NHS Resolution

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8 August 2025

REF: SHA/26608

APPEAL AGAINST LEICESTER, LEICESTERSHIRE AND RUTLAND ICB DECISION TO REFUSE AN APPLICATION BY CURED HEALTH LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 27 COBDEN HOUSE, COBDEN STREET, LEICESTER, LE1 2LB UNDER REGULATION 25

1 Outcome

1.1 The Pharmacy Appeals Committee ("Committee"), appointed by NHS Resolution, quashes the decision of the Commissioner and redetermines the application.

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Pharmaceutical Defence, on behalf of Cured Health Ltd
PCSE, on behalf of Leicester, Leicestershire and Rutland ICB
Jhoots Pharmacy

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1 The Application

By application dated 5 October 2024, Cured Health Ltd ("the Applicant") applied to Leicester, Leicestershire and Rutland ICB ("the Commissioner") for inclusion in the pharmaceutical list at 27 Cobden House, Cobden Street, Leicester, LE1 2LB under Regulation 25. In support of the application it was stated:

1.1 In response to "If you are undertaking to provide appliances, specify the appliances that you undertake to provide (or write 'none' if it is intended that the pharmacy will not provide appliances)" the Applicant left the box blank.

1.2 In response to why the application should not be refused pursuant to Regulation 31 the Applicant left the box blank.

1.3 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant left the box blank.

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

1.4 Please 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.

Please describe the procedure that will be followed where a patient attends the premises and asks for one or more of the essential services.

If you are undertaking to provide advanced services at the premises, please describe how you will do so without providing any element of essential services.

1.5 "See attached documents:

1.5.1 SOP Bundle

1.5.2 Pharmacy Procedures"

Cured Health Ltd Pharmacy Procedures

1.6 “Cured Health Ltd has prepared a draft of their initial Quality Management System and SOPs in preparation for securing the distance selling contract and to support this application. These DRAFT SOPs cover the essential services as required to be delivered by NHS pharmacy contractors and have been written to suit the Distance Selling model. The Superintendent Pharmacist will be responsible for the management of the SOPs and for training all staff on the SOPs according to their role within the pharmacy. After induction training, understanding of the SOPs will be validated by the Superintendent Pharmacist before new staff commence their shift.

1.7 The pharmacy will have SOPs in place for the provision of essential services. It is pertinent to know that only some of the SOPs have been provided to help facilitate the application, any specific SOP can be provided if requested.

1.8 Cured Health Ltd will have a website which facilitates the following:

1.8.1 Patient accesses website via a secure log-in procedure;

1.8.2 Patient provides details of prescription,

1.8.3 Patient will be contacted by the pharmacy and medical history assessed.

1.8.4 Patient posts prescription to pharmacy and/or prescription received via EPS.

1.8.5 Item is dispensed and details added to PMR.

1.8.6 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions. Any costs incurred for delivery will be met by the pharmacy.

1.9 The website will be built by a company called the ‘Shopify’ (https://www.shopify.com/uk) who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.

1.10 Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam. Records of all patient interactions will be maintained on the PMR in use at the pharmacy. Cured Health Ltd has decided to use Titan PMR (https://www.titanpmr.com) as the software provider which will be a key tool in providing a safe and effective provision of service.

1.11 Cured Health Ltd is committed to having all staff trained by the National Pharmaceutical Association at a level suitable to their role. All training will need to be recognised and accredited by the GPhC and all staff will hold NVQ qualifications in Pharmacy Services. Staff and Responsible Pharmacists will also be provided with training on the SOPs relevant to their role. By following a set of SOPs, the pharmacy will be able to provide a safe and effective service that is patient-centric and outcome focussed.

1.12 The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on design patients [sic] without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.

1.13 Cured Health Ltd is comprised of one director, [Mr D]. [Mr D] is the nominated superintendent and has suitable pharmacy experience. [Mr D] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He/she will be supported by a staff team of one full- time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.

1.14 The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential services under the NHS contract will be allowed entry to the premises and this will be made clear by the positioning of posters on any outward facing window and door of the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

1.15 **Essential Service – Dispensing**

1.16 **Uninterrupted service**

1.17 Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.

1.18 **Persons anywhere in England**

1.19 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS N3 network via BT.

1.20 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

1.21 **Safe and effectively**

1.22 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.

1.23 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk)

1.24 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.

1.25 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.

1.26 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking service which will give real-time information and is also available as an app for smart phone and tablets.

1.27 All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched with a view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. It will be packed so it is protected from the environment which may include using a double walled package design or using waterproofing on the packaging material. This will also ensure that the delivery person is protected from cytotoxics and sharps.

1.28 **Without face-to-face contact**

1.29 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.

1.30 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

1.31 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

1.32 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

1.33 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as

they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

1.34 Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.

1.35 If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed.

1.36 **Essential Service - Disposal of Unwanted Medication**

1.37 **Uninterrupted Service**

1.38 Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.

1.39 **Persons anywhere in England**

1.40 Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.

1.41 **Safe and Effectively**

1.42 Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.

1.43 Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.

1.44 **Without face-to-face contact**

1.45 Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy.

1.46 **Essential Service – Signposting**

1.47 **Uninterrupted Service**

1.48 Provision of signposting can be done through the opening hours of the pharmacy via phone, fax, email, post, website or webcam. Staff will be trained to assess the need for signposting and if any doubt will refer the matter to the pharmacist.

1.49 **Persons anywhere in England**

1.50 Patients anywhere in England would be able to access the signposting service from the pharmacy via phone, website, email, post or webcam. During communication the pharmacy staff will assess the need for signposting and if any doubt will refer the matter to the pharmacist.

1.51 **Safe and Effectively**

1.52 We would contact the relevant NHS organisations in Scotland, Wales and Northern Ireland to obtain resources. Furthermore, we would have access to Macmillan, NHS Choices and NHS Direct websites, as well as full internet access to further on-demand resources. Depending on the nature of patient queries and assessment of the information provided by the patient we could then either contact patients for further information refer them to their GP or signpost them to a local NHS or non NHS service as appropriate. We will provide referral notes by email, fax and post to the appropriate health and social care providers in cases where the pharmacy is unable to meet the needs of the patient. We will aim to ensure that patients are referred correctly to minimise inappropriate use of health and social care services. We will keep records of all referrals made on the PMR including any advice given to maintain audit trails.

1.53 **Without face-to-face contact**

1.54 Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction. The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model.

1.55 **Essential Service - Repeat Dispensing**

1.56 **Uninterrupted Service**

1.57 Provision of repeat dispensing throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the repeat dispensing service. The CPPE certificate of the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the repeat dispensing. The pharmacy IT system will be ETP 2 compliant to allow for repeat prescriptions to be received electronically from surgeries anywhere in England that are ETP release 2 compliant. This will be promoted to patients as a quick way to receive prescriptions from participating surgeries for nominated patients repeat and acute prescriptions for quick despatch of medicines without any delay.

1.58 **Persons anywhere in England**

1.59 Patients anywhere in England can access the Repeat Dispensing service by signing consent form which is available on the website for anyone wishing to use the service. This consent from can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP 2 compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the Doctor signs off the electronic prescription. The prescriptions medicines will be dispensed and despatched for delivery by our in-house delivery service or the courier without any delay.

1.60 **Safe and Effectively**

1.61 Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. Once a patient signs up we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post. Either the patient will contact the pharmacy via phone, email post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment. Before each RD dispensing activity we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition. If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service.

1.62 **Without face-to-face contact**

1.63 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.

1.64 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further

benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.

1.65 **Essential Service – Discharge Medicine Service**

1.66 **Uninterrupted Service**

1.67 Provision of discharge medicine service throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the discharge medicine service. The CPPE certificate for the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the discharge medicine service. The pharmacy IT system will be compliant to allow for discharge medicine service to be undertaken via Pharmoutcomes website or the pharmacy dedicated NHS mailbox.

1.68 **Persons anywhere in England**

1.69 Patients anywhere in England can access the discharge medicine service via the phone, email, chat, video link. When the pharmacist identifies an intervention on the service he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

1.70 **Safe and Effectively**

1.71 Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. 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. Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.

1.72 **Without face-to-face contact**

1.73 All discharge medicine service patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using

our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. If medicines need to be returned, this will be done in accordance to disposal of unwanted medication. We have SOPs in place to manage these services without face-to-face contact. This discharge medicine service will ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines.

