NHS Resolution

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REF: 26620

APPEAL AGAINST NORTH EAST AND NORTH CUMBRIA ICB DECISION TO GRANT AN APPLICATION BY PHARMACY@HOME LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 32 OAKWOOD GARDENS, GATESHEAD, NE11 0DE 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 granted.

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Pharmacy@Home Ltd (the Applicant)
PCSE on behalf of North East and North Cumbria
PSC on behalf of JSBH Limited (the Appellant 1)
Templebright LLP on behalf of Lobley Hill Pharmacy Ltd (the Appellant 2)
Boots UK Ltd
Community Pharmacy Gateshead & South Tyneside

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1 The Application

By application dated 17 August 2024, Pharmacy@Home Ltd ("the Applicant") applied to North East and North Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 32 Oakwood Gardens, Gateshead, NE11 0DE 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 stated:

1.2 [Left blank].

1.3 In response to why the application should not be refused pursuant to Regulation 31 the Applicant stated:

1.4 [Left blank].

1.5 In response to why the application should not be refused pursuant to Regulation 25(2)(a) the Applicant stated:

1.6 [Left blank].

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

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

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

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

1.8 [The Applicant provided a selection of its Standard Operating Procedures Appendix A for Committee – SOPs with Application].

1.9 Pharmacy @ Home 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.

1.10 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.

1.11 Pharmacy @ Home will have a website which facilitates the following:

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

1.11.2 Patient provides details of prescription,

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

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

1.11.5 Item is dispensed and details added to PMR.

1.11.6 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.

1.12 The website will be built by a company called the 'Dash Media' (https://dashmedia.co.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.

1.13 This will then enable us to deliver a service safely and effectively to anyone in England without face to face contact.

1.14 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.

1.15 Pharmacy @ Home has decided to use Analyst https://positive-solutions.co.uk/analyst-pmr) as the software provider which will be a key tool in providing a safe and effective provision of service.

1.16 Pharmacy @ Home 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.

1.17 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 without face to face contact, an example being how to elicit a comprehensive medical history by telephone or webcam.

1.18 Pharmacy @ Home is comprised of one director, Arash Nava. Mr Nava is the nominated superintendent and has suitable pharmacy experience. Mr Nava 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.

1.19 The team is expected to grow with the business and new members will be added as and when required.

1.20 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. 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 breach.

1.21 **Essential Service – Dispensing**

1.22 **Uninterrupted service**

1.23 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.

1.24 **Persons anywhere in England**

1.25 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.

1.26 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.

1.27 **Safe and effectively**

1.28 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.

1.29 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).

1.30 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.

1.31 If patient counselling is required for any dispensed medication, the pharmacy will have procedures so this can be done via the telephone 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.

1.32 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.

1.33 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.

1.34 **Without face-to-face contact**

1.35 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.

1.36 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.

1.37 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.

1.38 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.

1.39 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.

1.40 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. Temperature 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.

1.41 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.

1.42 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.

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

1.44 **Uninterrupted Service**

1.45 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.

1.46 **Persons anywhere in England**

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

1.48 **Safe and Effectively**

1.49 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.

1.50 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.

1.51 **Without face-to-face contact**

1.52 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.

1.53 **Essential Service – Signposting**

1.54 **Uninterrupted Service**

1.55 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.

1.56 **Persons anywhere in England**

1.57 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.

1.58 **Safe and Effectively**

1.59 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.

1.60 **Without face-to-face contact**

1.61 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.

1.62 **Essential Service - Repeat Dispensing**

1.63 **Uninterrupted Service**

1.64 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 CCG 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.

1.65 **Persons anywhere in England**

1.66 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.

1.67 **Safe and Effectively**

1.68 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.

1.69 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.

1.70 **Without face-to-face contact**

1.71 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.

1.72 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.

1.73 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.

1.74 **Essential Service – Discharge Medicine Service**

1.75 **Uninterrupted Service**

1.76 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 of the Responsible Pharmacist will be provided to the CCG 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.

1.77 **Persons anywhere in England**

1.78 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.

1.79 **Safe and Effectively**

1.80 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.

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

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

1.83 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.

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

1.85 **1. Prescription linked intervention**

1.86 **Uninterrupted service**

1.87 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.

1.88 **Persons anywhere in England**

1.89 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.

1.90 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.

1.91 **Safe and effectively**

1.92 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.

1.93 **Without face-to-face contact**

1.94 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.

1.95 **2. National Health Campaign**

1.96 **Uninterrupted Service**

1.97 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.

1.98 **Persons anywhere in England**

1.99 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.

1.100 **Safe and Effectively**

1.101 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.

1.102 **Without face-to-face contact**

1.103 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.

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

1.105 **Uninterrupted Service**

1.106 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.

1.107 **Persons anywhere in England**

1.108 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.

1.109 **Safe and Effectively**

1.110 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.

1.111 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.

1.112 **Without face-to-face contact**

1.113 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.

1.114 **Essential Service - Clinical Governance**

1.115 There will be a named Clinical Governance Lead who will also be the Superintendent Pharmacist, Arash Nava.

1.116 **Patient and public involvement**

1.117 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.

1.118 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.

1.119 **Clinical audit**

1.120 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.

1.121 **Risk management**

1.122 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.

1.123 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.

1.124 Pharmacy @ Home have produced Version 0- 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.

1.125 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.

1.126 **Staffing and staff management**

1.127 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.

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

1.129 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.

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

1.131 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. Pharmacy @ Home will ensure all employees will comply with data protection and confidentiality, including the Data Protection act 1998, Human Rights Act 1998 and common law of confidentiality. Pharmacy @ Home 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.

1.132 Pharmacists will be using their own professional judgement to make records of interventions they have made and any advice they may have given. Pharmacy @ Home 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.

1.133 **Proof of exemption/prescription charges**

1.134 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.

1.135 **Additional Information**

1.136 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 14 day comments to the Commissioner

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

2.1 RUSHPORT ADVISORY LLP REPRESENTING THE APPLICANT

2.1.1 "Thank you for your letter of 17 December 2024 sent to my client via email. I act for Pharmacy @ Home Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

2.1.2 We note that interested parties have raised numerous concerns about the content of the SOPs that my client had provided. My client has now provided updated SOPs that deal with the points raised by interested parties and the updated SOPs are attached with this reply.

2.1.3 In addition, the interested parties raise a number of points that we deal with below.

2.1.4 **PSC**

2.1.5 PSC states;

2.1.6 *From the information provided, it is not clear how certain patient groups such as those with severe disabilities, sight loss or hearing loss will have equal access to the services offered by this pharmacy. Where services require internet or telephone access they may discriminate against patients who are not able to make use of these communication methods for any reason.*

2.1.7 As with any pharmacy, my client will communicate with patients in the manner that is most suitable for them, except that my client will not use face to face contact at the premises to provide essential services.

2.1.8 It must be remembered that the patient will have chosen to use a distance selling pharmacy and will therefore have considered that the communication methods available are appropriate for their needs.

2.1.9 It is not clear what PSC is referring to when they refer to patients having "equal access to the services offered". No such requirement for "equal access" is found in the Regulations or the Equality Act.

2.1.10 Primary Care Appeals has dealt with this argument in previous applications and found;

2.1.11 *"The Committee considered that having elected to use the distance selling pharmacy, people who would have difficulty in communicating with the pharmacy, would likely authorise another person to do so on their behalf."*

2.1.12 The requirement under the Regulations is to provide essential services to any patient in England who requests those services and my client has shown how they the meet this requirement.

2.1.13 PSC also queries the floorplan provided by my client. As the Committee will note, this is a basic floor plan that was provided to show a simple layout of the premises and demonstrate that a consultation room will be available. Patients will not have access to the dispensary. In any event, it is the GPhC that will inspect and approve pharmacy premises and no approval will be given to premises that are not safe.

2.1.14 **Temple Bright**

2.1.15 Temple Bright notes the type and location of premises and states;

2.1.16 *The applicant does not explain how it will deal with patients who present at the pharmacy and request essential services, which is an inherent risk given the nature of the proposed premises.*

2.1.17 This point is dealt with at paragraphs 3.3 and 3.4 of the attached SOPs.

2.1.18 All other points raised by Temple Bright are not relevant to the updated SOPs.

2.1.19 Boots raises no specific objection to my client's application and the LPC comments are not relevant to the legal test that the ICB must apply.

2.1.20 We look forward to hearing from you in due course.*"*

2.1.21 [A revised suite of SOPs entitled "Pharmacy@Home Dispensary Standard Operating Procedures Distance Selling Pharmacy" was provided with Rushport LLPs 14 day comments on 11 February 2025. Appendix B for Committee – SOPs with 14 day comments.]

