

SUPERVISED CONSUMPTION Service Specification

Between

Bury Council 1st Floor, 3 Knowsley Place Duke Street Bury BL9 0EJ

(Named Commissioner: Sarah Turton)

s.turton@bury.gov.uk

And

The local pharmacy contracted through CHL to provide this service

For the Locally Commissioned Service Supervised Consumption 2023/24

Service Specification updated: 04/09/2023

Service Specification review: 04/09/2024

1. Service description

- 1.1 This service will require the pharmacist to supervise the consumption of prescribed medicines at the point of dispensing in the pharmacy, ensuring that the dose has been administered to the client.*
- 1.2 Pharmacies will offer a friendly, non-judgmental, client-centred and confidential service.
- 1.3 Pharmacies will provide support and advice to the client, including referral to primary care or specialist centres/services where appropriate.
- 1.4 Examples of medicines which may have consumption supervised include methadone and other medicines used for the management of opiate dependence.

2. Aims and intended service outcomes

- 2.1 To ensure compliance with the agreed recovery plan by:
 - dispensing in specified instalments doses may be dispensed for the client to take away to cover days when the pharmacy is closed.
 - ensuring each supervised dose is correctly consumed by the client for whom it was intended.
- 2.2 To reduce the risk to local communities of:
 - over usage or under usage of medicines;
 - diversion of prescribed medicines onto the illicit drugs market; and
 - accidental exposure to the supervised medicines.
- 2.3 To provide clients with regular contact with health care professionals and to help them access further advice or assistance. The client will be referred to specialist treatment centres or other health and social care professionals where appropriate.
- 2.4 To communicate with the local drug and alcohol treatment provider when required i.e., to notify of missed doses and/or raise any concerns regarding the patient. This can be done by contacting the service directly or through PharmOutcomes.

3. Service outline

3.1 It is strongly recommended that community pharmacies are signed up to the supervised consumption contract between Bury Council and the pharmacy, managed by CHL, to undertake supervised consumption of prescribed medication. This enables the community pharmacy to receive

^{*}Doses given to the client to take away are not classed as supervised consumption under this service and cannot be claimed for

- remuneration for the service, as well as providing an extra level of governance and patient safety when carrying out this service.
- 3.2 Pharmacists that meet the competencies detailed in the 'Declaration of Competence for pharmacy services Supervised Consumption of Prescribed Medicines Service' and have completed the self-declaration for the service level may provide supervised consumption.
- 3.3 The declaration of competence (DOC) should be retained in the pharmacy. Evidence of this will also need to be uploaded on to PharmOutcomes via enrolment. There will be a three month grace period from the start of the service; after this, if not completed, pharmacies will not be able to access the service.
- 3.4 Before making this declaration of competence, the following must be completed:
 - Centre for Postgraduate Pharmaceutical Education (CPPE) Substance use and misuse package (modules 1-4)* <u>Substance use and misuse: CPPE</u>
 - CPPE assessment 'Substance Use and Misuse delivering Pharmacy services'* <u>Substance use and misuse (2023): CPPE</u>
 - CPPE eLearning for healthcare 'Safeguarding adults level 2'* https://www.cppe.ac.uk/programmes/l/safegrding_elfh-e-02
 - 3.5 The declaration of competence must be completed at least every two years. Guide to DOC: https://www.cppe.ac.uk/services/docs/doc%20how%20to%20use%20guide.pdf
- 3.6 The Substance Misuse in General Practice website is also a useful source of information and guidance and contains discussion groups to support those working with substance users. This can be found at Addiction Professionals
- 3.7 The UK psychiatric pharmacists' substance misuse e-mail group (www.ukppq.org.uk) is another forum for discussion.
- 3.8 The pharmacy has a duty to ensure that all staff and other pharmacists (including locums) involved in the provision of the service have relevant knowledge and are appropriately trained to ensure the smooth continuation of the service.
- 3.9 The Council recommends that all pharmacists involved in the provision of the service should have completed the learning and assessments outlined at 3.5., as well as any other relevant training. In addition, they should also be familiar with relevant national and local guidance. Links can be found on page 9 of this document.

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^{*} As training packages are updated or replaced from time to time, participating pharmacists will undertake to complete any appropriate new or updated package as soon as reasonably convenient.

