

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

National Health Act 1953

National Health (Australian Community Pharmacy Authority Rules) Determination 2018

This legislative instrument determines the pharmacy location rules against which most applications made by pharmacists under section 90 of the *National Health Act 1953* (the Act) must comply. It also revokes the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011* (No. PB 65 of 2011).

Section 90 of the Act provides that the Secretary may, upon application by a pharmacist, approve that pharmacist to supply pharmaceutical benefits at particular premises.

Subsection 90(3A) of the Act determines the types of applications, made by a pharmacist under section 90 of the Act, that must be referred to the Australian Community Pharmacy Authority (the Authority) and considered against the requirements of the pharmacy location rules (the Rules).

The legislation supporting the operation of the Rules is contained in Division 4B, Part VII of the Act. Division 4B provides for the establishment of the Authority and its functions, and that the Minister must determine the rules against which applications, to be approved to supply pharmaceutical benefits under section 90 of the Act, must comply.

The function of the Authority is to consider applications by pharmacists for approval to supply pharmaceutical benefits at particular premises and to make recommendations to the Secretary as to whether or not such applications should be approved. In making its recommendations, the Authority must comply with the Rules determined by the Minister under section 99L in Division 4B, Part VII of the Act.

The Rules relate to the establishment of a new pharmacy and the relocation of an existing pharmacy. The Rules describe the circumstances in which the Authority must recommend that a pharmacist be approved under section 90 of the Act in respect of particular premises. The Authority must not recommend approval if all of the relevant criteria in the Rules are not met.

Applications for approval under section 90 of the Act for a change of pharmacy ownership or to expand or contract the size of pharmacy premises can be approved by the Secretary without referral to the Authority, therefore these kinds of applications are not subject to the Rules.

However, the Secretary may, at his or her discretion, refer an application for an expansion or contraction of pharmacy premises to the Authority for its recommendation (for example, if an expansion of pharmacy premises is likely to result in a pharmacy being directly accessible from within a supermarket, the Secretary may consider it necessary for the Rules to be applied).

The Secretary may only approve a pharmacist to supply pharmaceutical benefits at particular premises if the Authority has recommended that approval.

This Determination comes into effect on 3 October 2018 and will apply to the consideration, by the Authority, of an application made on or after that date.

The structure of the determination is at Attachment A. An explanation of the content of the determination is at Attachment B.

This Determination is a legislative instrument for the purpose of the *Legislation Act 2003*.

Consultation

The Department of Health (the Department) has consulted on the proposed changes with the Pharmacy Guild of Australia (the Guild), the peak body that represents the interests of community pharmacy proprietors. The Guild has endorsed the changes proposed. The Department of Human Services, responsible for the administration of the Pharmaceutical Benefits Scheme program on behalf of the Department, has been made aware of the proposed changes.

From the time this Determination is signed by the Minister to when it commences on 3 October 2018, pharmacists are being advised about the new determination and the application process. This is being done through letters sent to representatives of pharmacists and stakeholder organisations; pharmacy journal articles; the Guild's communication channels and the Department's website.

Structure of Determination No. PB 46 of 2018

Part 1: sets out the provisions that deal with the name of the Determination and its commencement, interpretation of key terms such as meaning of approved premises, meaning of commercial establishment, measurement of distances between premises and in what circumstances the Authority may consider information provided by an applicant pharmacist after an application is made.

Part 2: sets out the circumstance in which the Authority must recommend that an applicant be approved and the circumstances in which the Authority must recommend that an applicant not be approved.

Part 3: sets out the provisions that deal with the revocation of the current determination made under subsection 99L and transitional arrangements.

Schedule 1: sets out the different kinds of applications and the requirements that must be met for each kind of application.

- Part 1 sets out the kinds of applications that involve the cancellation of an existing approval (that is, an expansion or contraction of approved premises or relocation to new premises); and
- Part 2 sets out the kinds of applications that do not involve the cancellation of an existing approval (that is, a new approval at particular premises).

Schedule 2: sets out additional requirements that must be met by applications that involve the cancellation of an existing approval (otherwise known as relocation of an existing approval).

- Part 1 sets out the requirements that involve the cancellation of an existing approval and apply to every application of this kind; and
- Part 2 sets out additional requirements that apply to certain kinds of relocation applications.

Details of the NATIONAL HEALTH (AUSTRALIAN COMMUNITY PHARMACY AUTHORITY RULES) DETERMINATION No. PB 46 of 2018

PART 1 – PRELIMINARY

Part 1 of the Determination sets out provisions that deal with the names of the Determination, its commencement and interpretation of key terms.

1. Name of Determination

Subsection 1(1) provides that the name of the Determination is the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018*.

Subsection 1(2) provides that the Determination may also be referred to as Determination No. PB 46 of 2018.

2. Commencement

Section 2 provides that the Determination will commence on 3 October 2018.

3. Authority

Section 3 provides the legislative basis that the instrument is made, that is section 99L of the Act.

4. Schedules

Section 4 provides for the instrument listed in Schedule 3 to be amended or repealed.

