SENATOR THE HON RICHARD COLBECK
Minister for Aged Care and Senior Australians
Minister for Youth and Sport

Ref No: MC20-002495

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

28 FEB 2020

Dear Senator Concetta,

Thank you for your correspondence of 13 February 2020 concerning an issue from the Committee's assessment of the *Aged Care Quality and Safety Commission Amendment (Integration of Functions) Rules 2019* (amending instrument), against the scrutiny principle outlined in Senate Standing Order 23(3)(c). The amending instrument amends the *Aged Care Quality and Safety Commission Rules 2018* (Commission Rules).

The Committee seeks my advice in relation to 'whether individuals appointed as 'quality assessors' under subsection 53A(1) of the instrument [sic] are required to possess any particular qualifications, expertise or experience'. The Committee states that where an instrument provides for the appointment of a person or class of persons to a position in which they may be empowered to exercise search and entry powers, the Committee expects those persons to possess the appropriate qualifications or experience necessary to exercise those powers.

Division 3 of Part 8 of the *Aged Care Quality and Safety Commission Act 2018* (Commission Act) relevantly empowers a quality assessor, as a regulatory official, to exercise search and entry powers (with consent) for regulatory purposes, including purposes relating to a quality review of an aged care service or a Commonwealth funded aged care service. New paragraph 53A(1)(a) of the Commission Rules provides that 'the Commissioner must appoint one or more quality assessors to form an assessment team to conduct a quality audit of a home service.'

While the amending instrument inserts new paragraph 53A(1)(a) to provide for the appointment of an assessment team (consistent with the conduct of site audits under Part 2 of the Commission Rules), the amending instrument does not provide for the appointment of a quality assessor itself or equivalent arrangements. These matters are dealt with under the existing Commission Rules and not the amending instrument.

Part 6 of the pre-existing Commission Rules establish arrangements for the registration of quality assessors (Section 7 of the Commission Act defines a quality assessor as a person who is registered as a quality assessor under the rules). A person may apply to be registered as a quality assessor under subsection 89(1), or registered as a quality assessor for a further period under subsection 91(1). The Commissioner must not accept an application that does not comply with the requirements for either application as set out under subsections 89(2) or 91(2).

The Commissioner must register an applicant as a quality assessor for a period of one year or for a further period of one year, if the Commissioner is satisfied of certain matters listed under subsection 90(1) or subsection 92(1).

Relevantly, subsection 90(1) of the Commission Rules requires the Commissioner to register a person as a quality assessor for a period of one year, if the Commissioner is (among other matters) satisfied that:

- The applicant has successfully completed any relevant course specified by the Commissioner (with the Quality Assessor Training Program currently specified by the Commissioner) under paragraph 90(1)(a).
- If the applicant was previously registered as a quality assessor—the applicant's performance of the functions, and exercise of the powers, as a quality assessor was satisfactory under paragraph 90(1)(e).
- The applicant meets any other requirements specified by the Commissioner, including for example compliance with the *POL-ACC-0040 Conflict of Interest: Quality Assessor Policy* and the applicant not having any current parallel engagement with the aged care or health care industry.

Subsection 92(1) of the Commission Rules requires the Commissioner to register a person as a quality assessor for a further period of one year, if the Commissioner is (among other matters) satisfied that:

- The applicant has complied with the obligations set out in a notice given to the applicant in accordance with paragraph 92(1)(a), which for example includes compliance with the Quality Assessor Code of Conduct.
- The applicant has completed mandatory training required by the Commissioner and not less than 15 hours of professional development approved by the Commissioner during the applicant's current period of registration under paragraph 92(1)(b).
- The applicant's performance of the functions, and exercise of the powers, as a quality assessor has been satisfactory under paragraph 92(1)(c).

The Commissioner must also refuse to register an applicant as a quality assessor for a period of one year or for a further period of one year if the Commissioner is not satisfied of the requirements under subsection 90(1) or 92(1) of the Commission Rules.

I trust the above will assist the Committee in its consideration of the amending instrument.

Thank you for raising this matter.

