



AUSTRALIAN  
SENATE

Senate Standing Committee for the  
Scrutiny of Delegated Legislation

Parliament House, Canberra ACT 2600  
02 6277 3066 | [sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au)  
[www.aph.gov.au/senate\\_sdlc](http://www.aph.gov.au/senate_sdlc)

13 February 2020

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

Via email: [Greg.Hunt.MP@aph.gov.au](mailto:Greg.Hunt.MP@aph.gov.au)

CC: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

  
Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019) [F2019L01542]**

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 particular scrutiny concerns in relation to the above instrument, and the committee seeks your advice about this matter.

Section 25 of the instrument provides that the secretary may authorise a person to perform any of the secretary's functions or exercise any of the secretary's powers under the instrument on the secretary's behalf. The committee is concerned about the source of legislative authority for this provision, and the proposed scope and form of the authorisation.

***Compliance with authorising legislation***

The instrument is made under section 100 of the *National Health Act 1953* (National Health Act). Section 100 enables the minister to make special arrangements relating to providing an adequate supply of pharmaceutical benefits. It does not expressly provide for the authorisation of persons to administer such arrangements, or perform the functions of the secretary in administering such arrangements. In the absence of further information in the explanatory statement, it is unclear to the committee how the legislative authority for such an authorisation could be implied from section 100 of the National Health Act.

In this regard, the committee notes that there is a question as to whether third parties might be impliedly authorised to perform the secretary's functions in accordance with the decision in *Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560 ('*Carltona*'). However, it is unclear to the committee how that decision could apply in this instance, noting that it concerned the implied authorisation of a senior departmental officer by the

minister to exercise the minister's powers, in the absence of an express delegation. By contrast, this matter involves the authorisation of a private contractor by the secretary, rather than minister, to perform administrative functions conferred by legislative instrument on the secretary. The committee is unaware of any common law principle which provides authority for the implied authorisation of private contractors to perform administrative functions conferred by legislative instrument on departmental secretaries.

**The committee therefore requests your advice as to how section 100 of the National Health Act provides implied authority for the secretary to authorise third parties to perform the secretary's functions or exercise their powers; noting, in particular, the committee's concerns that the authorisation is not supported by the decision in *Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560, for the reasons outlined above.**

#### ***Scope and form of the authorisation***

##### *Scope of powers and functions to be performed by authorised persons*

Subsection 25(1) of the instrument provides that the Secretary may authorise persons to perform 'any of the Secretary's functions' and 'any of the secretary's powers' under the instrument. In the absence of further information in the explanatory statement, it is unclear to the committee why it is necessary to authorise third parties to perform such a broad category of powers and functions.

**The committee therefore requests your advice as to why it is considered reasonable and necessary to authorise a third party to perform all powers and functions which can be exercised by the secretary under the instrument.**

##### *Qualifications of the persons authorised to perform the secretary's functions*

Subsection 25(1) of the instrument also provides that the persons who may be authorised to perform the secretary's functions must have 'suitable qualifications and experience'. Noting the very broad scope of the powers and functions which the secretary may authorise such a person to perform and exercise, the committee is concerned that the instrument does not specify the relevant qualifications and experience which such a person must possess.

**The committee therefore requests your advice as to whether the instrument can be amended to provide greater specificity as to the qualifications and experience which an authorised person must possess.**

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.

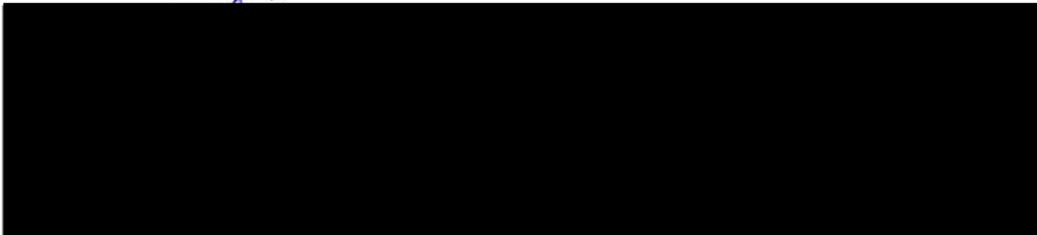
Noting this, and to facilitate the committee's consideration of the matters above, the committee would appreciate your response by **27 February 2020**.

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](mailto: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: MC20-002485

02 MAR 2020

Senator the Hon Concetta Fierravanti-Wells  
Chair  
Senate Standing Committee for the Scrutiny of Delegated Legislation  
Parliament House  
CANBERRA ACT 2600  
[sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au)

Dear Senator

I refer to your letter of 13 February 2020 from the Senate Standing Committee for the Scrutiny of Delegated Legislation (Committee) requesting information about the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)* (Arrangement).

As you know, the Australian Government is investing \$10 million in a take home naloxone pilot (pilot) in three states to help save the lives of people who may overdose on opioids. Every day, three people die from drug-induced deaths involving opioid use in Australia, while nearly 150 hospitalisations and 14 emergency department admissions involve opioids<sup>1</sup>. The pilot is part of the Government's commitment to reducing the adverse health, social and economic consequences of drug use through the National Drug Strategy.

The pilot will provide people at risk of opioid overdose, and those who may witness an overdose, with easy access to free naloxone. Through the pilot, the drug naloxone will be available from a range of sites including pharmacies, alcohol and other drug treatment centres, and needle and syringe programs, at no charge. No prescription will be required. The pilot will run between 1 December 2019 and 28 February 2021, in New South Wales, South Australia and Western Australia.

