

## **EXPLANATORY STATEMENT**

### ***National Health Act 1953***

#### ***National Health (Entitlement to Pharmaceutical Benefits – Special Evidentiary Categories) Determination 2017—PB 83 of 2017***

The broad aims of Part VII of the *National Health Act 1953* (the Act) are to assist patients to receive high quality health care through quality use of medicines, to subsidise the costs of prescribed pharmaceuticals and to provide appropriate accountability for expenditure of public funds.

To ensure accountability in respect of payments made under the Pharmaceutical Benefits Scheme (PBS), Part VII of the Act requires, amongst other things, that a patient's medicare number must be recorded when a pharmaceutical benefit is supplied on prescription by an approved supplier. These provisions are designed to ensure that pharmaceutical benefits are supplied only to persons who are entitled to them without impeding an eligible person's legitimate access to the PBS.

Subsection 86E(1) of the Act empowers the Minister to determine, by legislative instrument, classes of persons whose entitlement to pharmaceutical benefits can be evidenced otherwise than by provision of a medicare number.

Subsection 86E(2) of the Act provides that the classes may include persons requiring drugs or medicinal preparations in an emergency and foreign persons who are treated as being eligible for Medicare because they are covered by reciprocal health care agreements. Persons in the latter class may be required to produce evidence such as their passport or proof of permanent residency in order to prove their entitlement to be treated as an eligible person for Medicare. The Minister may determine classes of persons other than those listed in the specific examples in this subsection.

Subsection 86E(3) of the Act provides that a determination under subsection 86E(1) may set out the particular matters in respect of which an approved supplier must be satisfied before being satisfied that a person falls within a particular class determined under subsection 86E(1). A determination may also set out the procedure to be followed by an approved supplier in establishing such matters.

Subsection 86E(4) of the Act requires the Minister to include in each determination under subsection 86E(1) the procedure for allocating a special number applicable to a person who is a member of a particular class of persons.

The *National Health (Entitlement to Pharmaceutical Benefits – Special Evidentiary Categories) Determination 2017* (the replacement determination) replaces the *National Health (Entitlement to Pharmaceutical Benefits – Special Evidentiary Categories) Determination 2001* (the original determination). The original determination sunsets on 1 October 2017 in accordance with subsection 50(2) of the *Legislation Act 2003*.

The general purpose of the replacement determination is to enable persons who are entitled to pharmaceutical benefits but who, for various reasons, do not have a medicare card or whose medicare number will not be known or available at the time of supply, to receive pharmaceutical benefits and for the supplier of the pharmaceutical benefits to be

able to claim reimbursement from the Commonwealth for that supply. In these circumstances a designated "special number" can be used by approved suppliers in lieu of the person's medicare number for the purpose of claiming pharmaceutical benefits.

The replacement determination:

- identifies the classes of persons to whom entitlement to pharmaceutical benefits can be evidenced other than by provision of a medicare number (Part 2);
- sets out the particular matters in respect of which an approved supplier must be satisfied before being satisfied that a person is included within a particular class (Part 3);
- sets out the procedure to be followed by the approved supplier in establishing such matters (Part 3);
- lists the special numbers applicable to persons included within the specified classes of persons (Part 4); and
- sets out procedure for allocation of special numbers (Part 4).

The replacement determination contains a number of minor changes from the original determination which will:

- remove redundant requirements for an approved supplier to be satisfied that a person in a class is the person to whom a prescription relates. Sections 86B and 86C of the Act already make clear that this determination only deals with the person to whom the prescription relates, and that a special number is being used for that person;
- remove redundant requirements for an approved supplier to request a medicare number from the person or the person's agent. Paragraph 86C(6)(b) of the Act already requires such a request to be made as a prerequisite for using a special number;
- remove redundant requirements for an approved supplier to ensure a medicare number is not retained in the approved supplier's records. Paragraph 86C(6)(c) of the Act already requires this as a prerequisite for using a special number;
- reflect updated requirements to classify a person in a particular class and the procedures to be followed before using a special number in place of a valid medicare number for two classes:
  - foreign persons covered by a reciprocal health care agreement; and
  - persons for whom an inapplicable medicare number is shown on a seemingly valid medicare card;
- simplify the drafting and clarify the current procedures that an approved supplier must follow in order to use a special number for a person in each class determined to reflect current practice;
- remove obsolete references to the Health Insurance Commission (HIC) and replace them with references to the Chief Executive Medicare (CEM);
- update certain terms and definitions to align with changes made to the Act since the determination was originally made;
- update other obsolete terms and definitions.