Yours sincerely

Richard Colbeck

SENATOR THE HON JANE HUME
ASSISTANT MINISTER FOR SUPERANNUATION, FINANCIAL SERVICES AND FINANCIAL TECHNOLOGY

Ref: MS20-000409

24 MAR 2020

Senator the Hon Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegate Legislation
Suite S1.111
Parliament House
CANBERRA ACT 2600

Dear Senator Fierravanti-Wells

I am writing in response to your letter dated 27 February 2020, on behalf of the Senate Standing Committee for the Scrutiny of Delegated Legislation (Committee), requesting further information in relation to *ASIC Corporations (Hawking-Life Risk Insurance and Consumer Credit Insurance) Instrument 2019/839* [F2019L01570] (the Instrument).

The Committee has requested more detailed advice as to the reasons for the modification of subsection 992A(3) of the *Corporations Act 2001* (the Act) by the Instrument, rather than by parliamentary enactment. Separately, the Committee has requested information as to whether there is an intention to amend the Act to incorporate the modifications set out in the Instrument.

Modification of the Act by the Instrument

ASIC considers that it was necessary and appropriate to modify subsection 992A(3) of the Act via delegated legislation to reduce consumer harm.

Consumer harm

ASIC considers it has a robust evidence base to justify the use of its modification powers in this instance. ASIC's reviews of direct life insurance and consumer credit insurance (CCI) identified significant consumer harms associated with the design and sale of these products. In particular, ASIC identified a link between outbound telephone sales and poor consumer outcomes, given the complexity of the products and the lack of opportunity for the consumer to assess whether the product met their needs prior to making a purchase (see Report 587 The Sale of Direct Life Insurance, Report 588 Consumers' Experiences with the Sale of Direct Life Insurance, and REP 622 Consumer Credit Insurance: Poor Value Products and Harmful Sales Practices). These concerns were identified in the 'direct' sales context i.e. where no personal advice was provided to the consumer.

In 2019, the Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry (the Royal Commission), having considered case studies concerning the mis-selling of direct life insurance and CCI, recommended that the hawking of all insurance products should be prohibited (Recommendation 4.1).

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Given ASIC's findings about consumer harm and those of the Royal Commission, ASIC considered it appropriate to take steps to prevent further consumer harm by restricting unsolicited sales of direct life insurance and CCI. While the government had accepted the recommendations of the Royal Commission, ASIC considered it necessary and appropriate to use its modification power to modify subsection 992A(3) of the Act to ban unsolicited telephone sales of CCI and direct life insurance sold without personal advice, to provide interim protections to consumers ahead of the primary legislative reform. Had ASIC not taken this action, consumers would have remained at risk of unsolicited sales, which were known to increase the risk of poor consumer outcomes where personal advice was not provided.

ASIC engaged in robust public consultation on its proposal (see CP 317 Unsolicited Telephone Sales of Direct Life Insurance and Consumer Credit Insurance). The responses from stakeholders provided further evidence of consumer harm associated with unsolicited telephone sales of these products. Amongst the 15 non-confidential responses ASIC received from insurers, industry associations, professional bodies, community legal centres, state legal aid commissions and consumer groups, no respondents opposed the introduction of a ban through the use of ASIC's modification powers. Additionally, no industry stakeholders made submissions that the ban would have a significant negative effect on competition or the cost of compliance.

ASIC provided a comprehensive public response to the submissions received and any concerns raised in those submissions (see Report 640 Response to Submissions on CP 317 Unsolicited Telephone Sales of Direct Life Insurance and Consumer Credit Insurance). We note that nine submissions called on ASIC to go further in the use of its modification powers to extend the ban to other products not already covered under the proposal. While some submissions provided anecdotal evidence of this harm, ASIC decided not to broaden the ban given a lack of evidence to suggest a similar degree of systemic harm in relation to these products.

Significant penalty

ASIC's modification power in paragraph 992B(1)(c) of the Act, which allows it to modify section 992A, reflects a parliamentary intention that ASIC would use this power if it is necessary and appropriate, subject to the relevant processes and requirements. That a breach of section 992A creates a criminal offence does not, of itself, present a reason for ASIC to not consider the use of the power in paragraph 992B(1)(c).