- 3.10 Locums have a responsibility to ensure their own relevant knowledge and training in the operation of the service. The wider pharmacy team should be able to provide assistance to a locum pharmacist carrying out this service.
- 3.11 The pharmacy will maintain a list of pharmacists that have provided this service for a period of 2 years and retain a copy of their signed self-declaration of competence and training records. This should be available if required for post payment verification checks and act as an assurance to Bury Council that only competent staff deliver the service.
- 3.12 Pharmacists participating in this service will be expected to take on the number of clients that they feel appropriate for their pharmacy within the parameters of good practice, taking into account all of their community responsibilities.
- 3.13 A pharmacist who is involved in the provision of healthcare to a vulnerable person is recommended to undergo a Disclosure and Barring Service (DBS) check.
- 3.14 The pharmacy will recommend Hepatitis B vaccination to all staff, including locums and support staff who will be working on the premises where a supervised consumption service is provided.
- 3.15 The pharmacy has a duty to ensure that pharmacists and staff involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service. Pharmacists (including locum pharmacists) will be expected to complete a Declaration of Competence via the Centre for Pharmacy Postgraduate Education (CPPE) which includes the training module in Substance Use and Misuse within three months of signing this agreement, if not previously completed. Enrolment will be required on PharmOutcomes to provide this service.
- 3.16 A Standard Operating Procedure (SOP) for the service must be in place in the pharmacy, and the pharmacist must ensure that all dispensary staff, including locums, are aware of the content of the SOP, and have signed to confirm their understanding (refer to Appendix 1 Community Pharmacy Procedure).
- 3.17 The pharmacist must ensure that all members of staff are familiar with the Department of Health 'You're Welcome' quality criteria:

 https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services
- 3.18 The part of the pharmacy premises used for provision of the service must provide privacy and safety. Transactions should take place within a designated private and safe area, not in the dispensary. Clients must be made aware by the pharmacist that this private safe area is available for use.
- 3.19 The procedure detailed in Appendix 1 must be followed. This procedure applies to supervised consumption in the management of opiate dependence.

- 3.20 The pharmacist will present the medicine to the client in a suitable receptacle and will provide the client with water to facilitate administration and/or reduce the risk of doses being held in the mouth.
- 3.21 Pre-packing of doses for supply the next day must be in line with a written procedure and be undertaken in line with current guidance for Good Manufacturing Practice.
- 3.22 The pharmacy should maintain all appropriate and legally required records to ensure effective ongoing service delivery and audit.
- 3.23 Dispensing records for each supervised dose are to be recorded on PharmOutcomes. This system will also be used for monitoring and audit purposes and for the purpose of remuneration.
- 3.24 Pharmacists are responsible for maintenance of PharmOutcomes. There should be a record of daily attendance, missed doses and other concerns that may need to be reported back to the prescribers.
- 3.25 The Bury Council Officer responsible for contract monitoring will review and analyse the data collected on PharmOutcomes quarterly. Pharmacies may be contacted to identify or resolve any barriers to service delivery and to identify best practice where required. Other relevant information may also be requested, for example, training records or logs of compliments and complaints. In addition, Bury Council may undertake spot questionnaires and random auditing (LPC to be made aware in advance).
- 3.26 Appendix 3 (Client Recording Sheet) must be used in the event of system failure. Information to be added to PharmOutcomes when the system resumes.
- 3.27 The Client Contract (Appendix 2) states the terms of agreement set up between the substance misuse worker, prescriber, pharmacist and client (a four-way agreement) to agree how the service will operate, what constitutes acceptable behaviour by the client, and what action will be taken by the prescriber and pharmacist if the client does not comply with the agreement.
- 3.28 Pharmacists will share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements. Incidents should be documented on the Incident form provided (Appendix 4) and communicated to the relevant prescriber/substance misuse worker. This is in addition to the pharmacy's usual incident and near-miss reporting procedure.
- 3.29 Pharmacists will develop and maintain close links with the prescriber/substance misuse provider.
- 3.30 The pharmacist should receive notification from the prescriber in advance of a new client presenting a prescription; where the prescriber has failed to contact the pharmacist in advance, the pharmacist should always contact the prescriber to confirm arrangements.

