

SUPERVISED ADMINISTRATION OF MEDICINES – SUBSTANCE MISUSE

This document describes the specification and standards pertaining to the provision of supervised administration of medicines local enhanced service. This document does not constitute a Service Level Agreement (SLA) although the provisions within the document must be contained within any SLA between a Local Health Board and pharmacy contractor for the provision of the service. SLA requirements in addition to those contained in this specification cannot be added in at a local level.

INTERPRETATION

In this document:

Patient means any person in receipt of the service;

Pharmacy means any premises where drugs are provided by a pharmacist as part of pharmaceutical services;

Pharmacy contractor (or contractor) means a person lawfully conducting a retail pharmacy business.

Registered Pharmacist (or pharmacist) means a person who is registered in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

Registered pharmacy technician (or pharmacy technician) means a person who is registered in Part 2 of the GPhC register.

Approved service provider means a registered pharmacist, pre-registration pharmacist or registered pharmacy technician who meets the requirements of the HEIW Substance Misuse Enhanced Service Accreditation Framework.

PART A

1. SERVICE AIM

- 1.1. To provide, in accordance with an appropriate prescription, supervised administration of medication, contributing to a reduction in risks associated with inappropriate use or diversion of prescribed medicines.

2. SERVICE OUTCOMES

- 2.1. Improved adherence to an agreed treatment plan;

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- 2.2. Reduction of the risk of inappropriate medicines taking which might result in harm to the patient;
- 2.3. Reduction of the risk to local communities arising from diversion of prescribed medicines;
- 2.4. Reduction of the risk to others arising from accidental exposure to prescribed medicines;
- 2.5. Regular contact with suitably identified healthcare professionals;
- 2.6. Provision of support for patients' access to further advice and assistance including referring patients to specialist treatment services or other health and social care services where appropriate.

3. SERVICE OUTLINE

- 3.1. The service may be provided to people who live, or are registered with a GP or substance misuse treatment agency in Wales;
- 3.2. The approved service provider shall supervise the administration of those medicines listed in 4.147 in accordance with a valid prescription issued by a practitioner;
- 3.3. The pharmacy will offer a user-friendly, non-judgmental, patient-centred and confidential service;
- 3.4. The pharmacy shall provide advice, which may include the provision of written information, on the safe storage of prescribed medicines in the home;
- 3.5. The registered pharmacist shall not supply, nor the approved service provider supervise the administration of, medicines where:
 - 3.5.1. the registered pharmacist believes that doing so might result in harm to the patient or to others; or
 - 3.5.2. the patient has missed three or more consecutive doses, unless the pharmacist has received the express agreement of the prescriber.
- 3.6. In circumstances described in 3.5, the approved service provider should, as soon as is practicable, inform the patient's prescriber and/or key worker;
- 3.7. The approved service provider shall contribute to delivering the patient's care plan by communicating with the patient's prescriber and/or key worker any issues which might, in the opinion of the approved provider, give them cause for concern for the welfare of the patient or others;

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- 3.8. Where available, the approved service provider shall complete the relevant section of the National Electronic Claim and Audit Form (NECAF) or any subsequent national claim and audit process to ensure effective ongoing service delivery and audit.

4. PROVIDER RESPONSIBILITIES

Contractors

- 4.1. Contractors wishing to provide the service shall complete and submit a service level agreement to their Local Health Board. The service may only be provided following the receipt of written confirmation from the health board;
- 4.2. Other than with the agreement of their Local Health Board, the contractor shall ensure that the service is only provided from an area of the pharmacy which is;
- 4.2.1. distinct from the general public areas of the pharmacy;
and
 - 4.2.2. an area where both the patient receiving the service and the approved service provider may talk at normal speaking volumes without being overheard by other visitors to the pharmacy.
- 4.3. The contractor shall ensure that appropriate indemnity arrangements are in place for all staff providing the service;
- 4.4. All support staff shall be fully informed and suitably trained in relation to their involvement in the service which may include the provision of any part of the service provided on behalf of an approved service provider, provided that they are competent and it is legal for them to do so. For the purpose of this agreement, staff shall include any person or persons employed or engaged by the contractor, to provide any part of the service;
- 4.5. The contractor shall have awareness of, and ensure the service is provided in accordance with any relevant nationally agreed standards;
- 4.6. The contractor shall ensure that all standards required by the General Pharmaceutical Council, so far as they relate to pharmacy owners and superintendent pharmacists, are met;
- 4.7. The contractor shall ensure that, prior to entering into any agreement to provide the service; they are satisfactorily complying with his or her obligation under Schedule 2 to the Pharmaceutical Services Regulations to provide pharmaceutical essential services and have a system of clinical governance that is acceptable;