5. Definitions

Section 5 defines the common terms used in the Determination. Some examples are set out below:

Note 1 is included to assist readers to understand that a number of terms used have the same meaning as the terms are defined in the Act.

Note 2 is included to assist readers to understand that certain terms have the same meaning as the terms are defined in other legislation, as well as the reference to the relevant provisions.

“designated complex” means a small shopping centre, a large shopping centre, a large medical centre or a large private hospital.

“full-time” for a prescribing medical practitioner (or PBS prescriber), is intended to mean practising 38 hours in a calendar week. If one part-time medical practitioner practises 20 hours a week and another practises 18 hours a week, then they are considered equivalent to one full-time medical practitioner (i.e. combined they practice 38 hours). Similarly, if one medical practitioner practises 57 hours a week, then they are considered equal to one and a half full-time medical practitioners.

“gross leasable area” for a group of shops and associated facilities, is intended to mean the total floor area of the group and includes space occupied by the centre management, information desk, toilets and baby change rooms, ATMs, as well as entertainment and leisure facilities (e.g. cinema), but does not include loading docks and carparks.

For a supermarket, is intended to mean the total floor area of the supermarket and includes space approved by council (or relevant development authority) to conduct a supermarket business, including supermarket trading floor area and minimal back of house (typically no more than 25-30% of the total floor area). It does not include portable storage units, such as shipping containers, used for the purpose of storing supermarket items; or separate tenancies rented by the supermarket proprietors to store supermarket items, unless those tenancies are approved for the purpose of operating a supermarket business.

Evidence of total Gross Leasable Area should be sourced from Council (or relevant approval authority), or other public document such as retail strategies, activity centre strategies prepared by local governments or state government departments; or from subscriber or proprietary databases.

“large medical centre” is intended to mean a medical centre that is open to the public extended hours for the purpose of providing general practice consultations to patients by a medical practitioner.

It provides that one or more medical practitioners be at the medical centre providing general practice consultations to patients for no less than 70 hours each week that the medical centre is open to the public.

Any time that a medical practitioner is not providing general practice consultations at the medical centre, or is not available to provide routine general practice consultations at the medical centre (e.g. performing administrative duties), is not included in the time that the medical practitioner is at the medical centre. Also, any time that a medical practitioner is “on-call” or only available for “urgent” consultations, regardless of whether such consultations are general practice in nature, is not included in the time that the medical practitioner is at the medical centre.

“large private hospital” is intended to mean a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007*, that the hospital is a private hospital, provided the hospital is capable of admitting at least 150 patients at any one time. “Admit” is intended to mean where a patient is admitted to hospital for treatment as a private patient and includes same-day admitted patients, as well as overnight admitted patients. That is, not patients attending the hospital for general treatment as outpatients.

“large shopping centre” is intended to mean a group of shops and associated facilities within a building or building complex which is retail based. A large shopping centre is typically anchored by one or more supermarket tenants as well as department store/s and operates seven days a week, attracting significant and regular custom from the broad community.

“same town” is intended to convey where two towns share the same name, as well as the same postcode. The name of a town, in respect of particular premises, means the physical locality of those premises assigned by the local planning authority/council. Two towns that are in close proximity to one another and share the same postcode, but not the same name, are not considered to be in the “same town”.

“single management” for a shopping centre or medical centre, is intended to mean where one or more managers are cooperatively managing the centre (under an agreement) as a whole, for

the purpose of encouraging the use of the centre as a single integrated centre. It would include managing such things as security, pedestrian and vehicular access, cleaning, signage, trading hours, marketing and maintenance of buildings, common areas and utilities, for the centre.

Single management does not include owners or tenants that cooperate only on particular occasions or only in relation to some (not all) of the matters described above. For example, a group of shop owners in a shopping arcade might only cooperatively promote the arcade over the Christmas shopping period or they may cooperatively manage the arrangements for cleaning and maintenance of the arcade, however, each owner individually manages the marketing and trading hours of their own shop. In these circumstances, the requirement of single management would not be met.

This means that if a medical centre has a web site, yellow pages advertisement and/or patient information sheet that list each of the medical practitioners, opening hours and contact details, then it is considered to be marketed as one medical centre. It also means that if the medical centre has a centralised system for patient appointments, if doctor's rosters are managed centrally and if cleaning and security contracts are managed centrally then it is considered to be administered as one medical centre.

Similarly, if a shopping centre has a web site, store directory and/or customer flyer that lists each of the shops and facilities available in the shopping centre, then it is considered to be marketed as one shopping centre. If a shopping centre has a centre manager responsible for building maintenance, cleaning and security contracts, as well as the opening hours for each of the tenants in the shopping centre, then the shopping centre is considered to be administered as one shopping centre.

“small shopping centre” is intended to mean a small group of shops and associated facilities within a building or building complex which is retail based. A small shopping centre is usually anchored by a supermarket tenant and operates at least five days a week, attracting custom from the local, as well as neighbouring, community.

“supermarket” is intended to mean a retail store, usually self-service, the primary business of which is the retail sale of a range of food, beverages, groceries and other domestic goods which can be purchased in a single transaction.