1.74 **Essential Service - Public Health (Promotion of Healthy Lifestyles)**

1.75 **1. Prescription linked intervention**

1.76 **Uninterrupted service**

1.77 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.

1.78 **Persons anywhere in England**

1.79 Patients anywhere in England can access these services via the pharmacy website, phone, email, chat, video link or distribution of leaflets within the prescription that is delivered to the patient. When the pharmacist identifies an intervention on a prescription he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

1.80 **Safe and effectively**

1.81 This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist. In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested the patients PMR, or the online questionnaire completed by new patients. Once a prescription linked intervention has been made, a note will be made on the patient's PMR. This note will ensure continuity of advice and as a reference for future interactions with the patients.

1.82 **Without face-to-face contact**

1.83 The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted into the packaging of any dispensed prescriptions. We have SOPs in place to manage these services without face to face contact.

1.84 **2. National Health Campaign**

1.85 **Uninterrupted Service**

1.86 Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website, telephone, fax email, web chat or video link. Promotional material prepared by the Local Area Team and/or Public Health England will be made available for any patients. Trained staff will be available at the pharmacy to run the campaigns during the opening hours.

1.87 **Persons anywhere in England**

1.88 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.

1.89 **Safe and Effectively**

1.90 This service will be delivered safe and effectively. The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. Other campaigns may be advised by the Local Area Team/Health and Wellbeing Board. Throughout the campaigns the pharmacy will maintain a record of the number of people that receive the advice to ensure traceability. The pharmacy will use the approved content provided by the relevant bodies. This may include briefing packs, patient literature, NHS funded merchandise or services.

1.91 **Without face-to-face contact**

1.92 The service will be delivered without face-to-face contact via the pharmacy website telephone, email or live chat. We have SOPs in place to manage these services without face to face contact

1.93 **Essential Service - Support for Self-Care**

1.94 **Uninterrupted Service**

1.95 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Communication links to maintain the service through the core opening hours of the pharmacy will be via the pharmacy website, telephone, email, live chat or video link.

1.96 **Persons anywhere in England**

1.97 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat or video link. The majority of interactions will come whilst giving advice to the patient using these methods.

1.98 **Safe and Effectively**

1.99 Support for self-care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model. Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers.

1.100 **Without face-to-face contact**

1.101 This service will be delivered without face-to-face contact via telephone, email, live chat or video link. Support for Self-Care will be prevalent in all patient interactions which will be maintained using these methods. Any deliveries of OTC products will be made using City Sprint courier who will act as a third party. We have SOPs in place to manage these services without face to face contact.

1.102 **Essential Service - Clinical Governance**

1.103 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, Mr [D].

1.104 **Patient and public involvement**

1.105 A practice leaflet will be easily accessible on the front page of the pharmacy website and we will also supply a paper copy to all patients when first delivering to them. Updated leaflets will sent to all registered patients should there be any significant changes. All services provided by the pharmacy will be listed on the leaflet and whether the service is funded by the NHS or privately. In addition, the pharmacy will produce an annual patient satisfaction survey presented to patients who use our service electronically and along with delivery of medication. Patients will have the option to return the satisfaction surveys electronically or through the post via a pre-paid envelope. The results of the patient satisfaction survey will be published on the pharmacy website and practice leaflet. The results will feed into the pharmacy's continuous quality improvement scheme.

1.106 The pharmacy will also have in place procedures to deal with complaints which will be regularly reviewed to allow us to improve our performance compliant with GPhC guidance. The employed Pharmacy Manager will deal with any complaints. Procedures to deal with medication owed to patients will also be in place and patients given a written note either via email or along with their delivery of medication to inform them of exactly what is owed and when the medication is expected to be supplied. Notes of medication owed will be kept on the PMR and regularly reviewed so stock levels can be adjusted appropriately.

1.107 **Clinical audit**

1.108 The pharmacy will participate in a minimum of two clinical audits annually. At least one practice based audit and one multidisciplinary audit determined by NHS England, the Area Team or any other relevant organisation. Suitable personnel will be made available to ensure these audits are carried out.

1.109 **Risk management**

1.110 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.

1.111 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.

1.112 Cured Health Ltd have produced DRAFT- Standard Operating Procedures (SOPs) at this point in time to cover the Essential Services. These procedures will continue to be developed up until when we secure the contract and commence trading. The SOPs will be reviewed at a minimum annually or a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The Superintendent Pharmacist will be responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.

1.113 All pharmacy staff will be trained in and aware of child and vulnerable adult safeguarding procedures, and have access to safeguarding arrangements and reporting to all areas of United Kingdom via access to internet at the pharmacy. Any documentation will be kept for audit purposes.

1.114 **Staffing and staff management**

1.115 There will be a set of induction packs at the pharmacy to ensure that all have access to all necessary Clinical Governance information. Appropriate training will be given to all staff relevant to their positions in the pharmacy. Staff appraisals will be conducted regularly to ensure that all members of staff meet GPhC standards. If standards are not met then support will be offered and remedial action taken. We would expect Pharmacists and any registered technicians to demonstrate continual professional development and keep records of events to meet GPhC requirements.

1.116 **Education, training and continuing professional and personal development**

1.117 All pharmacists working at the pharmacy are able to demonstrate a commitment to continuing professional development (CPD), via a CPD record and this will be in line with the national RPSGB scheme. Any necessary accreditation will be achieved prior to provision of any advanced or enhanced services.

1.118 **Use of information to support clinical governance and health care delivery**

1.119 Pharmacy staff will have full access to up to date reference sources such as the BNF and Drug Tariff and with appropriate IT links with electronic reference sources. Cured Health Ltd will ensure all employees will comply with data protection and confidentiality, including the Data Protection Act 2018, Human Rights Act 1998 and common law of confidentiality. Cured Health Ltd will ensure that all employees will conform to the NHS Code of Practice on confidentiality and will have systems and policies in place to support this including ensuring all staff are appropriately trained. Employee contracts will include a duty of confidence as a specific requirement linked to disciplinary procedures.

1.120 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Cured Health Ltd will ensure that NHS direct are aware of the pharmacy's actual working hours so that they can provide appropriate information to members of the public.

1.121 **Proof of exemption/prescription charges**

1.122 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail. If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

1.123 **Additional Information**

1.124 We will maintain a high level of standards regarding the premises in terms of cleanliness in order to ensure good working conditions and minimise risks of infections. This will be covered in our SOPs and also by having a cleaning rota that is monitored. All staff will be trained on basic hygiene and hand washing issues and appropriate materials will be provided to promote this."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 22 April 2022 states:

[Any reference to 'Committee' in this section is not to be confused with the Pharmacy Appeals Committee of NHS Resolution]

2.1 "Leicester, Leicestershire and Rutland ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning."

Decision report

2.2 "**Regulation 31 – refusal same or adjacent premises**

2.3 The committee noted that there is no person on the pharmaceutical list for the area of Leicester City Health and Wellbeing Board who is providing, or has undertaken to provide, pharmaceutical services from the premises to which the application relates or adjacent premises. It was therefore not required to refuse the application by virtue of this regulation.

2.4 **Regulation 25 – Distant Selling Premises Applications**

2.5 The committee noted that the application is for distance selling premises and therefore section 129(2A) of the NHS Act 2006 doesn't apply.

2.6 **Regulation (25)(2)(a)**

2.7 The committee were satisfied that applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. It was therefore satisfied that it is not required to refuse the application under this regulation.

2.8 **Regulation 25(2)(b)**

2.9 The committee were not satisfied that the pharmacy procedures for the proposed premises are likely to secure:

2.9.1 The uninterrupted provision of essential services, during the proposed opening hours, to persons anywhere in England who request those services, and

2.9.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

2.10 **Regulation 66 – conditions relating to providing directed services**

2.11 The applicant has undertaken to provide the directed services listed in the application if they are commissioned within three years of the date of either the grant of the application or, if later, the listing in relation to the applicant of the premises to which the application relates, to provide those services in accordance with an agreed service specification if they are commissioned, and not to withhold agreement to a service specification unreasonably.

2.12 The committee was of the opinion that if it was minded to grant the application then by virtue of regulation 66(5) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, the applicant would be required to provide the following directed services and not unreasonably withhold agreement to the service specifications for these services.

2.12.1 New Medicines Service (NMS) advanced service

2.12.2 Pharmacy First

2.12.3 Community Pharmacy Seasonal Influenza Service

2.13 If the application were granted, then the applicant would be required to register to provide the above-listed advanced services via the MYS portal within eight weeks of its inclusion in the pharmaceutical list for the area of Leicester City in respect of the premises listed in the application.