I note that the Committee has requested further information about how s100 of the *National Health Act 1953* (National Health Act) provides legislative authority for the power in s25 of the Arrangement for the Secretary to authorise third parties to perform his or her functions, and exercise his or her powers, under the Arrangement. To clarify, ss 100(1) and (3) do not provide authority for the Secretary's power in s 25 of the Arrangement on a *Carltona* basis (*Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560).

The *Carltona* principle provides that a person may 'authorise' another person to perform a

<sup>1</sup> Australian Bureau of Statistics (2018) 3303.0 - Causes of Death, Australia. Retrieved from <https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/3303.0~2018~Main%20Features~Opioid-induced%20deaths%20in%20Australia~10000>

function or exercise a power on their behalf, where the legislation conferring the power or function implicitly enables them to do so. Here, however, s25 is an express statutory authorisation power (i.e. power of authorisation which is expressly supported by legislation), which on its terms permits the Secretary to authorise other persons to perform his or her functions, and exercise his or her powers, under the Arrangement.

Section 100(1), read with s 100(3), allows an instrument to provide for arrangements 'for' or 'in relation to' 'providing that an adequate supply of pharmaceutical benefits will be available' to relevant persons, in such a way as to modify the effect of Part VII of the National Health Act. If a special arrangement modifies the Secretary's functions and powers under Part VII of the National Health Act consistently with ss 100(1) and (3), it could also provide for the Secretary to authorise other persons to exercise those modified functions and powers.

Such a provision would not take the arrangement beyond being an arrangement 'for' or (at least) 'in relation to' providing that 'an adequate supply of pharmaceutical benefits will be available to persons', within the meaning of s100(1) nor would it result in any modification to Part VII that would not be authorised by s 100(3). On basis outlined above, s25 of the Arrangement comes within the terms of ss 100(1) and (3) and is supported by s100 of the National Health Act.

To enable the important supply of naloxone to illicit and prescription opioid users as well as their carers, friends and family members at no cost, the Government is supporting pharmacies and other approved naloxone suppliers to claim the cost of naloxone supplied under the pilot through a program administrator. I note the Committee is also seeking my advice as to the appropriateness of amending s25(2) of the Arrangement to include the qualifications and experience that persons authorised may have to perform this function.

My Department considers suitable qualifications and experience for the purpose of s25 to be a provider who can conduct the administrative services of the pilot program, specifically manage claims for payment, collect data and undertake reporting functions. Section 25(2) of the Arrangement provides for an authorisation, by the Secretary, or delegate, in the form of a contract. Accordingly, my Department determined whether a provider has the suitable qualifications and experience by conducting a limited tender procurement process with the requirement that the provider must be able to undertake payments for supply of naloxone products, provide regular reporting on the pilot to my Department, and facilitate data collection for the evaluation of the pilot. The provider also had to demonstrate capacity to provide these services.

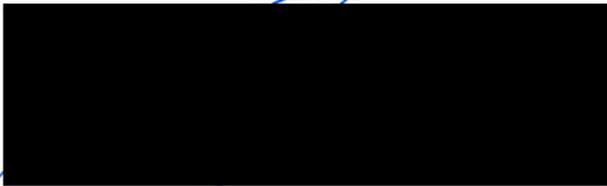
On this basis, Australian Healthcare Associates (AHA) were engaged to perform the necessary administrative services to ensure claims for payment for naloxone to s90 Approved Suppliers, s94 Approved Hospital Authorities and s92 Approved Medical Practitioners, as well as Authorised Alternative Suppliers as defined in the Arrangement, are made. This procurement process is in accordance with the *Commonwealth Procurement Rules, April 2019* and the *Public Governance, Performance and Accountability Act*. AHA were also engaged as the administrator of the naloxone pilot based on their experience in performing these same duties (i.e. managing claims for payment, data collection and reporting) in their role as the current administrator of the 23 Community Pharmacy Programs under the Sixth Community Pharmacy Agreement.

My view is that an amendment to specify suitable qualifications and experience for the purposes of s25 is unnecessary for several reasons. The take home naloxone pilot is a time-limited program and being too prescriptive may be unnecessarily restrictive, limit flexibility to trial different arrangements and negatively impact the operation of the pilot. In addition, if the Government decides to implement a national naloxone program, my Department will consider at that time as to whether it is appropriate to make amendments to the Arrangement to be more prescriptive around the qualifications and experience. However, my Department will arrange for a supplementary Explanatory Statement outlining in detail what it considers suitable qualifications and experience to be included on the Federal Register of Legislation.

The pilot, in conjunction with the various take home naloxone programs currently operating in the states, provides a great opportunity to increase access to naloxone to a wider population at risk of overdose. These programs together will provide critical evidence and information necessary for consideration of a national rollout.

Thank you for writing on this matter.

Yours sincerely



Greg Hunt



3 April 2020

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

Via email: [Greg.Hunt.MP@aph.gov.au](mailto:Greg.Hunt.MP@aph.gov.au)  
CC: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)  
[F2019L01542]**

Thank you for your response of 2 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.

Your detailed response has greatly assisted the committee in its consideration of the instrument. Nevertheless, the committee retains some scrutiny concerns about section 25 of the instrument, and has resolved to seek your further advice about the matters outlined below.

