

Service Level Agreement for Pharmacy Supervised Consumption

Service Name/Location	Recovery Steps Cumbria
Version	V8.0
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On behalf of Contractor:	
Organisation's Name	
Name	
Signature	
Date	
Position Address	
(if a multiple, list all relevant and	
lead address for notices to be	
sent to)	
On behalf of Commissioner Service Name Signature	Humankind Charity, (Humankind) a UK Registered Company No. 182 0492 and a Registered Charity No. 515 755, VAT No. 334 6763 43, whose Registered Office is Inspiration House, Unit 22, Bowburn North Industrial Estate, Durham DH6 5PF Recovery Steps Cumbria Becky White
Date Position Address	24/04/24 Area Manager Stocklund House, Castle St, Carlisle, CA3 8SY

Introduction

This document outlines the requirements for providing a supervised consumption of medication for managing substance misuse in the community pharmacy setting ('the Service') by a community pharmacy ('the Pharmacy').

Supervised consumption aids adherence and can be helpful to reduce the risk of diversion and safeguarding issues. Additionally, more frequent contact can enable development of a therapeutic relationship and provides additional opportunities for providing timely and supportive advice, escalation of concerns and monitoring of the service user. It is important that supervised consumption is considered for all new prescriptions and that the dispensing arrangements are liberalised as soon as it is safe and clinically appropriate to do so; however, it may be reinstated when required to manage risks accordingly. Community pharmacies are ideally placed to provide supervised consumption within an agreed and structured protocol.

1. Governance

- 1.1 This document supersedes all previous working agreements.
- 1.2 The Pharmacy must adhere to relevant legislative requirements, best practice guidance and the standards set, for example by the General Pharmaceutical Council (GPhC) and Royal Pharmaceutical Society (RPS), including 'Standards for registered pharmacies (2018)' and 'Drug Misuse and Dependence UK Guidelines on Clinical Management (2017)' published by the Department of Health
- 1.3 Humankind and the Pharmacy will fully adhere to their respective obligations set out in this document.
- 1.4 Both Parties agree to share relevant information regarding substance misuse data to allow safe and high-quality Service provision/improvements and in line with the local PharmOutcomes licence agreement which detail data controller/processing/ sharing details.



- 1.5 Each party shall comply with its respective obligations pursuant to applicable data protection laws and/or regulations in relation to the processing of personal and/or special category data under this agreement, including but not limited to the General Data Protection Regulations and the Data Protection Act 2018.
- 1.6 The Pharmacy will demonstrate relevant Quality Standards to Humankind or will work towards achieving such a standard within an agreed timescale. The Quality Standards are specified in Appendix B Pharmacy Quality Standards for Supervised Consumption Quality Assurance Visits. If the Pharmacy remains in default following the expiry of the period specified, Humankind may proceed to terminate the Agreement (as outlined in Section 2).
- 1.7 The Pharmacy will take part in audit activity including the facilitation of Quality Assurance visits, where Humankind staff will use <u>Appendix B Pharmacy Quality Standards for Supervised Consumption</u> Quality Assurance Visits.
- 1.8 Should the Pharmacy not work in line with the agreed standards, Humankind shall immediately investigate and may review payment (as outlined in <u>Section 2</u>) and in the case of suspension or variation, report to the Pharmacy every 30 days until such investigation is complete. When the investigation is complete, Humankind shall immediately notify the Pharmacy of the outcome.
- 1.9 Any incidents or concerns must be reported immediately and appropriately actioned in accordance with respective organisations incident reporting processes.
- 1.10 Issues pertaining to concerns, incidents, indemnity, performance, disputes, confidentiality and data handling, must be promptly reported to Humankind within one working day, as soon as the Pharmacy become aware.
- 1.11 The Pharmacy must demonstrate they have appropriate insurance in place to be able to offer the Service and must ensure that Humankind is indemnified against any claim arising from the provision of the Service, and in the case of negligence of the Pharmacy: this liability may not be transferred.
- 1.12 The health and safety of Pharmacy staff (and any associated indemnity issues), remain the responsibility of the Pharmacy.
- 1.13 Any dispute, which cannot be resolved by negotiation, shall be referred to a nominated arbitrator for example the Local Authority Commissioner for Substance misuse Services or Chair of the Local Law Society.
- 1.14 Representatives of the Pharmacy (Community Pharmacy North Cumbria and Community Pharmacy Lancashire and South Cumbria) and Humankind are required to attend regular review meetings, which should occur at least once a year to discuss any concerns.