2.14 The Committee agreed that if the application were granted it would have no negative impact on those with protected characteristics or on NHS Leicester, Leicestershire and Rutland ICB's duty on health inequality.

2.15 **Decision**

2.16 The committee determined the application is to be refused by virtue of regulation 25(2)(b).

2.17 **Third party rights of appeal**

2.18 As the application was refused, the only person with a right of appeal against the decision is the applicant, Cured Health Limited."

3 The Appeal

By the online form for pharmacy application appeals, dated 3 May 2025, Pharmaceutical Defence, on behalf of the Applicant, appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "The decision letter and attached decision report did not contain any information so that the applicant could be satisfied that the application had been fully considered. Both the decision letter and reasons are attached.

3.2 It is submitted that the decision letter and decision report provided by NHS Leicester, Leicestershire, and Rutland ICB:

3.2.1 Is woefully inadequate as it contains no information as to why the committee reached the refusal decision save that it states it has been refused

3.2.2 The decision report failed to:

3.2.2.1 a. Explain any aspects of the reasoning

3.2.2.2 b. Explain any concerns that the committee had and why those concerns arose

3.2.2.3 c. Explain how the committee applied the law to the application that they were tasked with deciding on

3.3 No person, be that the applicant or a member of the public, could be satisfied that the committee reached the correct decision based on the woefully inadequate information provided in the refusal decision and letter.

3.4 The applicant requests that the committee hear the appeal and consider the application afresh."

4 Comments to the Commissioner

4.1 On reviewing the paperwork provided by PCSE, it was noted that the comments made by the Applicant in response to the representations on the application [see paragraphs 4.3 – 4.12 below] had not been circulated or seen by parties.

4.2 In the interests of transparency and fairness, NHS Resolution sought to rely on the discretion afforded in paragraph 7 of Schedule 3 of the Regulations to vary the normal procedures and to circulate these comments to parties for them to make representations on them if they so wished.

4.3 "The responses that have been received are very weak indeed. Boots - don't even give the response the time and effort of thinking about it.

4.4 For Jhoots, I would recommend the following:

4.5 1. The decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development. The committee are reminded that the pharmacy is operating currently as a private pharmacy and has been inspected by the General

Pharmaceutical Council who are satisfied that the pharmacy was able to provide safe and effective pharmacy services.

4.6 2. As is common with SOPs, a third party is often engaged to supply those SOPs and Cured Health Ltd chose this method for the acquisition of such. The company who supplied the SOPs, Informacist, is a provider and provides SOPs to numerous companies. We remind the committee that the GPhC have already approved the premises which would have included a review of the SOPs.

4.7 3. Turning now to the point raised about the consultation room, the consultation room can be used for various services which will include the provision of advanced and enhanced services and for private services outside the NHS contract. No essential services will be delivered in the consultation room unless it is by a method which ensures that the patient is NOT present in the pharmacy i.e. videoconferencing, telephone, email etc etc. This leads onto the 3rd point raised by Jhoots regarding patient counselling. Without fear of repetition, the decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development.

4.8 4. With reference to the 4th point raised by Jhoots, the above comments in 1 and 2 are restated.

4.9 5. With reference to the 5th point raised by Jhoots, this information can be provided, if needed, once the NHS contract is awarded and the cold chain delivery service is commenced.

4.10 It is also noted that the letter from Jhoots, dated 9 December 2024, is not signed and there is no indication that it has been sent from [SJ]'s company email or personal email.

4.11 We also ask the committee to consider whether there are other motives at play when the response from Boots and Jhoots have been received, for example, a financial motivation by either company to stop other contractors being awarded NHS contracts which could diminish NHS prescription and NHS services market share for these companies.

4.12 We request that the committee give little or no weight to the responses received from Boots or Jhoots."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 JHOOTS PHARMACY

5.1.1 "Thank you for your letter dated 19th May 2025 enclosing a copy of the appeal by Cured Health Ltd, against the decision by NHS England to refuse their application to provide pharmaceutical services under Regulation 25 as a Distant Selling Pharmacy. As an interested party Jhoots pharmacy would like to submit the following response to be taken into consideration.

5.1.2 The applicant's reason for the appeal is they believe the "decision letter and attached decision report did not contain any information so that the applicant could be satisfied that the application had been fully considered". The NHS Committee did however confirm in their report, they were not satisfied that the pharmacy procedures for the proposed premises are likely to secure:

5.1.2.1 The uninterrupted provision of essential services, during the proposed opening hours, to persons anywhere in England who request those services, and

5.1.2.2 The safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

5.1.3 As part of the determination of the appeal I would wish Primary Care Appeals to have regard to the comments we submitted to NHS England as part of its consideration of the application. I attach our letter dated 9th December 2024.

5.1.4 I note the applicant/appellant has included with its appeal proforma a copy of their email dated 29th December 2024 they provided as response to interested party comments. I would wish to submit the following in response to the comments made in that email.

5.1.4.1 The applicant reminds the Committee the SOPs are draft and therefore under constant review and development. I submit that for the purpose of the application the Committee must base its decision on the evidence presented and not on the basis it may change in the future.

5.1.4.2 The applicant/appellant confirms the SOPs were provided by a different company i.e. the Informacist. The fact such SOPs may have been provided to other companies is irrelevant.

5.1.4.3 The applicant in response states "This leads onto the 3rd point raised by Jhoots regarding patient counselling. Without fear of repetition, the decision makers are reminded that the SOPs are Draft SOPs and so are under constant review and development". We submit this response does not address what process and procedures are in place to facilitate this.

5.1.4.4 With regard to point 4 no further information is provided.

5.1.4.5 The applicant states in reference to cold chain delivery that information can be provided if necessary. Relevant information should be provided in the application.

5.1.5 The applicant also suggests our letter of response Date 9th December (attached) was not signed. It was signed but this appears to have been redacted by PCSE.

5.1.6 In summary, I submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64. I thereby ask that the appeal is rejected."

Letter to Primary Care Support England dated 9 December 2024

5.1.7 "Thank you for your letter dated 8th November 2024 enclosing a copy of the application listed, to provide pharmaceutical services under Regulation 25 as a Distant Selling Pharmacy. As an interested party Jhoots pharmacy would like to submit the following response to be taken into consideration.

5.1.8 We submit that the application fails to meet the requirements set out in Regulation 25 and the conditions set out in Regulation 64.

5.1.8.1 The application is submitted by Cured Health Ltd but the SOPs included, supporting the application, refer to and include the logo of the Informacist.com which is a different Limited Company.

5.1.8.2 The application includes a copy of a floor plan of the premises. We note this includes a consultation room next to the dispensary area. This would suggest that patients will and can access the premises. We would ask the NHS to satisfy themselves that the consultation room will be not and cannot be used for the provision of pharmaceutical services in the context of Regulation 25.

5.1.8.3 The applicant's supporting information states 'if patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication'. There are not any details of such procedures in the application.

5.1.8.4 On Page 27 of the SOP bundle it states SOP 1 of 3 for Owed prescriptions. The start page number listed on the document says 3 of 17 which would suggest two pages are missing. In addition, this section is titled for 'As pcb Pharmacy' which suggests this not Cured Pharmacy. [sic]

5.1.8.5 For the Delivery of Refrigerated Medicinal Products the applicant states 'Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity'. Limited information is provided with regards to how these will be packed to ensure the temperatures will be maintained.

5.1.1 We submit this application should not be granted as Regulation 25 is not met."

6 Summary of Observations

This is summary of observations received.

6.1 PHARMACEUTICAL DEFENCE, ON BEHALF OF THE APPLICANT

6.1.1 "After reading the appeal letter and original responses to the application from the parties who did respond to the circulation of the application, we respond as follows:

6.1.2 1. The appeal committee will be aware that the application must be heard afresh.

6.1.3 2. The appeal committee is referred to our original appeal points.

6.1.4 3. Further, the letter from Jhoots Pharmacy states no new information accept to repeat the information that was in the decision report. We have already made comment on this when the appeal was lodged.

6.1.5 4. Jhoots Pharmacy have further commented on the points that we raised in our letter dated 29 December 2024 which was in response to the objections raised by Jhoots Pharmacy on 9 December 2024. It would be rather incongruous if the further responses from Jhoots Pharmacy were now

considered by this committee. If the committee were to take note of the further responses by Jhoots Pharmacy in their latest letter, this would be allowing Jhoots Pharmacy a 2nd or 3rd bite at the cherry. That time has long past, and we ask the committee to disregard any recent, and all, comments by Jhoots Pharmacy regarding our original points that were raised on 29 December 2024.