The penalties contained in section 992A of the Act reflect a legislative view that breaches of hawking provisions are serious. The provision, which the Instrument modifies, created an exception to an offence, requiring firms to meet a range of procedural and mostly disclosure-based requirements in order to be allowed to engage in unsolicited telephone calls which would otherwise be prohibited (paragraphs 992A(3)(a) to (e)). The modification effected by the Instrument removes this exception for two classes of products.

ASIC considers that the use of its modification powers was consistent with the intent of the legislature, as the obligations in the Act relating to hawking differ depending on the nature (including the complexity and potential risk) of the financial product. In particular, section 992AA regulates the hawking of interests in managed investment schemes and does not contain exemptions equivalent to those in paragraphs 992A(3)(a) to (e). A breach of section 992AA is also a criminal offence.

We also note that the public consultation process did not reveal any concerns by industry or other stakeholders regarding the modification of a provision that creates a criminal offence.

Parliamentary oversight

The Guidelines accompanying Senate Standing Order 23(3)(j) (*Principle (j): Matters more appropriate for parliamentary enactment*) state that:

> where an instrument nevertheless includes such provisions [which modify primary legislation], it should cease to operate no more than three years after the commencement date for the instrument. This is to ensure a minimum degree of parliamentary oversight.

ASIC advises that once primary legislation has taken effect, it plans to repeal the Instrument. With regard to primary legislation, the Treasury released the exposure draft of the *Financial Sector Reform (Hayne Royal Commission Response – Protecting Consumers (2020 Measures) Bill 2020: Hawking of financial products* for public consultation on 31 January 2020. The proposed changes to the hawking regime in the exposure draft include replacing section 992A (including subsection 992A(3)) of the Act with a revised general hawking prohibition which applies to all financial products. The Government expects the Bill to be introduced into Parliament in the 2020 Winter sittings as set out in the Financial Services Royal Commission Implementation Roadmap released by the Government in August 2019.

I trust this information will be of assistance to you.

Yours sincerely

Senator the Hon Jane Hume

The Hon. David Littleproud MP

Minister for Agriculture, Drought and Emergency Management
Deputy Leader of the Nationals
Federal Member for Maranoa

Ref: MS20-000199

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

24 FEB 2020

Dear Senator Fierravanti-Wells

Thank you for your correspondence of 13 February 2020 concerning the Senate Standing Committee for the Scrutiny of Delegated Legislation's (the Committee's) concerns with the *Competition and Consumer (Industry Codes–Dairy) Regulations 2019* (Dairy Code) or (the Instrument).

The Committee has raised concerns with two matters and my response to each follows.

Advice as to why the Instrument does not require reports of reviews to be tabled or published online

The Department of Agriculture, Water and the Environment (the department) has advised me that it will publish online the reports of the reviews of the Dairy Code, so as to ensure that all stakeholders have the opportunity to consider the findings and the recommendations from the reviews. The department has already done so for other industry code reviews undertaken on the *Competition and Consumer (Industry Codes – Sugar) Regulations 2017* (the Sugar Code) and the *Competition and Consumer (Industry Codes – Port Terminal Access (Bulk Wheat)) Regulations 2014* (the Wheat Port Code), which the department also administers. The department will advise industry stakeholders of the intention to publish the reports of the reviews as part of undertaking the reviews. Publishing the reports of the reviews online will promote transparency and accountability as well as ensure appropriate oversight of the review process. I do not consider that a requirement to this effect is needed in the Instrument.

The Instrument is not drafted to require tabling of the written reports of the reviews in Parliament because this is not a feature of other industry code review processes and because, as noted above, the department commits to publishing the written reports of the reviews online – which will of itself allow for transparency, accountability and appropriate public oversight of the review process. Not having a tabling requirement also allows for flexibility to be maintained on the timing of the public release of the reports when the review is completed.

Advice as to whether the Instrument could be amended to ensure that the scope of the civil penalty provisions is limited by terms defined in written law, and if not, why not

The department has advised me that it does not consider the Instrument can be amended such that the relevant civil penalty provisions are limited by terms defined in written law, in a way that maintains consistency with the objectives and purpose of the Instrument.

