

Further Information in Relation to Provision of Essential Services in Accordance with the Regulatory Requirements for Distance Selling Pharmacies

The information contained within this document has been approved by the applicant prior to submission

Please find below information to explain how the pharmacy procedures used within the premises will secure:

- (a) the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services, and
- (b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or someone else's behalf, and the applicant or the applicant's staff.

NHS Premises Standards

The NHS has published premises standards that the Pharmacy will comply with, however, it should be noted that not all these standards apply directly to distance selling premises other than where a patient is accessing non-essential services.

The pharmacy will be a Healthy Living Pharmacy and comply with the change management and organisational development criteria, ensuring premises and facilities are fit for purpose and engaging with the community to deliver consistently high quality health and wellbeing services.

The pharmacy will be equipped with facilities to allow for both phone (or other live audio link) and live video communication with patients in a manner which maintains patient confidentiality.

GPhC Guidance

The Applicant will operate the pharmacy in accordance with current GPhC guidance for registered pharmacies providing pharmacy services at a distance, including on the internet.

PHARMACY SYSTEMS AND PROCEDURES

All Essential Services will be delivered in accordance with:

- Company Standard Operating Procedures
- NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
- NHS Act 2006
- Human Medicines Regulations 2012
- GPhC – Professional Standards and Guidance on Distance Selling Pharmacies
- Relevant Data Protection laws

This will ensure that the Applicant provides safe, effective and uninterrupted provision of all essential services to persons anywhere in England who request those services during the opening hours of the premises. Essential Services will be provided without face to face contact between anyone receiving the services, whether on their own or someone else's behalf, and the pharmacy staff.

The Applicant's wholly Internet/Delivery Pharmacy will operate from secure premises, with a controlled entry system, to which members of the public will not have access. Any patient that requests essential services to be provided at the premises will be informed that the pharmacy is not permitted to provide those services at the premises.

Access to information about the provision of NHS Essential Services will be achieved by using:

- Telephone
- Live Video Call
- The website will enable patients or their carers to communicate remotely but directly allowing quick and easy access and provide clear unambiguous details of how safe, efficient, uninterrupted NHS Essential Services will be provided by the Pharmacist and qualified, knowledgeable, experienced support staff on duty throughout the opening hours of the pharmacy premises without having 'face to face' contact with the patient or their representative.
- Email
- Postal services

All NHS services will be delivered free of charge in accordance with the NHS Act 2006.

Essential Services may be delivered using:

- Telephone, including text messaging where appropriate
- Electronic Prescription Service (EPS)
- Website
- Email
- Royal Mail postal service
- Courier service
- Specialist Waste Management Services
- Live video services.
- Specialist cold chain courier services will ensure the integrity of the cold chain and the maximum stability of thermo-labile drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness is always preserved. This will be a dedicated, fully monitored and temperature controlled delivery service.

Provision of NHS Essential Services

Dispensing Services

Prescriptions will be received by the EPS, post, or where practicable, with the patient's informed consent, collected from a surgery. Prescriptions will be clinically and legally assessed to determine if they can be dispensed.

In the event of any clinical or legal issues with the prescription, the pharmacist will follow Standing Operating Procedures to resolve these issues before dispensing items. This may involve contacting the prescriber as soon as possible to make sure the patient receives their medication without delay.

When appropriate prescription interventions take place, for example drug/drug interactions, suspected over/under prescribing, etc. the pharmacist on duty will telephone and discuss with the prescriber and patient prior to dispensing or delivering the medication.

Repeat Dispensing Services

The Terms of Service require pharmacy contractors to ensure that appropriate advice about the benefits of repeat dispensing is given to any patient who—

- (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and
- (ii) requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

Such advice will be provided by the Pharmacy using its permissible methods of non face-to-face contact with patients.

Dispensing of repeat NHS prescriptions including those dispensed in dosette boxes as may be required under the Equality Act 2010 will be carried out in partnership with patients, carers, pharmacists and prescribers. It will cover requirements additional to those for dispensing, assessing the patients' need for repeat supply. Any clinical issues identified will be addressed to the prescriber. Where considered necessary by a pharmacist, the patient may be contacted by telephone and given verbal advice in addition to information delivered with the repeat prescription.