6.1.6 5. If the committee do take note of contents within the letter from Jhoots Pharmacy, dated 3 June 2025, the appeal committee are reminded that Draft SOPs are Draft SOPs. They can be amended before Cured Pharmacy, if successful in this appeal, begin to offer services under the NHS contract. The appeal committee is further reminded that they can place conditions upon Cured Pharmacy if they are awarded a contract, such as to supply further or amended SOPs for further review by the ICB before they begin trading and so on and so forth. A further condition that could be placed upon Cured Pharmacy is that they are to supply any further information as the ICB see fit before they begin trading if Cured Pharmacy are successful in the appeal.

6.1.7 6. The appeal committee must also ask itself the real reason why the objections have been placed. Is it out of genuine need to prevent an unnecessary provision of services or is it out of the other parties' fear of financial detriment and reduced market share of the NHS prescription business. We also make the same comment within this appeal. Any further objection to the application by any contractor, we say, is lodged not out of a genuine need to prevent unnecessary provision but as a further attempt to undermine and block the DSP application through fear of financial detriment to them. We say that the further objection by any contractor is a last-ditch attempt to be able to retain their market share of NHS business.

6.1.8 7. Taking all of this into account, we urge the appeal committee to allow the appeal in its entirety and to allow the contract application by Cured Pharmacy to proceed by granting the application."

7 Amendments to Regulation 25

On 23 June 2025, amendments to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 came into force, which affect the application. Given the amendments represent a new test, the Applicant was invited to provide comments in support of the application:

7.1 "Please find attached an updated set of SOPs and also an updated Pharmacy Procedures documents. Both of these documents together satisfy the new test as set out in Regulation 25."

Pharmacy Procedures

7.2 "Cured Health Ltd has prepared a draft of their initial Quality Management System and SOPs in preparation for securing the distance selling contract and to support this application. These DRAFT SOPs cover the essential services as required to be delivered by NHS pharmacy contractors and have been written to suit the Distance Selling model. The Superintendent Pharmacist will be responsible for the management of the SOPs and for training all staff on the SOPs according to their role within the pharmacy. After induction training, understanding of the SOPs will be validated by the Superintendent Pharmacist before new staff commence their shift.

7.3 The pharmacy will have SOPs in place for the provision of essential services. It is pertinent to know that only some of the SOPs have been provided to help facilitate the application, any specific SOP can be provided if requested.

7.4 Cured Health Ltd will have a website which facilitates the following:

7.4.1 Patient accesses website via a secure log-in procedure;

7.4.2 Patient provides details of prescription,

7.4.3 Patient will be contacted by the pharmacy and medical history assessed.

7.4.4 Patient posts prescription to pharmacy and/or prescription received via EPS.

7.4.5 Item is dispensed and details added to PMR.

7.4.6 The medication is delivered nationwide via a tracked delivery service. There will be no charge to the patient for delivery of medication dispensed against NHS prescriptions. Any costs incurred for delivery will be met by the pharmacy.

7.5 The website will be built by a company called the 'Shopify' (https://www.shopify.com/uk) who are web developers that have experience within the pharmacy web development market. Each patient will have their own personal login account once registered which will include their own personalised password for added security. Upon patient consent the pharmacy will then nominate them for EPS. This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.

7.6 Communication between the pharmacy and patients will be facilitated by phone, fax, email and webcam. Records of all patient interactions will be maintained on the PMR in use at the pharmacy. Cured Health Ltd has decided to use Titan PMR (https://www.titanpmr.com) as the software provider which will be a key tool in providing a safe and effective provision of service.

7.7 Cured Health Ltd is committed to having all staff trained by the National Pharmaceutical Association at a level suitable to their role. All training will need to be recognised and accredited by the GPhC and all staff will hold NVQ qualifications in Pharmacy Services. Staff and Responsible Pharmacists will also be provided with training on the SOPs relevant to their role. By following a set of SOPs, the pharmacy will be able to provide a safe and effective service that is patient-centric and outcome focussed.

7.8 The Superintendent Pharmacist will train all the staff members on the conditions of being a distance selling contractor. They will receive specific training on design patients [sic] without face-to-face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.

7.9 Cured Health Ltd is comprised of one director, [MYMP]. Mr [P] is the nominated superintendent and has suitable pharmacy experience. Mr [P] will act in overseeing the operations of the pharmacy and will maintain role of the Information Governance Lead, Clinical Governance Lead and Smartcard Sponsor. A full-time Responsible Pharmacist will be employed to be in attendance during the opening hours. He/she will be supported by a staff team of one full- time and one part-time dispenser. This level of staff will be able to cover initial trade levels once the pharmacy is open and will ensure an uninterrupted provision of essential services during the opening hours. The team is expected to grow with the business and new members will be added as and when required.

7.10 The premises have been carefully chosen to prevent face to face contact for any person seeking the provision of essential services, in, or within the vicinity of the premises. No person who is seeking essential services under the NHS contract will be allowed entry

to the premises and this will be made clear by the positioning of posters on any outward facing window and door of the premises. All entrances and exits will remain inaccessible to members of the public who are seeking the provision of essential services. An alarm system will cover the pharmacy premises which will notify the owner of unauthorised access when the premises are closed. All access routes will always be secured and kept locked when the premises not in use. Keys to the pharmacy premises will only be kept with authorised persons employed by the company. Schedule 1, 2 and relevant 3 drugs will always be stored in a locked CD cabinet. Security of premises will be reviewed regularly. A chosen member of staff will be available for emergency outcall in case of a breach.

7.11 **Essential Service – Dispensing**

7.12 **Uninterrupted service**

7.13 Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.

7.14 **Persons anywhere in England**

7.15 Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS N3 network via BT.

7.16 All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.

7.17 **Safe and effectively**

7.18 The service will be delivered safe and effectively by using SOPs to manage the process. Please see the attached SOPs provided to show examples of how the pharmacy will be managed safely and efficiently at all times.

7.19 We will have a suitable number of staff who will be trained to a minimum of an NVQ level 2 standards. This training will be undertaken by National Pharmaceutical Association (NPA) (www.npa.co.uk).

7.20 Requests from patients to show the Pharmacist visual symptoms of conditions will be done via a secure video link. All conversations will be recorded on the PMR in detail.

7.21 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone, videoconferencing or email before dispatch of medication. The pharmacy will require acknowledgment from the patient or another person that the counselling points have been understood. Patient interactions will be recorded on the PMR. A label will also be attached to the packaging asking the patient to contact the pharmacy for further details.

7.22 Prior to medication being delivered, staff will contact patient to confirm delivery address, date and time. Deliveries will be monitored with the online courier tracking

service which will give real-time information and is also available as an app for smart phone and tablets.

7.23 All medication will be delivered in tamper-proof and seal-proof packaging. Several companies who produce packaging material have been researched with a view to order corrugated cardboard boxes and 5-panel wraps which are able to withstand a single trip. It will be packed so it is protected from the environment which may include using a double walled package design or using waterproofing on the packaging material. This will also ensure that the delivery person is protected from cytotoxics and sharps.

7.24 **Without face-to-face contact**

7.25 This service will be delivered without face-to-face contact via the pharmacy website as a communication link as well as telephone post/email/fax/webcam. A courier service will provide a third-party delivery if this is required when it would not be practicable to use the in-house delivery service.

7.26 If needed, Controlled Drug (CD) deliveries will be undertaken by City Sprint who are accredited to handle and transport CDs. Their drivers will deliver to patients at a pre-determined time and the CD's must be signed for on receipt. Their drivers will only deliver the CD to the named recipient and they will ask for photographic proof of ID. In the instance of a failed delivery attempt, City Sprint will return any CDs to their overnight safe storage facility and the pharmacy will be contacted to arrange alternative delivery date to patient.

7.27 City Sprint is approved by the MHRA and has fully trained couriers to deal with all pharmacy deliveries including controlled drugs and fridge items. As well as collecting prescriptions from surgeries and collection of unwanted waste medication from patients. This will ensure there is no face to face contact.

7.28 Delivery of Refrigerated Medicinal Products - For cold chain products, delivery times will always be pre-arranged with the patient to minimise the risk of failed delivery. The patient's contact number will be given to the City Sprint delivery driver so they can again call the patient approximately 15-30 minutes prior to so they can check that somebody will be at the address to receive the medication. Cold chain products will be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their labelling requirements to maintain product integrity.

