

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

National Health Act 1953

National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2015 (No. 1)

Section 90 of the *National Health Act 1953* (“the Act”) provides that the Secretary may, upon application by a pharmacist, approve a pharmacist to supply pharmaceutical benefits at particular premises.

Subsection 90(3A) of the Act provides that an application made under section 90 must be referred to the Australian Community Pharmacy Authority (“the Authority”).

The Authority is established under section 99J of the Act and has the functions outlined in section 99K. The Authority’s functions include the consideration of applications made under section 90 of the Act and to make a recommendation to the Secretary as to whether or not a pharmacist should be approved in respect of particular premises.

Subsection 99K(2) of the Act provides that in making a recommendation in relation to applications under section 90, the Authority must comply with the relevant rules determined by the Minister under subsection 99L(1) of the Act. The *National Health (Australian Community Pharmacy Authority Rules) Determination 2011* (“the Pharmacy Location Rules”) was determined by the Minister on 13 September 2011.

The Pharmacy Location Rules describe the circumstances in which the Authority must recommend that a pharmacist be approved under section 90 of the Act in relation to particular premises. The Authority must not recommend approval in relation to particular premises if a relevant requirement in the Pharmacy Location Rules is not met.

The *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2015 (No. 1)* (“this Determination”) amends the Pharmacy Location Rules. It does this by:

- a) removing obsolete provisions;
- b) clarifying the definition of certain terms;
- c) clarifying that a pharmacy should not be double counted;
- d) clarifying circumstances when a pharmacist is exempt from remaining at approved premises for at least 2 years;
- e) clarifying the intention that premises should not be able to be recommended for approval if they are already approved premises;
- f) clarifying the intention regarding the relocation of an existing pharmacy;
- g) clarifying the intention regarding the establishment of a new pharmacy in a large medical centre;
- h) better articulating the meaning of particular provisions; and
- i) making provisions more concise where possible.

This Determination comes into effect on 10 November 2015 and will apply to the consideration, by the Authority, of an application made on or after that date. Details of this Determination are set out in the **Attachment**.

Consultation

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

Details of the *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2015 (No. 1)*

1. Name of Determination

Subsection 1(1) provides that this Determination is called the *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2015 (No. 1)*.

Subsection 1(2) provides that this Determination may also be referred to as PB 89 of 2015.

2. Commencement

Section 2 provides that this Determination commences on 10 November 2015.

3. Amendments to PB 65 2011

Section 3 provides that Schedule 1 of this Determination amends the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011* (PB 65 of 2011).

Schedule 1 Amendments

Amendments to Part 1, section 4

Item 1 replaces the previous transitional arrangements with new transitional arrangements. It provides that an application made before 10 November 2015 will be considered under the *National Health (Australian Community Pharmacy Authority Rules) Determination 2011*, as in force at that time.

Amendments to Part 1, section 5

Item 2 inserts a new definition for the term “at all relevant times”.

Item 3 amends the definition of “facility” to clarify the term “large private hospital”.

Item 4 substitutes the definition of “full-time”. The inserted definition of “full time” allows, for example, consideration to be given to when a public holiday falls during the period that a “full-time” prescribing medical practitioner or PBS prescriber is required to be practising. It does this by removing the phrase ‘for at least 38 hours each week’ and substituting ‘for 38 hours in a week’.

Item 5 substitutes the definition of “gross leasable area” as it relates to a shopping centre and supermarket. This definition provides that the total floor area of a supermarket is the area that is accessible by customers for the purpose of purchasing supermarket items, not including loading docks and car parks. It does not include areas that are not generally accessible by customers, such storage areas, staff administration areas or food preparation areas.

Item 6 inserts a new definition for “large private hospital”.

It provides that a large private hospital is a private hospital that can admit at least 150 patients at any one time in accordance with the hospital’s license or registration under the law of the State or Territory in which the private hospital is located. For example, an admitted patient would include an admitted day patient, but would not include an outpatient who receives treatment at the hospital.

Item 7 amends the definition of “large shopping centre” to incorporate the single management requirement, previously provided for in the definition of “shopping centre”.

Item 8 removes the definition of “shopping centre” which is included within the definition of “large shopping centre” and “small shopping centre”.