3 The Commissioner restarted the 45 day consultation in view of the revised SOPs received on 11 February 2025.

However, the 14 day comments received by the Commissioner dated 31 March 2025 were not circulated to parties. NHS Resolution therefore circulated along with the appeals.

14 day Comments:

3.1 RUSHPORT ADVISORY ON BEHALF OF THE APPLICANT

3.1.1 "Thank you for your letter of 31 March 2025. I act for Pharmacy @ Home Ltd in the above application and have been instructed by my client to submit the following reply to the consultation comments received.

3.1.2 As my client's previous response and new SOPs were circulated to interested parties for comment, we will only address the updated letters of objection as the previous letters would not have been referring to the updated SOPs provided.

3.1.3 Preliminary Issue

3.1.4 On 31 March 2025 it was announced that amendments to relevant regulations would be introduced in coming months that will likely prevent NHS distance selling pharmacies from providing Advanced and Enhanced services to patients who attend the pharmacy premises and that any such services would have to be provided remotely (eg NMS via a video call).

3.1.5 There is no draft of the proposed amendments available at the time of writing and the current Regulations remain in force until such time as any amendment is made and becomes law. If required in the future my client will amend their Advanced / Enhanced services and provide an update in accordance with Schedule 2, Part 1, Paragraph 9, which requires the Applicant to notify the ICB within 7 days of any material changes to the information provided in the application that occurs before the application is determined.

3.1.6 At this point there is no requirement for any such notification to be made.

3.1.7 **PSC comments of 7 March 2025**

3.1.8 PSC refers to the historic information provided by my client that is no longer relevant and we do not comment further on those points.

3.1.9 We can confirm that Pharmacy @ Home Limited is our client and is therefore entitled to use the SOPs provided by Rushport.

3.1.10 **PSC Comment re Accessing Services**

3.1.11 As with any pharmacy, my client will communicate with patients in the manner that is most suitable for them, except that my client will not use face to face contact at the premises to provide essential services.

3.1.12 It must be remembered that the patient will have chosen to use a distance selling pharmacy and will therefore have considered that the communication methods available are appropriate for their needs.

3.1.13 Primary Care Appeals has dealt with this type of objection in previous applications and found *"The Committee considered that having elected to use the distance selling pharmacy, people who would have difficulty in communicating with the pharmacy, would likely authorise another person to do so on their behalf."*

3.1.14 The requirement under the Regulations is to provide essential services to any patient in England who requests those services and my client has shown how they the meet this requirement.

3.1.15 **PSC Comment re Controlled Drugs Delivery**

3.1.16 My client has set out how controlled drugs will be delivered to patients. Patients will be provided with estimated delivery times and these will be updated as required. As with any other delivery of this type, if a patient is not in when the delivery is attempted then a card will be left for the patient with instructions on how to rearrange delivery.

3.1.17 **Layout of Premises**

3.1.18 Whilst the approval of premises is a matter for the GPhC rather than the ICB, my client has continued to update their premises plans and I attached an updated layout for the ICB's reference.

3.1.19 **Temple Bright on behalf of Lobley Hill Pharmacy – letter dated 24 March 2025**

3.1.20 Temple Bright claims to be confused by the new SOPs provided by my client, however we trust that the ICB will not share this confusion. The updated SOPs reflect how the pharmacy will operate and supersede any previous procedures. My client has approved the new SOPs.

3.1.21 Temple Bright takes issue with the SOPs having been largely written by Rushport. However, this argument has been made many times by Temple Bright and rejected on each occasion.

3.1.22 Given that almost all pharmacies (distance selling or "normal" bricks and mortar) purchase their SOPs from third party organisations it is unclear why this argument is still being made by Temple Bright. Indeed, it is highly likely that its own client, Lobley Hill Pharmacy, uses SOPs written by a third party organisation. The updated SOPs provided are the SOPs that my client wishes to use and they are entitled to do so.

3.1.23 Temple Bright then attempts to create confusion by quoting from sections of old versions of SOPs provided by my client instead of the updated SOPs. As none of the matters raised by Temple Bright are relevant, given that they quote information that is no longer relied upon, we do not address these points further. Instead, we trust that the ICB will base their decision on the updated SOPs that have been circulated to all parties.

3.1.24 My client notes the comments from Boots and the LPC which largely to not require any response. We note however that both Temple Bright and the LPC raise concerns about the property that my client will operate this pharmacy from.

3.1.25 Temple Bright provides pictures of the property in its current state (ie prior to being fitted out as a distance selling pharmacy) and both Temple Bright and LPC refer to the premises being on a minor retail parade.

3.1.26 As the ICB will be aware, the Regulations are silent on the type of property that may be used to operate a distance selling pharmacy from, other than to prevent the use of premises that are on the same site or building as an NHS doctor or dentist. The premises chosen by my client are perfectly suited for use as a

DSP and will operate on a “closed door” basis so that patients cannot walk into the pharmacy. Any request for face to face services is dealt with at paragraphs 3.3 and 3.4 of my client’s SOPs.

3.1.27 The information already provided demonstrates how the legal test will be met in full and the application should therefore be approved.

3.1.28 We look forward to hearing from you in due course.”

4 **The Decision**

The Commissioner considered and decided to grant the application. The decision letter dated 2 May 2025 states:

4.1 “North East and North Cumbria ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.

4.2 The report details the conditions that will be placed upon your inclusion in the relevant pharmaceutical list should a valid notice of commencement be received.

4.3 Enclosed is a form confirming acceptance of these conditions. It should be completed by an authorised person and returned to me with your notice of commencement.

4.4 Also enclosed is a template of the notice of commencement which you are required to submit to us. Please note that if this is submitted before the end of the 30 day appeal period and a valid notice of appeal is then received by the Secretary of State, the notice of commencement will cease to have effect. This means that if you have opened your new premises then you will be required to close with immediate effect.

4.5 Please note that you must submit the notice of commencement no fewer than 30 days before the date you intend to start service provision. If it is received fewer than 30 days in advance it is not a valid notice of commencement and will not be accepted by North East and North Cumbria ICB unless you successfully ask to give a shorter notice period. Should you wish to ask to give a shorter notice period please complete the enclosed application form.”

Decision report

4.6 **APPLICATION: CAS-318977-Y0X7N3- for inclusion in a pharmaceutical list:**

4.7 **Distance Selling Premises (Excepted Application)** by **Pharmacy@Home Ltd at 32 Oakwood Gardens, Gateshead, Tyne and Wear, NE11 0DE**

4.8 Decision

4.9 On 30th April 2025, the Pharmaceutical Services Regulations Committee (PSRC) **approved** this **Distance Selling Premises Application** on the following basis:

4.10 **Regulation 25(2)(a)** does not apply as no primary care provider with a patient list is present within the same premises as the proposed site – **Regulation not applicable.**

4.11 **Regulation 25(2)(b)** the applicant has demonstrated how services will be provided remotely, without interruption throughout the given opening hours and without face-to-face contact with patients - **Regulation met.**

4.12 **Regulation 31** does not apply as there is no pharmacy at the same or adjacent premises to the proposed site – **Regulation not applicable.**

4.13 **Regulation 64(3)** does apply and is satisfied as:

4.13.1 the applicant is not offering to provide pharmaceutical services to patients who are present at, or in the vicinity of, the listed chemist premises;

4.13.2 services will not be provided to patients at the listed chemist premises;

4.13.3 the listed 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;

4.13.4 the pharmacy procedures for the premises will secure the uninterrupted provision of essential services to patients anywhere in England;

4.13.5 safe and effective essential services will be provided without face-to-face contact with patients;

4.13.6 there is nothing to suggest that any publicity material indicates essential services are going to be restricted to patients in particular areas of England or that the applicant is likely to refuse to provide drugs or appliances presented by specific categories of patients - **Regulation met.**

4.14 **Regulation 64(4)** is satisfied as the NENC ICB will not vary or remove the conditions set out in paragraph 64(3) - **Regulation met.**

4.15 The HWB's **Pharmaceutical Needs Assessment** is not relevant to this application as DSP applications are excepted.

4.16 **Consultation** – Two objections to the application have been raised by Temple Bright on behalf of Lobley Hill Pharmacy and Pharmacy Advice and Consultancy services Ltd (PSC) on behalf of Oakfield Pharmacy.

4.17 Appeal rights:

4.17.1 Lobley Hill Pharmacy, 72 Malvern Gardens, Lobley Hill, Gateshead, Tyne and Wear, NE11 9LJ;

4.17.2 Oakfield Pharmacy, 2 Ravensworth Road, Dunston, Gateshead, Tyne and Wear, NE11 9JF."

Decision letter to those with appeal rights:

4.18 "North East and North Cumbria ICB has considered the above application and I am writing to confirm that it has been granted. Please see the enclosed report for the full reasoning.