- 3.31 If a client has 'violent markers', the prescriber or substance misuse worker must inform the pharmacy in advance of the client presenting a prescription. Pharmacy to discuss concerns with the prescriber or substance misuse worker.
- 3.32 The client's key worker will be responsible for obtaining the patient's agreement to supervised consumption. The agreement will be initiated outlining the responsibilities of the prescribing team, pharmacy and the patient. This must be agreed prior to first presentation for supervised consumption. (Appendix 1)
- 3.33 If a pharmacist has any cause for concern relating to a client, and the prescriber or substance misuse worker is not available (e.g. outside service hours), the pharmacist must use their professional judgment in deciding whether to supply.
- 3.34 The decision to discuss a client with the prescriber/substance misuse provider is a professional one that should be made after considering the risk to the client of non-disclosure and the damage that could be done to the supportive relationship between pharmacist and client.
- 3.35 Bury Council and the substance misuse provider will provide details of relevant referral points which pharmacy staff can use to signpost clients who require further assistance. Health promotion material relevant to clients will also be provided and must be displayed.
- 3.36 The pharmacy will operate a robust adult and child safeguarding procedure in line with locally agreed inter-agency safeguarding policy and procedures. https://theburydirectory.co.uk/services/bury-local-safeguarding-policy-and-procedures
- 3.37 The substance misuse provider should carry out risk assessments on clients prior to attending the pharmacy and if a client has 'violent markers' or risks are identified, the prescriber or substance misuse worker should inform the pharmacy in advance of the client presenting a prescription. However, the pharmacy should be risk aware and carry out risk assessments in line with routine pharmacy guidelines where necessary.
- 3.38 The pharmacy must demonstrate it has sufficient indemnity cover to support provision of this service.
- 3.39 All controlled drug incidents and concerns have to be reported to NHS England via the website www.cdreporting.co.uk, please do not include patient identifiable data.
- 3.40 Public Health England policies on substance misuse and needle exchange will apply to this locally commissioned service.
- 3.41 The pharmacy will be required to provide core opening hours covering Monday to Saturday inclusive, in order to provide this service, except for

bank/public holidays. All patients accessing the service must be provided with information on opening times and arrangements for bank holiday services.

- 3.42 The pharmacy will provide healthy life-style support to the client and proactively offer or signpost to services which promote wellbeing and prevent ill health e.g. sexual health services, including Chlamydia and Gonorrhoea screening, vaccinations, stop smoking and advice on alcohol use/cessation.
- 3.43 The pharmacy is responsible for ensuring they have appropriate insurance cover.

4. Key Performance Indicators

Key Performance Indicator	Description
Pharmacists will complete the relevant self-declaration of competence.	Before making this declaration of competence the relevant training must be completed.
•	The pharmacy will maintain a list of pharmacists that have provided this service for a period of 2 years and with this retain a copy of their signed self-declaration of competence and training records. This will be available for post payment verification checks and act as an assurance to Bury Council that only competent staff deliver the service.
The pharmacy must demonstrate that all pharmacists and staff involved in the provision of this service have undertaken the appropriate training.	100% of pharmacy staff involved in the provision of this service must be appropriately trained (detailed in section 3.5), and training or CPD records must be available.
The pharmacy must review its standard operating procedures and the referral pathways.	The pharmacy must demonstrate that SOPs (including all SOPs relating to controlled drugs) and referral pathways relating to this service are reviewed and updated at least every two years, or before, if notified of a major change to the service specification.
The pharmacy must have health promotion material available for the client group and promote its uptake.	Health promotion materials must be promoted within the pharmacy, and all staff (including locums) must be aware of local services for substance misusers and be able to signpost clients to these.
The pharmacy must ensure that any incidents (see Section 14 of the community pharmacy protocol - Appendix 1) must be reported to the prescriber/substance misuse worker.	The pharmacy must demonstrate that in 100% of cases, an incident form (Appendix 4) is completed and sent to the prescriber/ substance misuse worker as required. Missed doses must be reported to the substance misuse treatment provider.

All claims for service provision must be submitted to the Council no later than five working days following the month end that the claim relate to.	to the Council no later than 5 working days
The pharmacy participates in a Council organised audit of service provision.	As and when required.
The pharmacy co-operates with any locally agreed Council- led or local substance misuse provider led assessment of client experience.	As and when required.

