**EXPLANATORY STATEMENT**

***National Health Act 1953***

***National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023***

**PB 61 of 2023**

**Purpose**

The purpose of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023* (PB 61 of 2023) (**Instrument**) is to temporarily provide for responsible persons (pharmaceutical companies) of opioid dependence treatment (**ODT**) medicines to continue to supply certain dosing sites directly, and for responsible persons to claim payment directly from the Commonwealth for those supplies until 30 November 2023.

This Instrument is intended to support dosing sites to transition patients to usual Pharmaceutical Benefits Scheme (**PBS**) arrangements for the supply of ODT medicines under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (**HSD Special Arrangement**). ODT medicines were included in the HSD Special Arrangement as a result of amendments made on 1 July 2023 by the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (PB 57 of 2023) (**Amendment Instrument**).

The Instrument is time-limited, and only applies to supplies of ODT medicines made until the end of November 2023.

**Background**

ODT medicines currently listed on the PBS include methadone oral liquid, buprenorphine sublingual tablets, buprenorphine with naloxone sublingual films and long-acting injectable buprenorphine.

State and territory governments operate individual ODT programs in their respective jurisdictions. These programs include patient eligibility criteria, take-away dosing policies, as well as the approval or authorisation of participating prescribers (medical practitioners and nurse practitioners) and dispensing (dosing) points for participation in individual jurisdictional programs. The operation of state and territory ODT programs are currently and will continue to be governed by the respective policies, guidelines and regulations within each jurisdiction. The provision of ODT medicines under the PBS is intended to operate in parallel with jurisdictional ODT programs.

ODT medicines are listed as controlled drugs in Schedule 8 of the Poisons Standard (*Therapeutic Goods (Poisons Standard-June 2023) Instrument 2023*, available at [www.legislation.gov.au](http://www.legislation.gov.au)), and therefore have specific requirements for handling, storage, prescribing and dispensing which are given effect through the relevant state and territory legislation. Prescribers and suppliers such as pharmacies must comply with the provisions of state and territory regulations for controlled drugs when prescribing and dispensing medicines for the treatment of opioid dependence.

Reforming access to ODT medicines

From 1 July 2023 the Amendment Instrument incorporates ODT medicines into the Section 100 Highly Specialised Drugs (**HSD**) Program (Community Access). This means ODT medicines will be supplied in the same way as other community access Section 100 HSD Program medicines from PBS approved suppliers, including the PBS co-payment and safety net arrangements for patients. PBS approved suppliers are approved pharmacies, approved hospital authorities or approved medical practitioners.

In addition, a new ODT Community Pharmacy Program will take effect from 1 July 2023 and will be administered by the Pharmacy Programs Administrator (**PPA**). The ODT Community Pharmacy Program will complement, but is not part of, PBS arrangements for the supply of ODT medicines.

Transitional arrangements for ODT medicines

Reforming ODT access will mean a change to the way state and territory dosing sites operate as, only approved suppliers can supply HSD medicines. The Instrument provides a time-limited transition period, ending on 30 November 2023, during which responsible persons can continue to supply ODT medicines directly to non-PBS dosing sites. This arrangement is like pre-1 July 2023 arrangements which were established under section 100 of the *National Health Act 1953* (**Act**) where the Commonwealth pays the responsible person the full cost of ODT medicines supplied directly to dosing sites.

The intent is for patients to be safely supported to transition to arrangements whereby they can access the PBS co-payment and safety net arrangements under the HSD Program, prior to the end of the 5-month transition period for non-PBS dosing sites.

This Instrument does not apply to supplies to patients of ODT medicines by PBS approved suppliers. Rather, it applies to supplies made by suppliers authorised by the relevant state or territory to supply ODT medicines and who are not PBS approved suppliers (***authorised suppliers***). This means, these transition arrangements will not apply to approved pharmacies, approved hospital authorities (including HSD hospital authorities) or approved medical practitioners who can start to supply ODT medicines to their patients under the HSD Special Arrangement ([www.legilsation.gov.au](http://www.legilsation.gov.au)) from 1 July 2023.

Authorised suppliers include private clinics, non-PBS community pharmacies, GP practices, correctional facilities, and other non-PBS dosing sites. Authorised suppliers will receive supplies of ODT medicines from responsible persons at no cost. Authorised suppliers will supply ODT medicines to patients participating in state and territory ODT programs, as prescribed by authorised prescribers.

Responsible persons will submit claims for payment to the Department of Health and Aged Care and be paid the approved ex-manufacturer price of ODT medicines supplied to authorised suppliers.

Patients are not required under the Act to make a PBS contribution for the cost of the medicine (PBS co-payment), as authorised suppliers are not able to submit claims for payment through Services Australia in the same way as approved suppliers do for other PBS medicines and are supplied ODT medicines for free. The amount that contributes to a patient’s PBS Safety Net is zero because there is no requirement to make a PBS co-payment. It is understood that some dosing sites may continue to charge patients dispensing or dosing fees for the supply of their ODT medicines during this transition period until patients can be transitioned to receiving their supplies under the Section 100 HSD Program and pay the PBS co-payment.

