



**PRIMARY CARE COMMUNITY PHARMACY**

**LOCAL PHARMACY SPECIFICATIONS**

**CLINICAL CARE OF**

**SUBSTANCE MISUSE SERVICES PATIENTS**

**(INCORPORATING DISPENSING AND SUPERVISION**

**OF**

**SELF ADMINISTRATION OF ORAL BUPRENORPHINE)**

### **Document Control Sheet**

|                      |                                                                                                                                                                 |
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| Author:              | Anne Shaw, Alexander Adam                                                                                                                                       |
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<sup>1</sup> 'Oral Buprenorphine' will be used throughout this SLA as a term denoting the 'rapid dissolution' (e.g. the oral lyophilisate formulation - Espranor<sup>®</sup>) and 'standard dissolution' oral formulations. This SLA does not include provision for supervision of 'standard dissolution' formulations of sublingual buprenorphine or sublingual buprenorphine/naloxone, although these may still be supplied unsupervised.

**Revision History:**

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| V0.1     | Sept 2020  | Version Control and Updating Current Specification                                                             | Anne Shaw/Carolyn Dickson           |
| V1.1     | Feb 2021   | Version Control and Updating Current Specification                                                             | Anne Shaw/Carolyn Dickson           |
| V2.1     | Jan 2022   | Addition of Buprenorphine/Naloxone film and definition of rapid dissolution forms. Changes to contact details. | Anne Shaw/Carolyn Dickson/Alex Adam |
| V3.1     | April 2023 | Updating Service Specification                                                                                 | Anne Shaw/Carolyn Dickson/Alex Adam |
| V4.1     | March 2024 | Updating Service Specification                                                                                 | Alex Adam                           |
| V5.1     | March 2025 | Removed Suboxone Film, clarified that only Espranor is to be supervised.                                       | Alex Adam                           |
| V6.1     | Jan 2026   | Updating Service Specification                                                                                 | Alex Adam                           |

**Approvals:** this document was formally approved by:

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## **Specification for Clinical Care of Substance Misuse Services Patients (Incorporating Dispensing and Supervision of Self-Administration of Oral Buprenorphine<sup>2</sup>)**

### **1. Aim of Service**

#### **1.1 *To promote patient wellbeing and recovery through:***

- 1.1.1** Close liaison with Community Pharmacists and treatment services.
- 1.1.2** Dispensing of oral Buprenorphine in specified instalments, including, where requested supervised self-administration of *Espranor*®.
- 1.1.3** Ensuring that each supervised dose is consumed appropriately and completely by the patient.
- 1.1.4** Monitoring the patient's response to prescribed treatment.
- 1.1.5** Provision of general health advice and information on how to access public health services.
- 1.1.6** Promotion of patient safety and wellbeing.
- 1.1.7** The treatment of all patients with due care and respect with reference to the standards of care and confidentiality expected by NHS patients.

#### **1.2 *To reduce the incidence or risk of:***

- 1.2.1** Accidental or intentional inappropriate use of prescribed medicines.
- 1.2.2** Diversion of prescribed medicines for illicit sale or supply.

### **2. Service Outline**

#### **2.1 *General***

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<sup>2</sup> 'Oral Buprenorphine' will be used throughout this SLA as a term denoting the 'rapid dissolution' (e.g. the oral lyophilisate formulation - *Espranor*®) and 'standard dissolution' oral formulations. This SLA does not include provision for supervision of 'standard dissolution' formulations of sublingual buprenorphine or sublingual buprenorphine/naloxone, although these may still be supplied unsupervised.

- 2.1.1 The pharmacy contractor will hold stocks of oral Buprenorphine and will dispense these on receipt of an appropriate prescription.
- 2.1.2 The pharmacy contractor will make arrangements for the supervision of self-administered doses of oral Buprenorphine (**Espranor®**) on receipt of an appropriately annotated prescription requesting this service.