5. Payment for the service

- 5.1 Each pharmacy will receive an annual retainer fee of £265 (to be paid annually in arrears, pro-rata for part or full months during periods of less than 12 months) plus a fee for each transaction of £1.80 (£3.50 for sublingual buprenorphine). Supervised consumption is considered zero-rated for VAT, as it is considered as part of the dispensing process.
- 5.2 Payment of the annual retainer will be dependent upon the timely submission of monthly invoices and accompanying data. If data is not received by the 5th working day following the month to which the claims relate 1/12th of the annual retainer payment will be deducted. i.e. if a pharmacy submits data late for 6 out of 12 months it will only receive 50% of the annual retainer payment.
- 5.3 The service will only be considered to have commenced once the first transaction has taken place.
- 5.4 Any claims submitted more than 30 days following the month end to which the claims relate <u>will not be paid.</u>
- 5.5 One transaction is defined as one client visit to receive supervised consumption on the premises, irrespective of the number of doses issued at the visit.
- 5.6 Pharmacies that become unable to carry out the service in line with the contract and service specification must notify CHL and Bury Council.
- 5.7 All supervised consumption claims must be made using the PharmOutcomes system.

Important Additional Information (please see updated versions where applicable)

A full copy of the 'Drug Misuse and Dependence – Guidelines on Clinical Management' can be found at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/673978/clinical_guidelines_2017.pdf

Guidance for the Use of Buprenorphine for the Treatment of Opioid Dependence in Primary Care:

https://www.drugsandalcohol.ie/13633/1/RCGP buprenorphine.pdf

NICE Guidance - Health Technology Assessment:

https://www.nice.org.uk/guidance/ta114/chapter/1-Guidance

NICE Guidance - Controlled drugs and drug dependence:

Controlled drugs and drug dependence | Medicines guidance | BNF | NICE

Medico-legal aspects

The Royal Pharmaceutical Society of Great Britain provides guidance on all legal aspects and standards for professional indemnity, both of which can be found in the latest edition of 'Medicines, Ethics, and Practice'.

https://www.rpharms.com/

Supervised Consumption of Prescribed medicines – Declaration of Competence:

https://www.cppe.ac.uk/services/declaration-of-competence2?srv=9#doc

The CPPE viewer facility allows commissioners or employers access to view a pharmacy professional's learning and assessment record. Pharmacy professionals will need to enable the CPPE Viewer via their Profile section of the My CPPE page to allow access to others.

GPC Guidance for Registered Pharmacies preparing unlicensed medicines:

https://www.pharmacyregulation.org/sites/default/files/document/guidance for registered pharmacies preparing unlicensed medicines august 2018 0.pdf

Appendix 1

Community Pharmacy Procedure: Supervised Consumption Scheme

- 1. The key worker and prescriber will agree with each new client participating in the Supervised Consumption Scheme the pharmacy from which his/her prescription will be dispensed and will notify the pharmacist accordingly. Clients will primarily be offered a choice of pharmacy registered with the supervised consumption scheme.
 - 2. All clients who are to receive daily dispensing should agree and sign a client contract this is initiated from the prescribing doctor. The pharmacist on duty should also explain the contract and sign together with the client and the key worker. The client should keep their copy.
 - 3. The pharmacist should receive notification from the prescriber in advance of a new client presenting a prescription; where the prescriber has failed to contact the pharmacist in advance, the pharmacist should always contact the prescriber to confirm arrangements. If the prescriber/substance misuse worker is unavailable, the pharmacist cannot accept the client unless the client can produce a completed client contract.
 - 4. If a client has 'violent markers', the prescriber or substance misuse worker will inform the pharmacy in advance of the client presenting a prescription.
 - 5. The pharmacist should ensure that all new client details are entered on to PharmOutcomes.
 - 6. The pharmacist should introduce the client to the counter staff, so that the client can be dealt with promptly each day.
 - 7. When a prescription is presented, the pharmacist should check that the prescription is legally correct and whether the client has an existing contract with the pharmacy.
 - 8. Daily doses on current prescriptions and for clients expected to collect regularly should be prepared in advance and stored as appropriate in the Controlled Drugs cabinet, to avoid undue delay when the client presents in the pharmacy. Daily doses should be prepared according to best practice.
 - 9. Initial daily supervised consumption will be for a period of 12 weeks. Should there be significant stability, positive changes in circumstances e.g. client attains a job, has sole child care responsibilities for example, this arrangement can be reviewed. Full agreement needs to be given by the key worker, prescriber and pharmacist.
 - 10. The pharmacist should not dispense the dose if the client is intoxicated at presentation. The pharmacist should contact the prescriber to advise that the client was intoxicated on presentation and the dose was not dispensed.