***Scope of administrative powers***

In its letter of 13 February 2020, the committee sought your advice as to the scope of section 25 of the instrument and, in particular, whether the instrument could be amended to provide greater specificity as to the qualifications and experience which an authorised person must possess. Your response identifies a number of reasons why it is unnecessary to amend the instrument in this manner, including the time-limited and pilot nature of the program. Your response also indicates that, should the government decide to implement a national naloxone program, your department will 'consider at that time as to whether it is appropriate to amend the instrument be more prescriptive around the qualifications and experience'.

**In light of your advice, the committee has concluded its consideration of this matter.**

***Compliance with authorising legislation***

The committee also sought your advice as to the source of legal authority for section 25 of the instrument. Your response helpfully clarifies that the government considers that this section relies exclusively on the authority of section 100 the *National Health Act 1953* (the

Act), rather than the decision in *Carltona Ltd v Commissioners of Works* [1943] 2 All ER 560. It further explains that the authorisation of a third party to perform the secretary's powers and functions with respect to the special arrangement constitutes a matter 'in relation to' the provision of an adequate supply of pharmaceutical benefits to certain persons, within the meaning of subsection 100(1) of the Act.

Whilst noting this interpretation, the committee remains concerned that the use of section 100 of the Act to support the authorisation of private third parties to perform the powers and functions of the secretary to administer a special arrangement constitutes an unusual and potentially unintended use of that power. The committee would expect clearer evidence in the enabling provision than 'in relation to' to support a statutory intention to authorise outsourcing of administrative powers.

**Accordingly, the committee requests your advice as to what evidence is available beyond the terms of section 100 of the Act to indicate that Parliament intended section 100 to provide legislative authority for the authorisation of private third parties to perform all of the powers and functions of the secretary in administering special arrangements.**

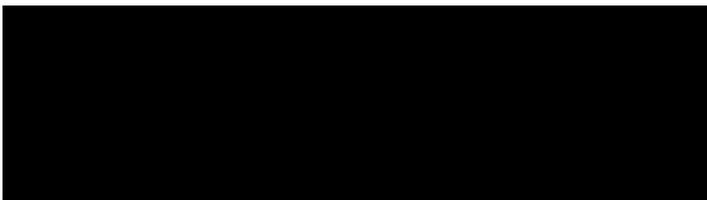
To facilitate the committee's consideration of the matters above, the committee would appreciate your response by **17 April 2020**.

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](mailto: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: MC20-008280

24 April 2020

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

Dear Senator

I refer to your letter of 3 April 2020 from the Senate Standing Committee for the Scrutiny of Delegated Legislation requesting additional information concerning section 25 of the National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019) (Arrangement).

You have asked my Department to provide advice as to what evidence is available beyond the terms of section 100 of the *National Health Act 1953* (Act) to indicate that Parliament intended section 100 to provide legislative authority for the authorisation of private third parties to perform all of the powers and functions of the Secretary in administering special arrangements.

The Explanatory Memorandum for the originating bill, the Health and Ageing Legislation Amendment Bill relevantly provides:

*Section 100 of the National Health Act 1953 provides an important mechanism to enable special distribution arrangements for pharmaceutical benefits where, in particular circumstances, the normal PBS supply arrangements are not convenient or efficient...*

*These amendments will make it clear that these special arrangements can be used for the funding of particular medicines that are not available through the normal operation of the PBS.*

This demonstrates that at the time that section 100 of the Act was enacted, Parliament clearly intended that section 100 of the Act would provide for funding of medicines outside the normal operation of the PBS including, where it is necessary or convenient to do so, arrangements such as those provided for under this Arrangement.

As it is particularly relevant, I also draw your attention to *ADCO Constructions Pty Ltd v Goudappel* [2014] HCA 18 (16 May 2014), where the High Court of Australia indicated that Henry VIII clauses (such as that at section 100(1) of the Act) need not be construed strictly. The joint judgment of French CJ, Crennan, Kiefel JJ at [31] and Gageler J at [61] concluded that such provisions strike 'a legislated balance between flexibility and accountability in working out of the detail of replacing one modern complex statutory scheme with another'.

Consequently, it is clear that section 100 of the Act provides authority for the Secretary to authorise, qualified persons to perform any of the Secretary's functions, or exercise any of the Secretary's powers as are required for the purposes of the supply of pharmaceutical benefits as part of the Take Home Naloxone Pilot under section 25 of the Arrangement.

I trust this information is of assistance in clarifying your concerns.

Thank you for writing on this matter.

Yours sincerely

A large black rectangular redaction box covering the signature area.

Greg Hunt



21 May 2020

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

Via email: [Greg.Hunt.MP@aph.gov.au](mailto:Greg.Hunt.MP@aph.gov.au)

CC: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)  
[F2019L01542]**

Thank you for your response of 24 April 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee), in relation to the above instrument. The committee considered your response at its private meeting on 20 May 2020.

Your response has further assisted the committee in its consideration of the instrument. Nevertheless, the committee retains significant scrutiny concerns about the source of legal authority for section 25 of the instrument, and has resolved to request amendments to the *National Health Act 1953* (the Act) to address these concerns, for the reasons outlined below.

***Compliance with authorising legislation***

The committee has twice sought your formal advice about the source of legal authority for section 25 of the instrument, following preliminary, informal engagement with your department.