Where the primary business of the retail store is the sale of liquor or petrol, that retail store is not a supermarket.

Reference to a *range* of food, beverages, groceries and domestic goods means 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 extend to a convenience store, department or variety store that has a deli or café section, nor does it include a petrol station or market (retail/wholesale) selling a range of produce.

A liquor store may be included as part of a supermarket where items from the liquor store can be purchased along with items from the supermarket in a single transaction, or where a liquor aisle is contained within the supermarket footprint.

6. Meanings of *approved premises*

Subsection 6(1) provides that, unless premises are considered to be redundant under subsection (2), the Authority will treat any premises that are approved under section 90 and any premises in respect of which it has recommended approval, as approved premises.

That is, where the Authority has recommended a pharmacist be approved in respect of particular premises and a decision has not been made by the Secretary under section 90, those premises are considered approved premises. If the Secretary has made a decision under section 90 and that decision is to not approve the pharmacist, then those premises are not considered approved premises.

This means that where more than one application is received in respect of the same area, the first application recommended by the Authority will be treated as approved premises when the Authority considers the second application.

Subsection 6(2) provides the circumstances in which the Authority will regard premises to be redundant and therefore not treated as approved premises. It is intended to convey that where premises, approved under section 90, have ceased operating as a pharmacy and a recommendation has been made by the Authority for its relocation, then those premises are not treated as approved premises by the Authority.

Disregarding “redundant premises” ensures the community has reasonable access to pharmaceutical benefits if a pharmacist makes an application to open a pharmacy in an area that previously had a pharmacy. An approved pharmacist may cease supplying pharmaceutical benefits at approved premises (“redundant premises”) in preparation to relocate to new premises, with the agreement of the Secretary (or their delegate). If the redundant premises continued to be treated as approved premises it could cause delays in community access to pharmaceutical benefits in that particular area.

Note 1 is included to assist readers to understand that an approval under section 90 may also include an approval granted by the Minister using the discretionary power, under section 90A of the Act.

Note 2 is included to assist readers to understand that an approval under section 90 may also include other types of approvals treated as having been granted under section 90, for example where permission has been granted under subsection 91(7).

Subsection 6(3) provides the circumstances in which the Authority will not consider premises to be approved, despite it recommending approval.

This means that when the Authority is considering an application to establish a new additional pharmacy in a town under Item 132, or in a large shopping centre under Item 134, any pharmacist that has previously been recommended to relocate within that same town/large shopping centre (under item 122, 123 or 124), but is not yet approved, is not to be considered two approved premises (i.e. not double counted).

7. Meaning of *commercial establishment*

Section 7(1) describes the types of businesses which the term “commercial establishment” is intended to convey. That is, a retail shop, food outlet and other types of businesses providing retail services to customers (e.g. hairdresser, beautician, clothing alterations, optometrist,

medical centre or cinema). It is intended that the types of businesses attract customers to the shopping centre.

The term *likely to be occupied by* is intended to include premises in a shopping centre where a lease has been entered into to operate such a business and that business has not yet commenced operating at those premises.

A vacant tenancy at premises in a shopping centre that is not occupied and/or leased is not considered a “commercial establishment”.

Subsection 7(2) describes those types of businesses which the term “commercial establishment” does **not** include. For example, a child care centre or child minding facility is not considered a “commercial establishment” unless it is for the exclusive use of shoppers at the shopping centre, in which the proposed premises is located, for ad-hoc care or minding (i.e. it is not a long stay child care centre with permanent bookings).

A temporary selling point is intended to mean a seasonal type pop-up store with no permanent premises, for example a kiosk selling raffle tickets or calendars.

Subsection 7(3) provides how certain commercial establishments are counted in determining the number of commercial establishments in a shopping centre. It is intended that each commercial establishment operates independently of one another.

Paragraph (a) provides that multiple premises occupied (or likely to be occupied) by the same business are only counted as one commercial establishment.

Similarly, where more than one business activity is being conducted from the same premises, irrespective of whether the businesses are being conducted by the same or different business entity/ies, it is considered to be one “commercial establishment”. This can occur where a business operates another business under an agent type arrangement and items can be purchased from both businesses in a single transaction.

Alternatively, if council has approved the division of premises into two distinct and separate premises, operating independently of one another, they should be counted as two commercial establishments. *Independently* means where goods or services are unable to be purchased from each of the businesses in a single transaction.

Examples of how subsection 7(3)(a) operates:

- Premises in a shopping centre that are occupied (or are likely to be occupied) by a newsagency that includes a lotto agency, dry cleaning agency, or similar, within that newsagency, is considered to be one commercial establishment.
- Premises in a shopping centre that are occupied (or are likely to be occupied) by a medical centre, and a separate diagnostic imaging business operates under a separate lease with separate telephone numbers, staff and booking arrangements, is considered to be two commercial establishments.
- If a mobile phone business operates (or is likely to operate) from Shop 12 on the ground floor of a shopping centre, and the same business also operates (or is likely to operate) from Kiosk 2C on the 2nd floor, this will only be considered to be one commercial establishment.
- Alternatively, two separate coffee shops of the same company that are operated separately (by different franchisees) would be considered to operate independently and therefore be considered to be two commercial establishments.