7.29 For delivery of medication with short journey times of less than 3 hours, validated medical cool boxes will be used as recommended by the MHRA. For extended journeys, gels/ ice packs will be added to the packaging to maintain appropriate temperatures throughout. Extra caution will be taken with regards to the positioning of these packs within the consignments as this would be deemed extremely important as they must not be allowed to come into direct contact with the medicines being delivered. Temperatures will be strictly controlled and monitored with calibrated temperature probes to provide temperature data for the entire journey. This will be done by the courier driver. Temperatures will be recorded at the beginning of the journey and again at the point of delivery to ensure it stays between 2-8°C. If the temperature is outside of the required range, then the product will be deemed unsafe to deliver, marked as waste and returned to the pharmacy for destruction. Thermometer(s) will be calibrated annually against a certified standard to ensure safe and effective use. When used to deliver medication, the City Sprint delivery driver must only remove the item from cold storage once the patient has answered the door and verified their identity. In the event of failed delivery, the cold storage item must be returned to the pharmacy as soon as possible, with the maximum and minimum temperatures again being recorded at the

point of return. Once again, if temperature monitoring suggests that the medication may have been transported outside of the required range, then the product will be destroyed by the pharmacy and then item will be re-dispensed by the pharmacy. Once again, a new delivery will be agreed with the patient prior to redelivery.

7.30 Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.

7.31 If a prescription is received for an appliance which requires measuring and fitting, the patient will be telephoned and emailed to state that the pharmacy cannot provide this service because the pharmacy must operate without face to face contact. The patient will then be advised that they would need to have the prescription dispensed by a pharmacy where a pharmacist would be able to measure and fit the appliance. We would facilitate this by gaining the permission of the patient to contact their nominated pharmacy and explaining the situation. We would then return the prescription to the patient or to the NHS spine so that the prescription can be dispensed.

7.32 **Essential Service - Disposal of Unwanted Medication**

7.33 **Uninterrupted Service**

7.34 Provision for disposal of unwanted medications can be requested by any patients during the core opening hours of the pharmacy. This can be requested via telephone, fax, email or webcam. All staff will be trained to deal with such enquiries.

7.35 **Persons anywhere in England**

7.36 Patients anywhere in England can request for safe disposal of their unwanted medication from our pharmacy via phone, fax, email, post or webcam.

7.37 **Safe and Effectively**

7.38 Patients, anywhere in England, can contact the pharmacy for collection of their unwanted medicines. We will take details of medication being returned by patients and assess if we are allowed to take them. We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient. All legal records will be kept and we would have procedures in place to comply with Hazardous Waste Regulations and we would keep any additional legal records such as those required for Controlled Drugs. Returned medication can be collected from patients' homes and residential homes but we will not be accepting from nursing homes. Returned medication will be stored in UN type containers provided by PHS.

7.39 Returned medication will be stored in UN type containers provided by PHS. Returned solid medicines/ ampoules, liquids and aerosols will be separated. Schedule 2 and 3 Controlled Drugs that are subject to safe custody regulations which are returned by patients will be segregated from other returned medicines and stored in compliance with the Safe Custody Regulations until they have been rendered irretrievable. As the Environment Agency has suggested that the denaturing of CDs is likely to constitute a waste treatment, the pharmacy will hold a waste management license. We will ensure that the courier collecting returned medication is registered as a waste carrier with each local environmental agency office that it operates in. We will keep full records of any waste collected and disposed of for at least three years.

7.40 **Without face-to-face contact**

7.41 Disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, out in-house delivery service. This courier service will provide a third party delivery. Patients would communicate with the pharmacy via phone, fax, email website, post or webcam. We have SOPs in place to ensure this service is offered without having them to be present the pharmacy.

7.42 **Essential Service – Signposting**

7.43 **Uninterrupted Service**

7.44 Provision of signposting can be done through the opening hours of the pharmacy via phone, fax, email, post, website or webcam. Staff will be trained to assess the need for signposting and if any doubt will refer the matter to the pharmacist.

7.45 **Persons anywhere in England**

7.46 Patients anywhere in England would be able to access the signposting service from the pharmacy via phone, website, email, post or webcam. During communication the pharmacy staff will assess the need for signposting and if any doubt will refer the matter to the pharmacist.

7.47 **Safe and Effectively**

7.48 We would contact the relevant NHS organisations in Scotland, Wales and Northern Ireland to obtain resources. Furthermore, we would have access to Macmillan, NHS Choices and NHS Direct websites, as well as full internet access to further on-demand resources. Depending on the nature of patient queries and assessment of the information provided by the patient we could then either contact patients for further information refer them to their GP or signpost them to a local NHS or non NHS service as appropriate. We will provide referral notes by email, fax and post to the appropriate health and social care providers in cases where the pharmacy is unable to meet the needs of the patient. We will aim to ensure that patients are referred correctly to minimise inappropriate use of health and social care services. We will keep records of all referrals made on the PMR including any advice given to maintain audit trails.

7.49 **Without face-to-face contact**

7.50 Signposting will be delivered without face-to-face contact via the website email phone, post fax or webcam. All patients will communicate with the pharmacy via these methods and as such there will be no face-to-face patient interaction. The SOPs in place ensure we can deliver the service without face to face contact in a distance selling model.

7.51 **Essential Service - Repeat Dispensing**

7.52 **Uninterrupted Service**

7.53 Provision of repeat dispensing throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the repeat dispensing service. The CPPE certificate of the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the repeat dispensing. The pharmacy IT system will be ETP 2 compliant to allow for repeat prescriptions to be received electronically from surgeries anywhere in

England that are ETP release 2 compliant. This will be promoted to patients as a quick way to receive prescriptions from participating surgeries for nominated patients repeat and acute prescriptions for quick despatch of medicines without any delay.

7.54 **Persons anywhere in England**

7.55 Patients anywhere in England can access the Repeat Dispensing service by signing consent form which is available on the website for anyone wishing to use the service. This consent from can be emailed, faxed or posted directly to the pharmacy. Patients from surgeries that are ETP 2 compliant will have their prescriptions sent and received at the pharmacy electronically almost instantly after the Doctor signs off the electronic prescription. The prescriptions medicines will be dispensed and despatched for delivery by our in-house delivery service or the courier without any delay.

7.56 **Safe and Effectively**

7.57 Repeat Dispensing will be delivered safe and effectively via the staff completing sufficient clinical and legal assessments before dispensing the medicine. Once a patient signs up we will obtain the batch prescription (both the Repeat Authorising Prescription RA and the Repeat Dispensing Prescriptions RD) either from the surgery, electronically or via post. Either the patient will contact the pharmacy via phone, email post, website or webcam to dispense the next RD instalment prescription or the pharmacy contacts the patient when they are due their next RD instalment. Before each RD dispensing activity we will contact the patient to clarify which items are required and whether or not there has been a change in medical condition. If treatment needs to be reviewed by the prescriber, the patient will be notified by telephone and/or email. We will keep records of dates of dispensing for each individual batch for each patient, to monitor compliance. Records of interventions made by the pharmacist considered by the pharmacist to be clinically significant will be maintained on the PMR. These actions will ensure a safe and effective service is delivered for patients using the repeat dispensing service.

7.58 **Without face-to-face contact**

7.59 All repeat dispensing patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. We have SOPs in place to manage these services without face-to-face contact.

7.60 For patients who request our service and who are NOT signed up to the repeat dispensing service, we will request that they contact the pharmacy so that we can discuss their suitability for the service but also provide further information on the benefits of the service. The initial contact with the patient will be via a leaflet which will be included within their dispensed medication. Benefits will include saving time for the patient and the prescriber due to a decreased workload on both parties. A further benefit will include an improvement of medication safety as the pharmacy will check each and every request to ensure that the medication is still suitable before dispensing. During these checks, if a medication is flagged as being unsuitable or there are side effects, then the patient will be referred to the prescriber for discussion.

7.61 **Essential Service – Discharge Medicine Service**

7.62 **Uninterrupted Service**

7.63 Provision of discharge medicine service throughout the opening hours of the pharmacy will be maintained by phone, fax, email, post or webcam. The Responsible Pharmacist will have undertaken the necessary training and is competent to provide the discharge medicine service. The CPPE certificate for the Responsible Pharmacist will be provided to the local NHS team for their records. During the opening hours the Responsible Pharmacist will be supported by a suitable trained team sufficient to deliver the discharge medicine service. The pharmacy IT system will be compliant to allow for discharge medicine service to be undertaken via Pharmoutcomes website or the pharmacy dedicated NHS mailbox.