4.19 You have a right of appeal to the Secretary of State against North East and North Cumbria ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or:

4.20 Primary Care Appeals, NHS Resolution, 8th Floor, 10 South Colonnade, Canary Wharf, London, E14 4PU."

5 **The Appeals**

In a letter dated 23 May 2025, PSC representing JSBH Limited t/a Oakfield Pharmacy appealed against the Commissioner's decision. The grounds of appeal are:

5.1 "We act for JSBH Limited and have enclosed a letter of authorisation confirming our instructions in this matter.

5.2 Our client has been notified by North East and North Cumbria ICB ("The ICB") that the above application, made pursuant to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("The Regulations"), has been approved. I have enclosed a copy of their decision letter and report for your information.

5.3 Our client wishes to appeal against this decision.

5.4 The key ground of appeal is that our client raised a significant number of areas of concern with this application in respect of the failure of the applicant to provide evidence that the legal tests would be met. Similar concerns were raised by other objectors. However, the decision report from the ICB provides no information to show it considered the matters raised.

5.5 The report from the ICB simply states that the requirements of the various regulatory tests are met despite the evidence submitted by objectors to the contrary. As the Primary Care Appeals Committee will consider this matter afresh we are confident that the evidence will now be considered in full.

5.6 We do not intend to reproduce all of the information submitted by our client previously, as Primary Care Appeals will receive a copy of our client's objection letter from the ICB. However, we wish to draw the committee's attention to the following points in particular:

5.7 *Insufficient detail is provided (in the absence of complete and final SOPs) as to how the applicant will secure services in a safe and secure manner. For example, no detail is provided on how risks will be managed in respect of failed delivery of controlled drugs as undelivered parcels may not be immediately returned to the pharmacy due to the nature of the delivery arrangements.*

5.8 *We note that the applicant states: "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". We would suggest it is for the applicant to satisfy itself that controlled drugs are stored securely and it cannot do so if it is reliant on overnight storage facilities provided by a third party.*

5.9 *No information is provided generally in respect of measures to deal with failed deliveries when patients are not at home. It is important to ensure that suitable audit trails are maintained in the event that patients do not receive their medication.*

5.10 *The applicant has provided floor plans that show a consultation area and has listed services for provision, such as 'Flu vaccinations and Hypertension Case Finding that clearly require face to face contact.*

5.11 *It is also noteworthy that the applicant's floor plan shows that patients will be required to walk through the dispensary, where confidential information will be held (and most likely visible) to access the consultation room. There is a significant risk of a breach of confidentiality in respect of patient information where members of the public are required to walk through a working dispensary.*

5.12 *Whilst the applicant is permitted to offer 'advanced' pharmaceutical services on a face to face basis, measures must be put into place to ensure that 'essential' pharmaceutical services are not provided inadvertently at the same time. In fact, section 7.3 on the application form asks the applicant to address this specific question.*

5.13 *However the applicant appears to have made no attempt to answer this question.*

5.14 *Furthermore, as there have been no SOPs provided for these advanced services, the ICB cannot be satisfied that the applicant has given any consideration to how these services will be provided without the concurrent provision of face to face essential services.*

5.15 We believe there is enough evidence within this appeal for the Primary Care Appeals committee to refuse the application based on the written evidence. However, should the committee wish to convene a hearing our client would wish to attend.

5.16 We look forward to hearing the outcome of this appeal in due course."

In a letter dated 27 May 2025, Temple Bright LLP representing Lobley Hill Pharmacy Limited appealed against the Commissioner's decision. The grounds of appeal are:

5.17 "I act for Lobley Hill Pharmacy Limited which is included in the pharmaceutical list for premises at 72 Malvern Gardens, Gateshead, NE11 9LJ.

5.18 On behalf of my client, I write to appeal a decision of NHS England to grant an application in respect of distance selling premises by Pharmacy@Home Limited for premises at 32 Oakwood Gardens, Gateshead, Tyne and Wear, NE11 0DE. The decision was notified to my client by letter dated 2nd May 2025.

5.19 My client's ground of appeal is that NHS England failed to give any reasons for its decision to grant this application. NHS England stated in its decision report that it was satisfied that the requirements of regulation 25(2)(b) were met by the applicant but did not explain, in the context of the representations made by my client, why it was so satisfied.

5.20 As NHS Resolution will be aware, there is a significant amount of background to the application by Pharmacy@Home Limited for inclusion in the pharmaceutical list at the proposed premises.

5.21 An application was first submitted by the applicant in 2023. My client submitted representations on that application setting out why the applicant had failed to satisfy the relevant regulatory test. Notwithstanding those representations, the application was granted by NHS England by a decision dated 7th February 2024.

5.22 My client appealed the grant by NHS England by an appeal dated 28th February 2024. My client's appeal was upheld and the application refused by a decision dated 5th July 2024 (appeal reference SHA/26168).

5.23 On 17th August 2024, the applicant reapplied in respect of distance selling premises for 32 Oakwood Gardens. The new application was, to all intents and purposes, simply a resubmission of the previous application, with very little change in the information that had previously been given by the applicant and which had been rejected as insufficient to satisfy the relevant regulatory test by NHS Resolution.

5.24 My client was notified of the application by NHS England by letter dated 28th October 2024. On behalf of my client, I submitted representations on the application by letter

dated 2nd December 2024. A copy of those representations is attached to this letter of appeal to avoid repetition.

5.25 After submitting those representations, NHS England then indicated (by letter dated 11th February 2025) that it was restarting the statutory consultation period since the applicant had provided a significant amount of additional information in response to the representations submitted on the application by interested parties (including by my client).

5.26 On behalf of my client, I submitted further representations to NHS England by letter dated 24th March 2025. A copy of those representations is attached to this letter of appeal to avoid repetition. However, in summary, my client submitted to NHS England that the applicant had still failed to provide sufficient (or coherent) information to satisfy NHS England that the regulatory test in regulation 25 would be met by the granting of this application.

5.27 In particular, my client commented that the applicant had now, as part of this application, submitted three documents which purported to explain how the proposed pharmacy would provide each essential service in the distance selling context. However, each document gave different explanations as to how services would be provided by the proposed pharmacy.

5.28 As a result, the totality of the information provided by the applicant was often contradictory, meaning that it was impossible to ascertain how the applicant intended to provide each essential service in the distance selling context. Examples of the contradictory nature of the information are included in the attached letter of 24th March 2025.

5.29 Notwithstanding the obvious difficulties presented by the information provided by the applicant, NHS England granted the application. However, in its decision report, NHS England appears to have made no attempt to reconcile the various different pieces of conflicting information provided by the applicant. Instead, the decision report simply states that the regulatory test was “met”.

5.30 For the reasons given above and those given in my client’s letters of 2nd December 2024 and 24th March 2025 (the contents of which my client relies upon in support of this appeal), my client submits that the applicant has failed to discharge the burden of demonstrating how the application would meet the requirements of regulation 25. My client therefore asserts that this application should have been refused by NHS England.

5.31 On behalf of my client, I therefore invite NHS Resolution to uphold my client’s appeal and to refuse the application.

5.32 I look forward to hearing from you.”

Temple Bright LLP letter dated 2 December 2024 to the Commissioner in response to the original application.

5.33 “We act for Lobley Hill Pharmacy Limited which is included in the pharmaceutical list for premises at 72 Malvern Gardens, Gateshead, NE11 9LJ.

5.34 On behalf of our client we write further to your letter of 28th October 2024 and in order to submit representations to NHS England in relation to an application by Pharmacy@Home Limited for inclusion in the pharmaceutical list in respect of distance selling premises at 32 Oakwood Gardens, Gateshead, NE11 0DE.

5.35 Background

5.36 As NHS England will be aware, there is some background to the applicant applying for inclusion in the pharmaceutical list in respect of distance selling premises at this location.

5.37 A previous application was submitted by the applicant in January 2023. Whilst this was granted by NHS England, our client appealed the decision and the appeal was upheld with the application being refused by NHS Resolution by a decision dated 5th July 2024 (26168-Pharmaceutical-Decision-2013-Reg-25-Gateshead.pdf).

5.38 The reasons given by NHS Resolution for refusing the previous application are contained at section 6 of the decision (pages 21 to 48).

5.39 The applicant has now resubmitted its application. However, in all material respects, the new application is the same as the application previously submitted and refused by NHS Resolution.

5.40 For the reasons given by NHS Resolution in its decision dated 5th July 2024, our client therefore believes that the new application should also be refused.