In your initial response of 2 March 2020, you advised that section 25 of the instrument is expressly supported by subsection 100(1) of the Act, when read in conjunction with subsection 100(3), as this subsection provides broad authority for the Minister to make special arrangements 'for' or 'in relation to' providing that an adequate supply of pharmaceutical benefits will be available to certain persons.

Whilst noting your interpretation, the committee remained concerned that the use of section 100 of the Act to support the authorisation of private third parties to perform all of the powers and functions of a departmental secretary to administer a special arrangement constitutes an unusual and potentially unintended use of that power. The committee therefore sought your advice as to the evidence available, beyond the terms of section 100

of the Act, to indicate that Parliament intended that section to provide legislative authority for such authorisations.

In your most recent response, you advised that the explanatory material relating to section 100 of the Act demonstrates that Parliament clearly intended that section 100 would provide for funding of medicines outside the normal operation of the Pharmaceutical Benefits Scheme (PBS), including arrangements such as those provided for by the instrument. Your response also cited *ADCO Constructions Pty Ltd v Goudappel* [2014] HCA 18 (*ADCO Constructions*) in support of the proposition that Henry VIII clauses such as subsection 100(1) of the Act need not be construed strictly.

The committee shares your view, informed by the explanatory material to the Act, that section 100 of the Act provides clear authority for the minister to fund medicines outside the normal operation of the PBS by way of a special arrangement. However, the committee remains concerned that this does not extend to authorising private third parties to perform the powers and functions of the secretary to administer special arrangements.

While subsection 100(3) of the Act provides that Part VII of the Act and associated regulations or instruments have effect subject to a special arrangement made under subsection (1), the committee does not consider that *ADCO Constructions* can support the view that section 100 provides legislative authority for the authorisation private third parties to perform the powers and functions of the secretary to administer special arrangements. In this regard the committee notes that Gageler J's proposition regarding the construction of Henry VIII clauses does not appear to have been endorsed by the majority of the Court.

In summary, whilst noting your advice, the committee remains of the view that the authorisation of private third parties to perform the powers and functions of a departmental secretary is a significant matter that must be expressly authorised on the face of an Act. Accordingly, in this instance the committee considers that section 25 of the instrument cannot be impliedly authorised by subsections 100(1) and (3) of the Act, which enable the minister to make special arrangements 'for' or 'in relation to' providing that an adequate supply of pharmaceutical benefits will be available to certain persons.

**In light of the committee's views, the committee requests that the *National Health Act 1953* be amended to expressly provide for the authorisation of private third parties to perform all of the powers and functions of the secretary in administering special arrangements.**

I note that on 12 May 2020, the committee gave notice of a motion to disallow the instrument as a precautionary measure to allow additional time for the committee to consider the instrument. Your response to the committee's request will assist the committee in forming a view as to whether it would be appropriate to pursue the disallowance of the instrument.

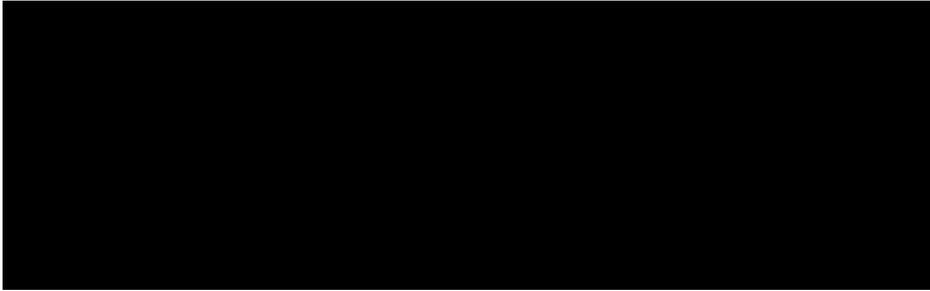
Noting this, and to facilitate the committee's consideration of the matters above, the committee would appreciate your response by **4 June 2020**.

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](mailto: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: MC20-020946

Senator the Hon Concetta Fierravanti-Wells  
Chair  
Senate Standing Committee for the Scrutiny of Delegated Legislation  
Senator for New South Wales  
[sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au)

4 JUN 2020

Dear Senator

I refer to your letter of 21 May 2020 from the Senate Standing Committee for the Scrutiny of Delegated Legislation (Committee), concerning the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (Instrument).

The purpose of this letter is to respond to your further concerns about s 25 of the Instrument and propose a way forward.

**Legal authority for s 25 of the Instrument**

I have considered your concerns regarding the legal authority for s 25 of the Instrument. However, I remain of the view that ss 100(1) and 100(3) of the *National Health Act 1953* (NHA) provide legal authority for s 25 of the Instrument. As I have previously explained, the fact that s 25 permits the Secretary to authorise other parties to perform their functions and exercise their powers does not, in my view, take the arrangement beyond being an arrangement 'for' or 'in relation to' providing that an 'adequate supply of pharmaceutical benefits will be available to persons'. In my view, I consider it unnecessary to amend the NHA on the basis that I am satisfied that the current arrangement is legally sound.

**The role of the third party administrator in practice**

To address your concerns about the role of third party administrators under s 25 of the Instrument, it may be useful to explain what powers and functions third party administrators exercise in practice.

