Tasmanian Government

Poisons Regulations 2018
Regulations 21 and 46

Application for Approval of Electronic Prescription Systems

Vendor Name:	
Business address:	
ABN/ACN:	
Telephone:	
Fax:	
Contact Email Address:	
Responsible Officer and Position:	
Software Name: (the *Software*)	
Software Type:	☐ **Prescribing** ☐ **Dispensing** ☐ **PDS** ☐ **Other**……
Conformance ID Number:	

I, ……
request approval under Regulations 21 and 46 of the *Poisons Regulations 2018* to use the *Software* for the electronic transmission of presciptions in Tasmania.

Signature of Responsible Officer: _____ Date: / /

Please forward completed form and supporting documentation to:

Pharmaceutical Services Branch
Department of Health
GPO Box 125 Hobart Tas 7001
(03) 6166 0400
email: pharmserv@health.tas.gov.au

If you have any queries or need to clarify the above, please contact Pharmaceutical Services Branch

Pharmaceutical Services Branch will assess applications for approval to safeguard that software systems meet the requirements of the Tasmanian poisons legislation. Any assessment also may include consideration of authentication (login), authorisation (signing), security, record keeping (storage of data), reporting and auditability features.

Demonstration the *Software* meets requirements will be required. Details required may include technical and security information, access procedures and reporting capabilities. The Department may require assessment of the system against relevant industry or quality standards. Any approval will be subject to conditions. The *Software* will need to:

1. Demonstate a Conformance ID is listed on the Australian Digital Health Agency *Electronic Prescribing Register of Conformance*.
2. Demonstrate how the record of the authorised health professional prescribing or dispensing is permanently linked to a prescription, and retained and retrievable upon demand by a Poisons Inspector.
3. Demonstrate how a digital copy of an electronically transmitted prescription is retained and retrievable upon demand by a Poisons Inspector.
4. Demonstrate how a prescriber must reauthenticate prior to issue of a prescription for a Schedule 8 substance.
5. Demonstrate how a repeat interval is electronically endorsed by a prescriber or electronically annotated by a pharmacist for a Schedule 8 or Schedule 4D substance; and demonstrate there is no arbitrary default value for the repeat interval.
6. Demonstrate how the part of a prescription that refers to an unusual dosage is underlined, or by some other means emphasised, by the prescriber and displayed to the pharmacist.
7. Demonstrate reports, including but not limited to:
    - Compliance and audit reporting of prescription details to a Poisons Inspector - showing minimum of:
        i. Human readable format
        ii. Available on demand
        iii. Indication of paper or electronic format
        iv. Global unique identifier
        v. Date of prescribing and/or dispensing
        vi. Patient full name and DOB
        vii. Prescriber and/or dispenser
        viii. Medication name, strength, form, quantity
        ix. Exportable format eg CSV or Excel®.
8. Demonstrate how the prescriber or dispenser can maintain control of the prescription token where required under Tasmanian legislation for patient and public safety purposes eg Section 59E authorisations.
9. Confirm the record of the dispensing of a relevant substance can be provided to the Tasmanian Department of Health database of *relevant substance*s, including the required information for that acquisition or disposal as close to immediately as practicable.
10. Comply with the provisions of the *Poisons Act 1971* and *Poisons Regulations 2018* in relation to the supply of the scheduled substances.