Medicines will only be supplied where the pharmacist is satisfied that the patient is taking and is likely to continue to take the drug appropriately and is not suffering from any side effects which indicate the need or desirability to review the patient's treatment.

Urgent Supply and Emergency Supply

Whilst the Distance Selling nature of the pharmacy is such that Urgent Supply or Emergency Supply is unlikely to occur as often as in a retail pharmacy, all staff will be aware of the procedures to be followed in the event of such a request.

The request may be received from a Prescriber (Urgent Supply) or from a Patient (Emergency Supply)

The following conditions must apply to the request made by a prescriber:

- The Pharmacist must be satisfied that the request is from the appropriate authorised prescriber, see list above.
- The Pharmacist is satisfied that a prescription cannot be supplied immediately due to an emergency.
- The Prescriber agrees to provide a written prescription within 72 hours.

- The medication is supplied in accordance with the prescriber's directions.
- The medication is permitted to be supplied on an Emergency Supply basis.
 - An emergency supply cannot be provided for a Schedule 1, 2 or 3 CD except Phenobarbital for epilepsy by a UK registered prescriber.
- EEA prescribers cannot request an emergency supply of any Schedule 1 - 5 CD.

Full records of the supply will be kept as per the relevant SOP.

The following conditions must apply to the request made by a patient:

- **Interview**

The Pharmacist must interview the patient. The interview may not be by way of face to face contact and must be by other means, e.g., telephone, Skype.

- **Records**

An entry must be made in the POM register on the day of supply and record all the relevant details.

The label for the dispensed medicine must contain the words "Emergency Supply".

- **Faxed Prescriptions**

A 'faxed prescription' or other forms of scanned prescriptions do not fall within the definition of a legally valid prescription because it is not written in indelible ink, and has not been signed by an appropriate practitioner. A faxed / scanned prescription can confirm that at the time of receipt a valid prescription is in existence, but no medicines should be supplied until the original prescription is received.

The pharmacist should not dispense against faxed prescriptions and instead should use the Emergency Supply procedures.

Delivery of Urgent Supplies

Given the nature of a request of this type, the Pharmacy will prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier the courier will be informed that items must be delivered ASAP by the quickest route possible. The Pharmacy will not charge additional fees to the patient even if these are incurred in the delivery process. Other than noting the urgent nature of the delivery, normal delivery procedures will apply.

Disposal of Unwanted Medicines

Patients will have a number of options for disposal of unwanted medicines.

- A specialist waste management company will provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes.
- Patients wishing to return unwanted medicines to the pharmacy may do so by courier, which will be provided and paid for by the pharmacy.

- Patients in locality may contact pharmacy by phone or email to arrange collection of unwanted medicines from their home or work by pharmacy staff.

Appropriate packaging will be sent to patients in advance and details of the service and how to book a collection will be available on the Pharmacy website.

Upon return to the pharmacy unwanted medicines will be sorted and placed in disposal units ready for waste management services to collect. The disposal service will be advertised on the website and any marketing leaflets.

Promotion of Healthy Lifestyles

Identification of patients for promotion of healthy lifestyles can take two forms, namely, passive or active.

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information.

Passive patients are those where the identification happens as part of another interaction with the patient, but where the patient does not appear to be actively seeking additional assistance. For example, the dispensing of a prescription which identifies the patient as having high blood pressure.

All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

Leaflets will be delivered to patients with their medication. Those identified (Active or Passive) as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns to increase the patient's knowledge and understanding of health issues relevant to them. The website will also be used to promote healthy lifestyles.

Health Campaigns

The Pharmacy will take part in national health campaigns to promote health messages to our patients across England. This will be achieved by sending out leaflets with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website.

Patients will be directed to the learning resources via email, text and other non face-to-face communication so that they are aware of the campaign.

Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the ICB specifies—

(i) a clinical audit carried out in a manner which is compatible with the ICB's arrangements for the receiving and processing of data from the audit, or

(ii) a policy based audit (to support the development of the commissioning policies of the NHSCB) carried out in a manner which is compatible with the ICB's arrangements for the receiving and processing of data from the audit.

Signposting and Support for Self-Care

Patient will be signposted to health and social care providers and/or any other assistance available whenever necessary. To assess whether patients require advice to minimise inappropriate use of health or social care services the pharmacist will use the same "Active and Passive" assessment tool already set out above.