In particular, I wish to emphasise that the powers and functions which the Secretary may exercise under the instrument – or authorise a third party administrator to exercise in accordance with s 25 – are relatively confined, and are of a routine administrative nature. The main powers and functions are to:

- determine the amount payable for a claim made under Part 2 of the Instrument, and make the payment (s 22), and
- request and collect further information in relation to certain claims (s 23).

In practice, the role of a third party administrator which is authorised to exercise these powers and functions is to receive and manage claims, process payments, collect data, and report information to my Department.

For example, in accordance with s 25 of the Instrument, my Department has entered into a Contract for Services to engage Australian Healthcare Associates (AHA) to perform these administrative functions. Under the Contract for Service, AHA provides a software solution to:

- enable approved suppliers (as defined in the Instrument) to make claims for payment of naloxone provided to designate persons
- collect data used to evaluate the pilot program, and
- provide regular reporting on the pilot to my Department.

The reason why it is necessary to engage a third party administrator is because my Department does not have the current resource capacity or IT systems or infrastructure to perform these administrative processes.

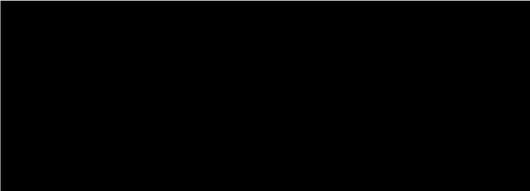
As well as being practically necessary, I consider it is reasonable as a matter of policy for a third party administrator to perform this kind of limited, routine administrative role in the context of the pilot program. The powers and functions which a third party administrator is authorised to exercise are clearly set out in the Instrument, and do not involve any discretionary decision-making. In my view, this does not represent an inappropriate conferral of powers and functions on a third party.

#### **Amending s 25 of the Instrument**

Although I consider that the current arrangement is legally sound and reasonable as a matter of policy, my Department would be open to the possibility of amending s 25 of the Instrument to address the Committee's concerns about the role of third party administrators. For example, it may be possible to amend s 25 to clarify the role of third party administrators, or to provide additional oversight by my Department of the third party administrators' activities. I would welcome any specific suggestions from the Committee in this regard.

Thank you for raising this matter.

Yours sincerely



Greg Hunt



18 June 2020

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

Via email: [Greg.Hunt.MP@aph.gov.au](mailto:Greg.Hunt.MP@aph.gov.au)  
CC: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)  
[F2019L01542]**

Thank you for your response of 4 June 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation (the committee), in relation to the above instrument, and for your willingness to engage constructively with the committee on this matter.

The committee carefully considered your response at its private meeting on 17 June 2020, and, on the basis of your response, has resolved to seek your further advice about the issues outlined below.

***Committee's approach to the scrutiny of instruments***

The committee takes this opportunity to emphasise that, as a technical scrutiny committee, the committee does not consider the policy merits of the instruments that come before it for consideration. In this regard, the committee understands that the instrument supports the implementation of an important pilot scheme to trial the supply of naloxone to persons who are at risk of an opioid overdose in New South Wales, Western Australia and South Australia. However, under the standing orders of the Senate, the committee is required to assess each instrument against its technical scrutiny principles and, where the committee forms the view that an instrument does not comply with these principles, it may recommend disallowance of the instrument to the Senate.

***Compliance with authorising legislation***

*Interpretation of section 100 of the National Health Act*

Your response advises that you remain satisfied that section 25 of the instrument is lawfully supported by subsections 100(1) and 100(3) of the *National Health Act 1953* (National Health Act), on the basis the relevant authorisation falls within the scope of the minister's power under the National Health Act to 'make arrangements for, or in relation to providing that an adequate supply of pharmaceutical benefits will be available to

persons'. You explain that you therefore consider it unnecessary to amend the National Health Act as requested by the committee in its correspondence of 21 May 2020.

The committee has detailed its concerns about this interpretation of subsections 100(1) and 100(3) of the National Health Act in its previous correspondence about this instrument. In summary, it considers that the authorisation of private third parties to perform the powers and functions of a departmental secretary is a significant matter that must be expressly authorised on the face of the Act. In the committee's view, section 100 does not contain such an express authorisation.

In this respect, section 100 contrasts with other provisions in the National Health Act, such as sections 84AAF, 84AAJ and 84AAB, which expressly provide for the authorisation of certain occupations to exercise prescribed powers and perform prescribed functions in relation to the supply of pharmaceutical benefits. The committee notes that the approach taken in those sections of the National Health Act is consistent with the standard approach taken across the Commonwealth to the delegation to, and authorisation of, third parties to perform the functions and exercise the powers of public officials using primary legislation.

#### *Consistency with other special arrangements*

In addition, the committee has also considered the approach taken in other special arrangements made under section 100 of the National Health Act to enabling private third parties to undertake certain actions 'in relation to' the provision of an adequate supply of pharmaceutical benefits to certain persons. In this regard, none of the other special arrangements considered by the committee appear to broadly authorise qualified private third parties to perform all of the functions and exercise all of the powers of a public official under that arrangement.

The special arrangements which require private third parties to perform specified functions or exercise specified powers can be grouped into two categories. Special arrangements in the first category only appear to concern private third parties that are approved and authorised under the National Health Act, such as 'approved hospital authorities' and 'approved pharmacists'. An example of a special arrangement in this category is the National Health (Botulinum Toxin Program) Special Arrangement 2015 (PB 87 of 2015).

