EXPLANATORY STATEMENT

National Health Act 1953

National Health (Eligible midwives) Amendment Determination 2016

Subsection 84AAE(3) of the *National Health Act 1953* (the Act) provides that the Minister may, by legislative instrument, determine one or more requirements that a person must meet in order to be an 'eligible midwife' for the purposes of Part VII of the Act. If there is no determination in force under subsection 84AAE(3), a person cannot be an 'eligible midwife' for the purposes of the Act (subsection 84AAE(2)).

Section 84AAF of the Act provides that an eligible midwife may apply to the Secretary to be an 'authorised midwife' for the purposes of Part VII of the Act. The Secretary may approve the application if he or she is satisfied that the eligible midwife meets the criteria set out in the Act. An authorised midwife is a type of PBS prescriber. PBS prescribers are able to prescribe certain medicines under the Pharmaceutical Benefits Scheme (PBS).

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

The purpose of the *National Health (Eligible midwives) Amendment Determination 2016* (the Amendment Determination) is to amend the *National Health (Eligible midwives) Determination 2010* (the Principal Determination), which sets out the eligibility requirements to be an eligible midwife, to reflect changes to registration standards for midwifery in Australia.

Currently, the Principal Determination specifies that a midwife must meet any registration standard for an eligible midwife developed by the Nursing and Midwifery Board of Australia (the Board) for subsection 38(2) of the Health Practitioner Regulation National Law (the National Law). Meeting this registration standard enables the registration of a midwife to be notated as an eligible midwife.

From 1 January 2017, the Board will start phasing out the registration standard for an eligible midwife, replacing it with a revised Registration Standard: Endorsement for scheduled medicines for midwives. A midwife who meets this new registration standard will be eligible for endorsement under section 94 of the National Law.

Section 94 of the National Law provides that the Board may endorse the registration of registered midwives subject to compliance with qualification requirements and any approved registration standard relevant to the endorsement.

From 1 January 2017, new applications for notation as an eligible midwife will no longer be accepted by the Board. Midwives granted notation as an eligible midwife before 31 December 2016 will have 18 months from the date of notation to complete a Board-approved program of study and apply for endorsement.

To reflect these changes, the Amendment Determination amends the eligibility requirements to be an 'eligible midwife' for the purposes of subsection 84AAE(3) of the Act. It also incorporates new definitions in relation to the revised registration standard developed by the Board and the National Law as in force in each state and territory.

Consultation

Consultation was undertaken with the Chief Nurse and Midwifery Officer, the Nursing and Midwifery Board of Australia, and other midwifery organisations. The Board is the professional body responsible for developing registration standards, professional conduct and extended areas of practice. The Board engaged in broad public consultations regarding the content and requirements to ensure the new standards for endorsement for scheduled medicines for midwives reflect contemporary professionally relevant criteria.

This instrument commences on 1 January 2017.

This instrument is a legislative instrument for the purposes of the Legislation Act 2003.

Details of this instrument are set out in the Attachment.

Details of the National Health (Eligible Midwives) Amendment Determination 2016

Preliminary

Section 1 - Name

Section 1 provides that the title of the instrument is the *National Health (Eligible midwives) Amendment Determination 2016* and that it may also be cited as PB 117 of 2016.

Section 2 - Commencement

Section 2 provides that the instrument commences on 1 January 2017.

Section 3 - Authority

Section 3 provides that the instrument is made under subsection 84AAE(3) of the *National Health Act 1953*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

National Health (Eligible midwives) Determination 2010

Item 1 - Section 3 (after definition of Act)

Item 1 inserts new definitions in section 3 of the *National Health (Eligible midwives) Determination 2010* (the Principal Determination) for 'Board' and 'endorsed by the Board'. The definition of 'Board' meaning, the Nursing and Midwifery Board of Australia replaces the definition of 'Nursing and Midwifery Board' which is repealed under Item 3. 'Endorsed by the Board' is defined to mean endorsed by the Board under section 94 of the National Law to prescribe schedule 2, 3, 4 and 8 medicines and to provide associated services required for midwifery practice in accordance with relevant state and territory regulation.

Item 2 - Section 3 definition of National Law

Item 2 repeals the definition of 'National Law' in section 3 of the Principal Determination and substitutes that 'National Law' means:

- (a) for a State or Territory other than Western Australia, the Health Practitioner Regulation National Law set out in the Schedule to the *Health Practitioner Regulation National Law Act 2009* (Qld) and adopted (with or without modifications) by legislation of that State or Territory of Australia as a law of that jurisdiction; and
- (b) for Western Australia, the legislation enacted by the *Health Practitioner Regulation National Law (WA) Act 2010* (WA) that corresponds to the *Health Practitioner Regulation National Law Act 2009* (Old).

This amendment has been made to improve consistency in defining the term across legislation administered by the Minister for Health and Aged Care and is not intended to alter the operation of the law.

Item 3 - Section 3 definition of Nursing and Midwifery Board

Item 3 repeals the definition of 'Nursing and Midwifery Board' in the Principal Determination. This definition is replaced by the definition of 'Board' under Item 1.

Item 4 - Section 4 Eligibility requirements

Section 4 of the Principal Determination provides that a person will satisfy the definition of 'eligible midwife' for the purposes of the Act only if they meet a registration standard for an eligible midwife developed by the Nursing and Midwifery Board of Australia for the purpose of subsection 38(2) of the National Law. This reflects the requirements of the Board for notation as an eligible midwife.

Item 4 repeals and substitutes section 4 in the Principal Determination with new sections 4 and 5.