Where it appears to the pharmacist, after reviewing the assessment and having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using the pharmacy would benefit from advice to help manage their medical condition then advice will be provided via non face to face methods of communication and this will include advice on both treatment options, non prescription medicines and lifestyle advice.

If a patient;

- (a) requires advice, treatment or support that the pharmacy cannot provide; but
- (b) another provider, of which the pharmacy is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

The pharmacy will provide contact details of that provider to that person and will, in appropriate cases, refer that person to that provider.

Referral for Certain Appliances

Where, on presentation of a prescription form or repeatable prescription, the pharmacy is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within the pharmacy's normal course of business, the pharmacist will—

- (a) if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and
- (b) if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to the pharmacist.

In appropriate cases, the pharmacist will keep and maintain a record of any information given or referral made to facilitate auditing and follow up care.

Support for People with Disabilities

This service will be provided in accordance with the Equality Act 2010. The Applicant will make reasonable pharmaceutical adjustment to ensure that those who qualify for help under the Act are provided with the right compliance aids.

The Applicant will conduct an initial assessment with the patient, care or representative to assess the support required to improve medication compliance. Such assessments will be carried out without patients having to access the pharmacy premises, so that no face-to-face contact at the premises will take place.

Compliance aid systems such as blister packs/dosette boxes will be provided in compliance with both service levels 1 & 2 respectively.

Clinical Governance

Note: Clinical Governance is not an 'essential service' and is therefore dealt with briefly in this submission.

The Applicant will be involved in and comply with all the components of clinical governance including, but not limited to, compliance with standard operating procedures, patient safety incident and near miss reporting, demonstrating evidence of Pharmacist and Pharmacy Technician CPD, conducting clinical audits, workforce survey and drug recalls.

'How to Make a Complaint or compliment' will be displayed and downloadable from the pharmacy website or upon request by telephone or post a copy will be posted.

All staff will be qualified or undergoing nationally accredited training. They will be competent to deliver the highest standards of Clinical Governance. All staff will receive individual and collective training, development and education provided in-house or from accredited external providers.

All staff will have an annual appraisal, receive and provide feedback.

Information Governance

The pharmacy will be registered and comply with Data Protection Act and the General Data Protection Regulations (GDPR) . It will also comply with the Access to Health Records Act 1990. All patient data will be kept private and confidential in accordance with NHS and legal obligations on data security, protection and confidentiality.

The pharmacy will receive support from the PMR provide to ensure that continuous access to the Electronic Prescription System is maintained.

Two members of staff will have the ability to login to the PMS system on all days (where there are 2 or more staff members working) and the NHS mail system will be checked every day for both general emails and also for any referrals under the Discharge Medicines Service.

Discharge Medicines Service ("DMS")

When NHS patients are discharged from hospital or there is, for other reasons, a transfer of care of them between different providers of NHS services, community pharmacies may be asked to perform a three stage service in respect of the patient, principally linked to changes in medication. The second and third stages of this service are linked to the first prescription presented post-discharge or post-transfer. Issues of concern may be raised by the pharmacy contractor not only with the patient or their carer but also with their general practitioner.

Under the DMS the pharmacy must provide assistance and support to, and in respect of, an NHS patient

(a) recently discharged from hospital who is referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or

(b) who is otherwise referred to the pharmacy for advice, assistance and support in respect of the patient's medication regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

The service allows and requires the pharmacy to help not only the patient directly, but also (within the bounds of confidentiality) their carers and also provide them with assistance and support.

The service is designed in 3 Stages, where each Stage builds on the last to provide additional support if required to the patient or, where appropriate their carer.

The pharmacist must use their clinical judgement when considering their actions and recommendations in respect of the service and consider the duty of confidentiality to the patient when involving a carer in discussions about the patient and their medication regimen.

If the DMS referral requesting that the pharmacy provides the DMS includes circumstances in which the pharmacy is not to provide, or is to cease to provide the DMS service, then the Pharmacy is not to, or is to cease to, provide the DMS in those circumstances (for example, X's or Y's admission or re-admission to hospital).

Pandemic Treatment Protocol ("PTP")

The pharmacy will provide medicines properly requested under any PTP arrangements.