### **References to other legislation**

The replacement determination refers to certain other legislative provisions which require a person to be an eligible person (or entitled to be treated as an eligible person) under the HIA, which may be obtained from the Federal Register of Legislation

(<https://www.legislation.gov.au>). The HIA, and other legislation incorporated by this determination, is incorporated as in force from time to time.

### **Consultation**

A review was conducted by the Department of Health, with the assistance of the Department of Human Services, which confirmed that the provisions in the old determination were still in use, still functioning effectively and still needed. However, there were some areas identified where modern online claiming processes were not adequately provided for under the existing determination and should be amended in the course of the remake.

The replacement determination retains the content of the old determination, with changes made only to update obsolete procedures and terms to better align with updates to the Act and to reflect the use of modern technology which have occurred since the determination was first written. Because the changes to be included in remaking this instrument are non-policy changes and are considered machinery in nature, no public consultation was undertaken as it was not considered necessary.

This instrument commences on 1 October 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.

## **Statement of Compatibility with Human Rights**

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

### ***National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2017.***

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**

*The National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2017* (the replacement determination) replaces in its entirety, the *National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2001* (the old determination), which sunsets on 1 October 2017.

The replacement determination preserves existing arrangements provided for in the old determination. Some minor and technical changes have been made to clarify existing policy. The changes also include updating the determination to reflect modern Pharmaceutical Benefits Scheme (PBS) claiming processes which are predominantly processed online, updating obsolete and incorrect references, rewording of provisions to better articulate existing intent, and redrafting and reformatting using modern drafting style and language.

#### **Human rights implications**

This Legislative Instrument promotes the right of individuals to the enjoyment of the highest attainable standard of physical and mental health (Articles 2 or 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)). This is because, if the instrument is not remade, those classes of persons who do not have a medicare number on their prescription and cannot present one at the time of supply would cease to have access to pharmaceutical benefits.

The replacement determination maintains existing provisions to ensure ongoing and unchanged access for individuals to subsidised medicines under the PBS in such circumstances as prescribed by the Act. The replacement determination also retains PBS suppliers' ability to claim reimbursement from the Commonwealth for the supply of PBS medicines to eligible persons. Any additional provisions or changes made from the old determination clarify and reinforce current arrangements and policy intent. The replacement determination does not alter the operation of the PBS and does not result in any change to PBS entitlements, PBS eligibility or cost to consumers.

#### **Conclusion**

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

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## ATTACHMENT

**Details of the *National Health (Commonwealth Price—Pharmaceutical Benefits - Special Evidentiary Categories) Determination 2017***

**Part 1 – Preliminary**

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2017* (the replacement determination). It also provides that the instrument may be cited as PB 83 of 2017.

Section 2 – Commencement

Section 2 provides that the whole of the replacement determination will commence on 1 October 2017.

The note to subsection 2(1) clarifies that the commencement information contained in the table relates only to the provisions of the instrument as originally made. It will not be amended to address any later amendments.

Section 3 – Authority

Section 3 provides that the replacement determination is made under subsection 86E(1) of the *National Health Act 1953* (the Act).

Section 4 – Schedules

Section 4 provides that each instrument specified in a Schedule to the replacement determination is amended or repealed as set out in the applicable items of the relevant Schedule. Any other item in a Schedule to the replacement determination will have effect according to its terms.

Section 5 – Definitions

Section 5 defines the terms used in the replacement determination. It retains most of the defined terms from section 1.3 of the *National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2001* (the old determination), but with some notable changes.

The definition for the term “*eligible person*” in the old determination will be moved to a note at the beginning of section 5 of the replacement determination, and will point readers to subsection 4(1A) of the Act and subsection 3(1) of the *Health Insurance Act 1973*.

Section 5 of the replacement determination does not retain the definition of the term “*agent*”, as the term is used extensively in the *National Health Act 1953* without being defined. It is intended that the term will take its ordinary meaning.

Section 5 of the replacement determination amends the definition of the term “*approved supplier*” to align with the Act and clarify that it is the approved supplier’s responsibility to ensure the correct procedures are followed in regard to special evidentiary categories.