The 'Obligation to deal in good faith' provisions in the Instrument are intended to promote farmers and processors acting honestly and fairly in their dealings with one another. Deterring a party from acting dishonestly or failing to have regard to the legitimate interests of the other party, and penalising such conducts, is a foundational concept behind the Dairy Code and other mandatory industry codes made under the *Competition and Consumer Act 2010*. For example, the *Competition and Consumer (Industry Codes—Franchising) Regulations 2014* (the Franchising Code) and the *Competition and Consumer (Industry Codes—Horticulture) Regulations 2017* (the Horticulture Code) also impose 300 civil penalty units for contravening the good faith obligation.

Good faith is a concept that has been developed through common law and which continually evolves through common law. Given that the common law continues to consider matters related to good faith, the list under section 11(4) of the Dairy Code is not framed as an exhaustive or comprehensive list, nor does it seek to expressly define its meaning. This allows the Dairy Code to remain consistent with common law as it evolves, and to avoid a situation where there is a disparity between the common law interpretations of good faith and the definition under the Dairy Code.

The list in section 11(4) was developed in consultation with industry stakeholders because of requests for greater clarity and certainty about the types of conduct that would be considered in assessing whether a party has acted in good faith. By providing a list of specific factors which could be taken into account, contextualised within the dairy industry, the Code provides guidance as to the meaning of 'good faith' whilst still allowing for some evolution should common law standards evolve.

By contrast, confining the relevant civil penalty provisions such that they only apply where certain defined circumstances, as set out in the Instrument, are met, would unduly restrict those provisions and risk permitting conduct that may be considered 'not in good faith' by evolving common law standards, but which has not been specified in the Instrument.

The approach adopted in the Dairy Code to defining the concept of good faith is consistent with that used in other industry codes such as the Franchising Code and Horticulture Code.

I trust this information is useful for the Committee.

Thank you for raising this matter.

Yours sincerely

[redacted]

DAVID LITTLEPROUD MP

cc. Treasurer, the Hon. Josh Frydenberg MP

The Hon Karen Andrews MP

Minister for Industry, Science and Technology

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MC20-001430

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

Dear Senator

Thank you for your letter of 13 February 2020 concerning the *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019*.

Reasons for use of Delegated Legislation – an interim first step

The *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* have improved the ability for Australian made complementary medicines to make 'made in Australia' claims. The *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* were necessary as the 2017 changes to the Country of Origin Labelling laws in the *Competition and Consumer Act 2010* resulted in unintended consequences impacting upon particular businesses ability to make Australian origin claims. The intent of section 255 of the Australian Consumer Law was to allow for examples of processes that meet the definition of substantial transformation.

My department and I have engaged with representatives of the $5 billion complementary medicines sector industry over many months. I have taken on board the advice received that a lack of clarity on Country of Origin Labelling requirements was having a deleterious effect on exports and employment in the sector. The sector reported that without clear and immediate action by government there was a high likelihood of business closures, a significant risk to domestic investment in complementary medicine manufacturing and the loss of jobs.

Following consultation with the Hon Michael Sukkar MP, Assistant Treasurer, and the Hon Scott Morrison MP, Prime Minister, and agreement through the Legislative & Governance Forum on Consumer Affairs, I considered it necessary and appropriate to use delegated legislation as an interim step towards achieving our policy objective of alleviating the imminent risks to the sector.

Background

In December 2018 my department initiated a multi-agency taskforce to review the effects of the 2017 Country of Origin Labelling changes on the sector. The taskforce reported in February 2019. The Taskforce noted increasing concerns the sector had regarding the effects of the Country of Origin Labelling changes on domestic and export sales and the potential loss of businesses and jobs. Noting the concerns, the Australian Government decided to engage the states and territories on possible changes to the Australian Consumer Law through changes to the *Competition and Consumer Act 2010* and the *Competitions and Consumer Regulations 2010*.

On 12 December 2019, the states and territories through the Legislative & Governance Forum on Consumer Affairs decided on a two-step action plan to alleviate the risks faced by the sector.