As this Instrument will operate in parallel with the broader reforms to ODT medicines, it will not delay access to new reformed PBS support for patients already accessing their ODT medicines from PBS approved pharmacies but will provide a transition period for some patients accessing their treatment from non-PBS dosing sites. It will also provide a transition period for GP clinics that offer treatment with long-acting injectable buprenorphine to put in place arrangements for obtaining supplies from PBS approved suppliers.

**Authority**

Subsection 100(1) of the Act enables 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:

* living in isolated areas or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or
* where the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect, subject to a special arrangement made under subsection 100(1).

Paragraph 85(7)(b) of the *National Health Act 1953* (Act) provides that the Minister may, by legislative instrument, determine the circumstances in which a prescription for the supply of a pharmaceutical benefit may be written.

**Commencement**

The Instrument commences on 1 July 2023.

**Consultation**

The Post-market Review of Opioid Dependence Treatment medicines, which informed the reforms to ODT access, included multiple opportunities for consultation with stakeholders regarding affordability and access to ODT medicines. This included public consultation on the draft Terms of Reference (28 May – 30 June 2021), submissions to the review (17 August – 1 October 2021), a stakeholder forum (held 24 February 2022) and targeted consultation with patients participating in ODT programs (throughout November 2022). Consultation included written submissions to the PMR, a stakeholder forum webinar as well as focus groups and individual interviews with consumers.

Consultation on the implementation of reform to ODT medicines and its move to supply under the HSD Special Arrangement occurred with key stakeholders including pharmacy organisations, prescriber organisations, consumer organisations, state and territory governments and pharmaceutical sponsors of ODT medicines. Specific organisations include the Pharmacy Guild of Australia, Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, Royal Australian College of General Practitioners, National Aboriginal Community Controlled Health Organisation, Australian Injecting & Illicit Drug Users League and Harm Reduction Australia. Consultation included meetings and written correspondence.

The Commonwealth has also been engaging regularly with jurisdictions on how to best support the transition to usual PBS arrangements and ensure continuity of care for patients, while allowing patients to access PBS co-payment and safety net arrangements as quickly as possible to remove financial barriers to treatment.

Specific consultation on the Amendment Instrument as it relates to ODT medicines was held 5 – 9 June 2023 with jurisdictions and the key stakeholders mentioned above.

Commencement of ODT reforms from 1 July 2023 will benefit patients so most patients are no longer required to pay out of pocket dispensing fees to access ODT medicines. In addition, on 1 July 2023, the Act will be amended to expressly provide that section 100 special arrangements must be made by legislative instrument. This Instrument, along with the inclusion of ODT medicines in the HSD Special Arrangement via the Amendment Instrument, will also mean that all special arrangements will be registered by 1 July 2023.

The arrangements provided in this Instrument are in response to stakeholder concerns regarding continuity of care for patients receiving treatment at non-PBS dosing sites and requests from states and territories for a transition period. As this Instrument continues pre-1 July 2023 arrangements (for authorised suppliers) and is in response to consultation and ongoing engagement with states and territories, no further consultation on this Instrument was undertaken.

Jurisdictions are in support of these transition arrangements for a time-limited period acknowledging that some private clinics and non-PBS community pharmacy dosing sites may continue to charge patients out of pocket fees until patients transition to the PBS for their medicines.

**Regulatory Impact**

The Office of Impact Analysis was consulted and advised that an Impact Analysis was not required to be prepared in relation to the Instrument (OIA ref: 23- 05119).

**Incorporation by reference**

The Instrument incorporates by reference the following pieces of legislation, or provisions of these pieces of legislation, as in force from time to time:

* *Health Insurance Act 1973*;
* *National Health Act 1953*;
* *National Health (Highly Specialised Drugs Program) Special Arrangement 2021*;
* *National Health (Listing of Pharmaceutical Benefits) Instrument 2012;*
* *National Health (Pharmaceutical Benefits) Regulations 2017*.

Each of these pieces of legislation can be accessed free of charge on the Federal Register of Legislation ([www.legilsation.gov.au](http://www.legilsation.gov.au)).

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

Details of the Instrument are set out in **Attachment A**.

The Instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

**ATTACHMENT A**

**Details of the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023***

**Part 1 – Preliminary**

**Section 1 - Name**

Section 1 provides that the name of the instrument is the *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023* (**Instrument**). It can also be cited as PB 61 of 2023.

**Section 2 – Commencement**

Section 2 provides that the Instrument commences on 1 July 2023.

**Section 3 – Repeal of this instrument**

Section 3 provides that the Instrument is repealed at the start of 1 March 2024.

**Section 4 – Authority**

Section 4 provides that the Instrument is made under paragraph 85(7)(b) and section 100 of the *National Health Act 1953* (**Act**).