- 11. Unless a 'take home' dose is required, the medication must be consumed on the premises under the supervision of the pharmacist or pre-registration pharmacist. This should take place in a quiet private area; it should never take place in the dispensary.
- 12. The pharmacy will present the medicine to the client in a suitable receptacle and will provide the client with water to facilitate administration and/or reduce the risk of doses being held in the mouth.
- 13. The pharmacist must be satisfied that the dose has actually been swallowed, either by observing water being swallowed after the dose, or by conversing with the client to ensure that the medication is not retained in the mouth.
- 14. <u>Supervision of consumption of buprenorphine (or other sublingual tablets):</u>
- 1. A drink should be available for clients who may require it before dosing to moisten the mouth or after the tablet has gone to refresh the mouth. A drink should never be offered during dosing.

2. Either:

- the pharmacist should pop the tablets out of the blister pack into a named pot; or
- the client takes their own tablets out of blister(s) which had previously been dispensed into a named carton.
- 3. The tablets should be placed underneath the tongue by the client and left to dissolve. The client should swallow as little as possible in that time as any swallowed drug is inactivated. The client should be observed for around 5 minutes. The pharmacist should be aware of the client during this time and check the client is all right. The client should remain in the pharmacy until the tablets are in an indistinguishable form.
- 4. Before leaving, the client must satisfy the pharmacist that the dose has dissolved and is not concealed in the mouth. Look under the client's tongue, converse with them, or offer them a drink.
 - 15. All containers should be discarded after self-administration.
 - 16. Pharmacists are responsible for maintenance of PharmOutcomes. There should be a record of daily attendance, missed doses and other concerns that may need to be reported back to the prescribers.
 - 17. The Prescriber/substance misuse worker should be contacted in any of the following circumstances:
 - The client does not consume the whole dose under supervision
 - The client tries to avoid supervision or the process for proper administration
 - Following THREE consecutive missed doses [as the client may lose tolerance to the drug]

- In anticipation of THREE consecutive missed doses, for example, if the client misses a dose on a Friday and the Pharmacy is closed over the weekend, the consequence will be THREE consecutive missed doses and the Prescriber/substance misuse worker should be contacted in anticipation
- If the client regularly misses a single day's dose, for example, three doses in a seven day period, or are a frequent irregular attender
- Missed doses should not be replaced or issued at a later date
- There are problems with the prescription, for example, uncertainty about dates, validity, has been tampered with etc.
- Unacceptable behaviour when visiting the pharmacy
- Evidence of increasing health, emotional or other problems
- The client appears to be ill
- Requests for help that the pharmacist is unwilling or unable to meet
- The client is intoxicated at presentation and the dose cannot be dispensed
- Breach of client contract
- On any other occasion when the pharmacist is concerned about the well-being of the client
- 18. If the Prescriber/substance misuse worker is unavailable (e.g. out of hours) the pharmacist must use his/her own professional judgment in deciding whether to supply.
- 19. A copy of this protocol must be included with any briefing given to locum pharmacists brought in to cover holidays or other absences.