Other definitions removed from the replacement determination include the terms “*Australian Resident*”, “*eligible overseas resident*”, “*person to whom the prescription for the supply of a pharmaceutical benefit relates*”, “*subsidised non-medicare number medical service*” and “*unsubsidised non-medicare number medical service*”, which are not used in the replacement determination.

Section 5 of the replacement determination does not retain the definition of the term “*prescriber*”, as that term has been replaced in the replacement determination by “*PBS prescriber*”, as defined in the Act. The term “*prescriber*” in the old determination was limited to medical practitioners and participating dental practitioners. In the replacement determination, the use of a special number will be available to a person (and their approved supplier) regardless of the class of prescriber who writes the prescription, so long as the person meets the criteria for inclusion in a particular class of persons under Part 2.

Finally, Section 5 of the replacement determination does not include the note from the old determination which provided a list of definitions which were previously defined in subsection 84(1) of the Act, and includes them in the list of defined terms.

#### Section 6 – Purpose of instrument

Section 6 provides that the purpose of the replacement determination is to:

- determine the classes of persons to whom entitlement to pharmaceutical benefits can be evidenced otherwise than by provision of a medicare number (Part 2);
- set out the particular matters in respect of which an approved supplier must be satisfied before being satisfied that a person is included within a particular class (Part 3);
- set out the procedure to be followed by the approved supplier in establishing such matters (Part 3);
- set out the procedures for allocation of a special number to a person included within a class (Part 4).

This is unchanged from the purpose of the old determination.

### **Part 2 – Classes of persons**

#### Section 7 – Determination of classes

Section 7 determines six classes of persons for whom entitlement to pharmaceutical benefits can be evidenced other than by provision of a medicare number. The classes determined are unchanged from those determined under section 2.1 of the old determination. Those classes are:

- eligible persons requiring drugs or medicinal preparations in an emergency;
- foreign persons covered by reciprocal health care agreements;
- persons without medicare number who a PBS prescriber identifies as entitled to pharmaceutical benefits;
- persons without a medicare number who an approved supplier considers are entitled to pharmaceutical benefit;
- eligible persons requiring drugs or medicinal preparations as a matter of clinical urgency; and
- persons for whom an inapplicable medicare number is shown on a seemingly valid medicare card or document.

### **Part 3 – Matters of which approved suppliers must be satisfied**

#### Section 8 – Eligible persons requiring drugs or medicinal preparations in an emergency

Section 8 sets out the matters an approved supplier must be satisfied of in order to classify a person as an eligible person requiring drugs or medicinal preparations in an emergency. Upon satisfying these requirements, following the procedure as set out, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

This provision is intended to be used in an emergency where:

- a person holds a prescription for a pharmaceutical benefit,
- they do not have a valid medicare number,
- there is not enough time to establish the person's eligibility and
- the pharmaceutical benefit must be supplied to the person (or the person's agent) immediately.

For example, an insulin dependent diabetic who requires an emergency supply of insulin but within a period that is too short to enable questions relating to eligibility or identity to be asked and answered.

This section differs from the corresponding section (section 2.2) in the old determination by:

- removing the requirement for the approved supplier to be satisfied that the person is the person to whom the prescription relates. Sections 86B and 86C of the Act already make clear that this determination deals with the person to whom the prescription relates, and that a special number is being used for that person;
- use of a tightened definition of the term "approved supplier". The old determination specified that the term "approved supplier" included an employee of an approved supplier. This is no longer the case. Refer to explanatory notes under section 5 – Definitions.

It is the responsibility of the approved supplier to ensure all requirements have been satisfied prior to submitting a claim containing a special number in place of a valid medicare number.

#### Section 9 – Foreign persons covered by reciprocal health care agreements

Section 9 sets out the requirements which must be satisfied and the procedure which must be followed by an approved supplier in order to classify a person as a foreign person covered by a reciprocal health care agreement. Upon satisfying these requirements, following the procedure as set out, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

Australia currently has Reciprocal Health Care Agreements (RHCAs) with Belgium, Finland, the Republic of Ireland, Italy, Malta, the Netherlands, New Zealand, Norway, Slovenia, Sweden, and the United Kingdom.