Paragraph (b) provides that if premises in a shopping centre are occupied (or are likely to be occupied by) a shopfront for an accountant, analyst, architect, engineer, lawyer, planner, stockbroker or surveyor, the total number of these types of commercial establishments is limited to one for a small shopping centre and two for a large shopping centre.

8. Measurement of distance between premises

Section 8 describes how the distance between two premises is to be measured.

Subsection 8(1) describes that a straight line distance between two premises is to be measured from the mid-point at ground level of the centre of the public access door of each relevant premises.

Subsection 8(2) describes that a shortest lawful access route is the distance measured from the mid-point at ground level of the centre of the public access door, of each relevant premises. The shortest lawful access route is one generally available to be taken between premises that could reasonably be used by the average person travelling that route. It can be by car, walking or any other legal means of travel, or a combination of these. The route can include travelling through public land such as parks and reserves. It must be one available to the public and not a route catering to persons or groups with specialised needs.

Subsection 8(3) provides that if either (or both) of the premises has more than one public entrance, the distance is a reference to the shortest distance measurement in relation to the two premises.

9. Information to be considered by the Authority

Section 9 provides that the Authority may consider information provided in support of an application only if it was provided at the time the application was made, or, if the Authority has requested the information.

PART 2 – RECOMMENDATIONS BY THE AUTHORITY

Part 2 of the Determination sets out the circumstances in which the Authority must recommend that an applicant be approved, and the circumstances in which the Authority must recommend that an applicant not be approved.

10. When the Authority must recommend approval of applicant

Section 10 outlines the circumstances in which the Authority must recommend approval of an applicant in respect of particular premises.

Applications involving the cancellation of an existing approval - subsection 10(1) outlines the requirements for applications involving the cancellation of an existing approval. That is, a relocation of an existing approval. These items are:

Item 121 – *Expansion or contraction*

Item 122 – *Relocation within a designated complex*

Item 123 – *Relocation within the same town (10 km)*

Item 124 – *Relocation up to 1 km*

Item 125 – *Relocation of 1 to 1.5 km*

Applications not involving the cancellation of an existing approval - subsection 10(2) outlines the requirements for applications not involving the cancellation of an existing approval. That is, a new approval. These items are:

Item 130 – *New pharmacy (at least 1.5 km)*

Item 131 – *New pharmacy (at least 10 km)*

Item 132 – *New additional pharmacy (at least 10 km)*

Item 133 – *New pharmacy in a designated complex (small shopping centre)*

Item 134 – *New pharmacy in a designated complex (large shopping centre with no approved premises)*

Item 134A – *New additional pharmacy in a designated complex (large shopping centre with approved premises)*

Item 135 – *New pharmacy in a designated complex (large private hospital)*

Item 136 – *New pharmacy in a designated complex (large medical centre)*

General requirements – subsection 10(3) sets out the general requirements that every application must meet, regardless of whether the application involves the cancellation of an existing approval or not.

Proposed premises are not approved premises

Paragraph 10(3)(a) requires the Authority to be satisfied that on the day on which the application is made and on the day the Authority makes its decision, the proposed premises are not approved premises. *Approved premises* is defined in section 6.

Legal right to occupy proposed premises

Paragraph 10(3)(b) requires the Authority to be satisfied that the applicant had, on the day on which the application was made, and on the day on which the Authority makes its decision in respect of the application, a legal right to occupy the proposed premises. The commencement date to occupy the premises may be prior to the day the application is made or after that day. For example, if the applicant is leasing the proposed premises then the lease must have been

fully executed prior to the application being made, with the date of commencement of the lease being either before, on or after the day the Authority makes its decision in respect of the application. If the lease has expired prior to the day the Authority makes its decision, then the applicant may no longer have a legal right to occupy the proposed premises.

If there is more than one pharmacist making the application jointly, the Authority must be satisfied that the legal right applies to each of those pharmacists.

Proposed premises can be used as a pharmacy

Paragraph 10(3)(c) requires the Authority to be satisfied that, on the day the application is made and on the day on which the Authority makes its decision in respect of the application, the proposed premises could be used to operate a pharmacy under the applicable local government and State/Territory laws relating to land development.

This requirement would be satisfied if, for example, planning approval for the proposed pharmacy has been obtained or if this is not necessary under the local planning laws where the pharmacy would be located, then the proposed premises are on land that is zoned so as 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 (e), depending on the operation of applicable land development laws.

Proposed premises are accessible by the public

Paragraph 10(3)(d) requires the Authority to be satisfied that the proposed premises would be accessible by the public and not just certain classes of the public. For example, if the proposed premises are located in a medical centre, pharmaceutical benefits must be able to be supplied to all members of the public and not restricted to patients of the medical centre. *Accessible* in this context means that the proposed premises will be physically accessible and that there are no restrictions that would prevent access to the pharmacy premises by any member of the public. This supports the overall purpose of the Pharmaceutical Benefits Scheme, which is to ensure the Australian community has reasonable access to pharmaceutical benefits.