The RP should (and if requested to do so by the person being supplied must)

- Provide an estimate of the time the drug will be ready and delivered.
- If the drug is not ready by the time then provide a revised estimate of when the drug will be ready and continue to update the patient on this time should the estimate change.
- Contact the patient to confirm dispatch of the medication.

In addition to the normal requirements, the dispensing label on the packaging of the product supplied must also contain the additional wording shown below;

**THIS PRODUCT IS BEING SUPPLIED IN ACCORDANCE
WITH THE [INSERT NAME] PANDEMIC TREATMENT
PROTOCOL**

And insert the name of the relevant protocol.

Refusal to Supply under PTP

The pharmacy may refuse to provide an order for a drug that is or is purportedly in accordance with a PTP where—

- (a) The RP reasonably believes it is not a genuine order for the person who requests ,or on whose behalf is requested, the provision of the drug;
- (b) providing it would be contrary to the RP's clinical judgement;
- (c) The RP or other persons are subjected to or threatened with violence by the person who requests the provision of the drug, or by any person accompanying (see footnote re “accompanying”) that person; or
- (d) the person who requests the provision of the drug, or any persona accompanying (see footnote re “accompanying”) that person, commits or threatens to commit a criminal offence.

The pharmacy must refuse to provide, pursuant to a PTP, an order for a drug that is or is purportedly in accordance with the PTP where P is not satisfied that it is in accordance with the PTP.

Any refusal to supply must be noted on the patient and / or pharmacy record system.

Delivering Medicines

The Responsible Pharmacist (RP) has overall responsibility for ensuring the delivery of medicines to intended patients. Medicines must be delivered safely and with appropriate instructions.

The RP must take adequate measures to ensure that the delivery mechanism used is secure and that medicines are delivered to the intended user promptly, safely, and in a condition appropriate for use. If the delivery to patients is local, this will be undertaken by the delivery driver except fridge lines which must be sent by courier. All other nationwide deliveries (other than fridge lines) will be delivered by Royal Mail special delivery or courier and signed for by the patient, their notified carer or other patient authorised representative. Fridge Lines will be delivered by courier (see further below).

Medicines will be packed, transported and delivered in such a way that their integrity, quality and effectiveness are preserved. The delivery mechanism used will provide a verifiable audit trail for medicine from the initial request through to its final delivery, or its return to the pharmacy in the event of a delivery failure. Packaging must maintain patient privacy and confidentiality.

Choice of packaging will depend on the nature of the items being delivered and the appropriate level of protection must be used to ensure that the item can withstand the normal rigours of the delivery process.

All packaging must have the tamper proof seals provided in the pharmacy attached to the packaging so that any tampering with the packaging will be evident.

Medicine for local delivery which is (A) not fragile and (B) is to be delivered by the delivery driver can be packaged in the using the normal pharmacy bags supplied for standard prescription items.

Medicines classified as non-flammable or non-toxic must be securely closed and placed in a leak-proof container such as a sealed polythene bag (for liquids) or a siftproof container (for solids). Must be tightly packed in strong outer packaging and must be secured or cushioned to prevent any damage.

This means that for postal / courier items, either:

At the very least - padded envelopes even for non-fragile items as this will help to ensure the integrity of the manufacturers packaging.

For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. Cardboard boxes must be the re-enforced type.

Large or any fragile medicines should be packed into cardboard boxes with bubble packaging and filling material to protect from damage.

The patient, carer or notified, authorised patient representative must always sign and date a receipt to prove safe receipt of the medicines. A patient who is not at home when delivery is attempted will be informed using a non-delivery notice and an alternative delivery date will be arranged.

A list of the approved cold chain couriers will be maintained within the Pharmacy. Coldchain items will be stored in styrofoam filled cardboard boxes prior to being passed to the courier and marked with the "FRAGILE" and "FRIDGE LINE" stickers. Additional packing will not be required as the courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box and are fully monitored. Some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and will therefore not be used in direct contact with any medicine. The courier service will be a dedicated, fully monitored and temperature controlled delivery service. Any breach of the cold chain will be automatically notified to the driver who will then follow the failed delivery procedure and notify the pharmacy accordingly so that re-delivery can be arranged. Where the cold chain breach notice is issued items will not be re-used.