Most overseas visitors from RHCA countries are eligible to be issued with a reciprocal health care card, which contains a valid medicare number. This provision is intended to ensure the small number of eligible visitors who do not have a reciprocal health care card (for example, those visiting for short periods), but are entitled to pharmaceutical benefits under an RHCA, may still access any pharmaceutical benefits they require on presentation of a current passport from a recognised RHCA country.

This section differs from the corresponding section (section 2.3) in the old determination in a number of ways.

The replacement determination creates a positive requirement for an approved supplier to be satisfied that a person is to be treated as an eligible person to be included in this class. Therefore, any requirements in the old determination that required an approved supplier to have no reason to believe the person is not an eligible person (or entitled to be treated as one) have not been retained.

Finally, the replacement determination simplifies the information or documentation that the approved supplier must examine or consider in order to be satisfied that the person is a foreign person covered by an RHCA. It requires only that the approved supplier must examine the passport covering the person and that the approved supplier must have asked the person or their agent whether there is a medicare number applicable to the person.

#### Section 10 – Persons without a medicare number who a PBS prescriber identifies as entitled to pharmaceutical benefits

Section 10 sets out the matters an approved supplier must be satisfied of in order to classify a person as a person without a medicare number who a prescriber considers entitled to pharmaceutical benefits. Upon being satisfied of these matters, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

Some eligible people in Australia do not have a medicare number. For example, where a newborn baby requires medication but they are not yet registered with Medicare and have not been allocated a medicare number. The prescriber may indicate on the prescription that they consider that the person would be entitled to a pharmaceutical benefit in relation to the prescription. The approved supplier could then supply the pharmaceutical benefit.

The following may be an indication of the prescriber's belief that the person is entitled to a pharmaceutical benefit:

- writing on the prescription that the person is entitled to pharmaceutical benefits; or
- inserting the appropriate special number into the allocated space for a medicare number on the prescription.

This section differs from the corresponding section (section 2.4) of the old determination in the following ways.

- the words “*non-medicare-number service*”, “*nonMNS*” or “*non-MNS*” were previously required to be included on the prescription by the prescriber when



indicating their belief that the person was entitled to the benefit. This requirement has not been retained as these terms are no longer used in practice; and

- provisions which set out matters the prescriber must be satisfied of have not been retained. The replacement determination only sets out requirements and procedures applicable to the approved supplier.

#### Section 11 – Persons without a medicare number who an approved supplier considers are entitled to pharmaceutical benefits

Section 11 sets out the matters which an approved supplier must be satisfied of in order to classify a person as a person without a medicare number who an approved supplier considers are entitled to pharmaceutical benefits. Upon being satisfied of these matters, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

This provision is intended to be used where a person is unable to provide a medicare number, but the approved supplier considers the person to be an eligible person within the meaning of the *Health Insurance Act 1973*, other than a person covered by an RHCA.

For example, a homeless person presents a prescription from a STD clinic and is unable to provide his/her medicare details. The approved supplier forms the view that the person has received medical treatment from a health care service and is an eligible person within the meaning of the *Health Insurance Act 1973*. The approved supplier could supply pharmaceutical benefits.

This section differs from the corresponding section (section 2.5) of the old determination by not retaining a provision requiring the approved supplier to be satisfied that the pharmaceutical benefit was prescribed as the result of a subsidised non-medicare number medical service, since the term is obsolete. The replacement determination only sets out requirements applicable to the approved supplier, not the prescriber.

#### Section 12 – Eligible persons requiring drugs or medicinal preparations as a matter of clinical urgency

Section 12 sets out the matters which an approved supplier must be satisfied of in order to classify a person as a person requiring drugs or medicinal preparations as a matter of clinical urgency. Upon satisfying these requirements, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

This special number applies when a person is in a situation requiring prescription drugs and the approved supplier considers that, in his or her professional opinion, the immediate supply of the medicine is necessary to initiate urgent treatment or to continue without interruption an existing regime (urgent, but not life threatening - that is clinical urgency).

For example, at the time of supply of the pharmaceutical benefit, the urgent supply of medicines may be necessary for treating a chronic disease (such as anti-hypertensive

agents), the approved supplier has requested the person to provide a medicare number but a medicare number is not available. If the approved supplier has no reason to believe that the person is not eligible to receive pharmaceutical benefits, they could supply pharmaceutical benefits.