5.41 Regulation 25

5.42 As NHS England will be aware, the application has been submitted pursuant to regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), being an excepted application for distance selling premises. It is therefore incumbent upon the applicant to provide suitable and sufficient information to satisfy NHS England that the applicant has in place procedures which are likely to secure the uninterrupted, safe and effective provision of all essential pharmaceutical services without face-to-face contact and irrespective of where in England the patient may live.

5.43 Whilst an applicant need not repeat every element of the Terms of Service in its application documents, where compliance with a paragraph of the Terms of Service would ordinarily require face to face contact (and would be straightforward in that context), the applicant must explain how *it* is going to achieve compliance (and therefore safe and effective provision) in the distance selling context.

5.44 It is evident from the information provided by the applicant in its application form that NHS England cannot be satisfied that the application meets the requirements of regulation 25.

5.45 Regulation 25(2)(b) requires an applicant to provide details of the pharmacy's procedures; that is, the procedures that will be adopted by the applicant in its operation of the proposed pharmacy.

5.46 At section 7 of the application form, the applicant refers to the information attached to the application form together with draft SOPs that have been provided. However, the information provided within this document and the draft SOPs is insufficient to satisfy NHS England that the requirements of regulation 25 are met by this application and, for example, provides information that is contradictory so that NHS England cannot be sure how the applicant would provide each essential pharmaceutical service in the distance selling context. By way of example:

5.47 Should this application be granted, it will be conditional upon the applicant complying with the additional terms of service included in regulation 64 of the Regulations.

5.48 As NHS England will be aware, regulation 64 provides that an NHS Pharmacist providing pharmaceutical services through a distance selling pharmacy "*must not offer*

to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises".

5.49 However, it is clear from the information provided by the applicant that it does intend to offer to provide pharmaceutical services to patients who are present at (or in the vicinity of) the proposed premises.

5.50 NHS England is referred to the section of the supporting information document with the application which states:

5.50.1 *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.*

5.51 However, the premises themselves do not support the assertion that they have been "carefully chosen to prevent face to face access". Below is a photograph which shows the proposed retail unit. As can be seen, this has a prominent "shop window".

5.52 [Photograph provided]

5.53 The premises are located within a small retail parade which will, of course, have a significant amount of "passing trade". This is shown in the photograph below (the proposed premises are on the right hand side of this image, next door to the proposed premises is a hairdressers and beauty salon and retail premises can be seen across the road).

5.54 Photograph provided]

5.55 The applicant does not explain how it will deal with patients who present at the pharmacy and request essential services, which is an inherent risk given the nature of the proposed premises. In relation to the delivery of dispensed medicines, the information provided by the applicant is confusing and contradictory.

5.56 In relation to the delivery of dispensed medicines, the information provided by the applicant is confusing and contradictory.

5.57 By way of example, in its supporting document the applicant initially states that "*All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint*". The applicant further explains that "*Prior to medication being delivered, staff will contact patients 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*", which further implies that all medicines will be delivered by a courier.

5.58 However, further into the supporting information document, the applicant states "*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*", implying that, in fact, not all medicine will be delivered by City Sprint.

5.59 The applicant has provided an SOP for "Running a prescription delivery service" which implies that the delivery service is an alternative to patients picking up their medication in-person at the pharmacy. Since it is not permitted for patients to receive dispensed medication whilst present at the pharmacy, the implication that patients may choose to collect medication rather than it being delivered should cause NHS England to refuse this application.

5.60 Additionally, the delivery SOP makes no mention of using a courier service at all and only refers to deliveries using the pharmacy's delivery driver.

5.61 In relation to the receipt of prescriptions, again the information is contradictory.

5.62 The "pharmacy procedures" document states that prescriptions will be received by "post, fax and EPS release 2". However, the SOPs appear to suggest that prescriptions may also be collected by the pharmacy from GP surgeries. This is not referred to in the "pharmacy procedures" document at all.

5.63 Additionally, the SOP suggests that prescriptions will be collected by the pharmacy's "driver". The applicant does not explain how this service will be provided nationally on the assumption that the pharmacy's driver will not collect prescriptions from surgeries throughout England.

5.64 In relation to the return of unused medication, again it is not clear how the applicant intends to provide this service, and the information given is contradictory.

5.65 Firstly, it is not clear how the applicant intends to communicate this service to patients.

5.66 Secondly, the applicant states that "*We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient*", implying that this service will be provided through City Sprint.

5.67 However, later in the document, the applicant states that the disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, our in-house delivery service.". This suggests that, in fact, the applicant will not use City Sprint for all patient returns, and that an "in-house delivery service" may be used "for local requests". This contradicts information previously given and the applicant does not explain what it means by "local requests".

5.68 The relevant SOP then confusingly states that medication may be returned by patients "via the driver/courier", but does not explain how this will happen, including how "suitable packaging" would be provided to patients who are returning medication via "courier".

5.69 In relation to repeat dispensing, the applicant does not explain how it intends to meet the requirements of paragraphs 10(1)(d) and 10(1)(da) of the terms of service.

5.70 In its supporting material, the applicant refers to its "practice leaflet" but fails to confirm that the practice leaflet will satisfy the requirements of regulation 64(3)(e) of the Regulations.

5.71 The applicant refers to the pharmacy's proposed website but does not provide information as to how the website will comply with paragraph 28C of the terms of service.

5.72 As a general observation, the applicant's SOPs repeatedly refer to "the driver", but do not deal with situations where the patient is receiving services via a courier. In fact, the SOPs only refer to a "courier" twice, and only in relation to patient returns. The strong inference in the SOPs is that the service that will be provided by the proposed pharmacy is local (through its delivery driver) rather than national as required by regulation 25.

5.73 The intention of the applicant to provide only a "local" delivery service is supported by comments made from patients using my client's pharmacy prior to this application being

submitted which were along the lines that patients had been told that a new pharmacy is opening and once they have their "delivery licence" they will be doing local deliveries.

5.74 Information about collecting the prescription charge appears to be inconsistent. In the supporting information document, the applicant states that the prescription charge may be collected via credit card over the phone, using a secure online payment system or "*The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service*." However, the prescription reception SOP only refers to prescription charges being paid either by credit card or by collection by "*the driver*", making no reference to the courier service collecting the charge.

5.75 In the SOP for prescription reception, there appears to be missing text at the end of the sentence "*Check the front is filled in with the patient's name and address, including postcode and has been signed by the doctor. If it is an EPS prescription, ensure that*"

5.76 The applicant provides information in its "pharmacy procedures" document in relation to the supply of cold chain medicines, but the information is confusing. It is not clear exactly how the applicant intends to supply cold chain medicines to patients anywhere in England, and how the applicant can assure itself that the integrity of the cold chain supply will be maintained.

5.77 For example, the applicant refers to using certain packaging and packing material but does not explain how the applicant can be sure that this packaging will be sufficient to maintain the integrity of the cold chain and how this can be monitored and audited.

5.78 Additionally, the information in the "pharmacy procedures" document is contradicted by information in the SOPs. For example, the SOP for "delivery via cold chain" refers to cold chain items being placed in a "cool bag" for delivery. The SOP makes no mention of packaging or deliveries via courier and is entirely inconsistent with the information given in the "pharmacy procedures" document.

5.79 In relation to controlled drugs, the "pharmacy procedures" document states that all CD deliveries will be made by "City Sprint", but the SOP for controlled drugs only refers to CDs being delivered by the pharmacy's delivery driver and makes no mention of a courier or City Sprint.

5.80 **Conclusion**

5.81 Regulation 25(2)(b) requires the applicant to satisfy NHS England that the applicant will provide all NHS essential pharmaceutical services safely and effectively to patients anywhere in England who request those services.

5.82 NHS England must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS England must have regard to each essential service individually and consider whether the applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each essential service.

5.83 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the applicant has failed to provide sufficient information in relation to each individual essential service and, in particular, has provided information that is contradictory. This means that NHS England cannot know how, in fact, the applicant proposes to provide all essential services in the distance selling context.

5.84 In conclusion, in the absence of suitable or sufficient information from the applicant regarding the procedures that it will have in place for the provision of all essential

services, NHS England cannot be satisfied that the requirements of regulation 25 are met.

5.85 On behalf of our client we therefore invite NHS England to refuse this application."

Temple Bright letter dated 24 March 2025 to the Commissioner in response to the updated SOPs provided with the 14 day comments letter.

5.86 "We continue to act for Lobley Hill Pharmacy Limited which is included in the pharmaceutical list for premises at 72 Malvern Gardens, Gateshead, NE11 9LJ.

5.87 On behalf of our client, we write further to your letter of 11th February 2025 and in order to submit further representations to NHS England in respect of this application.