Controlled Drugs

Delivery of Controlled Drugs

There is provision within controlled drugs legislation to cover occasions when a controlled drug (CD) may temporarily be in the possession of a third party, e.g. a delivery person or postal carrier, while it is being transferred from one authorised person to another authorised person who is entitled to be in possession of the drug. Delivery of CD will be carried out by couriers with pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores.

Return and Destruction of CONTROLLED DRUGS

Appropriate packaging will be sent to patients in advance with instructions for packaging any returned medicines and this will be provided and paid for by the pharmacy. The Superintendent Pharmacist will specify the appropriate method of collection depending on the items being returned and the distance from the pharmacy. Patients may also be signposted to alternate pharmacies if they prefer to return medicines to a different pharmacy. Any 'returned' Controlled Drugs must not be re-used or entered

into the CD register. The Applicant will denature and render them irretrievable as soon as possible in order to avoid storage problems and an increased security risk.

Destruction must be witnessed by another member of staff. If not immediately destroyed, they should be segregated from main stock, clearly marked 'Patient Returns' to minimise the risk of errors and inadvertent supply and stored securely in a CD Cabinet waiting to be denatured. A record of destruction will be recorded in a separate CD Destruction Register designated for this purpose and will be available in the pharmacy for inspection.

Cover for Breaks / Working Time Directive

Any breaks in working time taken by the RP will be covered by a second pharmacist who will then assume the responsibility of the RP.

Contingency Planning

The Applicant will have accounts direct to pharmacy manufacturers and many full-line and short-line pharmaceutical wholesalers to try and increase the availability of stock and reduce Owings. A Contingency Plan will be in place to ameliorate the effects of any disruption to provision of pharmaceutical services such as medicines shortage, postal strike, EPS systems failure, etc.

Verification of Declarations of Prescription Exemptions

The reverse of the prescription should be fully completed (other than age exempt patients) in black ink.

Where evidence of exemption is required or provided by the patient it can be sent to the pharmacy for verification via the delivery driver and then returned to the patient. The PMR system should be updated to reflect that necessary check has been carried out and a note of when the next check is required should be entered onto the system. The Regulations require a patient to produce 'satisfactory evidence' to confirm exemption. Where appropriate (ie for deliveries made other than by the pharmacy's delivery driver), the patient may scan copies of the evidence to the pharmacy (or use the postal / courier service, but see NOTE below) and the pharmacy can record that the evidence provided was not in the original format. It is for the pharmacist in charge to determine if the evidence is satisfactory or not and, if not, then cross the 'Evidence not Seen' box.

The type of exemption and date of expiry will be recorded in their Patient Medication Record. If they are not exempted prescription charge payments will be made using a secure on-line payment method.

Exemptions may be sent to the pharmacy by post and the pharmacy will pay for postage and return the exemption to the patient free of charge. Scanned email copies of exemptions are also acceptable. The nature of any exemption will be recorded on the PMR system with a copy attached to the patient's file.

Payment for prescription charges will be received via the secure payment portal on the website and when payment is received the prescription will be marked as paid.

Pharmacy Profile

The pharmacy profile will be properly maintained in the NHS Digital Directory of Services

Central Alerting System

The pharmacy will maintain access to the MHRA Central Alerting System using the premises specific NHS mail email address which will be checked on a daily basis.

Registration of the Premises with the GPhC

It is not lawful to operate a Pharmacy without registering the premises and Superintendent Pharmacist with the GPhC. The Applicant will apply to register the premises with the GPhC following the grant of an NHS Contract application. The GPhC will send an inspector to inspect the premises for approval before commencement of any Pharmacy services. The GPhC has a team of inspectors who undertake the routine monitoring and inspection of premises.

Practice Leaflet

Nothing in the Applicant's practice leaflet, or publicity material in respect of the listed chemist premises, in material published on behalf of the Applicant publicising services provided at or from the listed chemist premises or in any communication (written or oral) from the Applicant or the Applicant's staff to any person seeking the provision of essential services will represent, either expressly or impliedly, that—

- (i) the essential services provided at or from the premises are only available to persons in particular areas of England, or
- (ii) the Applicant is likely to refuse, for reasons other than those provided for in the Applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the Applicant is limited to other categories of patients).

Advanced or Enhanced Services

The pharmacy will only offer services that can be delivered remotely and do not require patients to attend the premises.