As a first step, the Legislative & Governance Forum on Consumer Affairs agreed to seek an interim regulatory change to provide certainty about the circumstances in which complementary medicines manufacturers can claim Australian origin if at least the last activity in the 'manufacture of dosage form step' of their manufacture occurs in a Therapeutic Goods Administration licensed Australian facility. This first step commenced on 18 December 2019 when the *Competition and Consumer Amendment (Australian-made Complementary Medicines) Regulations 2019* came into force.

Proposed changes to Primary Legislation – the second and final step

The second step, agreed by the Legislative & Governance Forum on Consumer Affairs, will require amendments to the *Competition and Consumer Act 2010* allowing regulations to prescribe processes that satisfy the definition of substantial transformation for complementary medicines. Under this second step, consumers will gain additional support as new regulations will be made requiring labels of complementary medicines to display the proportion of Australian ingredients if an Australian origin claim is made under the proposed new laws.

I intend to present to the Parliament later this year the necessary amendments to the Australian Consumer Law and subsequent regulations.

Consumer protection will be further strengthened when proposed changes to the *Competition and Consumer Act 2010* are made and new regulations are passed requiring greater disclosure of the proportion of domestic ingredients in complementary medicine products.

Yours sincerely

Karen Andrews

27/2 /2020

THE HON JOSH FRYDENBERG MP
TREASURER

Ref: MS20-000361

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

Connie

Dear Senator Fierravanti-Wells,

I am writing to in response to your letter of 13 February 2020 regarding the *Corporations Amendment (Design and Distribution Obligations) Regulations 2019* [F2019L01626] (the Regulations).

In that letter, the Committee requested my advice as to why it was considered necessary and appropriate to include the exemptions to the design and distribution obligations in delegated legislation rather than primary legislation. The committee noted that the provisions to which the exemptions apply are yet to commence.

The use of delegated legislation reflects the broad scope of the financial products and arrangements in relation to which the design and distribution obligations in the primary law apply, namely financial products within the meaning of the *Corporations Act 2001* and additional financial products within the meaning of the *Australian Securities and Investments Commission Act 2001*. Given the breadth of the coverage of the design and distribution obligations, the number and technical nature of financial products within its scope, and the variety of ways in which those products are distributed, it is desirable that limits to and expansions of the regime in relation to specific types of products may be effected by delegated legislation. Accordingly, I consider it appropriate that the exemptions in the Regulations are contained in delegated legislation.

Further, significant consultation was undertaken in developing the Regulations to ensure they operate as intended and properly reflect the technical nature of the financial products they are intended to cover as they exist in the market today.

As the explanatory statement notes, public consultation was undertaken on an earlier version of the Regulations, from 23 October 2018 to 13 November 2018. Eleven submissions were received from consumer groups, industry groups and financial services entities.

Public consultation was also undertaken on a revised version of the Regulations reflecting the Parliamentary amendments incorporated into the final Act, from 12 September 2019 to 11 October 2019. Seventeen submissions were received from consumer groups, industry groups and financial services entities on the revised version of the Regulations. Public consultation was also undertaken on the primary legislation.

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As the committee notes, the provisions are yet to commence. However, it was considered desirable that the Regulations were settled well in advance of the commencement date of the design and distribution obligations, given the need for industry to develop processes and systems to ensure compliance with the new obligations.

Thank you for bringing your concerns to my attention.

Yours sincerely

THE HON JOSH FRYDENBERG MP

29/2 /2020

The Hon. David Littleproud MP

Minister for Agriculture, Drought and Emergency Management
Deputy Leader of the Nationals
Federal Member for Maranoa

Ref: MC20-001131

3 MAR 2020

Senator the Hon. Concetta Fierravanti-Wells
Chair
Senate Standing Committee for the Scrutiny of Delegated Legislation
Parliament House
Canberra ACT 2600

Dear Senator Fierravanti-Wells

Thank you for your letter of 13 February 2020 relating to scrutiny concerns with the Export Control (Sheepmeat and Goatmeat Export to the European Union Tariff Rate Quotas) Order 2019 (the Order). I appreciate the time you have taken to bring this matter to my attention.

With regard to decisions under the Order, subsections 19(4), 20(7) and 23(2) are not made using computer programs for the express purpose of preventing the issues you have raised. The use of computer programs to make automated decisions are limited to non-discretionary decisions within the Order.