Special arrangements in the second category only appear to provide for the approval of private third parties where they meet prescribed conditions, rather than any form of authorisation to exercise a public officer's powers or perform their functions. Once approved, these private third parties can be supplied with pharmaceutical benefits by other third parties approved and authorised under the National Health Act. For example, the National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017 (PB 107 of 2017) (Remote Area Aboriginal Health Services instrument) sets out a framework for the approval of Aboriginal health services to be supplied with pharmaceutical benefits by 'approved pharmacists' and 'approved hospital authorities', which are approved under section 90 and 94 of the National Health Act.

Subsection 9(2) of the Remote Area Aboriginal Health Services instrument sets out the conditions of which the Secretary must be satisfied before it approves an Aboriginal health service. The explanatory statement to that instrument helpfully clarifies that the

Secretary's decision to approve Aboriginal health services under the instrument is not subject to independent merits review, as the Secretary has no discretion to refuse an approved applicant if they meet the conditions set out in subsection 9(2) are satisfied.

In the committee's view, the instrument does not appear to be consistent with the approach taken in the two categories of special arrangements outlined above, which also require certain actions to be performed by private third parties.

**In light of committee's persistent scrutiny concern about the source of legal authority for section 25 of the instrument, the committee requests your advice as to:**

- **why it was considered necessary to authorise suitably qualified and experienced persons to perform all of the functions and exercise all of the powers of the Secretary, when this approach does not appear to have been used in other special arrangements made under section 100 of the National Health Act which also require certain actions to be performed by private third parties; and**
- **whether the department obtained external legal advice on the source of legal authority for section 25 of the instrument, and, if so, whether the committee may be provided with that advice.**

***Role of the third party administrator in practice***

Your response helpfully outlines the powers and functions that third party administrators exercise and perform pursuant to section 25 of the instrument. In particular, you emphasise that the powers and functions of the third party are administrative in nature and do not involve any discretionary decision making. You also indicate your openness to instructing the department to amend section 25 to address the committee's concerns about the role of third party administrators.

At this stage, the committee remains most concerned about the legality of section 25 of the instrument. However, as a technical scrutiny matter, the committee is also concerned to ensure that, where a private third party is lawfully authorised to exercise certain powers and perform certain functions of a public official, the decision to authorise that third party, and the actions of that authorised party, are subject to appropriate public accountability safeguards. These include the availability of independent review of the decision to authorise the third-party and any decisions made by the third party, and the application of privacy and freedom information laws as though the third party were a public official.

In this regard, the committee notes that it is unclear whether the Secretary's initial decision to authorise a third party to perform their functions or exercise their powers is subject to any form of independent review. In contrast, decisions to authorise other private individuals under the National Health Act, such as midwives, nurse practitioners and optometrists, appear to be subject independent merits review (see, for example subsections 105AB(2) and (3)). It is also unclear to the committee whether the third party administrator is subject to the same privacy and freedom of information laws as the Secretary when they perform the Secretary's functions and exercise the Secretary's powers.

**Accordingly, whilst the committee remains most concerned about the source of legal authority for section 25, the committee would also welcome your advice as to:**

- **the availability of independent merits review of the Secretary's decision to authorise third parties to exercise the Secretary's powers and perform the Secretary's functions; and**
- **the application of the *Privacy Act 1988* and *Freedom of Information Act 1982* to third parties purportedly authorised by the Secretary under section 25 of the instrument.**

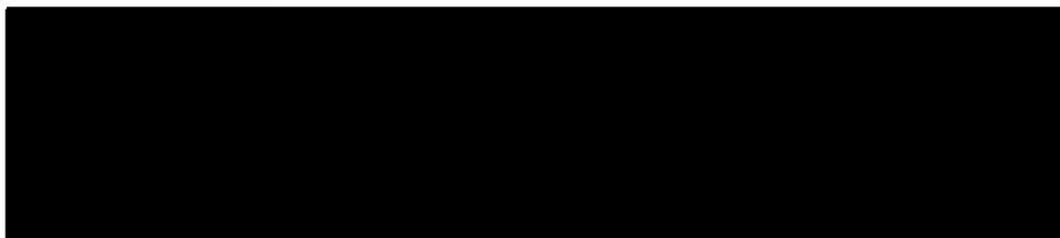
To facilitate the committee's consideration of the matters above, and noting that the notice of motion to disallow the instrument is due to be considered by the Senate on 12 August 2020, the committee would appreciate your response by **2 July 2020**.

Finally, please note that, in the interests of transparency, the committee has published a summary of its scrutiny concerns in Chapter 1 of *Delegated Legislation Monitor 8 of 2020*, and this correspondence and your response will be published on the committee's website, and may be referred to in future Monitors.

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](mailto: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: MC20-026341

Senator the Hon Concetta Fierravanti-Wells  
Chair  
Senate Standing Committee for the Scrutiny of Delegated Legislation  
[sdlc.sen@aph.gov.au](mailto:sdlc.sen@aph.gov.au)

**03 JUL 2020**

Dear Chair

Thank you for your letter of 18 June 2020 from the Senate Standing Committee for the Scrutiny of Delegated Legislation (Committee), concerning the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (Instrument).

The purpose of this letter is to respond to your further questions about s 25 of the Instrument.