This section simplifies the drafting and clarifies the existing requirements and procedures from the corresponding section (section 2.6) of the old determination.

Section 13 – Persons for whom an inapplicable medicare number is shown on a seemingly valid medicare card or document

Section 13 sets out the matters of which an approved supplier must be satisfied and the procedure which must be followed by an approved supplier in order to classify a person as a person for whom an inapplicable medicare number is shown on a seemingly valid medicare card or document. Upon being satisfied of these matters, the approved supplier is permitted to use a special number in place of a valid medicare number to make a claim for payment from the Commonwealth for the supply of the pharmaceutical benefit in accordance with Part 4 of the replacement determination.

This special number applies when the person has supplied a medicare number which subsequently turns out to be inapplicable to the person according to Department of Human Services' (DHS) records. The purpose of this particular provision is to enable the approved supplier to submit a claim without obtaining the correct medicare number for that person where there is no evidence before the approved supplier that the person is not an eligible person and the approved supplier has done everything possible to verify the person's medicare number.

This section contains a number of changes from the corresponding section (section 2.7) of the old determination which reflect the move from an entirely manual claiming process to a predominantly automatic, online claiming process

Firstly, the old determination provided in paragraph 2.7(c) and subparagraph 2.7(e)(i) that in processing a previous claim for payment from the approved supplier in relation to supply of a pharmaceutical benefit to the person, DHS must have *found* that the medicare number provided in that claim did not correspond with the number held for that person in DHS records.

When claiming was an entirely manual process, a notification of an invalid medicare number would have been sent to the approved supplier, but claims containing the invalid medicare number would still have been paid for up to 90 days. This would allow the approved supplier reasonable time to obtain a new medicare number from the person.

Consequently, paragraph 2.7(f) of the old determination required an approved supplier to wait 60 days before lodging a subsequent claim containing a special number in place of a valid medicare number. It provided assurance of payment for an approved supplier who, despite their best efforts, was unable to obtain a new medicare number from the person.

The replacement determination retains the requirement that an approved supplier must be satisfied they have made a previous claim for payment in relation to supply of a pharmaceutical benefit to the person. However, the replacement determination requires that DHS must have *rejected the claim* on the basis that the medicare number provided

in that claim did not correspond with the number held for that person in DHS records, in order for the approved supplier to then use a special number in a subsequent claim.

Today, with the vast majority of claims being processed online and in real-time, a notice of rejection will occur at the time of supply, and the approved supplier can generally request a new medicare number from the person immediately. Where a person is not able to provide a new medicare number, the approved supplier can, with the person's permission, phone the DHS Improved Monitoring of Entitlements (IME) service, which allows approved suppliers obtain up to date entitlement details for that person.

Because a notice of rejection of a claim usually occurs in real-time, allowing the approved supplier to take all reasonable steps to obtain a new medicare number from the person at the time of supply, the requirement for an approved supplier to wait 60 days before submitting a subsequent claim for the supply is now obsolete and has not been retained in the replacement determination.

Finally, where an inapplicable medicare number was shown on a seemingly valid medicare card, the approved supplier had taken reasonable steps to obtain a new medicare number but had not been successful, paragraphs 2.7(h) and (i) of the old determination required the approved supplier to obtain and attach a photocopy or photograph of the seemingly valid medicare card when submitting claim containing the applicable special number in accordance with Part 4 of the replacement determination.

The replacement determination removes the requirement to attach the photocopy or photograph of the seemingly valid medicare card. Since the implementation of online claiming, approved suppliers are no longer required to provide a hard copy of a prescription when claiming. Therefore the requirement to attach a hard copy photocopy or photograph is rendered obsolete.

## **Part 4 – Procedure for allocation of special numbers**

### Section 14 – Allocating special numbers

Subsection 14(1) of the replacement determination sets out the procedure for allocation of special numbers. It provides that the special number allocated to a person must be the number specified in subsection (2) for the class of persons in which the person has been included.

Subsection 14(2) of the replacement determination sets out the particular combination of numbers that are to be the special numbers applicable to persons included within each class listed in Part 2.

## **Schedule 1— Repeals**

This item repeals the *National Health (Entitlement to Pharmaceutical Benefits — Special Evidentiary Categories) Determination 2001* as it is being replaced by the replacement determination.