5.88 As NHS England will be aware, there is a significant amount of background to this application. A previous application was submitted by the applicant in January 2023. Whilst this was granted by NHS England, our client appealed the decision and the appeal was upheld with the application being refused by NHS Resolution by a decision dated 5th July 2024 (26168-Pharmaceutical-Decision-2013-Reg-25-Gateshead.pdf).

5.89 The reasons given by NHS Resolution for refusing the previous application are contained at section 6 of the decision (pages 21 to 48).

5.90 The applicant then resubmitted its application. However, in all material respects, the new application was the same as the application previously submitted and refused by NHS Resolution. On behalf of our client, we submitted representations on the second application by letter dated 2nd December 2024. A copy of those representations is attached.

5.91 We assume that NHS England then provided the applicant with a copy of the representations received by it from interested parties (including our client's representations). In response to those representations, it appears that the applicant has purchased "off the shelf" SOPs from Rushport Advisory LLP and has now provided these SOPs in support of its applicant.

5.92 However, the Rushport Advisory LLP SOPs simply add to the confusion as to how this applicant proposes to provide pharmaceutical services from its distance selling pharmacy, since those SOPs contradict the information previously provided by the applicant.

5.93 It is therefore evident from the information provided by the applicant in its application form and the Rushport SOPs that NHS England cannot be satisfied that the application meets the requirements of regulation 25.

5.94 Regulation 24(2)(b) [sic] requires an applicant to provide details of the pharmacy's procedures. That is, the procedures that will be adopted by the applicant in its operation of the proposed pharmacy. It is self-evident from the totality of the information provided that NHS England cannot be satisfied as to how the applicant, itself, proposes to provide each essential service in the distance selling context.

5.95 In relation to the information provided with the application form, we have already addressed, in the attached letter, why this information is insufficient to meet the regulatory test.

5.96 In relation to the Rushport SOPs, it is clear that these bear no relationship, whatsoever, with how the applicant, itself, proposes to provide pharmaceutical services. They are

simply “off the shelf” SOPs which are not particular to the applicant’s proposed pharmacy.

5.97 As a starting point, the new SOPs are watermarked “Rushport” on every page and have the words “Copyright Rushport Advisory LLP” and “Client Approved SOPs” at the foot of each page.

5.98 The SOPs appear to be virtually identical to SOPs submitted to NHS England in support of other applications for distance selling pharmacies.

5.99 It is evident from a reading of the information provided in the Rushport SOPs that this is not information for the proposed pharmacy; rather, it is generic and “off-the-shelf” information which has been prepared not by the applicant but by Rushport Advisory and which has been used by Rushport Advisory in support of similar applications in the past.

5.100 Not only are the SOPs obviously generic in nature, but they also contradict the information previously provided by the applicant, meaning that NHS England has no way of knowing how each essential service will be provided. By way of example:

5.101 In relation to the delivery of dispensed medicines, the information provided by the applicant is confusing and contradictory.

5.102 In its supporting document the applicant initially states that “*All prescriptions dispensed will be delivered using a dedicated courier service provided by City Sprint*”. The applicant further explains that “*Prior to medication being delivered, staff will contact patients 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*”, which further implies that all medicines will be delivered by a courier.

5.103 However, further into the supporting information document, the applicant states “*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*”, implying that, in fact, not all medicine will be delivered by City Sprint. The applicant has provided an SOP for “Running a prescription delivery service” which implies that the delivery service is an alternative to patients picking up their medication in-person at the pharmacy. Since it is not permitted for patients to receive dispensed medication whilst present at the pharmacy, the implication that patients may choose to collect medication rather than it being delivered should cause NHS England to refuse this application.

5.104 Additionally, the original delivery SOP provided with the application makes no mention of using a courier service at all and only refers to deliveries using the pharmacy’s delivery driver.

5.105 Confusingly, the Rushport SOP in relation to deliveries states that a deliver driver will deliver medication for patients living within a “30-mile radius” and that Royal Mail will be used for deliveries “outside this area”.

5.106 Read together, the information provided by the applicant is unclear and contradictory.

5.107 The information variously provides that all deliveries will be via “courier”, that deliveries will be made by a delivery driver unless that is not practicable, that the delivery service is an alternative to patients picking up their medication from the pharmacy, that a delivery driver will be used if patients live within 30 miles of the proposed pharmacy and that Royal Mail will be used for other deliveries.

5.108 In relation to the receipt of prescriptions, again the information is contradictory.

5.109 The “pharmacy procedures” document states that prescriptions will be received by “post, fax and EPS release 2”. However, the original SOPs appear to suggest that prescriptions may also be collected by the pharmacy from GP surgeries. This is not referred to in the “pharmacy procedures” document at all.

5.110 Additionally, the original SOP suggests that prescriptions will be collected by the pharmacy’s “driver”. The applicant does not explain how this service will be provided nationally on the assumption that the pharmacy’s driver will not collect prescriptions from surgeries throughout England.

5.111 The Rushport SOP for “order receipt” states that patients will register for the service “on our website”. This is the first time that there is any mention of a requirement that patients have to register on a website in order to use the pharmacy. The Rushport SOP also refers to prescriptions being received “by post” or through ETP but makes no mention of prescriptions being collected by the pharmacy’s “driver”.

5.112 In relation to the return of unused medication, again it is not clear how the applicant intends to provide this service, and the information given is contradictory.

5.113 Firstly, it is not clear from the information provided in the application form how the applicant intends to communicate this service to patients.

5.114 Secondly, the applicant states in its application form that “*We would provide patients with adequate packaging so medication can be returned securely via City Sprint couriers at no charge to the patient*”, implying that this service will be provided through City Sprint. However, later in the document, the applicant states that the disposal of unwanted medication will be delivered without face-to-face contact via City Sprint couriers or, for local requests, our in-house delivery service.”. This suggests that, in fact, the applicant will not use City Sprint for all patient returns, and that an “in-house delivery service” may be used “for local requests”. This contradicts information previously given and the applicant does not explain what it means by “local requests”.

5.115 The relevant SOP provided with the application then confusingly states that medication may be returned by patients “via the driver/courier”, but does not explain how this will happen, including how “suitable packaging” would be provided to patients who are returning medication via “courier”.

5.116 The Rushport SOP then gives a different method of returning medication, referring to collection by the pharmacy’s deliver driver, a courier, Royal Mail, a specialist waste management contractor or by signposting to another pharmacy.

5.117 It is therefore not at all clear how patients are going to return medication to the pharmacy, as the applicant variously refers to all returns being via City Sprint, all returns via the delivery driver (with patients being provided with “suitable packaging”), or returns being made via Royal Mail, a waste management company or signposting.

5.118 Information about collecting the prescription charge appears to be inconsistent.

5.119 In the supporting information document, the applicant states that the prescription system or “*The pharmacy will cover the cost of postage by arranging for an insured courier to collect prescription charges nationally via a tracked service*.”

5.120 In contrast, the original prescription reception SOP only refers to prescription charges being paid either by credit card or by collection by “*the driver*”, making no reference to the courier service collecting the charge.

5.121 Confusingly, the Rushport SOP refers only to payment “via the online payment system”, making no mention of collecting the fee over the phone via credit card or through the courier.

5.122 The applicant provides information in its “pharmacy procedures” document in relation to the supply of cold chain medicines, but the information is confusing. It is not clear exactly how the applicant intends to supply cold chain medicines to patients anywhere in England, and how the applicant can assure itself that the integrity of the cold chain supply will be maintained.

5.123 For example, the applicant refers in its application form to using certain packaging and packing material but does not explain how the applicant can be sure that this packaging will be sufficient to maintain the integrity of the cold chain and how this can be monitored and audited. Additionally, the information in the “pharmacy procedures” document is contradicted by information in the SOPs. For example, the original SOP for “delivery via cold chain” refers to cold chain items being placed in a “cool bag” for delivery. The SOP makes no mention of packaging or deliveries via courier and is entirely inconsistent with the information given in the “pharmacy procedures” document.

5.124 Confusingly, the Rushport SOP gives an entirely different delivery method for cold chain items, referring only to using a cold chain courier with no mention of packaging.

5.125 In relation to controlled drugs, the “pharmacy procedures” document states that all CD deliveries will be made by “City Sprint”, but the original SOP for controlled drugs only refers to CDs being delivered by the pharmacy’s delivery driver and makes no mention of a courier or City Sprint.

5.126 Confusingly, the Rushport SOP refers to delivery by either the delivery driver or a courier (but makes no mention of which courier would be used).

5.127 It is therefore not clear whether deliveries of controlled drugs will be via the delivery driver, City Sprint, or a delivery driver or courier.