7.64 **Persons anywhere in England**

7.65 Patients anywhere in England can access the discharge medicine service via the phone, email, chat, video link. When the pharmacist identifies an intervention on the service he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

7.66 **Safe and Effectively**

7.67 Discharge Medicine service will be delivered safe and effectively via the staff completing sufficient clinical and legal training to provide the service. Hospitals will identify patients who will benefit from discharge medicine service and will send a referral to the patient's pharmacy via secure electronic system. When a referral is received, the pharmacist will review the information in the referral, including comparing the revised medicines prescribed to those the patient used before being admitted to hospital. If any issues are identified, these will be queried with the hospital or the general practice. Pharmacy team members will check whether there are any existing dispensed prescriptions waiting for the patient or any electronic repeat dispensing prescriptions on the NHS spine. If there are, these need to be checked to see if they are still appropriate for the patient. The pharmacist will have a consultation with the patient and/or their carer to check their understanding of what medicines they should now be using and to provide further advice. If there are medicines the patient is no longer using, we will offer to dispose of them, to avoid potential confusion in the future. When the first prescription for the patient is received by the pharmacy following discharge, there will be a check to compare the medicines prescribed by the hospital and those prescribed by the GP. If there are discrepancies or other issues, the pharmacist will try to resolve them with the general practice. 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.

7.68 Relevant information will be documented on the PMR/IT System for Stage 1, 2 and 3 to ensure continuity of the service.

7.69 **Without face-to-face contact**

7.70 All discharge medicine service patients will be communicated without face-to-face contact via phone, email, post, fax or webcam. All medications will be delivered using our in-house delivery service or the City Sprint courier service and will maintain service delivery without face-to-face contact. If medicines need to be returned, this will be done in accordance to disposal of unwanted medication. We have SOPs in place to manage these services without face-to-face contact. This discharge medicine service will ensure better communication of changes to a patient's medication when they leave hospital and to reduce incidences of avoidable harm caused by medicines.

7.71 **<u>Essential Service - Public Health (Promotion of Healthy Lifestyles)</u>**

7.72 **1. Prescription linked intervention**

7.73 **Uninterrupted service**

7.74 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.

7.75 **Persons anywhere in England**

7.76 Patients anywhere in England can access these services via the pharmacy website, phone, email, chat, video link or distribution of leaflets within the prescription that is delivered to the patient. When the pharmacist identifies an intervention on a prescription he/she will communicate with the patient and other healthcare professionals. All interventions will be documented on their PMR record.

7.77 **Safe and effectively**

7.78 This service will be delivered safe and effectively by pharmacists and appropriately trained staff. At risk patients will be targeted through prescription linked intervention. Opportunistic advice will be given by the pharmacist on specified healthy living/public health topics to patients who have their prescriptions fulfilled by the pharmacy. Staff will be trained to assess for prescription linked interventions and if any doubt will refer the matter to the pharmacist. In particular, patients with diabetes, coronary heart disease, high blood pressure, smokers and obesity. These patients will be identified through the type of medication being requested the patients PMR, or the online questionnaire completed by new patients. Once a prescription linked intervention has been made, a note will be made on the patient's PMR. This note will ensure continuity of advice and as a reference for future interactions with the patients.

7.79 **Without face-to-face contact**

7.80 The service will be delivered without face-to-face contact via telephone, email, live chat or video link. Any educational material relating to certain conditions can also be sent in the post or inserted into the packaging of any dispensed prescriptions. We have SOPs in place to manage these services without face to face contact.

7.81 **2. National Health Campaign**

7.82 **Uninterrupted Service**

7.83 Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website, telephone, fax email, web chat or video link. Promotional material prepared by the Local Area Team and/or Public Health England will be made available for any patients. Trained staff will be available at the pharmacy to run the campaigns during the opening hours.

7.84 **Persons anywhere in England**

7.85 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat, video link as well as sending out printed leaflets. The website will have a specific area for current health campaigns and allow outbound links to accredited organisations and clear routes to further resources.

7.86 **Safe and Effectively**

7.87 This service will be delivered safe and effectively. The pharmacy will contribute in up to 6 campaigns as directed by NHS England and Public Health England. Other campaigns may be advised by the Local Area Team/Health and Wellbeing Board. Throughout the campaigns the pharmacy will maintain a record of the number of people that receive the advice to ensure traceability. The pharmacy will use the approved content provided by the relevant bodies. This may include briefing packs, patient literature, NHS funded merchandise or services.

7.88 **Without face-to-face contact**

7.89 The service will be delivered without face-to-face contact via the pharmacy website telephone, email or live chat. We have SOPs in place to manage these services without face to face contact

7.90 **Essential Service - Support for Self-Care**

7.91 **Uninterrupted Service**

7.92 Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Communication links to maintain the service through the core opening hours of the pharmacy will be via the pharmacy website, telephone, email, live chat or video link.

7.93 **Persons anywhere in England**

7.94 Patients anywhere in England can access these services via the pharmacy website, telephone, email, live chat or video link. The majority of interactions will come whilst giving advice to the patient using these methods.

7.95 **Safe and Effectively**

7.96 Support for self-care will be delivered safe and effectively. Pharmacy staff will provide advice to patients including carers requesting help with the treatment of minor illness and long term conditions, including general information and advice on how to manage illness. Using website or telephone consultation, we can assess patients using a protocol based on the WWHAM model. Visual symptoms can be accessed via a video link if necessary. The pharmacy staff will advise on the appropriate use of the wide range of non-prescription medicines which can be used in the self-care of minor illness and long term conditions. When appropriate pharmacy staff will make healthy interventions in a similar manner to that provided in promotions of healthy lifestyle service. When appropriate and where necessary, pharmacy staff will signpost patients to other health and social care providers. Records of advice given, products purchased or referrals made will be put on to the patients PMR when the pharmacist deems it to be of clinical significance. Any medication sold online will be sent to the patient via City Sprint couriers.

7.97 **Without face-to-face contact**

7.98 This service will be delivered without face-to-face contact via telephone, email, live chat or video link. Support for Self-Care will be prevalent in all patient interactions which will be maintained using these methods. Any deliveries of OTC products will be made using City Sprint courier who will act as a third party. We have SOPs in place to manage these services without face to face contact.

7.99 **Essential Service - Clinical Governance**

7.100 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, Mr [P].

7.101 **Patient and public involvement**

7.102 A practice leaflet will be easily accessible on the front page of the pharmacy website and we will also supply a paper copy to all patients when first delivering to them. Updated leaflets will sent to all registered patients should there be any significant changes. All services provided by the pharmacy will be listed on the leaflet and whether the service is funded by the NHS or privately. In addition, the pharmacy will produce an annual patient satisfaction survey presented to patients who use our service electronically and along with delivery of medication. Patients will have the option to return the satisfaction surveys electronically or through the post via a pre-paid envelope. The results of the patient satisfaction survey will be published on the pharmacy website and practice leaflet. The results will feed into the pharmacy's continuous quality improvement scheme.

7.103 The pharmacy will also have in place procedures to deal with complaints which will be regularly reviewed to allow us to improve our performance compliant with GPhC guidance. The employed Pharmacy Manager will deal with any complaints. Procedures to deal with medication owed to patients will also be in place and patients given a written note either via email or along with their delivery of medication to inform them of exactly what is owed and when the medication is expected to be supplied. Notes of medication owed will be kept on the PMR and regularly reviewed so stock levels can be adjusted appropriately.

7.104 **Clinical audit**

7.105 The pharmacy will participate in a minimum of two clinical audits annually. At least one practice-based audit and one multidisciplinary audit determined by NHS England, the Area Team or any other relevant organisation. Suitable personnel will be made available to ensure these audits are carried out.

7.106 **Risk management**

7.107 All incident reporting will be carried out in the pharmacy and this will involve near misses using the GPhC near miss template and help identify trends or highlight weaknesses in pharmacy systems and procedures and would be rectified promptly. Any patient safety incidents will be reported to the National Patient Safety Agency (NPSA) online. We will analyse and learn from any patient safety incidents through a system of regular reviews. In addition, the pharmacist will be proactive in considering and preventing potential risks. This will include competence in risk management and the application of Root Cause Analysis. Health and Safety legislation will be complied with in order to reduce the risk of harm to pharmacy staff and the public.