Subsection 34(1) of the Order states that "the Secretary may arrange for the use, under the Secretary's control, of computer programs for making decisions under this instrument." The explanatory statement of the Order states that section 34 "provides the Department with the ability to use computer systems where suitable". Decisions under subsections 19(4), 20(7) and 23(2) of the Order are not suitable for being made by computer due to their discretionary nature, and this is reflected in policy and practice.

The computer programs used by the Department of Agriculture, Water and the Environment in administering tariff rate quotas (TRQs) under the Order are not used to make these decisions and are not capable of doing so. This has been a consistent approach taken by the department for over 10 years in using computer programs to support the administration of the TRQs. This ensures that the decision-maker makes such decisions personally. As the computer programs are also not used as automated assistance in the decision making process the decision-maker is not fettered in making a decision.

Thank you for raising this matter.

Yours sincerely

[redacted]

DAVID LITTLEPROUD MP

Parliament House, Canberra ACT 2600 Telephone: 02 6277 7190 Email: Minister.Littleproud@awe.gov.au

SENATOR THE HON MATHIAS CORMANN

Minister for Finance
Leader of the Government in the Senate

REF: MC20-000405

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

Dear Senator Fierravanti-Wells

I refer to the Committee's request of 13 February 2020 for further information on the item that provides legislative authority for a grant to the DP Jones Nursing Home, which is in the following instrument:

- the *Financial Framework (Supplementary Powers) Amendment (Health Measures No. 3) Regulations 2019.*

I can confirm the amount of funding that has been expended on this grant is $480,000 and I have agreed to update the explanatory statement.

I trust that this advice will assist the Committee with its consideration of the item, and my department will advise the Committee secretariat when the revised explanatory statement is published on the Federal Register of Legislation. I have copied this letter to the Minister for Health, and the Minister for Aged Care and Senior Australians.

Thank you for bringing the Committee's comments to the Government's attention.

Kind regards

[redacted]

Mathias Cormann
Minister for Finance

21 February 2020

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
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CANBERRA ACT 2600

13 MAR 2020

Dear Senator Concetta

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.

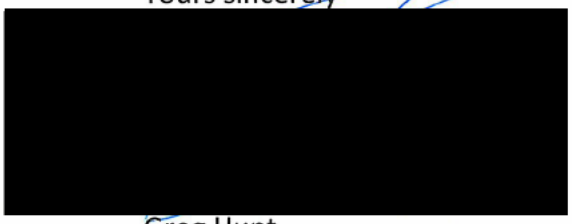
I also propose to include the definition of Pharmaceutical Reform Arrangements into the instrument. I propose to include the following definition for Pharmaceutical Reform Arrangements:

... 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

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

Dear Senator Connie

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[1]. 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 *(Cartlona ltd v Commissioners of Works* [1943] 2 All ER 560).

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

[1] 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

[redacted]

Greg Hunt

SENATOR THE HON ZED SESELJA
Assistant Minister for Finance, Charities and Electoral Matters

REF: MS20-000483

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

Dear Senator Fierravanti-Wells

Taxation Administration (Private Ancillary Fund) Guidelines 2019

I am writing in relation to correspondence from the Senate Standing Committee for the Scrutiny of Delegated Legislation (the Committee) relating to the Taxation Administration (Private Ancillary Fund) Guidelines 2019 (the Guidelines).

As advised to the Committee, merits review within the framework set out in Part IVC of the *Taxation Administration Act 1953* can only be applied to decisions made under a taxation law (an Act) or regulations made under such an Act. Therefore, merits review does not currently extend to other subordinate instruments made under a tax Act, such as the Guidelines.

Following representations made by the Committee, I have asked my Department to progress the development of an amendment to primary legislation that would enable merits review within the framework provided for in the *Taxation Administration Act 1953* to be provided to administrative decisions of the Commissioner of Taxation made under the Guidelines.

I have asked for the amendments to be progressed as soon as is practicable within the context of the Treasury's Minor and Technical Amendments process.

I trust this information will be of assistance to the Committee.

Yours sincerely

[redacted]

Senator the Hon Zed Seselja
Assistant Minister for Finance, Charities and Electoral Matters

17 / 3 / 2020