**Approach to the design of the Instrument**

You have asked why it was considered necessary to give the Secretary the power in s 25 of the Instrument to authorise a third party administrator to perform the functions and exercise the powers of the Secretary under the Instrument.

I have explained the background and purpose of s 25 of the Instrument in my previous correspondence to the Committee. In particular, I have said that my Department considered it necessary to authorise a third party to perform administrative processes under the Instrument – such as managing claims, processing payments, collecting data and reporting information – because my Department does not have the current resource capacity or IT systems or infrastructure to perform these administrative processes. I have also said that I consider that authorising a third party administrator to perform these routine and limited administrative functions is reasonable as a matter of policy, and would not represent an inappropriate conferral of powers and functions on a third party.

Your letter identified some other examples of special arrangements made under s 100 of the *National Health Act 1953* (NHA) which provide for third parties to perform certain activities, and which set out specific conditions that must be satisfied before third parties can be approved to perform those activities.

The examples you have given appear to relate to approvals for third parties to exercise powers and perform functions of a different nature than what is authorised under s 25 of the Instrument.

For example, you identified that the *National Health (Remote Area Aboriginal Health Service Program) Special Arrangement 2017* (Remote Area Aboriginal Health Service instrument) provides that the Secretary may approve an Aboriginal health service for the purposes of that instrument. An approved Aboriginal health service may obtain certain pharmaceutical supplies from an approved pharmacist or an approved hospital authority for provision to patients in accordance with state and territory legislation.

In contrast, the powers and functions that a third party administrator may be authorised to perform under s 25 of the Instrument do not involve the supply of pharmaceuticals by the administrator to patients. Instead, they relate to the performance of administrative processes, which I explained in further detail in my letter of 4 June 2020. Given this, s 25 of the Instrument is not directly comparable to the provisions relating to approvals under the Remote Area Aboriginal Health Service instrument (nor is it comparable to the other examples you identified, for the same reasons).

You also cite ss 84AAF, 84AAJ and 84AAB as provisions of the NHA, which are consistent with the standard approach to the authorisation of third parties to exercise powers of public officials.

These provisions respectively deal with applications for eligible health professionals to become authorised midwives, nurse practitioners and authorised optometrists in accordance with the specified criteria.

Authorised midwives, nurse practitioners and authorised optometrists are not 'public officials' (i.e. officers of the Commonwealth); they have authority as PBS Prescribers to prescribe drugs to their patients for the purposes of the supply of pharmaceutical benefits in accordance with Part VII of the NHA.

#### **Legal advice**

You have asked whether the Department obtained external legal advice on the source of legislative authority for s 25 of the Instrument, and whether I can provide a copy of that advice to you.

I confirm that the Department obtained external legal advice on the source of legislative authority for s 25 of the Instrument.

I have explained the reasons why I consider s 100 of the NHA to provide legal authority for s 25 of the Instrument in our previous correspondence and consider that release of the Department's legal advice to the Committee would be contrary to accepted and long-standing practice.

#### **Availability of merits review**

You have asked whether the Secretary's decision under s 25 of the Instrument is subject to independent merits review.

I understand that neither the NHA nor the Instrument provide for merits review in relation to a decision by the Secretary under s 25 of the Instrument, although judicial review of the Secretary's decision could be sought in accordance with general administrative law principles.

**Application of the FOI Act and Privacy Act**

You have asked whether the *Freedom of Information Act 1982* (FOI Act) and the *Privacy Act 1988* (Privacy Act) apply to the third party administrator.

**FOI Act**

I understand that the third party administrator is not directly subject to the FOI Act. However, I note that s 6C of the FOI Act requires my Department to take contractual measures to ensure that the Department receives a document from a 'contracted service provider' if:

- the Department receives an FOI request for access to the document
- the document relates to the performance of a 'Commonwealth contract', and
- the document is created by, or is in the possession of, the contracted service provider.

The third party administrator is a contracted service provider. My Department's contract with the third party administrator is consistent with this requirement.

**Privacy Act**

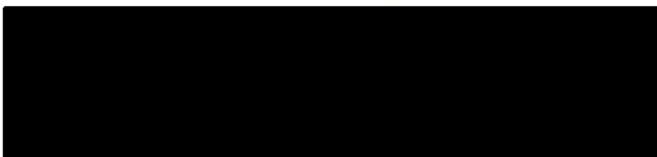
I note that s 95B of the Privacy Act requires my Department, when entering into a Commonwealth contract, to take contractual measures to ensure that a contracted service provider for the contract does not do an act, or engage in a practice, that would breach an Australian Privacy Principle (APP) if done or engaged in by the Department. My Department's contract with the third party administrator is consistent with this requirement.

I also note that the third party administrator, Australian Healthcare Associates, is an organisation which is itself subject to the obligations, which apply to APP entities under the Privacy Act.

**Next steps**

As I mentioned in my previous letter, my Department would be open to the possibility of amending s 25 of the Instrument to address the Committee's concerns about the role of third party administrators. I reiterate that my Department would welcome any specific suggestions from the Committee in this regard.

Yours sincerely

A large black rectangular redaction box covering the signature area.

Greg Hunt



22 July 2020

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

Via email: [Greg.Hunt.MP@aph.gov.au](mailto:Greg.Hunt.MP@aph.gov.au)  
CC: [Minister.Hunt.DLO@health.gov.au](mailto:Minister.Hunt.DLO@health.gov.au)

Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)  
[F2019L01542]**

Thank you for your response of 3 July 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation in relation to the above instrument. The committee remains grateful for your willingness, and the department's willingness, to engage constructively with the committee to resolve this matter.