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- 4.8. The contractor shall have appropriate arrangements in place to maintain service continuity and take all reasonable steps to ensure that patients are able to access the service in the event of unforeseen closure of the pharmacy;
- 4.9. The contractor shall notify the relevant Local Health Board, prescribers, key workers and patients of circumstances which result in the temporary unavailability of the service for any period which would preclude patients from access to any supply due to them in that period;
- 4.10. The contractor shall participate in any reasonable publicity of the availability of the service required by the Local Health Board and shall not publicise the availability of the service other than with the agreement of the Local Health Board;
- 4.11. The contractor shall participate in any reasonable review of the service required by the Local Health Board including the reporting of any incidents to the Accountable Officer of the relevant Local Health Board;
- 4.12. The contractor shall ensure that the service is provided by an approved service provider who:
 - 4.12.1. Meets the requirements of the HEIW Substance Misuse Enhanced Service Accreditation Framework; and
 - 4.12.2. Has a current certificate demonstrating compliance with 4.12.1; and
 - 4.12.3. Has their name included in the All Wales Pharmacy Database for the service.

Approved Service Providers

- 4.13. Registered pharmacists, pre-registration pharmacists and pharmacy technicians wishing to provide the service shall:
 - 4.13.1. Meet the requirements of the HEIW Substance Misuse Enhanced Service Accreditation Framework; and
 - 4.13.2. Have their name included in the All Wales Pharmacy Database for the service.
- 4.14. The approved service provider shall supervise, in accordance with a valid prescription issued by a practitioner, the administration of medicinal products containing:
 - 4.14.1. Methadone;

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4.14.2. Buprenorphine (including in combination with naloxone).

- 4.15. At the first dispensing for each patient the approved service provider shall check the client's details and register the patient on the Patient Medication Record (PMR) system. The approved service provider will present the patient with an agreement form. The patient and pharmacy shall agree:
- 4.15.1. The method of supervised dispensing (oral for methadone and sublingual for buprenorphine containing preparations);
 - 4.15.2. The approximate time at which the patient will in general present for collection;
 - 4.15.3. That methadone or buprenorphine shall not be dispensed if the patient has missed 3 or more consecutive days of treatment other than with the express agreement of the prescriber;
 - 4.15.4. That methadone or buprenorphine shall not be dispensed where the registered pharmacist or approved service provider has reason to suspect that the patient is intoxicated with either alcohol or drugs;
 - 4.15.5. That the patient shall attend alone during dispensing;
 - 4.15.6. That the patient shall not bring any food or drink into the pharmacy when presenting for supervised administration;
 - 4.15.7. That the registered pharmacist may discuss matters relevant to the patient's medical history with their prescriber, where this is in the best interests of the patient;
 - 4.15.8. The action that will be taken by the pharmacist and prescriber if the patient does not abide by the agreement;
 - 4.15.9. That neither methadone nor buprenorphine shall be dispensed to anyone other than the patient unless the patient's prescriber has previously agreed and communicated in writing the name of the person authorised to collect the specific dose(s) to the pharmacist.
- 4.16. The approved service provider and client shall both sign and date the agreement form. The form will be retained by the pharmacy and a copy of the agreement should be made available to the client;
- 4.17. At each supervision dispensing the approved service provider shall:

Methadone

- 4.17.1. Confirm the identity of the patient;
- 4.17.2. Transfer the patient's methadone into a suitable receptacle and present this to the client;

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- 4.17.3. Supervise the administration of the methadone;
- 4.17.4. Take steps to ensure that the dose has not been retained in the mouth (i.e. Offer the patient water to swallow or engage the patient in conversation).

Buprenorphine (including in conjunction with naloxone)

- 4.17.5. Confirm the identity of the patient;
- 4.17.6. Transfer the patient's buprenorphine into a suitable receptacle and present this to the patient;
- 4.17.7. Provide the patient with water to swallow prior to administration of buprenorphine;
- 4.17.8. Supervise that the tablet is placed by the patient directly under the tongue and is not swallowed;
- 4.17.9. Require the patient to lift their tongue in order to observe the number of tablets taken;
- 4.17.10. Supervise the patient for a period of no less than three minutes to ensure the dose is delivered¹ and is not removed from the mouth;
- 4.17.11. At the end of supervision require the patient to lift their tongue to observe the residue of the tablet(s).