**Section 5 – Simplified outline of this instrument**

Section 5 set out a simplified outline for the Instrument, outlining its purpose and summarising its key features, including that:

* the Instrument makes a special arrangement for the supply of certain pharmaceutical benefits for the purpose of treating opioid dependence (**ODT medicines**), including for detoxification (withdrawal) and maintenance of withdrawal, by authorised suppliers between 1 July 2023 and 30 November 2023;
* the ODT medicines will be supplied to persons who are receiving treatment by medical practitioners and authorised nurse practitioners;
* authorised suppliers for the Instrument will be persons and organisations who are not approved suppliers for the purposes of the Act, but who are authorised by states and territories to supply ODT medicines.
* the Instrument also deals with payments for these supplies, payments for other supplies of ODT medicines made before 1 July 2023, and administrative matters.

Note 1 to section 5 makes clear for readers that Part VII of the Act, and regulations or other instruments made for the purposes of Part VII, have effect subject to the special arrangement established by the Instrument. This is provided for in subsection 100(3) of the Act.

Note 2 to section 5 of the Instrument refers readers to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (**Main Listing Instrument**) and the *National Health (Highly Specialised Drugs) Program Special Arrangement 2021* (**HSD Special Arrangement**) for supplies of ODT benefits by PBS approved suppliers. From 1 July 2023, amendments to the HSD Special Arrangement will enable approved suppliers and also ‘HSD hospital authorities’ to supply ODT medicines under that special arrangement.

**Section 6 – Definitions**

A number of terms that are used in the Instrument are defined in section 6.

Section 6 defines an ***authorised supplier*** as a person or organisation:

* that has premises in a state or territory and that is authorised, however described, by an authority of that state or territory for the purposes of supplying ODT medicines for the purposes of the Instrument; and
* that is not an approved supplier or an HSD hospital authority (within the meaning of the HSD Special Arrangement). Under the HSD Special Arrangement, certain HSD hospital authorities that would not ordinarily be approved hospital authorities are PBS approved suppliers (of HSD medicines.

Section 6 also defines an ***eligible patient*** as a person who is, or is to be treated as, an eligible person as defined in the *Health Insurance Act 1973* (in other words, is eligible for Medicare), and who is receiving either medical treatment by a medical practitioner, or nurse practitioner treatment by an authorised nurse practitioner. State and territory opioid dependence treatment programs may also impose separate criteria, outside the PBS, for patients to be eligible to participate in their programs.

The following terms are defined to have the same meaning as in the HSD Special Arrangement:

* ***medication for the treatment of opioid dependence -*** these are the drugs buprenorphine, buprenorphine with naloxone and methadone;
* ***ODT pharmaceutical benefit*** - these are pharmaceutical benefits mentioned in Schedule 1 to the HSD Special Arrangement that have a drug that is a medication for the treatment of opioid dependence.
* ***pre-commencement benefit*** - section 50 of the HSD Special Arrangement sets out the list of pre-commencement benefits, being the pharmaceutical benefits for the treatment of opioid dependence as listed before 1 July 2023.
* ***pre-commencement prescription*** – this term is defined in section 40 of the HSD Special Arrangement as a prescription that:
  + was written before 1 July 2023 by an authorised nurse practitioner or a medical practitioner; and
  + is for the supply to a person of a medication for the treatment of opioid dependence; and
  + was written for the treatment of opiate dependence, including detoxification (withdrawal) and maintenance of withdrawal; and
  + immediately before 1 July 2023, the person for whom the prescription was written could have obtained a supply of a pre-commencement benefit on the basis of the prescription.

In addition, section 6 provides that a ***pre-commencement supplier*** is a person who was, before 1 July 2023, permitted (however described) by a state or territory to supply an ODT medicine to a patient in that state or territory.

The definitions of pre-commencement benefit, pre-commencement prescription and pre-commencement supplier are relevant for the purposes of ensuring that patients can receive supplies under the Instrument from 1 July 2023 on the basis of prescriptions written before 1 July 2023 under the existing special arrangement for the Opiate Dependence Treatment Program, which is ceasing at the end of June 2023, and that responsible persons (sponsors) for ODT medicines can be paid for supplies of ODT medicines before 1 July 2023 made under the ceasing special arrangement.

The following terms are defined to have the same meaning as in Part VII of the Act:

* ***approved ex-manufacturer price*** of a listed brand of pharmaceutical item;
* ***approved supplier*** - approved suppliers are section 90 approved pharmacists, section 94 approved hospital authorities and section 92 approved medical practitioners;
* ***authorised nurse practitioner*** and ***nurse practitioner treatment*** - authorised nurse practitioners must be approved under section 84AAJ of the Act;
* ***listed brand*** of a pharmaceutical item;
* ***pharmaceutical benefit*** and ***pharmaceutical item***;
* ***responsible person*** for a brand of pharmaceutical item.

Note 1 to section 6 of the Instrument explains to readers that terms used in the Instrument, including ***premises*** and ***Secretary***, may be defined in the Act.

Note 2 to section 6 explains that under subsection 4(1A) of the Act, a word or phrase defined for the purposes of the *Health Insurance Act 1973* has the meaning it would have if used in that Act. Relevant terms that are used in the Instrument include ***eligible person*** and ***medical practitioner***.