Applicant will begin operating a pharmacy at the proposed premises within six months

Paragraph 10(3)(e) requires the Authority to be satisfied that the applicant will be able to begin operating a pharmacy at the proposed premises within six months after the date the Authority makes its decision. 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.

Proposed premises are not accessible from within a supermarket

Paragraph 10(3)(f) requires the Authority to be satisfied that the proposed premises are not directly accessible by the public from within a supermarket. *Accessible* in this context means physically accessible, for example the public should not have direct access to the pharmacy from within the supermarket. That is, the pharmacy should not be located within the supermarket itself or have an entrance from the supermarket into the pharmacy.

Requirements relating to gross leasable area - subsection 10(4) requires the Authority to be satisfied that the gross leasable area is at least the minimum size required as it relates to a supermarket, a small shopping centre or a large shopping centre.

Note – the note is intended to assist readers to understand that evidence of gross leasable area should be from a plan approved as part of a development approval, a letter from a town planner or a copy of a registered lease for the supermarket/shopping centre. That is, draft plans that have not been approved by council are not sufficient evidence to support this requirement.

11. When the Authority must recommend applicant not be approved

Subsection 11(a) requires that the Authority must recommend that an applicant not be approved if an application does not meet the requirements specified in section 10, as it relates to the application.

Subsection 11(b) requires that the Authority must recommend that an applicant not be approved if the application is a relocation application specified in subsection 10(1) and the existing approval is the subject of a recommendation by the Authority that an applicant be approved. That is, an existing approval cannot be recommended for approval for relocation to more than one proposed premises concurrently.

PART 3 – APPLICATION, SAVING AND TRANSITIONAL PROVISIONS

Part 3 of the Determination sets out the saving and transitional provisions relating to the previous determination.

12. Saving provision relating to the repeal of the previous determination

Section 12 provides that the Determination that sets out the pharmacy location rules, as in force immediately before 3 October 2018 (Determination No. PB 65 of 2011), will apply to any application for approval made before 3 October 2018.

13. Transitional provision relating to the repeal of the previous determination

Section 13 provides the circumstances in which certain provisions in the pharmacy location rules, as in force immediately before 3 October 2018 (Determination No. PB 65 of 2011), will apply to any application for approval made before 3 April 2019 (i.e. 6 months after Determination No. PB 46 of 2018 commences).

Large shopping centre

Subsection 13(2) provides that if an application is made under item 134 or 134A and meets the transitional dates outlined in section 13, there is an opportunity (if relevant) to claim a gross leasable area of at least 1,000 m² for a supermarket, instead of a gross leasable area of at least 2,500 m².

Applications involving the cancellation of an existing approval where previous approvals were in force for a continuous period of at least 2 years

Subsection 13(3) provides that if an application is made involving the cancellation of an existing approval and meets the transitional dates outlined in section 13, one or more approvals in relation to the existing premises need to have been in force, immediately before the day the application was made, for a continuous period of at least 2 years, rather than 5 years.

SCHEDULE 1 – APPLICATION KINDS AND REQUIREMENTS

Schedule 1 sets out the different kinds of applications that may be made in relation to an existing approval (see Part 1) or a new approval (see Part 2). It also sets out the requirements relevant to each kind of application. As required by section 10 of Part 2 of the Determination, the Authority must recommend that an applicant be approved if, among other things, it meets the relevant requirements set out in column 2 of that item.

PART 1 of SCHEDULE 1 – Applications involving cancellation of existing approval

Part 1 of Schedule 1 applies to applications involving the cancellation of an existing approval, that is, applications to expand or contract existing premises or to ‘relocate’ an existing approval.

Expansion or contraction

Item 121 applies to the expansion or contraction of approved premises. It requires that the application is of the kind mentioned in subsection 90(3AE) of the Act, and that it has been referred to the Authority under subsection 90(3AF) of the Act.

Under subsection 90(3AE) of the Act, the Secretary is not required to refer an application to the Authority for consideration where it relates to an expansion or contraction of approved premises. However, under subsection 90(3AF), the Secretary may do so at his or her discretion. For example, the Secretary may decide to refer an application for an expansion of premises to the Authority for consideration if the expansion might result in the premises being directly accessible from within a supermarket, and thereby not meet the requirements set out at paragraph 10(3)(f).

Relocation within a designated complex

Item 122 applies to the relocation of an existing approval within the same *designated complex*. A *designated complex* is defined in section 5 of this Determination as being a small shopping centre, a large shopping centre, a large medical centre or a large private hospital. It aims to ensure flexibility for pharmacists to relocate without needing to remain at the existing premises for any minimum period of time, provided the proposed premises are located within the same *designated complex* as the existing premises.

Relocation within the same town (10 km)

Item 123 applies to the relocation of an existing approval within the *same town*. *Same town* is defined in section 5. It aims to ensure flexibility for pharmacists to relocate without needing to remain at the existing premises for any minimum period of time, provided there are no other approved premises located within 10 km, by shortest lawful access route, from the proposed premises.