## **2.2 Storage of oral Buprenorphine**

- 2.2.1 Oral Buprenorphine will be stored in accordance with the Misuse of Drugs (Safe Custody) Regulations.
- 2.2.2 There will be a standard operating procedure in place for the pre-packing of doses and this procedure will comply with the requirements described in Medicines, Ethics and Practice, Section 3.3.7, labelling of dispensed medicinal products.
- 2.2.3 The storage of pre-packed doses will be in accordance with the Misuse of Drugs (Safe Custody) Regulations.

## **2.3 Dispensing of oral Buprenorphine**

- 2.3.1 The responsible Pharmacist will operate a safe and robust system for the dispensing of oral Buprenorphine in keeping with the principles and standards provided by the GPhC for registered pharmacies.
- 2.3.2 A standard operating procedure should be in place in the pharmacy detailing this system or service provision.
- 2.3.3 Oral Buprenorphine will only be dispensed against a prescription written in accordance with the requirements of the Misuse of Drugs Regulations.
- 2.3.4 The pre-preparation of doses will be in accordance with all appropriate requirement of the Medicines Act.

## **2.4 Supervised self-administration**

- 2.4.1 Responsibility for ensuring the appropriateness of supervision arrangements for the self-administration of oral Buprenorphine will lie with the responsible Pharmacist.
- 2.4.2 The responsible Pharmacist will undertake any reasonable actions necessary to ensure that the entire prescribed dose has been self-administered and that procedures are in place to minimise the risk of diversion as far as is possible.
- 2.4.3 Supervision of the self-administered dose will be undertaken with due discretion and cognisance of the supervisee's rights to confidentiality and appropriate respect.

## **2.5     *Data collection and maintenance***

**2.5.1**     The Pharmacist will be responsible for the creation and maintenance of sufficient records to enable: verification of service provision; internal and external audit and evaluation.

**2.5.2**     Patient medication records will be maintained and appropriately updated.

## **2.6     *Claims for payment***

**2.6.1**     Claims for payment with regards to prescriptions out with Ayrshire & Arran Health Board and supplied under agreements of reciprocity will require additional submission (see 3.8).

## **2.7     *Confidentiality***

**2.7.1**     The service should be operated from premises that can provide appropriate levels of confidentiality around the supply and supervision of medication.

**2.7.2**     Due care must be taken to ensure that confidentiality is maintained.

# **3.     Shared Care Arrangements**

**3.1**     The pharmacist will be responsible for the provision of person-centred care and making the care of the person their priority in the care of patients under this Service Level Agreement (GPhC Professional Standards).

**3.2**     The pharmacist will foster and maintain appropriate working relationships with the prescribers and staff of NHS Ayrshire & Arran's Specialist Drug and Alcohol Treatment Services<sup>3</sup>.

**3.3**     Processes allowing information sharing, where required, will be established and agreed.

**3.4**     The pharmacy contractor will ensure that the appropriate details for contacting the Specialist Treatment Services teams are available within the pharmacy and that staff are aware of, and have access to, this information. This should include telephone numbers for each of the locality Specialist Treatment Service teams as well as contact information for the out of hours Services.

**3.5**     The Pharmacist, or a nominated proxy, will contact Specialist Treatment Services when appropriate to share information where there are concerns or evidence of issues relevant to patient care, wellbeing or the effectiveness of therapeutic interventions undertaken. This information will be used to inform future treatment decision within Specialist Treatment Services.

**3.6**     Any incidents involving controlled drugs will be reported to the Accountable Officer as well as the prescriber/treatment Services as appropriate.