2. Funding, Notices and Termination

- 2.1 Payment for this scheme is to be agreed between Humankind (local operational contract management supported by Director of Pharmacy) and relevant Local Pharmaceutical Committee(s) (Community Pharmacy North Cumbria and Community Pharmacy Lancashire and South Cumbria) to represent the Pharmacy.
- 2.2 Humankind hosts and manages Pharmacy claims for processing for payment via PharmOutcomes as outlined in the local PharmOutcomes licence agreement.
- 2.3 The agreed fee to be paid per supervised dose ('per swallow') is as follows:
 - Methadone liquid/tablets (all brands), Diazepam: £1.60
 - Espranor® oral lyophilisate: £1.60
 - Buprenorphine sub-lingual tablet (all brands): £3.60
- 2.4 This payment covers:
 - Pharmacy staff time and associated costs for the supervised consumption activity
 - Record keeping activities to include PharmOutcomes data entries and returning completed prescribed treatment agreements to Humankind
 - Issuing service users ad hoc (usually in exceptional circumstances) with locked boxes and/or prelabelled take-home naloxone supplies for named individuals (where Humankind have already assessed service user competency/need but would otherwise be unable to enable timely supplies) which will be supplied to the Pharmacy via Humankind
 - Communication with Humankind/relevant others relating to this Service
 - Completion of relevant CPPE substance misuse training self-declaration, and attendance at an annual training event to ensure maintenance of confidence and competence when supporting people who use substances



- Active participation in Quality Assurance visits and achieving required Quality Standards.
- 2.5 The Service as outlined is VAT exempt, and both Parties are aware of this exemption. However, if in the future the VAT status was to change then an opportunity to renegotiate the terms of the Agreement would be made available.
- 2.6 The Pharmacy accepts that Humankind is unable to guarantee future funding and may, owing to budgetary considerations be obliged to reduce funding by the giving of not less than 60 days' notice. Such reductions shall be timed to cause least disruption for service users. If Humankind invokes this clause to reduce payment, then the Pharmacy shall be entitled to cease providing the Service at the end of this notice period without incurring a penalty.
- 2.7 To enable payment, the Responsible Pharmacist assigned to the Pharmacy must complete the relevant PharmOutcomes supervised consumption sign up module. The Pharmacy is responsible for subsequently ensuring that Humankind are provided with the correct Pharmacy bank details to complete the enrolment process.
- 2.8 Humankind will make best endeavours to pay the Pharmacy within 30 days in arrears upon receipt of an invoice received via PharmOutcomes.
- 2.9 No payment will be made if the invoice covers activity that was undertaken more than 3 months prior to the date of the invoice being submitted.
- 2.10 Humankind will examine the data submitted and may seek to verify the Fees claimed.
- 2.11 Payments will only be made where Humankind is satisfied that the Service has been provided in accordance with the terms of this Agreement. Humankind shall be entitled to suspend payment and/or vary the amount of the payment if it considers the Pharmacy has committed a serious breach of the Agreement and shall forthwith notify the Pharmacy in writing accordingly. Once all relevant investigations are complete and if deemed appropriate, within 30 days Humankind will pay any sums to the Pharmacy that were suspended or varied.
- 2.12 Humankind may from time to time, require reasonable changes to the terms of this Agreement, and where reasonably practicable, up to 14 days' notice will be given. The Pharmacy shall use its reasonable endeavours to implement this change on the understanding that such change will not materially affect the nature of the Service or the Pharmacy's ability to provide the Service.
- 2.13 The Service and payment may be varied or discontinued if the Pharmacy and Humankind agree, or a change in Humankind service priorities is required either by changes in legislation or by other circumstances, including the cessation or reduction of the budget. Humankind also has the option to terminate funding should the Pharmacy enter receivership or become insolvent.
- 2.14 The Service must be offered every day that the Pharmacy is open. If the Pharmacy put in an application to reduce their opening days or times, then Humankind must be informed at the time of application.
- 2.15 Notices must be given in writing and by email (with acknowledged receipt) or recorded delivery post to the details provided for that purpose. A notice given by post will be deemed to have been served the first working day after it was posted.
- 2.16 This Agreement will be reviewed and subject to agreement, renewed on an annual basis. However, it may be ended earlier, either on dissolution of the Pharmacy or where at least 60 days' notice is given by either Party of their intention to terminate the Agreement.
- 2.17 Nothing in this Agreement confers or purports to confer on any third party any benefit or any right to enforce any term of this Agreement.