5.128 **Conclusion**

5.129 Regulation 25(2)(b) requires the applicant to satisfy NHS England that the applicant will provide all NHS essential pharmaceutical services safely and effectively to patients anywhere in England who request those services.

5.130 NHS England must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS England must have regard to each essential service individually and consider whether the applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each essential service.

5.131 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the applicant has failed to provide sufficient information in relation to each individual essential service and, in particular, has provided information that is contradictory. This means that NHS England cannot know how, in fact, the applicant proposes to provide all essential services in the distance selling context.

5.132 In conclusion, in the absence of suitable or sufficient information from the applicant regarding the procedures that it will have in place for the provision of all essential services, NHS England cannot be satisfied that the requirements of regulation 25 are met.

5.133 On behalf of our client we therefore invite NHS England to refuse this application."

6 Summary of Representations

This is a summary of representations received on the appeals.

6.1 RUSHPORT ADVISORY LLP REPRESENTING THE APPLICANT

6.1.1 "I act for PHARMACY@HOME LTD and have been instructed by my client to submit this reply to the appeals against the approval of my client's application submitted on behalf of Lobley Hill Pharmacy Ltd and JSBH Limited.

6.1.2 **JSBH Limited**

6.1.3 JSBH Limited raises no new matters and simply repeats the comments made in their original letter of objection to my client's application. As the Committee will note, those comments addressed the original supporting information provided by my client. After my client submitted their updated SOPs, JSBH was afforded a further period of time to raise any new issues but did not do so. The same applies in this appeal where no new issues have been raised.

6.1.4 As the issues raised by JSBH Limited do not refer to the updated SOPs provided by my client, we are unable to comment further other than to point out where each issue is dealt with in the current SOPs as follows.

6.1.4.1 FAILED DELIVERY OF CONTROLLED DRUGS – page 80, para 21.7 and 21.8

6.1.4.2 REQUESTS FOR FACE TO FACE SERVICES – page 18, para 3.2

6.1.4.3 FLOOR PLAN – an updated version was sent to the Commissioner and is attached with this letter.

6.1.5 As the Committee will note, my client will create 2 doorways to the pharmacy. One is for staff / deliveries and the other is for access to the consultation room at the front of the building which can also be accessed by staff from within the dispensary area. All entrances are kept locked and a patient with an appointment will have to use the intercom system to contact staff on arrival and then a staff member will open the door to the consultation room.

6.1.6 As per the attached SOPs, from 1 October 2025 patients will no longer be permitted to access the pharmacy in person for any advanced or enhanced service other than flu vaccination (until 31 March 2026).

6.1.7 **LOBLEY HILL PHARMACY LTD**

6.1.8 Lobley Hill Pharmacy Ltd's letter of appeal sets out the timeline of my client's application(s) and then continues to claim that they are unable to understand the information that has been provided. The Committee will note that I have already addressed each of the points that was raised by Lobley Hill Pharmacy in my letter of 31 March 2025 to the Commissioner and I refer the Committee to that letter.

6.1.9 **Final Note**

6.1.10 My client has made a small number of minor changes to their SOPs and attaches the latest version for the Committee's attention. These SOPs are the final version and approved for us in the pharmacy.

6.1.11 The changes made include a note at page 18, paragraph 3.3 noting the upcoming change in Regulations that means DSPs will no longer be able to provide NHS services face to face at the premises from 1 October 2025 (for flu vaccination only the date is 31 March 2026).

6.1.12 Whilst objectors may complain about changes being made to SOPs, the reality is that SOPs are considered as "living documents" and there is an ongoing requirement to update them to reflect changes in the law and the correct operation of pharmacies. Applications take many months to be decided and where changes occur during the application process the SOPs should be updated to reflect those changes.

6.1.13 We look forward to hearing from you in due course."

6.1.14 [SOPs – Appendix D for Committee note these are superseded by Appendix E for Committee see Paragraph 7 below.]

6.2 BOOTS UK LTD

6.2.1 "Boots UK Ltd have no further comments to make and we respectfully ask that NHS Resolution inform us of the decision in due course."

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 this application. Given the amendments represent a new test the Applicant was given the opportunity to make comments in support of its application and parties given the opportunity to provide comments in response.

7.1 RUSHPORT ADVISORY LLP REPRESENTING THE APPLICANT

7.1.1 "Thank you for your letter of 30 June 2025 seeking further representations in response to the changes recently made to Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the Regulations).

7.1.2 The Committee will be aware of the meaning of "pharmaceutical services" and in the context of my client's application has the meaning given in section 126(8) of the 2006 Health Act (arrangements for pharmaceutical services) which includes the provision of drugs and appliances as well as additional pharmaceutical services such as advanced or enhanced services. Not all pharmacies will provide all pharmaceutical services as many are subject to commissioning and in the context of appliances my client will only provide those that do not require measuring or fitting.

7.1.3 As a result of the changes made, the Committee will no longer consider only the safe and effective provision of essential services, and will instead consider the provision all NHS pharmaceutical services provided to patients.

7.1.4 In addition, the Committee will consider if the pharmaceutical services will be provided 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.

7.1.5 As the Committee will note, my client applied to provide the following pharmaceutical services.

7.1.5.1 Essential services

7.1.5.2 Seasonal Influenza Vaccination

7.1.5.3 CPCS

7.1.5.4 Hypertension Case Finding

7.1.5.5 Smoking Cessation

7.1.6 Given the difficulties of providing seasonal influenza vaccination, Hypertension Case Finding and Smoking Cessation remotely my client will no longer offer those services and they are no longer applied for. This notification is made under Schedule 2 paragraph 9 of the Regulations. In the event that my client wishes to provide those services remotely in the future, ie within a patient's home or elsewhere, but not at the pharmacy premises, then my client will be obliged to seek consent to do so from the Commissioner at that time.

7.1.7 In relation to CPCS, this service is no longer commissioned.

7.1.8 In relation to NMS, my client has provided the required SOP to show how the service will be carried out remotely.

7.1.9 As a result of the above my client has updated their SOPs to reflect the new legal test and changes as follows.

7.1.9.1 Clarify that no NHS pharmaceutical services will be provided to patients at the premises. See SOP 3 – Procedures For NHS Pharmaceutical Services.

7.1.9.2 Include SOPs for the **remote** provision of both NMS and Pharmacy First – See SOPs 7 and 8. **NOTE** Each service will only be provided where it is approved by the Commissioner. As neither service was applied for by my client they will seek permission from the Commissioner to provide it subsequent to opening the pharmacy.

7.1.9.3 Remove references to essential services and replace those with references to pharmaceutical services.

7.1.9.4 Other small minor and typographical changes.

7.1.10 These changes ensure that my client's application meets the updated legal test and I look forward to hearing from you in due course."

7.1.11 [SOPs – Appendix E for Committee.]

8 Summary of Observations

This is a summary of observations received.

8.1 TEMPLEBRIGHT LLP REPRESENTING LOBLEY HILL PHARMACY LIMITED

8.1.1 “I write further to your letter of 23rd July 2025 inviting comments on the correspondence from Rushport Advisory LLP dated 2nd July 2025. In your letter, I note that you are only inviting comments on the further correspondence from Rushport and, on behalf of my client, I do not, therefore, seek to repeat matters contained in my client’s previous correspondence. As will be evident to NHS Resolution, my client maintains that the position in relation to how the applicant proposes to provide NHS pharmaceutical services is entirely unclear by reason of the everchanging information being provided by the applicant and (latterly) by the applicant’s representative.

8.1.2 It is my client’s position that it would be inappropriate for NHS Resolution to simply disregard all the previous information given by this applicant in support of its application as that would undermine the integrity of the application process and would lead to an entirely inaccurate assessment of this application.

8.1.3 In relation to the letter from Rushport of 2nd July 2025 and, in particular, the “SOPs” attached to that letter my client comments as follows.

8.1.4 Proposed premises

8.1.5 As previously stated, the applicant’s proposed premises are located within a shopping parade which will, of course, have a significant amount of “passing trade”.

8.1.6 Whilst there are no restrictions within the Regulations on the premises from which distance selling pharmacy services may be provided, where the premises, themselves, tend to suggest that patients are likely to attend at the proposed premises in order to access services, it is incumbent upon an applicant to explain how the applicant would avoid being in breach of regulation 64.

8.1.7 The applicant’s “SOPs” explain how it will deal with patients who present at the pharmacy and request NHS essential pharmaceutical services in general terms. The “SOPs” still fail to recognise the specific issues presented by the applicant’s proposed location and premises type, no doubt because the “SOPs” are generic and, therefore, are not specific to either the applicant or the proposed premises.

