

LICENCE CONDITIONS FOR OUTPATIENT MEDICAL SERVICE LICENSEES PRESCRIBING AND SUPPLYING BENZODIAZEPINES AND OTHER HYPNOTICS

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1. These licence conditions (“**LCs**”) apply to all persons who have been licensed under the Healthcare Services Act 2020 (the “**HCSA**”) to provide Outpatient Medical Service (“**OMS**”) (such persons referred to as “**Licensees**”), and who prescribe and/or supply benzodiazepines and/or other hypnotics.
- 1.2. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:
 - (a) suspension or revocation of the Licensee’s licence to provide OMS;
 - (b) shortening the term of the Licensee’s licence to provide OMS;
 - (c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (d) a direction requiring the Licensee to pay a financial penalty.
- 1.3. For avoidance of doubt:
 - (a) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;
 - (b) these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient, and shall not affect the application of prevailing ethical codes and guidelines applicable to healthcare professionals, and the professional standards in relation to the prescription and/or supply of benzodiazepines and other hypnotics to patients; and
 - (c) the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, codes of practice made thereunder.

2 Definitions

- 2.1 The following definitions shall apply to these LCs:

- (1) "**benzodiazepines**" means a class of therapeutic products containing psychoactive substances that are commonly prescribed for treating insomnia, anxiety and other psychiatric and medical conditions.
- (2) "**other hypnotics**" means a non-benzodiazepine class of medications that have hypnotic properties, and are also known as Z-hypnotics.
- (3) "**patient health records**" shall have the same meaning as its definition in the Healthcare Services (General) Regulations 2021.
- (4) "**specialist**" means a medical practitioner who is registered as a specialist in the Register of Specialists under section 22 of the Medical Registration Act 1997.

3 Specific Obligations on the Documentation and Maintenance of Patient Health Records

- 3.1 The Licensee shall properly document and maintain the patient health records of each patient prescribed with benzodiazepines and/or other hypnotics. These patient health records shall minimally include the following:
 - (a) the patient's comprehensive medical and psychosocial history, including any previous use of benzodiazepines or any other hypnotics and/or obtainment of additional benzodiazepines or any other hypnotics from other medical practitioners;
 - (b) comprehensive clinical findings, including:
 - (i) the duration of symptoms; and
 - (ii) evidence of the patient's misuse of benzodiazepines or other hypnotics (e.g., needle tracks on skin, excessive lethargy), if any; and
 - (c) relevant clinical investigations conducted on the patient and referrals to appropriate specialists (e.g., psychiatrists), if any.
- 3.2 On each occasion that a patient is prescribed with benzodiazepines and/or other hypnotics, the Licensee shall ensure that the following information is properly documented in the patient health records:
 - (a) the prescribed type/name of the benzodiazepine or other hypnotic, its dose, frequency and duration of use;
 - (b) indication(s) and/or justification(s) for prescribing the benzodiazepine or other hypnotic; and
 - (c) any physical signs or evidence of the patient's tolerance, physical/psychological dependence or any misuse of benzodiazepines or other hypnotics (e.g. needle tracks on skin, excessive lethargy).

4 Specific Obligations on the Supply of Benzodiazepines and/or Other Hypnotics

4.1 The Licensee shall ensure that any medical practitioner employed or engaged by the Licensee and prescribing benzodiazepines or other hypnotics to patients adheres to the following:

- (a) the medical practitioner shall prescribe benzodiazepines or other hypnotics for intermittent use (e.g., 1 night in 2 or 3 nights) and only when necessary when benzodiazepines or other hypnotics are used for treating insomnia;
- (b) the medical practitioner shall routinely warn patients about rebound insomnia with the use of benzodiazepines or other hypnotics and document such warning accordingly;
- (c) the medical practitioner shall prescribe the dosage of benzodiazepine or other hypnotic at the lowest effective dose necessary to achieve symptomatic relief;
- (d) the medical practitioner shall avoid concurrent prescribing of two or more benzodiazepines or other hypnotics;
- (e) the medical practitioner shall **not** provide repeat prescriptions for benzodiazepines or other hypnotics without a clinical review;
- (f) where there are doubts about dosage prescription or tapering of benzodiazepines or other hypnotics, the medical practitioner shall consult a psychiatrist or other specialists;
- (g) the medical practitioner shall take note of and exercise caution when prescribing benzodiazepines or other hypnotics to patients who are already prescribed with or are on existing medications that may cause drowsiness, to avoid excessive sedation (which may pose a risk to the patient who drives, operates heavy machinery, etc); and
- (h) the medical practitioner shall exercise caution when prescribing benzodiazepines for patients with a history or evidence of alcohol or other substance abuse.

5 Specific Obligations on Referrals to Specialists

5.1 The Licensee shall ensure that any medical practitioner employed or engaged by the Licensee shall not prescribe benzodiazepines or other hypnotics to his or her patients and must refer the patients to appropriate specialist(s) for further management in any of the following scenarios:

- (a) patients who require or have been prescribed benzodiazepines or other hypnotics beyond a cumulative period of 8 weeks; and

(b) patients who are non-compliant with professional advice or warning to reduce intake of benzodiazepines or other hypnotics.

5.2 For patients who are already on high-dose or long-term benzodiazepines or other hypnotics from specialists, or on follow-up with OMS licensees who are concurrently Acute Hospital Service licensees, the Licensee shall not prescribe benzodiazepines or other hypnotics to these patients, and where possible, shall refer these patients back to their respective specialists or for follow-up under the said OMS licensees for further management.

5.3 The Licensee shall ensure that patients who refuse to be referred to a specialist based on the conditions specified in paragraphs 5.1 and 5.2 are counselled appropriately, and that such refusal and counselling are documented in the patient health records.

6 Obligation to Furnish Information on Suspected Drug Addicts

6.1 The Licensee shall ensure that medical practitioners employed or engaged by the Licensee comply with Regulation 19 of the Misuse of Drugs Regulations, in relation to furnishing information on suspected drug addicts.