**Part 2 – Special Arrangement supplies of ODT pharmaceutical benefits**

**Division 1 – Preliminary**

**Section 7 – Definition of *special arrangement supply***

Section 7 of the Instrument sets out the circumstances in which the supply of an ODT pharmaceutical benefit (being a pharmaceutical benefit mentioned in Schedule 1 to the HSD Special Arrangement that has a drug that is a medication for the treatment of opioid dependence) will be a ***special arrangement supply*** for the purposes of the Instrument.

A supply of an ODT pharmaceutical benefit is a special arrangement supply if the benefit is supplied:

* on or after 1 July 2023 and before 1 December 2023; and
* to an eligible patient by an authorised supplier; and
* either:
  + on the basis of a prescription written on or after 1 July 2023 where the prescription was for the treatment of opioid dependence; or
  + on the basis of a pre‑commencementprescription.

**Division 2 – Prescribing for special arrangement supplies**

**Section 8 – Prescription circumstances (Act s 85(7)(b))**

Subsection 85(7) of the Act allows the Minister to determine that a pharmaceutical benefit is a ‘relevant pharmaceutical benefit’ for section 88A of the Act and also the circumstances in which a prescription can be written for the supply of the benefit. Where a benefit is a relevant pharmaceutical benefit, for the purpose of the PBS a prescription can only be written in circumstances specified in the determination (see section 88A of the Act).

ODT medicines are determined as relevant pharmaceutical benefits in section 15 of the HSD Special Arrangement (see note 1 to section 8).

Subsection 8(1) of the Instrument provides that for the purposes of paragraph 85(7)(b) of the Act, the circumstances in which a prescription for a special arrangement supply of an ODT pharmaceutical benefit may beS written are that the prescription is for the treatment of opioid dependence.

Subsection 8(2) makes clear that the specification of conditions for prescribing an ODT medicine in the Instrument applies in addition to any conditions specified for paragraph 85(7)(b) of the Act in section 10 of the Main Listing Instrument.

Note 2 to subsection 8(2) refers readers to section 88 of the Act, section 9 of the Main Listing Instrument and section 14 of the HSD Special Arrangement for the authorisation of authorised nurse practitioners and medical practitioners to write prescriptions for the supply of ODT medicines. As a result of these authorisations, medical practitioners and authorised nurse practitioners do not need to be separately authorised in the Instrument.

**Section 9 – Determinations under section 85A of the Act do not apply**

Section 85A of the Act enables the Minister to determine, among other things:

* the maximum quantity or number of units of a pharmaceutical benefit that PBS prescribers can direct to be supplied to a patient on any one occasion;
* the maximum number of repeats that PBS prescribers can include in a prescription;
* conditions that must be met when writing a prescription for the maximum quantity or maximum number of repeats.

Section 9 provides that any determinations made under section 85A of the Act do not apply to a prescription for a special arrangement supply of an ODT medicine. This means that for the purposes of this Instrument, medical practitioners and authorised nurse practitioners may write prescriptions for quantities greater than the determined maximum quantity or for more repeats than the determined maximum number of repeats.

Prescribers remain subject to restrictions in applicable state and territory laws about the quantity and number of repeats (if any) of ODT medicines they may prescribe.

**Section 10 – Section 39 of the Regulations does not apply**

Section 39 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (**Regulations**) requires PBS prescriptions to be written in particular form, and include certain particulars.

Section 10 of the Instrument provides that section 39 of the Regulations does not apply to a prescription for a special arrangement supply of an ODT medicine. This means that a prescription does not need to meet the standard PBS form or particulars requirements.

Prescribers remain subject to restrictions in applicable state and territory laws about the form and content of prescriptions for ODT medicines.

**Division 3 – Supplying special arrangement supplies**

**Section 11 – Definition of *value for safety net purposes***

Section 11 of the Instrument provides that the ***value for safety net purposes*** of a special arrangement supply of an ODT medicine is zero. This is despite subsection 84(1) of the Act, which specifies the amount of patient charges that will usually count towards the patient’s PBS safety net.

The purpose of section 11 is to provide that there will be no value attributed towards a person’s PBS safety net for a supply of an ODT medicine under the Instrument.

**Section 12 – Charges to patients not limited**

Section 86 of the Act provides that an eligible person who is receiving certain kinds of treatment is entitled to receive a pharmaceutical benefit without payment or provision of money or other consideration, other than a charge made in accordance with section 87 of the Act. Section 87 sets out the fees that an approved supplier may charge to a person receiving a pharmaceutical benefit in certain circumstances.

Section 12 provides that section 86 of the Act does not apply to a special arrangement supply of an ODT medicine. Section 87 of the Act does not apply to supplies made under this Instrument as it only applies to supplies made by approved suppliers, and thus patient charges are not capped in accordance with that section.

The effect of section 12 is that authorised suppliers will not be prevented from applying patient fees or charges where otherwise not prevented from doing so by state or territory law, or the by the rules of the relevant state or territory ODT program.

**Section 13 – Entitlement to receive supplies from authorised suppliers**

Subsection 13(1) of the Instrument provides that an eligible patient is entitled to receive a special arrangement supply of an ODT medicine from an authorised supplier on the basis of a prescription written by an authorised nurse practitioner or medical practitioner from whom the eligible patient is receiving medical treatment or nurse practitioner treatment.

Subsection 13(2) provides that this section has effect despite section 89 of the Act. That section ordinarily prevents a person from receiving a supply of pharmaceutical benefits under the PBS unless the supply is made by a PBS approved supplier on the basis of a prescription written in accordance with the Act and Regulations, or in limited other circumstances such as through prescriber bag arrangements. PBS approved suppliers are expressly excluded from being authorised suppliers under the Instrument.

**Section 14 – Pre-commencement prescriptions directing supply of methadone**

Section 14 ensures that a change to the PBS listing of methadone on 1 July 2023 will not prevent patients from receiving supplies under the Instrument using prescriptions written for the form of methadone listed before 1 July 2023.

Subsection 14(1) provides that the section applies if a pre‑commencementprescription (see section 6) is for the supply of methadone.

Subsection 14(2) provides that on the basis of such a prescription, a patient is entitled to receive, and an authorised supplier may supply to the patient, any of the pharmaceutical benefits with the drug methadone mentioned in Schedule 1 to the HSD Special Arrangement, being the benefits as listed from 1 July 2023.

Subsection 14(3) provides that this section has effect despite section 89 and paragraph 103(2)(a) of the Act, which would ordinarily prevent a person receiving a pharmaceutical benefit under the PBS that is different to the benefit mentioned in their prescription (where a particular benefit is specified in the prescription).

**Section 15 – Repeated supplies of pharmaceutical benefits**

Section 15 of the Instrument provides that section 51 of the Regulations does not apply to a special arrangement supply of an ODT medicine. Section 51 deals with requirements for suppliers to prepare repeat authorisations in a particular form, where a prescription provides for repeated supplies of a pharmaceutical benefit.

**Section 16 – Authorised suppliers not entitled to payment by Commonwealth**

Section 16 of the Instrument provides that an authorised supplier who has made a special arrangement supply of an ODT medicine is not entitled to be paid by the Commonwealth in relation to the supply of the benefit.

The Commonwealth pays the responsible person (pharmaceutical company) the full cost of any ODT medicine they supply an authorised supplier for the purposes of this Instrument (see section 17). Responsible persons are therefore prevented from charging authorised suppliers any additional amount for the supply.

**Division 4 - Payment for supplies to authorised suppliers**

**Section 17 – Responsible persons entitled to payment by the Commonwealth**

Section 17 sets out arrangements for a responsible person to receive payment from the Commonwealth for the supply of an ODT medicine to an authorised supplier for the purposes of the Instrument.

Subsection 17(1) provides that section 17 applies where the responsible person for a listed brand of ODT medicine supplies the benefit to an authorised supplier on or after 1 July 2023 and before 1 December 2023.

Subsection 17(2) provides that a responsible person for a listed brand of an ODT medicine who supplies the benefit to an authorised supplier is entitled to payment from the Commonwealth.

Subsection 17(3) provides that the responsible person is entitled to be paid the approved ex-manufacturer price of the listed brand of the ODT medicine that was applicable on the day the responsible person supplied the medicine to the authorised supplier. However, the responsible person must make a claim in accordance with subsection 17(5) if they want to receive payment from the Commonwealth (subsection 17(4)).

Subsection 17(5) provides that the claim must:

* be made in writing to the Secretary;
* relate to a calendar month;
* for each ODT pharmaceutical benefit supplied to an authorised supplier in the calendar month, state:
  + the ODT benefit;
  + the name and address of the authorised supplier to whom the benefit was supplied; and
  + the date of supply.

Subsection 17(5) also requires the responsible person to include the following certification in the claim:

* that the information in the claim is true and correct;
* that the supplies of ODT pharmaceutical benefits covered by the claim were made for the purpose of special arrangement supplies of the benefits; and
* that the responsible person understands that giving false or misleading information is a serious offence under section 137.1 of the *Criminal Code*.

Although responsible persons will not be entitled to Commonwealth payment for supplies of ODT made to authorised suppliers on or after 1 December 2023, the Instrument is not repealed until 1 March 2024 (section 3). This will allow responsible persons time to submit their final claims for supplies made before 1 December 2023. It will also ensure there is sufficient time for any requests for internal merits review made under section 24 to be finalised before the Instrument is repealed.

The responsible person is not required to certify that any ODT medicines they supply to an authorised supplier were in fact dispensed to patients in accordance with this Instrument. It is recognised that responsibility for the appropriate use of ODT medicines lies with the authorised supplier as the final step in supply to the patient. It is also recognised that the responsible person does not have visibility of the patient or their clinical status and therefore they supply ODT medicines to the authorised supplier on good faith that the medicine is being used for the treatment of opioid dependence and in accordance with this Instrument.

Subsection 17(6) prohibits the responsible person demanding or receiving any payment or other valuable consideration from an authorised supplier in respect of a supply of ODT medicines. This provision is intended to prevent a responsible person receiving two payments (one from the Commonwealth, and one from the authorised supplier) in respect of a supply of an ODT medicine made for the purpose of this Instrument.

**Section 18 – Secretary to determine and pay claims**

Section 18 provides that the Secretary is to determine claims from responsible persons and to make any subsequent payment.

Subsection 6(5) of the Act relevantly permits the Secretary to delegate any of their powers under the Act, or in a legislative instrument made under the Act, except the power of delegation.

It is intended that the Secretary will delegate the power to determine amounts and make payments to Senior Executive Service (**SES**) employees in the Department.

**Part 3 – Payment for pre-commencement supplies**

**Section 19 – Application of this Part**

Part 3 of the Instrument sets out arrangements for payments for certain supplies of ODT medicines made before 1 July 2023. The existing special arrangement supporting the Opiate Dependence Treatment Program will cease at the end of 30 June 2023. Part 3 of the Instrument will enable payments for supplies made before 1 July to be made under this Instrument.

Section 19 provides that Part 3 of the Instrument applies if, before 1 July 2023:

* a pre‑commencement benefit was supplied to a pre‑commencement supplier by the relevant responsible person for the benefit;
* the responsible person had not received Commonwealth payment for the supply; and
* the responsible person had neither demanded nor received any payment or other valuable consideration from the pre‑commencement supplier for the supply. This condition applied under the Opiate Dependence Treatment Program that applied before 1 July 2023, and reflects that the Commonwealth pays the responsible person the full cost of the ODT medicine.

**Section 20 – Responsible persons entitled to payment by the Commonwealth**

Subsection 20(1) of the Instrument provides that, subject to section 20, the responsible person is entitled to payment from the Commonwealth.

Subsection 20(2) provides that the amount of the payment is the approved ex‑manufacturer price (AEMP) of the brand of ODT medicine that was applicable on the day the responsible person supplied it to the pre‑commencement supplier.

This entitlement to payment operates subject to the responsible person meeting the requirements for the making of claims set out in subsection 20(3). Subsection 20(4) sets out the requirements for making a claim. The claim must be made in writing to the Secretary. It also must relate to a calendar month and, in relation to that month specify all of the following:

* the name and address of each pre‑commencement supplier to whom pre‑commencement benefits were supplied;
* the number of packs of each pre‑commencement benefit supplied to each pre‑commencement supplier;
* the number of packs of each pre‑commencement benefit supplied in each State and Territory, and the amount claimed for each benefit in each State and Territory;
* the number of packs of all pre‑commencement benefits supplied in each State and Territory and the amount claimed for all of those benefits in each State and Territory;
* the total number of packs of each pre‑commencement benefit supplied in Australia, and the amount claimed for each benefit in Australia;
* the total number of packs of all pre‑commencement benefits supplied in Australia and the amount claimed for the supply of all of those benefits in Australia.

These reporting requirements reflect those that applied under the Opiate Dependence Treatment Program.

Subsection 20(5) prohibits the responsible person demanding or receiving any payment or other valuable consideration from a pre-commencement supplier in respect of a supply of a pre-commencement benefit. This is because the Commonwealth is paying the responsible person the full cost of the benefit.

**Section 21 – Secretary to determine and pay claims**

Section 21 of the Instrument provides that the Secretary must determine the amount payable for a claim made under this Part and make any payment relating to the claim. It is intended that the Secretary will delegate the power to determine amounts and make payments under section 21 to SES employees in the Department.

**Part 4 – Administration**

**Section 22 – Secretary may request information from responsible persons**

Subsections 22(1) and 22(2) of the Instrument allow the Secretary ask a responsible person for an ODT medicine or a pre-commencement benefit to give the Secretary further information in relation to any supply of the benefit to an authorised supplier.

A request from the Secretary must be in writing and specify the date by which the responsible person must comply with the request. This date must be at least 28 days after the day of the request (subsection 22(3)).

As the responsible person does not have involvement in the dispensing of ODT medicines or pre-commencement benefits to individual patients, the Secretary would not use this power to ask for personal information about patients receiving ODT medicines.

It is intended that the Secretary will delegate powers under section 22 to SES employees in the Department.

**Section 23 – Responsible persons to supply information on request**

Section 23 of the Instrument requires a responsible person to comply with a request for information under section 22, and to do so by the date specified in the request.

**Section 24 – Internal review of decisions**

Subsection 24(1) provides that a person who is affected by a decision of the Secretary under the Instrument may apply to the Secretary for review of the decision. It is anticipated that responsible persons will be the only persons affected by decisions under the Instrument, being decisions about claims for payment and decision to request information.

The application must be in writing and must be made within 28 days after the day the decision first came to the notice of the applicant. However, the Secretary can allow a longer period (subsection 24(2)).

Subsection 24(3) provides that on receiving an application for review of a decision, the Secretary must review the decision and affirm the original decision, vary it, or set the original decision aside and substitute a new decision.

A decision by the Secretary takes effect on the day specified in the decision on review. However, where a day is not specified in the decision on review it takes effect on the day the decision on review was made (subsection 24(4)).

After making a decision, the Secretary must give the applicant written notice of the terms of the decision and the reasons for the decision (subsection 24(5)).

It is intended that the Secretary will delegate the power to review decisions to SES employees in the Department. As a matter of good administrative practice, the review of an original decision will not be undertaken by the maker of that decision, but by a different person. The provision for internal merits review and supporting administrative practice will ensure that responsible persons have access to a mechanism for the reconsideration of decisions by the Department, which ensures procedural fairness and accountability.

External merits review of decisions made under the Instrument is not available under the Act. Section 105AB of the Act, which is in Part VIIA, sets out the decisions of the Secretary that can be the subject of review by the Administrative Appeals Tribunal. The decisions that are listed do not include decisions made by the Secretary under instruments made under section 100 of the Act, and subsection 100(3) of the Act does not provide for the modification of provisions of Part VIIA through an instrument.

Further, decisions under sections 18 and 21 (payment of claims) and section 24 (internal review) are not easily susceptible to merits review. In relation to a decision to make a payment under section sections 18 and 21, subsections 17(1) and 20(1) of the Instrument establish an entitlement for a responsible person to payment from the Commonwealth, provided the claim for payment meets the requirements set out in subsections 17(4) and 20(4).

Given the nature of the requirements, the question of whether those requirements are met will be a question of fact – either the requirements are met, or they are not. The requirements do not require the Secretary or delegate to make an evaluative judgment. Further, the Secretary or delegate has no discretion to decide that a requirement that has not been met should be taken to have been met. Where information is missing from a claim, section 22 provides a mechanism by which the Secretary or delegate can request the responsible person to provide further information.

Where the requirements are met, section 18 or 21 (as applicable) requires the Secretary to determine the amount payable for the claim, and to make the relevant payment to the responsible person.

An internal review under section 24 of a decision made under the Instrument will involve the review of the exercise of a similarly confined discretion – for example, where the responsible person sought review of the decision on the basis that the decision-maker calculated the payment incorrectly, the role of the reviewer would essentially be to check the correctness of the calculation.

Any decisions made by the Secretary or a delegate under the Instrument will be subject to judicial review under the *Administrative Decisions (Judicial Review) Act 1977*, and under section 75(v) of the Constitution or section 39B of the *Judiciary Act 1903*, as a decision of an officer of the Commonwealth.

**ATTACHMENT B**

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

*National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023*

*PB 61 of 2023*

The *National Health (Transitional Arrangements for Opioid Dependence Treatment Medicines) Special Arrangement 2023* (**Instrument**) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the legislative instrument**

The Instrument provides for responsible persons (pharmaceutical companies) of opioid dependence treatment (**ODT**) medicines to continue to supply ODT medicines to certain dosing sites directly, and for responsible person to claim payment directly from the Commonwealth for those supplies, for supplies made on or after 1 July 2023 but before 1 December 2023.

Authorised suppliers include private clinics, non-PBS community pharmacies, GP practices, correctional facilities, and other non-PBS dosing sites. Eligible dosing sites authorised by state and territory governments (**authorised suppliers**) will receive supplies of ODT medicines from responsible persons at no cost. Authorised suppliers will supply ODT medicines to patients participating in state and territory ODT programs, as prescribed by authorised prescribers.

PBS approved suppliers are excluded from being authorised suppliers under the Instrument. This means the Instrument will not apply to supplies of ODT medicines made by approved pharmacies, approved hospital authorities (including HSD hospital authorities) or approved medical practitioners who can start to supply ODT medicines to their patients under the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (**HSD Special Arrangement**) from 1 July 2023.

State and territory governments operate individual ODT programs in their respective jurisdictions. These programs include patient eligibility criteria, take-away dosing policies, as well as the approval or authorisation of participating prescribers (medical practitioners and nurse practitioners) and dispensing (dosing) points for participation in individual jurisdictional programs. The operation of state and territory ODT programs are currently and will continue to be governed by the respective policies, guidelines and regulations within each jurisdiction. The provision of ODT medicines under the Pharmaceutical Benefits Scheme (**PBS**) is intended to operate in parallel with jurisdictional ODT programs.

The Instrument has a time-limited application because it is intended to support dosing sites to transition patients to usual Pharmaceutical Benefits Scheme (**PBS**) arrangements for the supply of ODT medicines under the HSD Special Arrangement. ODT medicines were included in the HSD Special Arrangement as a result of amendments made on 1 July 2023 by the *National Health Legislation Amendment (Opioid Dependence Treatment and Maximum Dispensed Quantities) Instrument 2023* (PB 57 of 2023) (**Amendment Instrument**).

Responsible persons will submit claims for payment to the Department of Health and Aged Care and be paid the approved ex-manufacturer price of ODT medicines supplied to authorised suppliers.

As authorised suppliers are not able to submit claims for payment through Services Australia in the same way as approved suppliers do for other PBS medicines and are supplied ODT medicines for free, patients are not required under the Act to make a PBS contribution for the cost of the medicine (PBS co-payment). Because there is no requirement to make a PBS co-payment, the amount that contributes to a patient’s PBS Safety Net is zero. It is understood that some dosing sites may continue to charge patients dispensing or dosing fees for the supply of their ODT medicines during this transition period until patients can be transitioned to receiving their supplies under the HSD Special Arrangement.

The Instrument also includes arrangements allowing for Commonwealth payments to be made to responsible persons who supplied ODT medicines before 1 July 2023, to suppliers who were eligible suppliers under the Opiate Dependence Treatment Program as it operated before 1 July 2023, and who have not yet received Commonwealth payment.

**Human rights implications**

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

*The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation. The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health. The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

**Analysis**

ODT medicines currently listed on the PBS include methadone oral liquid, buprenorphine sublingual tablets, buprenorphine with naloxone sublingual films and long-acting injectable buprenorphine.

From 1 July 2023 the Amendment Instrument will incorporate ODT medicines into the Section 100 Highly Specialised Drugs (**HSD**) Program (Community Access). This means ODT medicines will be supplied in the same way as other community access Section 100 HSD Program medicines from PBS approved suppliers, including the PBS co-payment and safety net arrangements for patients. PBS approved suppliers are approved pharmacies, approved hospital authorities or approved medical practitioners.

In addition, a new ODT Community Pharmacy Program will take effect from 1 July 2023 and will be administered by the Pharmacy Programs Administrator (**PPA**). The ODT Community Pharmacy Program will complement, but is not part of, PBS arrangements for the supply of ODT medicines.

Transitional arrangements for ODT medicines

Reforming ODT access will mean a change to the way state and territory dosing sites operate as, only approved suppliers can supply HSD medicines. The Instrument provides a time-limited transition period, ending on 30 November 2023, during which responsible persons can continue to supply ODT medicines directly to non-PBS dosing sites. This is like pre-1 July 2023 arrangements which were established under section 100 of the *National Health Act 1953* (**Act**) where the Commonwealth pays the responsible person the full cost of ODT medicines supplied directly to dosing sites.

These transition arrangements will have a positive effect on the rights to health and social security because they will ensure patients can still access Commonwealth subsidised ODT medicines from their current non-PBS dosing sites while the states and territory governments transition patients to a PBS approved supplier where the patient will pay the PBS co-payment. In the absence of this Instrument, affected patients may have been required to pay the full private cost of their ODT medicines.

Although the Instrument only provides for Commonwealth subsidisation of supplies made by responsible persons to authorised suppliers until 30 November 2023, this is a legitimate and proportionate limitation. The Instrument has been put in place to allow states and territories to transition patients on their ODT programs to receive their supplies through a PBS approved supplier under standard arrangements for the Section 100 HSD Program. Under the Section 100 HSD Program, patients can only be required to pay limited patient co-payments for the supply of their ODT medicines, and their co-payments will contribute to meeting their PBS Safety Net threshold.

While this Instrument is necessary to ensure that patients of state and territory dosing sites that are not ready to transition to the Section 100 HSD Program arrangements on 1 July 2023 are still able to access Commonwealth subsidised ODT medicines, the time-limited operation of the Instrument will encourage patients to be transitioned to the Section 100 HSD Program where they can only be required to pay limited patient co-payments and have those co-payments contribute to meeting their PBS safety net threshold.

It is acknowledged that under this Instrument patients may continue be charged uncapped fees and charges by authorised suppliers and that amounts paid will not count towards patients’ safety net threshold. While these arrangements mean that patients receiving their ODT medicines from authorised suppliers have less beneficial arrangements than patients receiving supplies from approved suppliers, stakeholders including states and territory governments have advised there was a significant risk that authorised suppliers would stop supplying ODT medicines altogether on 1 July 2023 without this transitional period. The consequences of interruption of care (patient safety due to sudden withdrawal of treatment, risk of return to drug-seeking behaviour of potentially illicit substances and resulting societal consequences) is considered significantly worse than temporarily less beneficial arrangements that support continuity of care.

The department understands these private clinics have also charged patients unregulated out of pocket fees that can range from $150 to $200 a month to receive their opioid treatment medicines. Therefore, the department’s focus in engaging with states and territories is on how to best support the transition to usual PBS arrangements and ensure continuity of care for patients, while allowing patients to access PBS co-payment and safety-net arrangements as quickly as possible to remove these significant financial barriers to treatment.

The department will continue to work with state and territories to assist the transition of patients into receiving PBS subsidised treatment with a focus on patient safety and continuity of care

As this Instrument will operate in parallel with the broader reforms to ODT medicines, it will not delay access to new reformed PBS support for patients already accessing their ODT medicines from PBS pharmacies but will provide a transition period for some patients accessing their treatment from non-PBS dosing sites.

**Conclusion**

This Instrument is compatible with human rights as, overall, it promotes the rights to health and social security.

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