



BETTER ACCESS
— AUSTRALIA —

8 March 2021

Senator the Hon Concetta Fierravanti-Wells
Senator the Hon Kim Carr
Senator Raff Ciccone
Senator Perin Davey
Senator Nita Green
Senator Paul Scarr
The Senate Standing Committee for the Scrutiny of Delegated Legislation
Australian Parliament House

Dear Senators

Request for Committee Intervention on Unlawful Exercise of Delegated Powers

Better Access Australia was established in September 2020 to advance improvements in health, disability, and social services to achieve better access and continuity of care for all Australians by 2030.

We are writing to you in your role as members of the Senate Standing Committee for the Scrutiny of Delegated Legislation to bring to your attention, and seek your action upon, what we believe to be an unlawful exercise of power under the *National Health Act 1953* using delegated powers. We also consider that in exercising this delegation the Department of Health has breached anti-discrimination laws in its administration of the Pharmaceutical Benefits Scheme (PBS).

Had the exercise of these delegated powers been subject to the scrutiny of Parliament, which in our opinion is legally required, then this discrimination could have been prevented. We seek your urgent attention to address this matter which is impacting on some of the most vulnerable in the community.

Why we believe the current exercise of power is unlawful

Subsection 100(1) of the [National Health Act 1953](#) enables the Minister or their delegate to “*make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons.*” These arrangements can be made through delegated instruments.

The Department of Health is currently enforcing or giving effect to 15 s100 instruments, 14 of which are legislated instruments registered on the Federal Register of Legislation. The only s100 ‘special arrangement’ that is not a legislative instrument relates to the Opiate Dependency Treatment (ODT)

Program. The only publicly accessible copy of the current 2016 instrument is through a Department of Health response to a pharmacist's [FOI request](#) in 2019.

The 2016 ODT Program instrument, has the following effect on patients accessing PBS-subsidised medicines under this Program:

- Removes the normal operations of the PBS co-payment
- Removes a patient's access to the (PBS) safety net, and
- Allows for uncapped administration fees for the dispensing of the nominated medicines under the Program.

In removing both the obligations and protections of the PBS co-payment and safety net system for access to medicines under the ODT Program, the Department of Health has established a Program that can charge unfettered and unregulated fees for the dispensing of an essential medicine to a patient. Only PBS-subsidised medicines made available via this Program have both these protections removed and unregulated private fees applied.

It is our opinion that the delegate of the Department of Health does not have the power under law to make this instrument without it being subject to the scrutiny of the Senate Standing Committee for the Scrutiny of Delegated Legislation as a legislative instrument.

Subsection 8(4)(b)(ii) of the [Legislation Act 2003](#) states that:

- (4) An instrument is a *legislative instrument* if:
- (a) the instrument is made under a power delegated by the Parliament; and
 - (b) any provision of the instrument:
 - (i) determines the law or alters the content of the law, rather than determining particular cases or particular circumstances in which the law, as set out in an Act or another legislative instrument or provision, is to apply, or is not to apply; and
 - (ii) **has the direct or indirect effect of affecting a privilege or interest, imposing an obligation, creating a right, or varying or removing an obligation or right.** [emphasis added]

As outlined above, the Department of Health's instrument has a direct effect on removing a patient's 'privilege or interest' under the Pharmaceutical Benefits Scheme.

Furthermore, subsection 15K(1) of the [Legislation Act 2003](#) states that "A legislative instrument is not enforceable by or against any person (including the Commonwealth) unless the instrument is registered as a legislative instrument."

The ODT Program instrument has not been made as a Legislative Instrument, nor has it been registered as such, as required by the [Legislation Act 2003](#). It is for these reasons that Better Access Australia believes that the Department of Health's past and on-going exercise of power in relation to the ODT Program under s100 of the [National Health Act 1953](#) is unlawful.

We are also concerned that the Minister for Health and the Department of Health have been notified of this fact, and continue to operate the Program, thereby knowingly committing maladministration.

Why we believe the exercise of power is discriminatory

The Federal Court has confirmed that dependence on opioids (such as methadone or heroin) is a disability under the [Disability Discrimination Act 1992](#) (Cth) (DDA) ([Marsden v HREOC \[2000\] FCA 1619](#)).

In this case the Court found that, it is unlawful under the DDA for an employer to treat an employee or prospective employee less favourably than the employer would treat someone else because the person is addicted to opioids, has previously been addicted to opioids, or because the employer has imputed opioid addiction to the person. An employer may also breach the DDA by failing to make reasonable adjustments for an employee with an opioid addiction or by requiring an employee to comply with an unreasonable requirement or condition that he or she cannot comply with due to an opioid addiction.

Furthermore, as reported in [BioPharmaDispatch](#) on 2 March 2021:

In 2007, the Administrative Review Council, whose function was consolidated into the Attorney General's Department in 2015, released a best practice guide for lawful decision-making in the federal government.

According to the guide, "Discrimination means treating someone unfavourably or less favourably without good reason on the basis of specified grounds or attributes."

It listed a range of factors that would constitute discrimination under Commonwealth law, including a person's medical record.

Better Access Australia considers that the Department of Health's ODT Program is discriminatory as it removes the rights of patients on the basis of their disability – opioid dependency and their medical record.

It is only patients who are accessing PBS-subsidised medicines for the treatment of opioid addiction that have their protections of the PBS co-payment and safety net removed AND have that replaced with the Department of Health authorised charging of uncapped fees for the dispensing of the medicine in any setting. No other PBS-subsidised medicine has these limits both on PBS co-payments and safety net access AND the government-authorisation of uncapped fees to replace the PBS co-payment and safety net for a government-subsidised medicine.

Other organisations that have concerns about ODT Program

The following organisations have publicly raised their concerns with the Department of Health's ODT Program:

- [Harm Reduction Australia](#)
- [Pharmacy Guild of Australia](#)
- Consumers Health Forum
- [BioPharmaDispatch](#)
- Pharmaceutical Society of Australia

Circumventing Parliamentary Scrutiny

Better Access Australia is of the opinion that the ODT Program is unlawful as it has not met legislative requirements and is discriminatory.

The Minister for Health and the Department of Health have been made aware of these serious issues but to date have not acted to address the matter. In doing so, the Minister and the Department, have usurped the powers of the Australian Parliament and responsibilities of the Senate Standing Committee for the Scrutiny of Delegated Legislation.

This disregard for the law and the role of your Committee should not be tolerated, and that if the Minister and the Department refuse to address this issue, then the representatives of the Parliament with responsibility for the scrutiny of delegated legislation must.

We would welcome the opportunity to answer any questions you may have on this important issue. Better Access Australia can be contacted at dmackay@betteraccessaustralia.org.au or on 02 6198 3364.

Yours sincerely,



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