Relocation up to 1 km

Item 124 applies to the short distance relocation of an existing approval. It requires that the proposed premises are no more than 1 km, in a straight line, from the existing premises. It aims to ensure flexibility for pharmacists to relocate within their local area.

It provides that if the existing premises are relocating out of a large shopping centre, the proposed premises must be at least 300 m, in a straight line, from all approved premises. This aims to provide a degree of flexibility for pharmacists that may no longer be able to afford to rent premises in a shopping centre, whilst avoiding unnecessary clustering of pharmacies outside the shopping centre.

It provides that, to relocate out of any other designated complex, the proposed premises must be at least 500 m, in a straight line, from the existing premises. The 500 m distance requirement is reflective of the distance requirement that proposed premises need to be when establishing a new pharmacy in a small shopping centre. That is, to be established in a small shopping centre, proposed premises need to be at least 500 m, in a straight line, from the nearest approved premises. If the approval subsequently relocates out of the designated complex, it should remain the same distance from the nearest approved premises.

Relocation of 1 km to 1.5 km

Item 125 applies to the relocation of an existing approval to premises that are more than 1 km but less than 1.5 km, in a straight line, from the existing premises. It provides a degree of flexibility to relocate an existing approval whilst avoiding unnecessary clustering of approved premises, by requiring the proposed premises must be a minimum distance from the nearest approved premises.

As proposed premises under this item are required to be at least 1 km, in a straight line, from the existing premises, if existing premises are coming out of a large shopping centre there is no need to exclude approved premises in that same large shopping centre when measuring the distance to the nearest approved premises, as is required for relocations under item 124(b)(iii).

PART 2 of SCHEDULE 1 – Applications not involving cancellation of existing approval

Part 2 of Schedule 1 deals with applications to establish a new pharmacy. These kinds of applications do not involve the cancellation of an existing approval.

New pharmacy (at least 1.5 km)

Item 130 applies to applications for a new approval where there is a community need for the supply of pharmaceutical benefits. The objective test used to determine the likely need for a pharmacy is that, within 500 m, by straight line, from the proposed premises, there is at least the equivalent of one full-time prescribing medical practitioner and a supermarket with a gross leasable area of at least 1,000 m². Alternatively, within 500 m, in a straight line, from the proposed premises, there is a supermarket with a gross leasable area of at least 2,500 m².

The 1,000 m² supermarket and one general practitioner; or 2,500 m² supermarket requirement are proxies that reflect a location that is likely to be well frequented, with sufficient community need for a new pharmacy to operate viably.

Note: *full-time* and *gross leasable area* are defined in section 5.

New pharmacy (at least 10 km)

Item 131 aims to address the needs of communities isolated from existing pharmacies, such as in rural and remote areas. It requires only that the proposed premises are at least 10 km, by the shortest lawful access route, from the nearest approved premises.

New additional pharmacy (at least 10km)

Item 132 applies to applications to establish a second pharmacy in a town where there is only one approved pharmacy and the nearest other approved pharmacy is at least 10 km, by the shortest lawful access route, from the proposed premises. It aims to address single pharmacy towns where there are services and attractions likely to draw a sufficient number of people requiring the supply of PBS medicines, whilst ensuring the viability of a second pharmacy in that town.

The test used to determine the likely need for a second pharmacy in a town is where there are, in that same town, at least four full-time equivalent prescribing medical practitioners and one, or a maximum of two, supermarkets with a combined gross leasable area of at least 2,500 m².

Note: *same town*, *prescribing medical practitioner* and *gross leasable area* are defined in section 5.

New pharmacy in a designated complex (small shopping centre)

Item 133 applies to applications for a new approval in a supermarket based shopping centre. It aims to improve access to pharmaceutical benefits for a supermarket based shopping centre which has a 2,500 m² supermarket, as it is likely to have regular/consistent visitation by residents of the local community and surrounding areas.

Note: *gross leasable area* and *commercial establishment* are defined in section 5.

New pharmacy in a designated complex (large shopping centre with no approved premises)

Item 134 applies to applications for a new pharmacy in a large shopping centre that has no existing pharmacy. It aims to improve access to pharmaceutical benefits for large shopping centres that combine both major retailers and small retailers, including supermarkets, department stores, food outlets and entertainment and leisure facilities and restaurants, which attract customers from a larger area than that of the local community.

To meet the definition of *large shopping centre*, the shopping centre and supermarket are required to be a minimum size, in terms of *gross leasable area*; contain a minimum of 50 *commercial establishments* and have customer parking.

Note: *large shopping centre*, *approved premises*, *single management* and *commercial establishment* are defined in section 5.

New additional pharmacy in a designated complex (large shopping centre with approved premises)

Item 134A applies to applications for an additional new pharmacy in a *large shopping centre* that is sufficiently large enough to sustain two, or even three, pharmacies, depending on the number of *commercial establishments*.

It is not intended that an additional new pharmacy be approved where it is the replacement of a previous pharmacy that relocated out of the shopping centre within the previous 12 month period. Such practise is commonly referred to as 'backfilling', which is when a pharmacist at the existing premises relocates their approval to premises out of the shopping centre and subsequently submits an application for a new approval in the shopping centre, usually at the

vacated premises. Such practise, if allowed, would result in an increase in the overall number of pharmacies in the locality.

