attention to detail is key, and pharmacists may wish to seek legal advice on the evidence that is required, and how the various pieces of evidence can best be obtained and presented to the ACPA.

This article was written by Principal [Georgina Odell](#). For further assistance with pharmacy ownership, including buying and selling a pharmacy, please contact Georgina (NSW/QLD) or Principal [Mark Fitzgerald \(VIC/ SA\)](#).



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Further information

In addition to advising on retail leasing and *Pharmacy Location Rule* issues, our team of [pharmacy lawyers](#) regularly advise clients on buying and selling a pharmacy. We also provide advice about their obligations in employing and managing staff, franchising, privacy, obtaining finance, partnership arrangements, and dispute resolution.

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