3. Competency and Training

- 3.1 This Service may only be undertaken by competent Pharmacy staff (as outlined below) who must be under the supervision of the Responsible Pharmacist registered with the GPhC.
- 3.2 The Responsible Pharmacist must have completed Safeguarding training to Level 2 and be DBS-checked in line with current guidance, which must be rechecked/updated in response to any legislative/best practice guidance changes. The Responsible Pharmacist must ensure the suitability of any Pharmacy staff who are one-to-one with a vulnerable service user.
- 3.3 The Responsible Pharmacist must have completed self-declaration via PharmOutcomes to confirm completion of relevant CPPE substance misuse training within 3 months of commencing service provision.
- 3.4 Staff who are deemed as suitably competent to undertake the Service must be recorded as such on the Pharmacy's local Standard Operating Procedure for Supervised Consumption.



- 3.5 It is the responsibility of the Pharmacy to ensure that the staff undertaking the Service have received appropriate training, including completion of relevant supervised consumption competencies/accreditation.
- 3.6 Where locums or part time staff predominantly operate a pharmacy, the Superintendent Pharmacist or delegated deputy must nominate a lead person to act as a contact. This must be communicated to Humankind promptly.
- 3.7 Humankind will seek to provide at least one training event per year which will usually be available for access by the wider Pharmacy Team (including locum staff), to support broader development of competency and confidence in the management of substance misuse. The Pharmacy must be represented by at least one member of staff at a minimum of one event per year.
- 3.8 The Responsible Pharmacist on duty at any time will retain professional responsibility and the Pharmacy shall retain liability for the Service.

4. Supervised Consumption Process

- 4.1 To be eligible, the service user must meet all the following essential criteria:
 - Be prescribed medication for management of their substance misuse by the relevant Humankind service (or sub-contractor).
 - Reside/works within a geographical area that the Pharmacy reasonably covers.
 - Require supervised consumption due to safeguarding/clinical risk issues.
- 4.2 The Pharmacy chosen to provide the Service must be determined by service user choice except in exceptional circumstances (e.g. where the Pharmacy is not open on days when supervised consumption would be required, if the Service cannot be provided by the Pharmacy or the service user has been banned from their chosen Pharmacy premises). The Pharmacy must make all reasonable efforts to accommodate all requests and may only to refuse to accept the service user on professional grounds (e.g. at capacity, currently banned from the premises for aggressive behaviours), and the provided rationale must be clearly documented in the service users' clinical records.
- 4.3 In advance of the Service taking place, Humankind staff must contact the Pharmacy to confirm agreement of providing the Service for a named service user, and once agreed to, appropriate risk information and a completed Appendix C Prescribed Treatment Agreement, must be completed and shared with the Pharmacy prior to the Service commencing.
- 4.4 Once the Pharmacy complete their relevant sections of <u>Appendix C Prescribed Treatment Agreement</u> (including agreeing with the service user the most suitable time for providing the Service), a copy should be provided to the service user and another copy returned to the relevant Humankind service.
- 4.5 To ensure continuation of service delivery, supervised consumption for prison releases which cover the high risk immediate post-release period (usually up to two weeks), to allow time for the transfer of care to move to the local Humankind service, will be covered under the terms of this Agreement, even though the prescription has been written by the prison clinician.
- 4.6 Any relevant changes in the service user's circumstances, including amended risk status, must be promptly communicated between Parties.
- 4.7 Requests to discuss any clinical issues or queries should be appropriately responded to and ideally within the same working day.
- 4.8 Humankind should be notified every time a dose is missed/where the service users' attendance is erratic.
- 4.9 So that Humankind staff can assertively seek to engage/welfare check on the service user, Humankind **must** be notified immediately if:
 - Three or more consecutive/titration doses are missed
 - There are any concerns about the dose/medication prescribed
 - A dispensing error/near miss has occurred
 - There are concerns about diversion/safeguarding/risk issues
 - The dose cannot be given due to intoxication
 - There are concerns about physical/health care needs
 - The service user behaves unacceptably (e.g. shoplifting, physical/verbal abuse)
 - The service user does not consume the whole dose
 - The Pharmacy unexpectedly must close (e.g. no Pharmacist on premises due to sickness)