If however, an existing approval in a shopping centre is cancelled, without being associated with a relocation application, then an additional new pharmacy can be approved to replace the previously approved pharmacy, as it would not result in an overall increase in the number of pharmacies in the locality.

Note: *large shopping centre, approved premises, single management and commercial establishment* are defined in section 5.

New pharmacy in a designated complex (large private hospital)

Item 135 applies to applications for a new approval in a *large private hospital*. It aims to improve access to pharmaceutical benefits for patients and staff of, and visitors to, the hospital which are drawn from a larger area than that of the local community.

It requires that there be no existing approved premises located in the hospital on the day the Authority makes its decision. If the hospital authority is approved, under section 94 of the Act, to supply pharmaceutical benefits to its patients, the existence of that approval does not prevent the approval of a pharmacist to supply pharmaceutical benefits in the same hospital.

Note: *Large private hospital* is defined in section 5 and *private hospital* means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007*, that the hospital is a private hospital.

New pharmacy in a designated complex (large medical centre)

Item 136 applies to applications for a new approval in a *large medical centre*. It aims to facilitate timely and convenient access to the supply of pharmaceutical benefits for patients of large medical centres that operate extended hours, and also recognises the multidisciplinary health services that large medical centres may provide, for example, by dental practitioners or nurse practitioners approved to prescribe pharmaceutical benefits.

The intention of having a pharmacy in a large medical centre is primarily to meet the needs of medical centre patients outside normal business hours, when nearby pharmacies have closed. Irrespective of the hours that the medical centre operates or the number of medical practitioners rostered on during those hours, general practice services must be provided at the medical centre for at least 70 hours each week. If the medical centre closes for an hour over lunchtime then that hour is not counted towards the time that the medical centre is providing general practice services, as patients are unable to obtain a consultation with a medical practitioner during that hour. Where more than one medical practitioner's hours overlap, the total hours that the medical centre is providing general practice services is not the combined hours of the medical practitioners, it is instead the total hours that the centre is providing general practice services.

Time spent consulting 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, such as staff rosters, does not count towards the time spent practising at the medical centre.

It requires that the proposed premises must be situated in the medical centre and that there are no approved premises in the medical centre.

It requires the applicant will make all reasonable attempts to ensure that the proposed premises' hours of operation will meet the needs of patients of the medical centre. The intention of this provision is to ensure that, as far as is practicable, a majority of patients can access the pharmacy following a consultation by a doctor in that medical centre.

Note: *Large medical centre, full time, PBS prescriber and prescribing medical practitioner* are defined at section 5.

SCHEDULE 2 – REQUIREMENTS FOR APPLICATIONS INVOLVING CANCELLATION OF EXISTING APPROVAL

Schedule 2 sets out requirements for an application to relocate an existing approval. As required at subsection 10 of Part 2 of the determination, an application involving the cancellation of an existing approval must meet the requirements of Part 1 of Schedule 2.

PART 1 of SCHEDULE 2 – All applications

Part 1 of Schedule 2 applies to applications involving the cancellation of an existing approval, that is, applications to relocate an existing approval that is in force in respect of the existing premises, or applications to expand or contract premises.

Cancellation of existing approval

Item 311 provides that the Authority must be satisfied that an approved pharmacist has requested the cancellation of the existing approval immediately before the approval in respect of the application is granted.

It requires that, if the approved pharmacist has ceased carrying on business as a pharmacist at the existing premises, that the Secretary is aware of that and has agreed only to cancel the existing approval in accordance with the request made by the approved pharmacist. If a pharmacist has ceased carrying on business as a pharmacist and the Secretary is not aware of that, or has indicated to the pharmacist an intention to cancel the approval, under subsection 98(3) of the Act, then this requirement is not met.

Period existing premises have been approved premises

Item 312 relates to the period of time the existing approval must have been in force before it can be relocated.

It aims to ensure the distribution and stability of the network of approved pharmacies is not adversely affected by the relocation of existing approvals, whilst allowing some flexibility for relocations within the local area, particularly where such relocations have little or no impact on other pharmacies. It requires that an approval must have been in force at the existing premises for a continuous period of at least 5 years, which is consistent with most commercial lease arrangements, which are typically 5 years with a 5 year option to renew or 7 years with a 3 year option to renew. That is, an approval cannot be relocated more than once every 5 years, except in specified circumstances.

The intention of this provision is to prevent the establishment of a temporary/demountable pharmacy which is subsequently relocated, where there is no intention of servicing the community at the temporary location long term.

The time an approval has been at premises starts on the date the approval is granted in respect of those premises and continues as long as the approval remains at those premises. The 5 year period resets following each relocation application and subsequent approval.

If an existing approval has changed ownership at the existing premises, it is considered to be approved for a continuous period from the date the first approval was granted in respect of the existing premises.

Similarly, if the existing premises have been approved following an expansion or contraction, irrespective of whether that approval followed a referral to the Authority, under section 90(3AF), or not, the start of the continuous period is taken to be from the date of approval at the premises prior to the expansion or contraction.