The committee considered your response at its private meeting on 15 July 2020 and, on the basis of your response, has resolved to seek your further advice about the issue outlined below.

***Scope of powers and functions able to be performed and exercised by third party administrators***

In your response of 3 July 2020 you confirmed that your department sought legal advice about the source of legal authority for section 25 of the instrument, and remain of the view that section 25 is lawfully made. Nevertheless, you indicated your department's willingness to consider amending section 25 to address the committee's concerns on the scope of powers and functions of third party administrators.

**In light of your advice, the committee requests that the department make the following amendments to section 25 of the instrument:**

- amend subsection 25(1) of the instrument to expressly state the particular powers and functions which the Secretary may authorise the third party to perform or exercise under the instrument; and
- amend subsection 25(3) of the instrument to give the department greater control and oversight of the actions of the third party administrator by providing that the actions of the third party require the express approval of the Secretary or their delegate.

**Noting that the proposed amendment to subsection 25(3) may add additional administrative steps in the process of making a claim and potentially delay payments, the committee would be satisfied in the alternative if subsection 25(3) is instead amended to provide for internal review by the department of decisions of third party administrators.**

Should you and your department be amenable to making the proposed amendments, the committee has resolved to withdraw the notice of motion to disallow the instrument following the registration of the amending instrument on the Federal Register of Legislation.

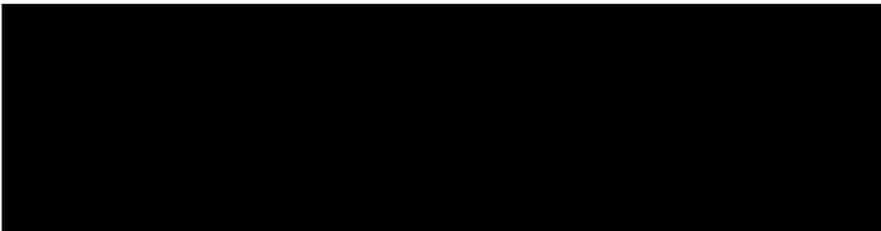
To facilitate the committee's consideration of the matters above, and noting that the notice of motion to disallow the instrument is due to be considered by the Senate on 1 September 2020, the committee would appreciate your response by **29 July 2020**.

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](mailto: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: MC20-030215

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

31 JUL 2020

Dear Chair

I refer to your letter of 22 July 2020 from the Senate Standing Committee for the Scrutiny of Delegated Legislation (Committee), concerning the *National Health (Take Home Naloxone Pilot) Special Arrangement 2019* (Instrument).

While I remain of the view that ss 100(1) and 100(3) of the *National Health Act 1953* provides legal authority for section 25 of the Instrument, to address your concerns about the role of third party administrators under section 25, I will instruct my Department to amend the Instrument as follows:

- amend subsection 25(1) to expressly state the particular powers and functions which the Secretary may authorise the third party to perform or exercise under the Instrument
- amend subsection 25(3) to provide for internal review by the Department of decisions of third party administrators.

I note that the Committee has resolved to withdraw the notice of motion to disallow the Instrument following registration of the amending Instrument on the Federal Register of Legislation. Registration of an amending Instrument will occur prior to 1 September 2020.

Thank you for the Committee's assistance in working with my Department to resolve 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](mailto:sdlc.sen@aph.gov.au)  
[www.aph.gov.au/senate\\_sdlc](http://www.aph.gov.au/senate_sdlc)

27 August 2020

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

  
Dear Minister,

**National Health (Take Home Naloxone Pilot) Special Arrangement 2019 (PB 97 of 2019)  
[F2019L01542]**

Thank you for your response of 31 July 2020 to the Senate Standing Committee for the Scrutiny of Delegated Legislation, in relation to the above instrument.

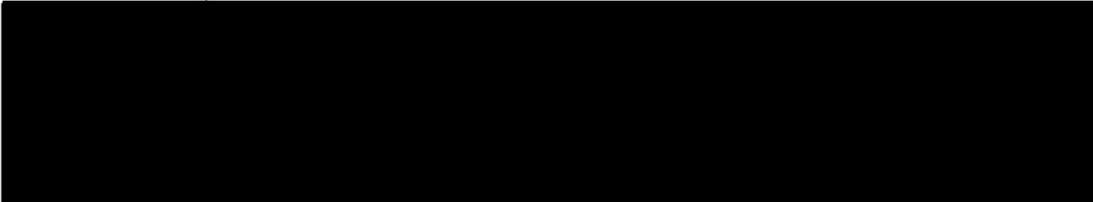
The committee considered your response at its private meeting on 26 August 2020. On the basis of your response, the committee has concluded its examination of the instrument, and has resolved to withdraw the notice of motion to disallow the instrument following the registration of the amending instrument on the Federal Register of Legislation. The committee's consideration of the instrument is detailed in Chapter 1 of its *Delegated Legislation Monitor 9 of 2020*, available on the committee's website at:

[https://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Scrutiny\\_of\\_Delegated\\_Legislation/Monitor](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Scrutiny_of_Delegated_Legislation/Monitor)

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

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

Yours sincerely,



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