EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) Legislation Amendment (Continuing treatment during Coronavirus pandemic) Instrument 2020

PB 32 of 2020

Authority

This legislative instrument is made pursuant to subsections 85(7) and 100(2) of the *National Health Act 1953* (the Act). Subsection 85(7) gives the Minister the power to determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit. Subsection 100(2) of the Act gives the Minister the power to make special arrangements to ensure adequate supply of pharmaceutical benefits will be available to persons.

This instrument is made in reliance on subsection 85(7) of the Act.

Subsection 33(3) of the *Acts Interpretation Act 1901* provides that 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.

Purpose

This legislative instrument amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) and the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) to modify prescription circumstances to enable continued treatment during the COVID-19 pandemic.

This legislative instrument temporarily modifies the circumstances mentioned in Part 1 of Schedule 4 of PB 71 of 2012, and Schedule 3 of PB 116 of 2010 for circumstances codes for pharmaceutical benefits where:

- the patient has previously been supplied that pharmaceutical benefit; and
- having regard to the individual patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish those circumstances.

This legislative instrument also determines that where the above criteria are met, the prescriber is required to keep a written record of the reason it is not practicable to establish the relevant circumstance.

These amendments are intended to operate where patients may not be able to meet the continuing treatment circumstances for practical reasons in the context of the current COVID-19 pandemic, but it may be clinically inappropriate to cease their treatment. Some examples of situations that may result in patients being unable to meet continuing treatment circumstances include where a patient cannot attend an outpatient clinic to perform a test because the patient is required to quarantine or where a prescriber considers it would be appropriate for an immunocompromised patient to self-isolate. Some examples of pharmaceutical benefits with circumstances that may not be able to be met are:

- The prescription of lumacaftor with ivacaftor for the treatment of cystic fibrosis for a patient who has previously received this treatment, where the patient is unable to attend a hospital outpatient clinic to have a lung function test due to COVID-19.

- The prescription of riociguat for the treatment of chronic thromboembolic pulmonary hypertension for a patient who has previously received this treatment, where the patient is unable to complete tests to demonstrate the benefit from therapy in an outpatient clinic due to COVID-19.
- The prescription of donepezil for the treatment of Alzheimer's disease for a patient who has previously received this treatment, where the prescriber is unable to have the patient complete a mini mental state exam during a telehealth consultation and the patient is unable to attend a consultation in person due to COVID-19.
- The prescription of somatropin for slow growth for a patient who has previously received this treatment, where the patient is unable to have height, weight and bone age measurements to demonstrate the benefit from therapy due to COVID-19.

These provisions will be repealed on 1 October 2020.

Consultation

This instrument affects authorised prescribers and patients who may be entitled to receive pharmaceutical benefits.

The Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body established by section 100A of the Act, made recommendations to the Minister about which pharmaceutical benefits are subject to circumstances where, having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it may not be reasonably practicable to establish those circumstances.

The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. In addition, an industry nominee has been appointed to the PBAC. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

The recommendations provided by the PBAC were informed by correspondence received from patient groups and pharmaceutical companies regarding subsidised access to growth hormone treatment and severe asthma treatment. The PBAC recommendations were also informed by enquiries from a number of prescribers concerning treatments for Alzheimer's disease, cystic fibrosis, chronic thromboembolic pulmonary hypertension, Pulmonary Arterial Hypertension, rheumatoid arthritis, psoriatic arthritis and relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma.

It was considered that further consultation for this instrument was unnecessary due to the nature of the consultation that had already taken place.

General

Details of the instrument are set out in the Attachment.

This instrument commences on 1 May 2020.

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

ATTACHMENT

Details of the National Health (Pharmaceutical benefits) Legislation Amendment (Continuing treatment during Coronavirus pandemic) Instrument 2020

1 Name

This section provides that the name of this instrument is the *National Health (Pharmaceutical Benefits) Legislation Amendment (Continuing Treatment during Coronavirus Pandemic) Instrument 2020)*. The instrument may also be cited as PB 32 of 2020.

2 Commencement

This section provides that the instrument commences on 1 May 2020.

3 Authority

This section states that this instrument is made under subsections 85(7) and 100(2) of the *National Health Act 1953*.

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 has effect according to its terms.

Schedule 1–Amendments

Part 1- Amendments of main listing instrument

1 After subsection 10(3)

This section inserts a new subsection 10(3A) in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012). This new subsection states section 3 of PB 71 of 2012 has effect subject to section 10A.

2 After subsection 10

This section inserts a new section 10A in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012). This section states that for pharmaceutical benefits set out in Schedule 6, the circumstances set out in Part 1 of Schedule 4 have effect as though the circumstance is not mentioned where:

- a patient has previously been supplied that pharmaceutical benefit; and
- having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish those circumstances.

This section also states that where the above criteria are met, the prescriber is required to keep a written record of the reason it is not practicable to establish the circumstance.

This section states this section, subsection 10(3A) and Schedule 6 are repealed at the start of 1 October 2020.

3 At the end of the instrument

This section inserts a new Schedule 6 in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012). Schedule 6 lists the pharmaceutical benefits with modified prescription circumstances during the COVID-19 pandemic.

Part 2- Amendments of special arrangement

4 At the end of section 9

This section inserts a new subsection 9(3) in the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010). This new subsection states section 9 of PB 116 of 2010 has effect subject to section 9AA.

5 After section 9

This section inserts a new section 9AA in the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010). This section states that for pharmaceutical benefits set out in Schedule 5, the circumstances set out in Schedule 3 have effect as though the circumstance is not mentioned where:

- a patient has previously been supplied that pharmaceutical benefit; and
- having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish those circumstances.

This section also states that where the above criteria are met, the prescriber is required to keep a written record of the reason it is not practicable to establish the circumstance.

This section states this section, subsection 9(3) and Schedule 5 are repealed at the start of 1 October 2020.

6 At the end of the instrument

This section inserts a new Schedule 5 in the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010). Schedule 5 lists the pharmaceutical benefits with modified prescription circumstances during the COVID-19 pandemic.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Legislation Amendment (Continuing Treatment during Coronavirus Pandemic) Instrument 2020

(PB 32 of 2020)

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 (Pharmaceutical Benefits) Legislation Amendment (Continuing Treatment during Coronavirus Pandemic) Instrument 2020* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) and the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

This legislative instrument temporarily modifies the circumstances mentioned in Part 1 of Schedule 4 of PB 71 of 2012, and Schedule 3 of PB 116 of 2010 for circumstances codes for pharmaceutical benefits where:

- a patient has previously been supplied that pharmaceutical benefit; and
- having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish those circumstances.

The amendments also determine that where the above criteria are met, the prescriber is required to keep a written record of the reason it is not practicable to establish the circumstance.

Human rights implications

This legislative instrument engages Articles 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 of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This legislative instrument is compatible with human rights because it advances the protection of human rights.

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