Buprenorphine Lyophilisate

- 4.17.12. Confirm the identity of the patient;
 - 4.17.13. Present the patient's buprenorphine in its foil packaging to the patient;
 - 4.17.14. Supervise that the wafer is placed by the patient directly on to the tongue and is not swallowed or placed under the tongue;
 - 4.17.15. Supervise the patient until the wafer has dissolved;
 - 4.17.16. At the end of supervision, advise the patient to try and avoid swallowing for 2 minutes and to avoid eating or drinking for at least 5 minutes.
- 4.18. The approved service provider shall develop and maintain links with prescribers and key workers involved in the care of patients.
 - 4.19. The approved service provider shall have sufficient knowledge of the treatment of substance misuse, the principles of harm reduction,

¹ Pharmacists should check the Summary of Product Characteristics (SPC) for the buprenorphine product dispensed for advice on an appropriate length of time.

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relevant Welsh Government policy and relevant legislation such that they can actively contribute to the multidisciplinary care of patients.

5. LOCAL HEALTH BOARD RESPONSIBILITIES

- 5.1. The Local Health Board shall enter into a Service Level Agreement (SLA) with all pharmacies commissioned to provide the service. The format of the SLA may be determined locally but its content shall not contain additional requirements over and above the provisions of this specification;
- 5.2. The Local Health Board, or its authorised officer, shall provide details of appropriate local substance misuse services, this will include any relevant telephone numbers, to which providers can signpost patients requiring further assistance. The Local Health Board will also have in place reasonable measures to ensure that pharmacies and other stakeholders are aware of local service provision;
- 5.3. The Local Health Board, or its authorised officer, shall ensure that procedures are in place to facilitate effective communication and referral between providers and appropriate local NHS services;
- 5.4. The Local Health Board, or its authorised officer, shall support the resolution of difficulties so far as they relate to issues within the control of the Local Health Board;
- 5.5. The Local Health Board, or its authorised officer, shall support the handling of any complaints or issues relating to the service so far as they relate to issues within the control of the Local Health Board.

6. WELSH GOVERNMENT RESPONSIBILITIES

- 6.1. The Welsh Government, or its authorised officer, shall in conjunction with Local Health Boards determine the fees and allowances payable in respect of the service.
- 6.2. The Welsh Government shall make provision for the NECAF or any replacement mechanism to be available to each pharmacy providing the service;
- 6.3. The Welsh Government shall make provision for the details of each pharmacy providing the service to be included in the All Wales Pharmacy Database;
- 6.4. The Welsh Government shall make provision for the details of each pharmacist and pharmacy technician approved to provide the service to be included in the All Wales Pharmacy Database. Contractors wishing to verify the accreditation of a pharmacist or pharmacy technician will have reasonable access;

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- 6.5. The Welsh Government shall make provision for an appropriate level of service performance information to be available to, the contractor, Local Health Boards and other organisations of NHS Wales (e.g. Public Health Wales NHS Trust), and to Community Pharmacy Wales;
- 6.6. The Welsh Government will develop a list of approved training providers that can be used to support this service.
- 6.7. The Welsh Government, or its authorised officer, shall in consultation with CPW support the resolution of difficulties which cannot be resolved in accordance with 5.3.
- 6.8. The Welsh Government, or its authorised officer, shall support the handling of any complaints or issues relating to the service which cannot be resolved in accordance with 5.4.

7. CONFIDENTIALITY AND DATA PROTECTION

The Provider will ensure that any Named Person shall not, whether during or after their appointment, disclose or allow to be disclosed to any person (except on a confidential basis to their professional advisers) any information of a confidential nature acquired by the Provider or any Named Person in the course of carrying out their duties under this Agreement, except as may be required by law or as directed by the commissioner.

The Provider must protect personal data in accordance with the provisions and principles of Data Protection Act and the Confidentiality: NHS Wales Code of Practice, and must ensure that all staff that have access to such data are informed of, and comply with this requirement.

The Provider shall at all times ensure that appropriate technical and organizational security measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

The Provider must be aware that the any information held by the Welsh Assembly Government, Local Health Boards or their authorised officers, may be subject to disclosure under the Freedom of Information Act.