8.1.8 In fact, the information contained within the “SOPs” demonstrates a potential breach of the NHS terms of service restrictions for distance selling pharmacies. Page 18 of the “SOPs” provides the following information:

8.1.9 “*If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any pharmaceutical service face to face on or in the vicinity of the premises then they must;*

8.1.10 *Inform the person that, for NHS services, no face-to-face contact may occur on the premises between the patient or their representative and any member of staff.*

8.1.11 *Provide the person with a copy of our patient information leaflet that explains what services the pharmacy provides and why they cannot be carried out face-to-face.*

8.1.12 *Refer the person to the Responsible Pharmacist if they require any further explanation.”*

8.1.13 The above proposed actions would be in breach of the NHS Terms of Service. In particular, providing the person with a copy of the patient information leaflet (it is assumed that this is a typographical error, and should be reference to the pharmacy's "practice leaflet"), which must include a list of the services available at the pharmacy and how these can be accessed. Would clearly amount to an "offer to provide" NHS services to patients who are present at, or in the vicinity of, the proposed premises (in contravention of regulation 64).

8.1.14 Rushport SOPs

8.1.15 In relation to the provision of NHS pharmaceutical services, it is my client's primary submission that the situation as to how the applicant actually proposes to provide pharmaceutical services remains entirely confused due to the contradictory and conflicting information given by the applicant through the lifetime of this application as detailed in my client's letter of appeal.

8.1.16 Even if NHS Resolution were to disregard all previous information provided by this applicant in support of its application (which, for the reasons given above, it is submitted would be inappropriate) the new "SOPs" provided with Rushport's letter of 2nd July 2025 still do not provide sufficient information to discharge the burden upon it of demonstrating that the application meets the requirements of regulation 25. For example:

8.1.16.1 The "SOPs" appear to suggest that the applicant's compliance with GPhC guidance for providing pharmaceutical services at a distance is not relevant to NHS Resolution's consideration of this application (see the text in bold and capitals at page 14). This is, of course, incorrect, since paragraph 29 of the Terms of Service provides that "*An NHS pharmacist must provide pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession*."

8.1.16.2 The "SOPs" refer to Clinical Commissioning Groups (or CCGs) at page 130, but these were abolished in 2022.

8.1.16.3 As stated above, the "SOPs" demonstrate that the proposed pharmacy would be in breach of regulation 64 in relation to the way in which it proposes to deal with patients who present at the pharmacy and seek access to pharmaceutical services, which is an inherent risk given the location and nature of the proposed premises.

8.1.16.4 In relation to the Pharmacy First "SOP" (pages 39 to 48) there is reference (at pages 43 and 47) to confirming the "delivery time" with the patient and ensuring that "this delivery time is suitable" or "still meets the need for the emergency supply". However, the applicant fails to identify what delivery method will be used for the provision of this service and what will happen if the delivery time is not suitable.

8.1.16.5 The applicant provides a "sample of delivery note" at page 27. The wording is confusing, however, stating "Please refer to the Product Information Leaflet Rushport sops enclosed with each product". Is the applicant intending to provide a copy of the "Rushport sops" with each delivery and, if so, why?

8.1.16.6 The section in the “SOPs” in relation to insulin supplies (page 61) is unclear, since it fails to provide sufficient information about how the appropriate records will be checked and discussed with the patient.

8.1.16.7 In relation to deliveries made by Royal Mail, the applicant fails to explain how these supplies will be made “with reasonable promptness” in accordance with paragraph 5 of the terms of service.

8.1.16.8 It does not appear that the “SOPs” for prescription reception includes providing information to the patient about a time estimate for the delivery of the dispensed medication as required by paragraph 7 of the Terms of Service.

8.1.16.9 The “SOPs” refer to the use of a cold chain courier for supplies of all cold chain items, but the “SOPs” do not state which cold chain courier has been identified by the pharmacy (presumably because of the generic nature of the SOPs). NHS Resolution cannot, therefore, be satisfied that an appropriate cold chain courier has been identified and will be used.

8.1.16.10 The “SOPs” refer to the use of a specialist controlled drugs courier, but no detail is provided about the identity of the courier to be used. NHS Resolution cannot, therefore, be satisfied that an appropriate courier has been identified and will be used.

8.1.16.11 In relation to the supply of CDs, the “SOPs” (at page 83) state that delivery will be via courier outside the delivery driver’s radius, but the “SOPs” then refer to the “driver” (presumably the delivery driver) with no mention of the “nominated controlled drugs courier”, for example:

8.1.16.11.1 At page 96 in relation to obtaining a signature for schedule 2 and 3 CDs

8.1.16.11.2 At page 97 in relation to making entries in the CD register “as soon as possible when issuing to a delivery driver”

8.1.17 **Conclusion**

8.1.18 Regulation 25(2)(b) requires the applicant to satisfy NHS Resolution that the applicant will provide all NHS pharmaceutical services safely and effectively to patients anywhere in England who request those services.

8.1.19 NHS Resolution must therefore consider Part 2 of schedule 4 to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. NHS Resolution must have regard to each pharmaceutical service individually and consider whether the applicant has provided sufficient information to satisfy it that the requirements of regulation 25(2)(b) would be met for each service.

8.1.20 Having regard to regulation 25(2)(b) and Part 2 of schedule 4, it is evident that the applicant has failed to provide sufficient information in relation to each individual pharmaceutical service and, for example, has provided information that is unclear, contradictory or suggests that the proposed pharmacy would be in breach of its terms of service obligations. This means that NHS Resolution cannot know how, in fact, the applicant proposes to provide all pharmaceutical services in the distance selling context.

8.1.21 In conclusion, in the absence of suitable or sufficient information from the applicant regarding the procedures that it will have in place for the provision of all pharmaceutical services, NHS Resolution cannot be satisfied that the requirements of regulation 25 are met.

8.1.22 On behalf of my client I therefore invite NHS Resolution to uphold my client's appeal and to refuse this application.

8.1.23 I look forward to hearing from you."

9 **Unsolicited Comments**

Comments received outside the consultation period on 28 August 2025.

9.1 COMMUNITY PHARMACY GATESHEAD & SOUTH TYNESIDE

9.1.1 "I am writing on behalf of Gateshead & South Tyneside LPC (Community Pharmacy Gateshead and South Tyneside); which represents pharmacies affected by this application within the Gateshead area.

9.1.2 It is obligatory for DSP applicants to submit SOPs distinctly demonstrating National operating procedures and arrangements. This applicant has now sent multiple versions of SOPS, and the latest set appear to be 'off-the-shelf' and not bespoke to this specific application.

9.1.3 This fails to demonstrate clearly how the applicant intends to operate Nationally and meet the requirements to provide Essential Services in a manner that is not face-to-face.

9.1.4 We would like to highlight that the Gateshead PNA does not consider Gateshead to be deficient in community pharmacies or services. The PNA recognises an extensive pharmacy delivery service is offered across the Gateshead geography (by existing community pharmacies and existing DSP's) and there are no gaps identified in provision.

9.1.5 The LPC maintains that this application should be rejected for all of the reasons above.

9.1.6 The LPC would like to be informed if this application progresses."

10 **Consideration**

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

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

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

Preliminary matters:

10.4 The Committee noted that Temple Bright LLP representing Lobley Hill Pharmacy made reference to an appeal decision SHA/26168, a distance selling application made by the Applicant which was refused on 5 July 2024. The Committee was mindful that this application would be considered on its own merits.

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

10.6 The Committee noted that Temple Bright LLP has stated in all correspondence that "*it would be inappropriate for NHS Resolution to simply disregard all the previous information given by this applicant in support of its application as that would undermine the integrity of the application process and would lead to an entirely inaccurate assessment of this application*." The Committee acknowledged that the Applicant had provided a number of Standard Operating Procedures (SOPs), updated in part after each stage of the application and appeals process and finally in response to an amendment to Regulation 25 which came into effect on 23 June 2025. The Applicant's representative, Rushport Advisory LLP has stated "*Whilst objectors may complain about changes being made to SOPs, the reality is that SOPs are considered as "living documents" and there is an ongoing requirement to update them to reflect changes in the law and the correct operation of pharmacies. Applications take many months to be decided and where changes occur during the application process the SOPs should be updated to reflect those changes*." The Committee was mindful that the appeal is a reconsideration of the application rather than a review of the Commissioner's decision. In this regard, the Committee noted that all information submitted by the Applicant including the new suite of SOPs (Appendix E for Committee) had been circulated to parties who had been invited to provide representations in this regard. Furthermore, the Committee was of the view that as Regulation 25 had been amended during the appeals process, as a matter of fairness, it must consider the latest SOPs which the Applicant's representative states "*reflect the new legal test and changes*" as provided.