- Due to risk of accidental overdose because of reduced tolerance, if three or more consecutive/any
 titration doses have been missed, the Pharmacy must not supply further doses until an appropriate
 prescriber has confirmed suitability of the dose.
- 4.10 The 'Reporting Issues' module on PharmOutcomes may be used for sending information to the service where a response is not required. It must not be used to replace direct verbal communication where there are notable safety concerns e.g. where three or more consecutive/titration doses are missed.
- 4.11 Locum Pharmacy staff must be made aware of this Service and the procedures in advance of them providing locum cover, as the presence of a locum is not a valid reason for the Service not to be appropriately implemented.
- 4.12 It is essential that communication channels (e.g. via PharmOutcomes/emails) are regularly checked and promptly actioned, otherwise the safety/quality of Service provision may be impacted and payment to the Pharmacy may be impacted (as outlined in Section 2).
- 4.13 The dispensing and supervised consumption of the medication will be undertaken in accordance with the Pharmacy's internal Standard Operating Procedures providing it is not contrary to the contents of this Agreement and as outlined in <u>Appendix A Pharmacy Guidance for Supervised Consumption</u>.



Appendix A - Pharmacy Guidance for Supervised Consumption

Supervised consumption must be completed in a location that considers the service users' privacy/dignity and Pharmacy staff/customer safety (this should usually be in the consultation room/area designated for delivering professional services): it must never be provided in the Dispensary. The Pharmacy must have sufficient staffing levels to ensure safe and effective service provision. The Pharmacy staff delivering the Service must not lone work.

Prior to providing the service user with the prescribed medication, the Pharmacy staff member responsible for supervising consumption must:

- Check the service user identity against their Appendix C Prescribed Treatment Agreement.
- Assess suitability of administering dose prior to supplying the person with the medication (e.g. checking for intoxication, potential drug interactions, missed doses, inappropriate behaviours, co-presenting physical/mental health issues which may be of concern).
- Show the service user the medication in order to confirm the details (including the dose) to verify that it is what they are expecting.

If the service user is intoxicated, this must be documented on their clinical records, Humankind must be informed, and the service user should be asked to return later that day to be reassessed for suitability. The time taken to overdose can vary from a few minutes to several hours and may be fatal; however, withdrawal symptoms may take a several hours/days to emerge and can be very uncomfortable, depending on what has been taken and how much has been used. Signs and symptoms of an opioid overdose/intoxication and withdrawal include:

Intoxication Withdrawal Pinpoint/constricted pupils Dilated Pupils • Nausea/vomiting/constipation Nausea/vomiting/diarrhoea • Pale skin colour, bluish tinge to lips, tip of nose, under the eyes, · Gooseflesh skin (piloerection) fingertips or nails Agitation/restlessness/anxiety/irritability • Low blood pressure/pulse (hypotension/bradycardia) Raised blood pressure/pulse • Sedation which may be worsening to include: (hypertension/tachycardia) No response to noise (they don't respond to shouting) • Sweating/flushing/chills ONo response to touch (they don't respond to being shaken by the • Bone/joint aches/pains shoulders) · Runny nose, tearing, yawning o Loss of consciousness (they cannot be woken) Tremor o Breathing problem (slow/shallow/infrequent breaths, snoring/rasping sounds or no breathing) Video to learn more: https://www.voutube.com/watch?v=uYz-scWacng

If the service user is being given their first dose of buprenorphine, it is important to check that a suitable amount of time has passed since they had their last dose of any opioid agonist (e.g. methadone, heroin) to minimise the risk of precipitating withdrawal.

Liquids: must be swallowed directly from the dispensing container. The service user should be offered a drink of water immediately after consuming and engaged with in conversation to help ensure that the medication has been swallowed.

Solid dose formulations to be swallowed: must be placed into a disposable pot and then handed to the service user for them to administer. The service user should be offered a drink of water immediately before and after consuming. They should be engaged in conversation and the mouth checked after swallowing, to help ensure that the medication has been swallowed.