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<sup>3</sup> Specialist Drug and Alcohol Treatment Services comprising North Ayrshire Drug and Alcohol Recovery Service (NADARS), East Ayrshire and Social Care Partnership Addiction Services and South Ayrshire Health and Social Care Partnership Addiction Services

- 3.7** Specialist Treatment Services will undertake to contact the Pharmacist to notify of new service users requiring Buprenorphine dispensing or supervision services prior to the service user presenting the prescription.
- 3.8** Where a prescription for supply of Buprenorphine is presented by an individual unknown to the Pharmacist, from out with the Health Board area or without prior notification from the Specialist Treatment Services, the Pharmacist will take all necessary steps to confirm the authenticity of the prescription request and establish the identity of the individual.
- 3.9** Where a prescription for supply of Buprenorphine which originates from out-with the Board area is confirmed as genuine and supplied the pharmacy contractor will inform the Specialist Pharmacist in Substance use Management (SPiSM). This contact shall be by email and completed in a timely manner (within 28 days) in order to ensure appropriate payment is made to the contractor.
- 3.10** The Pharmacist should maintain a treatment agreement for each service user. It is recommended that this be used to establish times of service availability, acceptable standards of behaviour by both parties and what level of service will be provided to the service user. This should be agreed and signed by both parties.

## **4. Training**

- 4.1** It is necessary that the Pharmacists involved in the provision of this service undertake appropriate training to demonstrate competence and maintain CPD.
- 4.2** In line with GPhC standard 2.1 the responsible Pharmacist must ensure that there are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.
- 4.3** In line with GPhC standard 2.2 the responsible Pharmacist must ensure that staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training.
- 4.4** Pharmacists and staff shall participate in local initiatives as appropriate.
- 4.5** Training or guidance shall be made available on request to the Specialist Treatment Services, if required, in addition to the reference materials and information available.

## **5. Quality Assurance**

- 5.1** The pharmacy contractor will undertake an audit of the service at least once per year.
- 5.2** The result of the audit will be available for inspection by NHS Ayrshire & Arran.

## **6. Health and Social Care Staffing Act**

- 6.1** The Health and Care (Staffing) (Scotland) Act 2019 (“the Act”) places requirements on the Health Board stating that: “In planning and securing the provision of health care from another person under an contract agreement must have regard to the guiding principles for health and care staffing, and the need for the person from whom the provision of health care is to be secured to have appropriate staffing arrangements in place”
- 6.2** The service provider will ensure that appropriate staffing arrangements are in place for the operation of this service.

## **7. Termination**

- 7.1** The provision of this service can be terminated by either party by providing THREE month’s written notice

## **8. Breach of Contract**

- 8.1** Where prima facie evidence of a breach of the terms of this scheme comes to the notice of NHS Ayrshire & Arran the matter will be referred in the first instance to the pharmacy contractor concerned for comment. If appropriate, the pharmacy contractor will be invited to submit proposals for the rectification of the breach. Failure to provide a satisfactory response, or to rectify the breach, will result in the matter being referred to the Chief Executive of the NHS Ayrshire & Arran for consideration by the NHS Board and determination of any further action or sanctions to be taken, including termination of the contract under this scheme and recovery of any payments made in respect of services which have not been provided.

| <u>Date</u> | <u>Version No.</u> | <u>Description of Amendments</u>                                                                                                                                                                                                                                                                                                                  | <u>Ratified By</u>  | <u>Date to be Reviewed.</u> |
|-------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------|
| 03/04/2024  | <b>V4.1</b>        | Updated to remove Suboxone Film as it is no longer marketed, and included a clarification that other forms of buprenorphine can be supplied under the SLA, but only the rapid dissolution formulation Espranor can be supervised under this SLA. Removed the confusing line suggestion payment is only for supervision and changed it to 'supply' | Joint Pharmacy Team | Feb 2025                    |
| 22/04/2024  | <b>V4.1</b>        | Section 6 & 7 added                                                                                                                                                                                                                                                                                                                               |                     |                             |
| 31/03/2025  | V5.1               | Correcting typographical errors and updating SPiSM job title.                                                                                                                                                                                                                                                                                     | Joint Pharmacy Team | Feb 2026                    |
| 09/12/2025  | V6.1               | Reviewed updated typographical errors.                                                                                                                                                                                                                                                                                                            | Joint Pharmacy Team | Feb 2027                    |