8. AUTHORISED OFFICERS

For the purpose of the service the Welsh Assembly Government and Local Health Boards shall inform the provider immediately, in writing, of the details of any officer authorised to act on its behalf. Any notice, information or communication given by the authorised officer shall be deemed to have been given by the Welsh Assembly Government or Local Health Board as the case may be.

9. REVIEW VARIATION AND TERMINATION

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The service specification shall be reviewed at least annually.

Variation to the service specification, Competency and Training Frameworks and NECAF can only be made with the agreement of the Welsh Government. Variation to the service specification can only be made following consultation with Community Pharmacy Wales.

Contractors will be notified of any variations to the service specification in writing. No variation to the specification will be made until 90 days after that notice is received.

Providers, as signatories to the SLA, may cease to provide the service by giving notice in writing to the Local Health Board. Local Health Boards will require the agreement of the relevant Area Planning Board before any notice of withdrawal of the service is served. In the event of such notice the service will be terminated 90 days after that notice is received.

10. FEES AND ALLOWANCES

- 10.1. The contractor shall receive a professional fee on each occasion that a dose of medication is supervised in the course of this service. Fees will be published in Part VIE of the Drug Tariff.
- 10.2. Contractors shall submit all claims via NECAF where available. Where NECAF is not available, contractors shall submit all claims as set out in Part B;
- 10.3. Claims should normally be submitted by the 5th day of the month following the month in which the service was provided (*e.g. claims for supervision in March should be submitted by the 5th of April*).
- 10.4. Claims must be submitted no later than the 5th May at the end of the relevant financial year. Claims made after this date will not normally be paid.
- 10.5. Fees and allowances shall be paid monthly in arrears;
- 10.6. Claims for payment shall be subject to Local Health Board arrangements for Post Payment Verification;

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PART B

1. Complete a supervised administration claim form (Form A) each month;
2. Complete a supervised administration patient record form (Form B) each month, for each patient & medication type;
3. Record details on NECAF and retain copies of all forms for 3 years (*submit copies of all forms to NWSSP if NECAF is not available*).

SUPERVISED ADMINISTRATION CLAIM FORM (Form A)

Pharmacy:	
Address:	
Month / Year of Claim:	
No. of Patient Record Forms Submitted:	

APPROVED SERVICE PROVIDERS

Name <i>(Please Print)</i>	GPhC No	Signature

I declare that:

- The service was provided as detailed in the current service specification;
- All doses claimed for were supervised by an approved service provider;
- The information given on this form is true and complete to the best of my knowledge.

Name:	
Signature:	
GPhC Number:	

NWSSP –CS use

Checked by:	
Authorised by:	

Retain a copy of this form for 3 years.

If required, send to: Payments Department, Primary Care Services, NHS Wales Shared Services Partnership, Floor 3, Matrix House, Northern Boulevard, Matrix Park, Swansea Enterprise Park, Swansea, SA6 8BX

SUPERVISED ADMINISTRATION PATIENT RECORD FORM (Form B)

Name of Pharmacy	
Month / Year of Supervision	
Form Reference Number <i>(mmm-sequential number e.g. Sep-01)</i>	
Patient Details	Initials: Yr of Birth: New: Y/N
Treatment Agency	
Supervised Medication <i>(Please tick one only. Use a new form for mid-month changes)</i>	<input type="checkbox"/> Methadone <input type="checkbox"/> Buprenorphine (incl. Suboxone) <input type="checkbox"/> Buprenorphine Lyophilisate

Date	Approved Provider <i>(please print)</i>	GPhC No.	Supervised Dose (ml/mg)	Incident Key DNA Did Not Attend SR Supervision Refused PI Presented Intoxicated HP Health Problems Identified POL Police Called PC Contacted Prescriber
1 st				
2 nd				
3 rd				
4 th				
5 th				
6 th				
7 th				
8 th				
9 th				
10 th				
11 th				
12 th				
13 th				
14 th				
15 th				
16 th				
17 th				
18 th				
19 th				
20 th				
21 st				
22 nd				
23 rd				
24 th				
25 th				
26 th				
27 th				
28 th				
29 th				
30 th				
31 st				

Total number of supervised doses for this patient _____

Retain a copy of this form for 3 years.

If required, send to: Payments Department, Primary Care Services, NHS Wales Shared Services Partnership, Floor 3, Matrix House, Northern Boulevard, Matrix Park, Swansea Enterprise Park, Swansea, SA6 8BX