Lyophilisates/sublingual tablets: must be placed into a disposable pot and then handed to the service user for them to administer. Inform the service user to avoid swallowing whilst the medication is dissolving. The service user should be offered a drink of water immediately before the dose is consumed. They should be observed as having the medication correctly in situ prior to/during the dissolution process (e.g. Espranor® dissolved on the tongue and hands must be dry before handling the lyophilisate). Excess saliva should be kept in the mouth and not swallowed for as long as possible. Different lyophilisates/sublingual tablet brands may have differing dissolution rates.

Water from the Pharmacy must be used for supervised consumption: the service users' own drink must not be used because of the increased risk of diversion. Any concerns (e.g. potential diversion, part-consumed doses, challenging behaviours) that occur during the supervised consumption process must be promptly recorded on the service user's notes, made known to the responsible pharmacist and communicated to Humankind.

If take home doses are provided, it is important to confirm that the service user has appropriate safe storage measures in place (including storing out of sight/reach of children/vulnerable adults).



Pharmacy Quality Standards for Supervised Consumption Quality Assurance Visits

Pharmacy Site	Date of Visit	
Responsible Pharmacist	Visit Completed by	

	Quality Standard	√=meets expected standard. No action required X=Doesn't meet expected standard. Add details of all agreed actions
ecks	Signed current SLA available in Humankind centrally held records	
site ch	CPPE self-declarations completed by all relevant Pharmacy staff (via PharmOutcomes) within 3 months of commencing the service	
e Off-	Attendance by at least one Pharmacy staff member at a minimum of one Humankind training event in the last year	
uranc	Pharmacy-completed Prescribed Treatment Agreement uploaded to all service user clinical records (if >10 service users, randomly check 5)	
Quality Assurance Off-site checks	Last 6 months of complaints/incidents suggest prompt reporting/appropriate actions.	
Quali	Last 6 months of PharmOutcomes data suggest timely submissions	
Quality Assurance On-site Pharmacy checks	Pharmacy can evidence having in place: Signed current SLA available in Pharmacy Correct insurance DBS for all Responsible Pharmacists Up to date safeguarding training Level 2 for all Responsible Pharmacists Prescribed Treatment Agreement fully completed for every service user Appropriate infection control measures (e.g. use of disposable cups) Suitable confidentiality/data protection methods (e.g. labels removed and placed in confidential waste) Pharmacy SOP for supervised consumption read and signed off by all relevant Pharmacy staff Observation during visit and feedback from service user(s) indicates service user treated with dignity and respect Pharmacy staff either observed or can verbally outline how to correctly: Assess service user appropriately prior to handing over of medication Verify service user identity correctly (including using Prescribed Treatment Agreement and as detailed in local Pharmacy SOP) Follow best practice when carrying out supervision (as detailed in SLA and local Pharmacy SOP) Respond to incidents/concerns including safeguarding issues Signpost to relevant local specialist services (e.g. Humankind, Housing, Mental Health) Provide written information about medication in service-user accessible format (via C&M website) Provide safe storage advice including written information in service-user accessible format (via C&M website) and locked boxes Respond to a service user who presents as intoxicated Provide brief harm reduction advice including take home naloxone supplies that have already been issued by Humankind Any additional comments (e.g. feedback about how to further improve current Service, learning from incidents yet to be implemented)	



Appendix C - Prescribed Treatment Agreement

The purpose of this agreement is to enable the safe and effective use of medication to support the service user in their recovery journey. The service user's photograph and personal information contained within this agreement will always be used for the sole purpose of identifying the service user during their prescribed treatment and stored securely. It will not be issued to or viewed by any individuals or agencies outside this agreement without prior consent.