7.108 All patient safety communications received at the pharmacy either by fax, email or post will be actioned by the Pharmacist and pharmacy staff promptly and records of this will be kept at the pharmacy for audit purposes. We will have adequate facilities in place to be able to dispose of any confidential waste. NHS Code of Practice on Confidentiality will also be met.

7.109 Cured Health Ltd have produced DRAFT- Standard Operating Procedures (SOPs) at this point in time to cover the Essential Services. These procedures will continue to be developed up until when we secure the contract and commence trading. The SOPs will be reviewed at a minimum annually or a result of changes in best practice, new regulations or as a corrective action following any adverse incidents. The

Superintendent Pharmacist will be responsible for the maintenance of the SOPs and training all staff in the SOPs relevant to their role.

7.110 All pharmacy staff will be trained in and aware of child and vulnerable adult safeguarding procedures, and have access to safeguarding arrangements and reporting to all areas of United Kingdom via access to internet at the pharmacy. Any documentation will be kept for audit purposes.

7.111 **Staffing and staff management**

7.112 There will be a set of induction packs at the pharmacy to ensure that all have access to all necessary Clinical Governance information. Appropriate training will be given to all staff relevant to their positions in the pharmacy. Staff appraisals will be conducted regularly to ensure that all members of staff meet GPhC standards. If standards are not met then support will be offered and remedial action taken. We would expect Pharmacists and any registered technicians to demonstrate continual professional development and keep records of events to meet GPhC requirements.

7.113 **Education, training and continuing professional and personal development**

7.114 All pharmacists working at the pharmacy are able to demonstrate a commitment to continuing professional development (CPD), via a CPD record and this will be in line with the national RPSGB scheme. Any necessary accreditation will be achieved prior to provision of any advanced or enhanced services.

7.115 **Use of information to support clinical governance and health care delivery**

7.116 Pharmacy staff will have full access to up to date reference sources such as the BNF and Drug Tariff and with appropriate IT links with electronic reference sources. Cured Health Ltd will ensure all employees will comply with data protection and confidentiality, including the Data Protection Act 2018, Human Rights Act 1998 and common law of confidentiality. Cured Health Ltd will ensure that all employees will conform to the NHS Code of Practice on confidentiality and will have systems and policies in place to support this including ensuring all staff are appropriately trained. Employee contracts will include a duty of confidence as a specific requirement linked to disciplinary procedures.

7.117 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Cured Health Ltd will ensure that NHS direct are aware of the pharmacy's actual working hours so that they can provide appropriate information to members of the public.

7.118 **Proof of exemption/prescription charges**

7.119 If the patient is under 16 or over 60 years of age and the date of birth is printed on the front of the prescription then no check of exemption status is required. The pharmacy will make use of real time exemption checking (RTEC) via the PMR system if appropriate. For all other exemptions, the pharmacy will make contact with the patient and ask them for proof of their exemption. The pharmacy will ask patients to send proof of exemption to the pharmacy via post, fax or as an email attachment. The exemption details can also be updated on the secure pharmacy website. The pharmacy will keep records of exemption on the PMR, including when the exemption runs out or expires. On each dispensing occasion, we would verify exemption details and seek explicit permission from the patient if they would like the pharmacy to fill in the back of the prescription on their behalf. We would make a record each time the patient gave us permission to fill in the back of the prescription on their behalf so there is an audit trail.

If the patient wishes to fill in the back of the prescriptions themselves we would send the prescription to the patient via courier for them to fill in and return to us. This could be done at the same time as the medication is being delivered or prior to delivery depending on patient preference. If patient is unable to provide proof of exemption, the pharmacy would mark the back of the prescription to indicate that the exemption has not been seen. Where prescription charge(s) need to be taken, the pharmacy will have facilities in place whereby card details can be taken over the telephone or via a secure internet site. The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service.

7.120 **Additional Information**

7.121 We will maintain a high level of standards regarding the premises in terms of cleanliness in order to ensure good working conditions and minimise risks of infections. This will be covered in our SOPs and also by having a cleaning rota that is monitored. All staff will be trained on basic hygiene and hand washing issues and appropriate materials will be provided to promote this.

7.122 As the regulatory framework has now changed so that no advanced or enhanced services can be delivered to a patient who is physically present at the premises, any SOPs that will be written for advanced and enhanced service delivery will ensure that any service MUST not be delivered face to face within the pharmacy. Any patient who requests any NHS service to be delivered face to face will be informed that this is not possible, under any circumstance. All staff employed by the pharmacy will be informed of this change in the rules."

7.123 [Revised SOPs provided]

8 Parties comments in response

8.1 No comments were provided in response to the Applicant's comments regarding the amendments to Regulation 25.

9 Consideration

9.1 The Pharmacy Appeals Committee ("Committee") appointed by NHS Resolution, had before it the papers considered by the Commissioner.

9.2 It also had before it the responses to NHS Resolution's own statutory consultations.

9.3 On the basis of this information, the Committee considered it was not necessary to hold an Oral Hearing.

9.4 The Committee had regard to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations").

Regulation 31

9.5 The Committee first considered Regulation 31 of the Regulations which states:

(1) A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

(2) This paragraph applies where -

(a) a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services ("the existing services") from -

(i) the premises to which the application relates, or

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

9.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee noted the Commissioner had determined that "*…there is no person on the pharmaceutical list for the area of Leicester City Health and Wellbeing Board who is providing, or has undertaken to provide, pharmaceutical services from the premises to which the application relates or adjacent premises*", which had not been disputed.

9.7 Based on the information provided, the Committee was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

9.8 The Committee had regard to Regulation 25 of the Regulations which reads as follows:

"(1) Section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application—

(a) for inclusion in a pharmaceutical list by a person not already included; or

(b) by a person already included in a pharmaceutical list for inclusion in that list in respect of premises other than those already listed in relation to that person,

in respect of pharmacy premises that are distance selling premises.

(2) NHS England must refuse an application to which paragraph (1) applies—

(a) if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

(b) unless NHS England is satisfied that the pharmacy procedures for the pharmacy premises are likely to secure—

(i) *the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and*

(ii) *the safe and effective provision of pharmaceutical services without face to face contact at the pharmacy premises between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

9.9 The Committee also had regard to the provisions of Schedule 2 to the Regulations shown below:

Additional information to be included with excepted applications

8. *If the applicant (A) is making an excepted application, A must include in that application details that explain—*

(a) A's belief that the application satisfies the criteria included in one of the regulations in Part 4 which need to be satisfied if section 129(2A) and (2B) of the 2006 Act (regulations as to pharmaceutical services) are not to apply in relation to that application; and

(b) if the regulation includes reasons for which the application must be refused, why the application should not be refused for those reasons.

Nature of details to be supplied

10. *Where, pursuant to this Part, a person is required to provide details, that obligation is only discharged if the information or documentation provided is sufficient to satisfy NHS England in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that NHS England may need to make of the information or documentation when carrying out its functions.*

Regulation 25(1)

9.10 In relation to Regulation 25(1), the Applicant is applying for inclusion in the relevant pharmaceutical list, as a person not already included in a pharmaceutical list, and paragraph (1)(a) therefore operates to disapply the specified provisions of section 129 of the National Health Service Act 2006, provided that paragraph (2) does not require the application to be refused.

Regulation 25(2)(a)

9.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner it is decision report stated that "*The committee were satisfied that applicant's premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*", which had not been disputed. Based on the information available to

it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

9.12 As far as Regulation 25(2)(b) is concerned, the Committee considered the information which had been provided by the Applicant in relation to its procedures for the provision of essential services and pharmaceutical services, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

9.13 The Regulations require the Committee to be satisfied as to a number of matters, including that essential services will be provided on an uninterrupted basis, across England, and that pharmaceutical services will be provided in a safe and effective way without face to face contact.

9.14 Paragraph 8 of Schedule 2 requires an applicant to provide details in relation to an application, and paragraph 10 of Schedule 2 indicates that the obligation is only discharged if the information or documentation provided is sufficient to satisfy the Commissioner in receipt of it, with good cause, that no relevant information or documentation is missing, having regard to the uses that the Commissioner may need to make of the information or documentation when carrying out its functions.

9.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application, together with the updated Pharmacy Procedures and the updated SOPs which the Applicant has prepared or commissioned.