New section 4 provides an 18-month period for the transition of requirements to be an eligible midwife from notation of a midwife's registration to endorsement by the Board.

New section 4 applies from 1 January 2017 to the end of 30 June 2018. This section provides two means by which a registered midwife may meet the additional requirements to be an eligible midwife for Part VII of the Act.

The first means under section 4 is meeting the additional requirements specified in subsection 4(3). This includes, among other things, holding current general registration as a midwife in Australia without restrictions on practice, midwifery experience that constitutes the equivalent of 3 years full-time post initial registration as a midwife, current competence as recognised by the Board, and successful completion of a professional practice review program approved by the Board for midwives working across the continuum of midwifery care, or giving a formal undertaking to the Board to complete such a course within 18 months. These reflect the requirements of the Board that allow notation as an eligible midwife. Therefore, notation of a midwife's registration as an eligible midwife would meet subsection 4(3).

The second means under section 4 is being endorsed by the Board (subsection 4(4)).

However, if a midwife is currently endorsed, or has been endorsed at any time after 1 January 2017, the midwife must rely on continued endorsement to be an eligible midwife under the Act. The specification of endorsement reflects the Board's phasing out of the concept of notation as an eligible midwife.

New section 5 applies from 1 July 2018. From that time, all registered midwives will require endorsement by the Board to be an eligible midwife for Part VII the Act.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Eligible midwives) Amendment Determination 2016

This Legislative Instrument 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 Legislative Instrument

Part VII of the *National Health Act 1953* (the Act) provides the legislative basis for the operation of the Pharmaceutical Benefits Scheme (PBS). The Act provides that a midwife who meets the requirements to be an 'eligible midwife' under the Act, may be approved by the Secretary to be an 'authorised midwife'; that is, a person authorised as a PBS prescriber to prescribe certain medicines under the PBS. The Minister may, by legislative instrument, determine one or more requirements that a person must meet in order to be an 'eligible midwife' for PBS purposes. If there is no instrument in force, a person cannot be an 'eligible midwife' under the Act.

Registration standards for midwifery in Australia are set by the Nursing and Midwifery Board of Australia (the Board). The *National Health (Eligible midwives)*Determination 2010 (the 2010 Determination) sets out the current eligibility requirements to be an eligible midwife for PBS purposes. The purpose of the *National Health (Eligible midwives) Amendment Determination 2016* (the Amendment Determination) is to amend the 2010 Determination to reflect changes to midwifery registration standards.

Currently, a registered midwife who meets the additional training and experience requirements in the Eligible Midwife Registration Standard can be notated by the Board as an eligible midwife (for registration purposes). The Board has developed a new Registration standard: *Endorsement for scheduled medicines for midwives* which will replace the Eligible Midwife Registration Standard from 1 January 2017. Consultation with midwives, practitioner organisations and health authorities was undertaken by the Board in developing the new registration standard.

From 1 January 2017, the Board will no longer accept new applications for notation as an eligible midwife. A transition period of 18 months will apply for current midwives granted notation as an eligible midwife to complete a Board-approved program of study and apply for endorsement under the Health Practitioner Regulation National Law.

The eligibility requirements in the 2010 Determination reflect the Eligible Midwife Registration Standard. The Amendment Determination replaces the current requirements with two new sections reflecting the Registration Standard Endorsement for scheduled medicines. One new section applies for the 18-month transitional period from 1 January 2017 to 30 June 2018 and the other applies from 1 July 2018.

During the transitional period, a registered midwife meets the additional requirements to be an eligible midwife for PBS purposes if the person is either:

- (a) endorsed by the Board to prescribe schedule medicines; or
- (b) meets the existing requirements to be an eligible midwife and has not been endorsed at any time after 1 January 2017.

From 1 July 2018, only midwives who are endorsed will be eligible midwives for PBS purposes under the Act. This is consistent with the Board's 18-month transitional period for notated midwives which ends on 30 June 2018.

Human rights implications

The Amendment Determination engages the following human rights:

Right to Health

The right to health – the right to the enjoyment of the highest attainable standard of physical and mental health – is contained in article 12(1) of the International Covenant on Economic Social and Cultural Rights (ICESCR). Whilst the UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not to be understood as a right to be healthy, it does entail a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Amendment Determination will ensure that during the transitional period, midwives who have met the additional requirements set by the Board under the current Eligible Midwife Registration Standard and have been granted notation, and midwives who meet the new Registration Standard: Endorsement for scheduled medicines and have been endorsed, are recognised as eligible midwives for PBS purposes.

The Amendment Determination also ensures that the requirements in the Act are consistent with the latest date by which a notated midwife can complete the additional training to achieve endorsement. After that time, a registered midwife must be endorsed by the Board to be an eligible midwife for PBS purposes. The changes made by the Amendment Determination are consistent with changes to other health legislation to reflect the new midwifery registration standard.

Effect for PBS users

There is no effect on access, eligibility, entitlements, subsidies, or cost for PBS users associated with the Amendment Determination. The changes do not touch on requirements for listing medicines on the PBS, the range of medicines available as pharmaceutical benefits, or the types of practitioners who can prescribe them.

Summary

The amendments will impact positively on the right to health by ensuring the requirements for midwives to be eligible to become PBS prescribers reflects the Board's current and future arrangements for recognising additional training and experience for midwives. In particular, the amendments ensure that the eligible midwife requirements recognise the phasing out by the Board of notation for midwives and the transition to endorsement. This will ensure continued provision of and access to quality pre- and post-natal health care, including the prescribing of PBS medicines.

Conclusion

The Amendment Determination is compatible with human rights because it advances the protection of human rights, specifically the right to health.

Penny Shakespeare
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health