Item 9 substitutes the definition of “single management”. This definition is simplified to more accurately reflect the management of both a shopping centre and medical centre.

It requires that the shopping centre or medical centre is managed by a single entity, or two or more entities working cooperatively under an agreement, responsible for the marketing, maintenance and administration for the centre as a whole. It does not include situations where independent owners or tenants in a building only cooperate on particular occasions, or in relation to some but not all matters relating to marketing, maintenance and administration for the centre as a whole.

This means that if a medical centre has a web site, yellow pages advertisement or patient information sheet that lists each of the medical practitioners and the medical centre opening hours then it is considered to be marketed as a single medical centre.

Similarly, if a shopping centre has a web site, store directory and/or customer flyer that lists each of the commercial establishments in the shopping centre, then it is considered to be marketed as a single shopping 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 a single medical centre.

Similarly, if a shopping centre has a centre manager responsible for building maintenance, cleaning and security contracts, as well as the opening hours of each of the commercial establishments in the shopping centre then the shopping centre is considered to be administered under single management.

Item 10 amends the definition of “small shopping centre” to incorporate the single management requirement, previously provided in the definition of “shopping centre”.

Amendments to Part 1, section 6

Item 11 inserts a new subsection to clarify that, when the Authority is considering an application to establish a new additional pharmacy in a town under Item 132, or large shopping centre under Item 134, any pharmacist that has previously been recommended to be approved, but is not yet approved, to relocate within the same town/large shopping centre under Item 122, Item 123 or Item 124 will not be considered as two approved premises and therefore not double counted. It does this by disregarding the recommendation of the proposed premises.

Amendments to Part 1, section 7

Item 12 amends the definition of “commercial establishment” to reflect the removal of the definition for “shopping centre”.

Amendments to Part 2, section 11

Item 13 amends the requirement for when the Authority must recommend that an applicant not be approved.

It provides that the Authority cannot recommend the relocation of an existing approval to more than one proposed premises simultaneously.

It does this by clarifying that where an existing approval has been recommended by the Authority to relocate under Item 122, Item 123 or Item 124, but not yet approved under section 90 of the Act, the Authority is unable to make a subsequent recommendation involving the same existing approved premises.

Amendments to Schedule 1, Part 1

Item 14 removes three obsolete provisions. A requirement of Item 125, Item 126 and Item 127 is that the application needs to have been made before 16 April 2012.

Amendments to Schedule 1, Part 2

Item 15 amends Item 130.

It removes the definition of “all relevant times” which is now contained in section 5.

Item 16 amends Item 132.

It removes the definition of “all relevant times” which is now contained in section 5.

Item 17 substitutes new Item 134.

It replaces the term “shopping centre” with “large shopping centre” to reflect the removal of the definition of “shopping centre” from section 5.

Item 18 substitutes new Item 135.

Item 135 refers to the term “large private hospital” and a new definition has been added in section 5, where other common terms are defined, to provide that a “large private hospital” is a private hospital that can admit at least 150 patients at any one time in accordance with the hospital’s license or registration under State/Territory law. An admitted patient includes an admitted day patient, but not an outpatient who receives treatment at the hospital.

Item 19 substitutes new Item 136.

It removes the term “all relevant times” which is now contained in section 5 and replaces it with a new paragraph that requires that, during the 2 months before the day on which the application is made and until the day the application is considered by the Authority, there is the equivalent of at least 8 full-time PBS prescribers, of which at least 7 PBS prescribers are prescribing medical practitioners.

Amendments to Schedule 2

Item 20 simplifies the drafting of the requirement that the applicant must have a legal right to occupy the proposed premises at “all relevant times”. It also incorporates the requirement that the proposed premises are not approved premises “at all relevant times”, rather than only on the day the application was made.

Item 21 substitutes new Item 312(b)(i) and Item 312(b)(ii).

It clarifies the intention that an approved premises in a facility or single pharmacy town, can relocate within the same facility or town less than 2 years after being approved.

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) Amendment Determination 2015 (No. 1)

The *National Health (Australian Community Pharmacy Authority Rules) Amendment Determination 2015 (No. 1)* (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(1) of the *National Health Act 1953* (Act), is to make minor amendments to 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.

Sussan Ley

Minister for Health