



27 February 2020

The Hon Greg Hunt MP
Minister for Health
Parliament House
CANBERRA ACT 2600

Via email: Greg.Hunt.MP@aph.gov.au

CC: Minister.Hunt.DLO@health.gov.au; rezana.berman@health.gov.au


Dear Minister,

National Health (Supplies of out-patient medication) Determination 2019 (No. 2) (PB 110 of 2019) [F2019L01703]

The Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee) assesses all legislative instruments subject to disallowance, disapproval or affirmative resolution by the Senate against the scrutiny principles outlined in Senate standing order 23. The committee has identified scrutiny concerns in relation to the above instrument, and seeks your advice about this matter.

Incorporation

Senate standing order 23(3)(a) requires the committee to scrutinise each instrument as to whether it is in accordance with its enabling Act and otherwise complies with all legislative requirements. These include the requirements prescribed by the *Legislation Act 2003* (Legislation Act).

Sections 8 and 10 of the instrument appear to incorporate the National Health Reform Agreement (the Agreement), as they rely on the Agreement to determine the scope and application of the law. For example, paragraph 8(2)(b) of the instrument provides that section 8 does not apply to supplies of out-patient medication made by a public hospital that is participating in Pharmaceutical Reform Arrangements 'within the meaning of the National Health Reform Agreement'. Similarly, subsection 10(1) limits the scope of section 10 to the supply of out-patient medication made by a public hospital participating in Pharmaceutical Reform Arrangements 'within the meaning of the National Health Reform Agreement'.

Section 5 of the instrument states that 'National Health Reform Agreement has the meaning given in the *Federal Financial Relations Act 2009*'. That Act defines the Agreement as the National Health Reform Agreement as agreed to by the Council of Australian Governments on 2 August 2011, as amended from time to time.

Subsection 14(2) of the Legislation Act provides that legislative instruments may not incorporate documents other than provisions of an Act, a Commonwealth disallowable legislative instrument or rules of court as in force from time to time, unless a specific provision

in the instrument's authorising Act (or another Act of Parliament) provides that the document can be incorporated in this manner.

The committee is unaware of any specific provision in the *National Health Act 1953*, under which the instrument is made, which provides that documents can be incorporated as in force from time to time. Following initial engagement with the department about this matter, a supplementary explanatory statement was registered to clarify that the section 5 of the instrument does not incorporate the Agreement by reference, nor does the instrument incorporate any other document by reference.

Despite the information contained in the supplementary explanatory statement, the committee remains concerned that, by defining the scope of certain provisions by reference to the definition of 'Pharmaceutical Reform Arrangements' in the Agreement, paragraph 8(2)(b) and subsection 10(1) of the instrument incorporate the Agreement as in force from time to time without the legal authority to do so.

In light of these concerns, the committee requests your advice as to whether the instrument could be amended to include the definition of 'pharmaceutical reform arrangements' on the face of the instrument, rather than relying on the definition in the National Health Reform Agreement.

The committee's expectation is to receive a response in time for it to consider and report on the instrument while it is still subject to disallowance. If the committee has not concluded its consideration of an instrument before the expiry of the 15th sitting day after the instrument has been tabled in the Senate, the committee may give notice of a motion to disallow the instrument as a precautionary measure to allow additional time for the committee to consider information received.

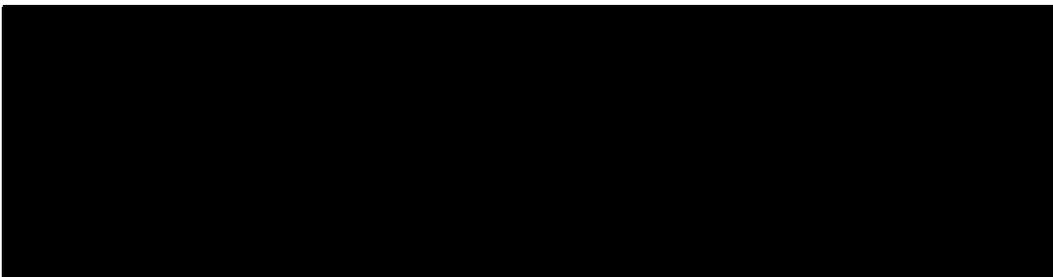
Noting this, and to facilitate the committee's consideration of the matters above, the committee would appreciate your response by **12 March 2020**.

Finally, please note that, in the interests of transparency, this correspondence and your response will be published on the committee's website.

