

COURT MAY FIND ACTIONS UNDER THE OPIATE DEPENDENCY TREATMENT PROGRAM TO BE UNLAWFUL

The Opiate Dependence Treatment (ODT) Program is the only program on the Pharmaceutical Benefits Scheme (PBS) where patients are not protected by co-payments and the safety net and instead charged uncapped fees often in excess of \$200 per month.

Minister Hunt and his Department have repeatedly asserted that the ongoing financial discrimination imposed on patients accessing PBS medicines via the ODT Program are legal and justified. They have commenced a protracted 18-month post market review (PMR) to defer taking any action on the Program.

The Senate Standing Committee on Delegated Legislation has challenged this assertion in its [letter of 16 August 2021](#) concluding that:

“...a challenge to the validity of the current special arrangement on the basis that it should have been registered as a legislative instrument may result in a court finding the actions undertaken under the current arrangement to be unlawful.”

[Better Access Australia](#) director David Mackay said, “Better Access Australia thanks the Delegated Legislation Committee for its efforts in pursuing Minister Hunt and the Department on this issue, and its robust consideration of the question of legality.

“Australian consumers must have confidence that our government institutions will apply the protections of the law fairly and equitably and without bias or discrimination. Today consumers who have been impacted by these uncapped unjustified fees, can have confidence that the Parliament is looking out for their best interest.”

Minister Hunt was informed of the Committee’s conclusion on 16 August some six weeks ago. Yet on 6 September Department of Health officials continued to obfuscate in response to questioning by Senator Siewert on this matter.

“The Department has made undertakings to various bodies since 2019 to address this issue, and yet its ongoing testimony to the Senate and advice to stakeholders has not reflected its knowledge of the legal status of the Program.” Mr Mackay said.

“We don’t need a post market review of the medicines, we need an independent review of the administration of the Program, and Better Access Australia will be asking for a parliamentary referral to the Australian National Audit Office of the administration of the ODT Program as a matter of urgency.” Mr Mackay added

The findings of the Delegated Legislation Committee were consistent with the concerns raised by Better Access Australia in its [letter](#) to the Committee in March 2021, advising Minister Hunt that:

“...it remains unclear whether the current special arrangement for the ODT program should be a legislative instrument.”

It appears to the committee that the ODT program special arrangement may be legislative in character, noting that, as set out in subsection 8(4) of the Legislation Act 2003, it appears to determine the law, and 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.

The committee notes that other special arrangements made under section 100 of the Act are recognised as being legislative in character, and therefore registered as legislative instruments, and it appears this status may apply equally to the ODT program special arrangement.”

Mr Mackay added, “This advice is a great start, but as the Minister has failed to take action in response to the Committee’s advice, it is clear the need to advocate for the immediate reform of the Program continues.

“Lives are being lost every day as a result of the Minister’s intransigency and delaying tactics. Just as Robodebt devastated so many vulnerable Australians, Minister Hunt’s refusal to take immediate action to end the discriminatory practices of the ODT Program is equally devastating. Enough is enough.

“With an 18-month PBAC review being used to defend the indefensible, the concern for patients and for pharmacists charging these fees is very real, and Better Access Australia is working with other parties on options that will hold Minister Hunt accountable under law.”

The Facts:

1. ODTP medicines are the only medicines on the PBS where a patient can be denied their Medicare (PBS) co-payment and safety net protections and be charged unlimited out-of-pocket fees on a daily basis to access their medicines.
2. The PBAC has acknowledged that over 75% of patients accessing these medicines face these out-of-pocket costs, and further acknowledge those costs are a barrier to people accessing treatment for their chronic disease.¹
3. The instrument establishing the ODT Program under the *National Health Act 1953* is the only s 100 instrument out of 15 not to be registered as a legislative instrument.
4. The ODTP instrument is likely to have been unlawful since the commencement of the *Legislation Act 2003* (requirement for legal instruments removing entitlements to be legislative instruments) and the *Parliamentary Scrutiny Act 2011* (legislative instruments cannot be discriminatory or infringe human rights).
5. The Delegated Legislation Committee assesses delegated legislation against a set of scrutiny principles that focus on compliance with statutory requirements, the protection of individual rights and liberties, and principles of parliamentary oversight. It was established in 1932 and is currently chaired by Government Senator the Hon Ferravanti-Wells with former Industry Minister Senator the Hon Kim Carr as deputy chair.

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For more information, visit www.betteraccessaustralia.org.au.

¹ [buprenorphine-psd-november-2018.pdf \(pbs.gov.au\)](https://www.pbs.gov.au/medicines/odt/buprenorphine-psd-november-2018.pdf)