Service user:				Service user Photograph
Name				
Address				
Date of Birth				
Contact Number				
Humankind:				
Staff Name				
Address				
Contact Number				
Pharmacy:				
Name				
Address				
Contact Number				
GP:				
Name				
Address				
Contact Number				
users' needs, so th make an informed	at they know ab decision. Inform	out the different that is at the different t	ypes of prescribed tre online from: <u>www.ch</u>	in a format that meets the service eatment options and enable them to oiceandmedication.org/Humankind tion, which has been:
accessed by other	s, especially chable safe storage	nildren. They hav	sks of medication/illion/e been offered a wr	it substances/paraphernalia being itten information leaflet about safe / REFUSED □ If they have declined
Mutually convenier	nt times for colle Mon Tues Weds	ection/delivery of From: From: From: From:	medication have beer To: To: To:	n agreed as follows:
	Thurs	From:	To:	

To:

Fri

From:



Sat	From:	To:
Sun	From:	To:

(to be completed by the pharmacy)

As the providers of prescribed treatment, the Pharmacy and Humankind, will:

- Always treat the service user with respect, courtesy, understanding, kindness, compassion and honesty and not judge if they stumble or lapse in their recovery.
- Fully support the service user with their recovery programme and the decisions made regarding medication in a way that helps to keep them safe and well.
- Keep the service user fully informed of their treatment options and provide information about medication, potential benefits and risks (including monitoring requirements and adverse effects of treatments) and respect that the service user has the right to decline or accept the treatment offered after being informed.
- Discuss and exchange information about the service user's behaviour, state of health, attendance and
 other factors relating to their treatment. They may also communicate with family, friends and other
 providers who may be involved in the service user's care (as agreed with the service user) to support
 their recovery.
- Inform the GP/other healthcare providers about prescribed medication, but will not share confidential
 information with others, unless concerned about service user safety and well-being and have no other
 options.
- Provide a service in an environment where the service user and staff feel safe and comfortable.
- Ensure that the consumption of medication is appropriately supervised.
- Avoid arranging appointments unless mutually agreed and notify the service user as soon as possible about any changes.
- Provide lockable boxes for safe storage of medication, particularly if the service user has children/vulnerable adult(s) living or regularly visiting their accommodation.
- Do all they can to ensure that any problems with prescriptions are corrected as soon as possible.
- Provide an easy and open complaints system and treat all complaints fairly.

The service user will:

- Let the treatment providers know about any changes in circumstances (e.g. new address/phone number).
- Let the treatment providers know what is wanted/needed (give at least 14 days' notice for any requests for changes to prescriptions e.g. holiday requests, do not assume that requests can always be granted).
- Not smoke or drink alcohol in the presence of staff.
- Not display or use, illicit drugs in the presence of staff.
- Act in an acceptable manner in the presence of staff: unacceptable behaviour includes being intoxicated, theft, verbal abuse or physical violence to staff or others.
- Unless otherwise agreed, be in attendance alone, within agreed times and at agreed intervals.
- Remove any hoods, hats or other items of clothing in order to assist staff with identification.
- Take medication as prescribed and not to share it with any other person.
- Drink water provided by the Pharmacy as requested during the supervised consumption process.
- Understand that any prescribed medication or prescriptions are their responsibility and may not be replaced (for example if they are lost, stolen or spilt).
- Understand that if more than 3 consecutive days doses are missed, or if attendance is irregular, medication may be withheld for safety reasons (due to loss of tolerance) and treatment services will need to be contacted before it can be resumed.
- Be patient if staff are delayed and understand that if there is a problem with the legality of a prescription, the pharmacist will not be able to dispense it.
- Understand that if doses are missed on a specified day, or if it cannot be given (for example due to intoxication), it cannot be collected on a later day.
- Store, transport and dispose of all medication, other substances, paraphernalia and keys to access safe storage facilities, safely and securely, including out of the sight and reach of children and vulnerable others.
- Inform if someone else takes their prescribed medication and tries to get the person immediate medical help if they are at risk of overdose (e.g. if accidentally taken by a child phone 999 immediately).
- Inform the DVLA about any prescribed medication.
- Not stock-pile medication and return any unused medication to the pharmacy for destruction.



- Not alter prescriptions in any way as this will be considered as fraud and will be reported to the police.
- Engage in psychosocial activities and drug testing as agreed in the recovery plan.
- Understand that if the above points are not adhered to then the pharmacological intervention may be reviewed to ensure that it is being prescribed safely and effectively.

We, the undersigned, agree to the terms laid out in this agreement.

Service User Name	Signature	Date	_/_/_
Humankind Representative Name	Signature	Date	_/_/_
Pharmacy Representative Name	Signature	Date	_/_/_
GP Name (for shared care ONLY)	Signature	Date	_/_/_