There are a number of exemptions to the period of time that the existing approval has been in force at the existing premises before it can be relocated.

There are provisions that allow an existing approval located in a designated complex, or a single pharmacy town where there are no other pharmacies within 10 km by shortest lawful access route, to be relocated within the same designated complex, or the same town (whichever applies) without the requirement that the existing approval have been in force at the existing premises for any specified period of time.

There are also provisions that allow for the temporary relocation of existing premises while refurbishments are undertaken, and relocations following disaster or exceptional circumstances, to premises that are not more than 1 km by straight line distance from the existing premises, without the requirement that the existing approval have been in force at the existing premises for any specified period of time.

The provision relating to disaster or exceptional circumstance, under paragraph 312(b)(v), is not intended to be an alternative to section 91A of the Act, but rather is intended to be for situations where the relocation is long term (i.e. not temporary), as a result of the disaster.

PART 2 of SCHEDULE 2 – Particular applications

Part 2 of Schedule 2 applies to particular applications involving the cancellation of an existing approval, that is, an application described in an item in Part 2 of Schedule 2 must meet the requirements set out in that item.

Relocation of new pharmacy

Item 313 applies to an application to relocate an approval which was granted following an application made under the provisions of item 130 (*New pharmacy (at least 1.5 km)*). This provision reflects the intention to ensure that new approvals that are granted to address community need remain in that area of need by requiring that an approval granted following an application made under item 130, stays within a 1 km radius of the premises in respect of which the approval was originally granted, for a period of five years.

Relocation within the same town

Item 314 applies to an application to relocate an approval granted following an application made under the provisions of item 131 - *New pharmacy (at least 10 km)* or item 132 - *New additional pharmacy (at least 10 km)* or item 114 - *New pharmacy (rural)* under previous determinations. The intention is that the proposed premises be in the same town in which the existing approval was granted and not extend beyond the town for which it was originally approved to serve. That is, an application, under item 124 or 125, is not intended to enable an approval, granted under item 131, 132 or 114, to relocate to a neighbouring town that is not the town in which it was originally approved.

Note: *Same town* is defined in section 5. Two towns, or suburbs, that are in close proximity to one another and share the same postcode, but not the same name, are not considered to be in the “same town”.

Relocation from a small shopping centre or a large shopping centre (exceptional circumstances)

Item 315 applies to an application to relocate an approval granted following an application made under the provisions of item 133 – *new pharmacy in a designated complex (small shopping centre)*, item 134 – *new pharmacy in a designated complex (large shopping centre with no approved premises)* or item 134A – *new additional pharmacy in a designated complex (large shopping centre with approved premises)*. The intention is that where a new approval was granted to serve the community of a shopping centre, the approval remain in that same shopping centre for a minimum of 10 years, unless there are exceptional circumstances.

Exceptional circumstances are intended to mean situations outside the control of the approved pharmacist, that is not commercial in nature (for example, where a shopping centre is being demolished or where there has been a disaster causing damage to the shopping centre, or part thereof). It is not intended to include situations where a lease for premises in a shopping centre has expired or otherwise been terminated.

Relocation from a large private hospital or large medical centre (exceptional circumstances)

Item 316 applies to an application to relocate an approval granted following an application made under the provisions of item 135 – *new pharmacy in a designated complex (large private hospital)* or item 136 – *new pharmacy in a designated complex (large medical centre)*.

The intention is that where a new approval was granted to serve the community of a private hospital or medical centre, the approval remain in that same hospital or medical centre indefinitely, unless there are exceptional circumstances.

Exceptional circumstances are intended to mean situations outside the control of the approved pharmacist, that is not commercial in nature (for example, where a hospital or medical centre relocates and the application to relocate the existing approval is to premises in the new location of the hospital or medical centre; or where the application to relocate the existing approval is temporary to facilitate structural repairs or alterations to the hospital or medical centre).

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
National Health (Australian Community Pharmacy Authority Rules) Determination 2018

The *National Health (Australian Community Pharmacy Authority Rules) Determination 2018* (the Determination) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Determination

The purpose of the Determination, made under subsection 99L of the *National Health Act 1953* (the Act), is to replace the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011* (the Pharmacy Location Rules).

Section 90 of the Act enables a pharmacist to make an application for approval to supply Pharmaceutical Benefits Scheme (PBS) medicines at particular premises.

Such an application must be referred to the Authority under subsection 90(3A) of the Act for consideration in accordance with the Pharmacy Location Rules.

This Determination clarifies certain terms and removes obsolete provisions in the Pharmacy Location Rules.

Human rights implications

This Determination engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right to everyone to the enjoyment of the highest attainable standard of physical and mental health. The United Nations Committee on Economic, Social and Cultural Rights (the Committee) has stated that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as a right to be healthy, but rather entails a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The PBS assists with advancement of this human right by providing access to subsidised medicines for people. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements support effective administration of the PBS.

Conclusion

This Determination is compatible with human rights as it advances the protection of human rights.

Greg Hunt

Minister for Health