If you have any questions or concerns, please contact the committee's secretariat on (02) 6277 3066, or by email to sdlc.sen@aph.gov.au.

Thank you for your assistance with this matter.

Yours sincerely,



Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation



The Hon Greg Hunt MP
Minister for Health
Minister Assisting the Prime Minister for the
Public Service and Cabinet

Ref No: MC20-003494

Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation
Senator for New South Wales
PO Box 6100
Parliament House
CANBERRA ACT 2600

13 MAR 2020

Dear Senator

I refer to your letter of 27 February 2020 on behalf of the Senate Standing Committee for the Scrutiny of Delegated Legislation requesting advice in relation to the *National Health (Supplies of out-patient medication) Determination 2019 (No. 2) (PB 110 of 2019)* (instrument).

You sought advice as to whether the instrument could be amended to include the definition of 'pharmaceutical reform arrangements' on the face of the instrument, rather than relying on the definition in the National Health Reform Agreement.

Background

Subsection 84BA(2) of the *National Health Act 1953* (Act) provides that the Minister must determine the amount that will be taken to have been paid to a public hospital for supplies of out-patient medication for the purposes of the Pharmaceutical Benefit Scheme patient safety net threshold.

The instrument, made under section 84BA of the Act, prescribes the maximum value of a supply of out-patient medication to a person who is a general patient for supplies of out-patient medication made by public hospitals that are participating in Pharmaceutical Reform Arrangements within the meaning of the National Health Reform Agreement.

The instrument states the National Health Reform Agreement has the meaning given in the *Federal Financial Relations Act 2009* (FFR Act). The FFR Act defines this as the National Health Reform Agreement agreed to by the Council of Australian Governments on 2 August 2011, as amended from time to time.

You have advised the committee is unaware of any specific provision in the *National Health Act 1953*, under which this instrument is made, which provides that documents can be incorporated as in force from time to time.

Proposed amendment

I propose to amend the instrument to remove all references to the National Health Reform Agreement and to refer only to the Pharmaceutical Reform Arrangements.

I also propose to include the definition of Pharmaceutical Reform Arrangements into the instrument. I propose to include the following definition for Pharmaceutical Reform Arrangements:

... means arrangements, made between the Commonwealth and a State or Territory, which provide for public hospitals that are Approved Hospital Authorities under Section 94 of the *National Health Act 1953* to supply pharmaceuticals determined to be pharmaceutical benefits within the meaning of the *National Health Act 1953*, for specific categories of patients including:

- admitted patients on separation;
- non-admitted patients; and
- same day admitted patients for a range of drugs made available by specific delivery arrangements under Section 100 of the *National Health Act 1953*.

Thank you for writing on this matter.

Yours sincerely



Greg Hunt



AUSTRALIAN
SENATE

**Senate Standing Committee for the
Scrutiny of Delegated Legislation**

Parliament House, Canberra ACT 2600
02 6277 3066 | sdlc.sen@aph.gov.au
www.aph.gov.au/senate_sdlc

3 April 2020

The Hon Greg Hunt MP
Minister for Health
Parliament House
CANBERRA ACT 2600

Via email: Greg.Hunt.MP@aph.gov.au
CC: minister.hunt.dlo@health.gov.au

Dear Minister,

National Health (Supplies of out-patient medication) Determination 2019 (No. 2) (PB 110 of 2019) [F2019L01703]

Thank you for your response of 13 March 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation, in relation to the above instrument.

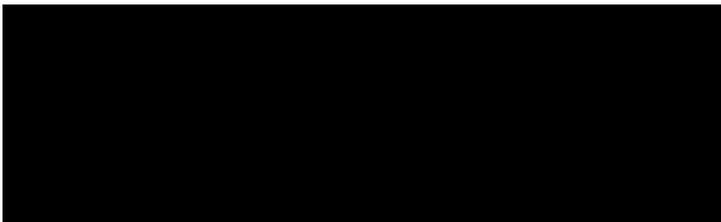
The committee considered your response at its private meeting on 1 April 2020. On the basis of your advice, the committee has concluded its examination of the instrument.

The committee welcomes your undertaking to amend the instrument to remove all references to the National Health Reform Agreement and to provide for a definition for Pharmaceutical Reform Arrangements on the face of the instrument.

In the interests of transparency, I note that your undertaking will be recorded in the *Delegated Legislation Monitor*, and that this correspondence will be published on the committee's website.

Thank you for your assistance with this matter.

Yours sincerely,



Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation