

**Poisons and Therapeutic Goods Regulation 2008 – Clause 100, 167, and 168
Drug Misuse and Trafficking Act 1985 – Section 25
Licence to supply by wholesale drugs of addiction**

Licence No OTP 001

1. This licence is issued to the following specified public health organisations:
 - A local health district
 - A specified affiliated health organisation, namely:
 - St Vincent's Hospital Sydney Limited
 - Calvary Health Care (Newcastle) Limited
 - Calvary Health Care Sydney Limited
 - A specified statutory health corporation, namely:
 - Justice Health and Forensic Mental Health Network
 (collectively, *the licensee*) in relation to the substances listed at Schedule 1.
2. This licence is subject to the conditions set out in Schedule 2.
3. This licence remains in force until **31 August 2023** unless earlier cancelled by the Secretary, NSW Health and is not transferrable.

In this instrument:

- *public health organisation, local health district, statutory health corporation, and affiliated health organisation* have the same meaning as in the *Health Services Act 1997 (NSW)*
- *pharmacy* has the same meaning as in the *Health Practitioner Regulation National Law (NSW) No 86a of 2009*.

Schedule 1

- | |
|--|
| <ul style="list-style-type: none"> • buprenorphine • methadone |
|--|

Schedule 2 – Schedule of conditions

- | |
|--|
| 1. The licensee must only supply a substance listed in Schedule 1 by wholesale to the pharmacist in charge of a pharmacy. |
| 2. The licensee must only supply a substance listed in Schedule 1 on the written order signed by the pharmacist in charge of the relevant pharmacy receiving the wholesale supply. |
| 3. The licensee must only supply a substance listed in Schedule 1 where the pharmacist in charge of the pharmacy has confirmed in writing that the pharmacy has insufficient stock of the Schedule 1 substance to dispense to patients on the program known as the NSW Opioid Treatment Program. |
| 4. A substance listed in Schedule 1 must only be supplied in the unopened ARTG registered packs. |
| 5. The licensee must notify the Secretary, NSW Health, of any requests for supply of the Schedule 1 substance in quantities which appear to be inconsistent with the activities of the business for which it is being supplied. |

- | |
|---|
| <p>6. The licensee can only issue records of the supply of the Schedule 1 substance in the name of the director of pharmacy, or director of drug treatment services (however named), supplying the Schedule 1 substance, and supply must be made to the pharmacist in charge of the pharmacy.</p> |
| <p>7. The licensee must make, and hold for a period of at least 2 years, a record of the supply of the Schedule 1 substance and provide a copy to the recipient.</p> |
| <p>8. The licensee must comply with storage and any cold chain requirements, including during transit of the product, in accordance with the Product Information Sheet for the Schedule 1 substance.</p> |
| <p>9. Appropriate cold chain records that comply with the Product Information sheet for the Schedule 1 substance must be maintained during transit and at storage sites and shared to verify cold chain storage as needed.</p> |