Appendix 2

Bury Council: Supervised Consumption Scheme CLIENT CONTRACT

1.	Iagree to the following condition	•	/) understand and
2.	I will be prescribedat the pharmacy on specified d taking the medicine. I will drinl so.	ays. I understand	l that	I will be observed

- 3. I will collect my medicine in person from the pharmacy named below, at the time arranged between the pharmacist and myself.
- 4. My prescriber and/or substance misuse worker will be told if there are concerns about my well-being where necessary, for example, in relation to missed doses.
- 5. I will keep all my appointments with my Prescriber named below unless by prior agreement.
- 6. I will see my substance misuse worker from the Specialist Service on a regular basis and keep all my appointments unless by prior agreement.
- 7. The people named below have the right to discuss my case and may wish to see me together if this is felt appropriate.
- 8. My prescriber and pharmacist have the right to refuse to prescribe for me if they feel that giving me my medication will put me at risk of overdosing: an example of this is if I am intoxicated when I attend the pharmacy for collection of my medication. I am aware this will cause a break in my daily prescription.
- 9. I will not cause problems, or be abusive or violent in or around the premises of anyone involved in my care. If I am, the service may be withdrawn immediately. I am aware this will cause a break in my daily prescription.
- 10. I will work towards stopping illicit drugs and I will provide a urine sample for analysis when requested.
- 11. I am responsible for any prescriptions or drugs which I am prescribed and if I should lose the prescription, or the medicine itself, break containers or take medicine other than as directed, they will not be replaced.
- 12. I can only obtain prescriptions from the prescriber named below unless alternative arrangements have been made to cover holidays; otherwise I understand that this will put my prescription in jeopardy.
- 13. I understand I have chosen to collect my prescription from the pharmacy named below. If I decide to have my prescription dispensed elsewhere I will contact the prescriber first.

- 14. I understand that I must collect my prescription on the day specified and, if required by the pharmacist, at the agreed time. If I fail to do so, I will not be able to collect that dose on any other day.
- 15. I may be requested to provide proof of identity when collecting my prescription.

Collection													
Other Pharmacist's instruction													
	Substance misuse worker	Prescriber	Pharmacy	Client									
Address				Telephone Number in emergency:-									
Signed													
Date													

Copy

Roles and Responsibilities (all parties to work in partnership and ensure contact details are exchanged)

Substance Misuse worker	Prescriber									
 Perform specialist assessment to determine if the treatment is appropriate Organise urine screens Completes Monitoring System form (with consent) Makes recommendations to GP/Prescriber Reviews with Client their stability/mitigating circumstances that may necessitate the transfer to take home doses Organises paperwork Liaises with named GP/Prescriber and Pharmacist Discusses contract and signs with client Review arrangements with client to ensure adherence to contract 	 Does not prescribe methadone until opiate dependency is confirmed Does not prescribe in isolation Provides general medical services/personal medical services (or acts as delegated Prescriber Liaises with named Nurse and Pharmacist Discusses contract and signs with client 									
Pharmacist	Client									
 Dispenses drug prescribed in accordance with procedure Fulfils legal requirements Ensure consumption is appropriately supervised Ensures medication is not dispensed if client presents while intoxicated Provides safe and private area for clients to consume medication Liaises with named GP/Prescriber and Nurse Collects, records and reports data Indicates to Client any specific addition to contract Discusses contract and signs with client Check/confirm medication has been swallowed Liaises with the local substance misuse treatment service and reports any incidents or concerns, including missed doses, to the service. 	 Attends assessment/appointments with key worker Attends appointments with Prescriber Must have a named Prescriber and Pharmacy Attends named Pharmacy Read the terms of the contract and sign all copies: abide by contract terms Give 14 days notice of planned holidays Do not attend for pick up of medication while intoxicated Attend the Pharmacy alone, let staff know you are there and wait to be seen Be aware that you may have to wait. You have equal priority, but to ensure your privacy, a customer may be served ahead of you Is expected to take the full amount of medication each time. May be requested to hand the empty medicine bottle to the Pharmacist and drink some water. 									

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Supervised Consumption Incident Form

Please complete this form and send (via secure e-mail) to the prescriber and substance misuse worker following any action taken for the following reasons. Retain copy for your own records.

Please be as comprehensive as you can. One form for each incident to be completed.

Client ID Date: Pharmacy name:

Incident	tick	Full details	of incident
Physical violence			
Verbal abuse]	
Unacceptable behaviour		1	
Theft			
THREE consecutive missed doses			
Not taking whole dose			
Regular missed doses			
Dropped out			
Apparently Intoxicated			
Observed deterioration in health			
Problems concerning prescription			
Pharmacist refusal to supervise			
Other			

Your	Detai	ls:
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Name: Pharmacy Address: Telephone Number:

[Type here]