9.16 It is not for the Committee to 'approve' or 'disapprove' of these SOPs (as they may contain matters not relevant to the Committee's consideration, and there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations) and the Committee has not sought to do so. The Committee has sought evidence within the SOPs [and application] in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

9.17 The Committee noted the Applicant had stated:

9.17.1 "*Patients anywhere in England can access these services via our pharmacy website a direct phone line to the pharmacy, fax, email as well as webcam. Internet connections at the pharmacy will be provided by the NHS N3 network via BT.*

9.17.2 *All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint (www.citysprinthealth.co.uk). This will include the delivery of prescriptions received via post, fax and EPS release 2. City Sprint will also be delivering cold chain items and CDs. This is addressed in the SOPs which have been included.*"

9.18 Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

9.19 With regard to the uninterrupted provision of essential services, the Committee noted the Applicant's Pharmacy Procedures state:

9.19.1 "*Provision of service through the opening hours of the pharmacy will be maintained by having a Responsible Pharmacist present at all times during the pharmacy opening hours and having sufficient support staff at all times. The pharmacy website will run throughout these hours together with a phone, fax, email and webcam service. If the responsible pharmacist is required to leave the premises, a further pharmacist will be on hand to ensure that there is no break in pharmacist cover during the opening hours.*"

9.19.2 "*Provision of service through the core opening hours of the pharmacy will be maintained by having a Responsible Pharmacist rostered on for all opening hours and having sufficient support staff at all times. Provision of service through the core opening hours of the pharmacy will be maintained by the pharmacy website email and telephone.*"

9.20 Based on the information before it, the Committee was therefore satisfied that the provision of essential services would be without interruption.

9.21 With regard to the safe and effective provision of pharmaceutical services without face to face contact, the Committee noted the Applicant had referred to communication with patients by phone, fax, email and webcam.

9.22 The Committee noted the Applicant's updated SOPs contain the statement "*All communication must be via email, phone or post for essential services but advanced and enhanced services can be done on the premises*" which is repeated numerous times. The Committee also had regard to the front page of the SOPs which states:

9.22.1 "*THESE ARE SOPs THAT ARE DRAFT IN NATURE.*

9.22.2 *NO FACE-TO-FACE CONTACT WITH PATIENTS OR THEIR REPRESENTATIVES IS PERMITTED WHEN DELIVERING ANY NHS SERVICES UNLESS DIRECTED BY THE ICB / LOCAL AREA TEAM*

9.22.3 *While care has been taken to remove any suggestion of face-to-face contact while delivering NHS Pharmacy Services, there may still be references to this. In the Final SOP bundle, all references to face-to-face contact for NHS services will be removed.*"

9.23 The Committee noted SOP i74 'Delivery of CDs by a delivery driver' which states:

9.23.1 "*If there is nobody in the house the CD must be returned to the pharmacy and other arrangements made either for collection, or a later delivery*."

9.24 The Committee further noted SOP i84 'Urgent Medicine Supply' which states:

9.24.1 "*If we decide to make an emergency supply, our pharmacist will arrange for the patient to come to the pharmacy for a face to face consultation. If the patient says they can't visit the pharmacy, we must make a judgement as to whether it is appropriate for a representative to collect the medicine/appliance.*"

9.25 Whilst the Committee appreciated that SOPs are subject to being updated, it must have regard to the information before it in order to satisfy itself regarding the distance selling conditions. In this instance, the Committee considered that the Applicant's repetition of the statement at 9.22, together with the statements in SOPs i74 and i84 as noted

above, created sufficient doubt that it could not be satisfied that pharmaceutical services would be consistently provided other than on a face-to-face basis at the pharmacy premises.

9.26 The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

9.27 The Committee closely considered each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

9.28 The Committee paid particular attention to the following aspects of the essential services, which it considered were more difficult to provide safely and effectively in a distance selling context:

9.28.1 Dispensing of drugs and appliances

9.28.2 Urgent supply without a prescription

9.28.3 Preliminary matters before providing ordered drugs or appliances

9.28.4 Providing ordered drugs or appliances

9.28.5 Refusal to provide drugs or appliances ordered

9.28.6 Further activities to be carried out in connection with the provision of dispensing services

9.28.7 Disposal service in respect of unwanted drugs

9.28.8 Promotion of healthy lifestyles

9.28.9 Prescription linked intervention

9.28.10 Health campaigns

9.28.11 Signposting

9.28.12 Support for self-care

9.28.13 Discharge medicines service

9.28.14 Websites and health promotion zones

9.29 The Committee was of the opinion that the procedures adopted by the pharmacy were not likely to secure the safe and effective provision by the Applicant of the following essential services:

Urgent supply without a prescription

9.30 The Committee considered whether the Applicant had explained how it proposes safely and effectively to receive requests from prescribers for urgent supplies of drugs and appliances.

9.31 The Committee noted the Applicant's pharmacy procedures state:

9.31.1 "*Acute or Urgent Dispensing Requests – Any acute, urgent medication received by ETP or directly via courier from a surgery for patients anywhere in England can be dispensed and dispatched the same day using City Sprint who offer a 24 hour, 365 day service for any type of delivery.*"

9.32 The Committee also had regard to SOP 20 'Emergency Supply of Medicines' and SOP 184 'Urgent Medicine Supply' which describe how the Applicant would process such a request. The Committee noted in particular that SOP 184 states:

9.32.1 "*If we decide to make an emergency supply, our pharmacist will arrange for the patient to come to the pharmacy for a face to face consultation. If the patient says they can't visit the pharmacy, we must make a judgement as to whether it is appropriate for a representative to collect the medicine/appliance.*"

9.33 The Committee noted the Applicant appeared to intend to provide this service on a face-to-face basis at the pharmacy premises. It could not therefore be satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Providing ordered drugs or appliances

9.34 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (i) the 'cold chain' is maintained, where relevant and (ii) that the requirements of the Misuse of Drugs Regulations 2001, and in particular, Regulation 14 and 16, are met).

9.35 The Committee noted SOP i74 "SOP for Delivery of CDs by a delivery driver which states:

9.35.1 "*Delivery of CDs to Patients*

…

If there is nobody in the house the CD must be returned to the pharmacy and other arrangements made either for collection, or a later delivery.

…"

9.36 The Committee noted the reference to "collection" within the SOP which would imply that the Applicant was intending to provide this service on a face to face basis at the pharmacy premises. It could not therefore be satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

9.37 In relation to all other essential services, the Committee was, on balance, satisfied that procedures adopted by the pharmacy (and general adherence to the Terms of Service) would be "likely to secure" safe and effective provision.

Summary

9.38 On the information before it, the Committee could not be satisfied that there are procedures likely to secure safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b). Also, for the reasons set out at 9.25, the Committee concluded pharmaceutical services would not be delivered by non-face to face means.

9.39 Pursuant to paragraph 9(1)(a) of Schedule 3 to the Regulations, the Committee may:

9.39.1 confirm the Commissioner's decision;

9.39.2 quash the Commissioner's decision and redetermine the application;

9.39.3 quash the Commissioner's decision and, if it considers that there should be a further notification to the parties to make representations, remit the matter to the Commissioner.

9.40 In view of the limited reasoning provided in the Commissioner's decision report, the Committee determined that the decision of the Commissioner must be quashed.

9.41 The Committee considered whether there should be a further notification to the parties detailed at paragraph 19 of Schedule 2 of the Regulations to allow them to make representations if they so wished (in which case it would be appropriate to quash the original decision and remit the matter to the Commissioner) or whether it was preferable for the Committee to reconsider the application.

9.42 The Committee noted that representations on Regulation 25 had already been made by parties to the Commissioner, and these had been circulated and seen by all parties as part of the processing of the application by the Commissioner. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 25.

9.43 The Committee concluded that further notification under paragraph 19 of Schedule 2 would not be helpful in this case.

10 Decision

10.1 The Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

10.2 The Committee:

10.2.1 quashes the decision of the Commissioner; and

10.2.2 redetermines the application as follows -

10.2.2.1 the Committee was satisfied that the proposed premises were not adjacent to or in close proximity to other chemist premises;

10.2.2.2 the Committee was satisfied that the premises of the Applicant are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list;

10.2.2.3 the Committee was satisfied that all essential services were likely to be secured without interruption during the opening hours;

10.2.2.4 the Committee was satisfied that all essential services were likely to be secured for persons anywhere in England;

10.2.2.5 the Committee was not satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

10.2.2.6 the Committee was not satisfied that pharmaceutical services were likely to be secured without face to face contact at the pharmacy premises.

10.2.3 The application is refused.

Case Manager
Primary Care Appeals