Regulation 31

10.7 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).

10.8 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 that no party had sought to argue that the application should be refused under Regulation 31.

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

Regulation 25

10.10 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."

10.11 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)

10.12 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)

10.13 As far as Regulation 25(2)(a) is concerned, 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 "*Regulation 25(2)(a) does not apply as no primary care provider with a patient list is present within the same premises as the proposed site – Regulation not applicable*." Based on the information available to it, which has not been disputed, 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)

10.14 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 SOPs that it intends to use at the proposed pharmacy premises.

10.15 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.

10.16 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.

10.17 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 and the updated SOPs which the Applicant has commissioned.

10.18 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.

10.19 The Committee noted both Appellants had concerns regarding potential face to face contact and the site of the premises which could potentially lead to passing trade. Lobley Hill Pharmacy's representative states "*The applicant has provided an SOP for "Running a prescription delivery service" which implies that the delivery service is an alternative to patients picking up their medication in-person at the pharmacy*." JSBH Ltd's representative states that "*It is also noteworthy that the applicant's floor plan shows that patients will be required to walk through the dispensary, where confidential information will be held (and most likely visible) to access the consultation room. There is a significant risk of a breach of confidentiality in respect of patient information where members of the public are required to walk through a working dispensary."*

10.20 The Committee noted in its representations, the Applicant's representative states "*the Committee will note, my client will create 2 doorways to the pharmacy. One is for staff / deliveries and the other is for access to the consultation room at the front of the building which can also be accessed by staff from within the dispensary area. All entrances are kept locked and a patient with an appointment will have to use the intercom system to contact staff on arrival and then a staff member will open the door to the consultation room*." The Committee is mindful that the Applicant's representative has provided updated SOPs since the appeal was lodged in response to the amendment to Regulation 25 and that it is these SOPs which it will consider.

10.21 The Committee noted in the SOPs provided by the Applicant that SOP 1 'Introduction and Background to SOPs' point 1.3 states that the pharmacy must provide: *"The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services."* Also; *"The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."*

10.22 Further, SOP 3 'Procedures for NHS Pharmaceutical Services' states: "*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet*. *Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so*."

10.23 In its SOP 34 'The Responsible Pharmacist' point 34.9, the Applicant states: "*As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted."* [emphasis in SOPs].

10.24 SOP 34 goes on to state*: "If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and*

arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

10.25 Based on the information before it, including the new suite of SOPs, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England and without interruption.

10.26 The Committee went on to consider whether pharmaceutical services would be without face to face contact.

10.27 The Committee noted that throughout the SOPs the Applicant states that pharmaceutical services will be provided without face to face contact between any patient and the pharmacy staff. SOP 1 'Introduction and Background to SOPs' point 1.3 states:

10.28 "*All staff must be made aware that face to face contact between patients (or their representatives) is prohibited in respect of any and all NHS services either on or in the vicinity of the premises*.

10.29 *Any reference to 'contact' with or 'contacting' a patient in relation to these SOPs means contact other than face-to-face contact either on or in the vicinity of the premises*."

10.30 The Committee noted, as per SOP 3 'Procedures for NHS Pharmaceutical Services', that patients would be able to utilise multiple methods to contact the pharmacy that did not result in face to face communication. The SOP, under the heading 'Communication Channels' point 3.1 states:

10.31 *"All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non-face to face communications such as text messages.*

10.32 *The pharmacy has provision for both live audio and live video communication with patients and this must always be carried out in the specified confidential area of the pharmacy premises."*

10.33 The Committee considered the information provided in the SOPs was sufficient to provide assurance that the Applicant, if granted, would be offering pharmaceutical services without face to face contact.

10.34 The Committee noted Lobley Hill Pharmacy's representative's comment that *"it is incumbent upon an applicant to explain how the applicant would avoid being in breach of regulation 64.*" It goes on to state that "*The "SOPs" still fail to recognise the specific issues presented by the applicant's proposed location and premises type*." Lobley Hill Pharmacy's representative's quotes SOP 3 'Procedures for NHS Pharmaceutical Services' paragraph 3.2 in full concluding that "*In particular, providing the person with a copy of the patient information leaflet (it is assumed that this is a typographical error, and should be reference to the pharmacy's "practice leaflet"), which must include a list of the services available at the pharmacy and how these can be accessed. Would clearly amount to an "offer to provide" NHS services to patients who are present at, or in the vicinity of, the proposed premises (in contravention of regulation 64*." The wording of such leaflet has not been provided. However, it is difficult to accept the Appellant's statement that the practice leaflet would list how services are available and that this would constitute an offer in contravention of Regulation 64. The SOP clearly indicates that the leaflet will explain why services cannot be provided face to face. Given that the leaflet is only being provided to a person where that person is at the pharmacy premises

or in the vicinity of the pharmacy premises and has expressly requested that the pharmacy staff provide services to them, the Committee was of the view that providing such explanation to the person as to why they cannot provide such services is entirely reasonable. The Committee did not consider the leaflet to be an open offer to provide services to persons who are present at (which includes in the vicinity of) the pharmacy premises and it considered that the provision of such leaflet to the person as indicated by SOP 3 was therefore not a contravention of Regulation 64. The Committee was mindful that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

10.35 The Committee noted JSBH Limited representative states "*as there have been no SOPs provided for these advanced services, the ICB cannot be satisfied that the applicant has given any consideration to how these services will be provided without the concurrent provision of face to face essential services."*

10.36 The Committee is mindful that in its representations regarding the amendments to Regulation 25, the Applicant's representative states "*my client will create 2 doorways to the pharmacy. One is for staff / deliveries and the other is for access to the consultation room at the front of the building which can also be accessed by staff from within the dispensary area. All entrances are kept locked and a patient with an appointment will have to use the intercom system to contact staff on arrival and then a staff member will open the door to the consultation room*." Further, "*patients will no longer be permitted to access the pharmacy in person for any advanced or enhanced service other than flu vaccination (until 31 March 2026)*". And, "*Given the difficulties of providing seasonal influenza vaccination, Hypertension Case Finding and Smoking Cessation remotely my client will no longer offer those services and they are no longer applied for*."

10.37 The Committee was satisfied that the provision of essential services would be without interruption, would be available to persons anywhere in England and pharmaceutical services would be without face to face contact. The Committee went on to consider whether safe and effective provision of pharmaceutical services was likely to be secured.

10.38 The Committee considered pharmaceutical services including each essential service in paragraphs 3 to 22 of schedule 4 of the Regulations ("Terms of Service") in turn.

Dispensing of drugs and appliances

10.39 Lobley Hill Pharmacy's representative states in its appeal "*In relation to the receipt of prescriptions, again the information is contradictory*." The Committee is mindful that the Applicant's representative has provided updated SOPs since the appeal in response to the amendment to Regulation 25.

10.40 The Committee considered whether the Applicant had explained how non-electronic prescriptions will be presented by the patients and how products would be provided.

10.41 From the information contained in the SOPs provided by the Applicant, SOP 3 'Procedures for NHS Pharmaceutical Services' in the first paragraph states:

10.42 *"Patients who wish to send paper prescriptions to the pharmacy by post should be sent stamped addressed envelopes to enable them to do so."*

10.43 SOP 6 'Online Order Receipt & Exemption Checking', point 6.2 under the heading 'Scope' states:

10.44 *"… Requests to collect and dispense NHS Prescriptions.*

10.45 *Requests to dispense a prescription received in the post.*

10.46 *Any requests from the "contact us" section of the website."*

10.47 The Committee had regard to SOP 20 'Order Delivery' which under the heading 'Choice of Delivery Method' at point 20.6 states:

10.48 *"For items **other than** cold chain / "fridge line" items, local deliveries (up to 30 miles radius, but may be extended at the discretion of the RP) the delivery driver should deliver medication. Outside this area Royal Mail should be used unless the prescription is for a controlled drug, in which case the nominated controlled drugs courier should be used (see SOP for Delivery of Controlled Drugs), or the items are fridge lines, in which case the cold chain courier must be used."*

10.49 The Committee was satisfied that the Applicant was proposing to offer the service to all of England, as per the information contained in the SOPs.

10.50 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 5(2)(3) of Schedule 4.

Urgent supply without a prescription

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

10.52 The Committee had regard to SOP 17 "Emergency Supply and Urgent Supply" which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to Essential Services being delivered by several methods of non face-to-face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

10.53 SOP 17 under the heading 'Delivery of Urgent and Emergency Supply Items' at point 17.11 also states:

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

10.55 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Preliminary matters before providing ordered drugs or appliances

10.56 The Committee considered whether the Applicant had explained how evidence will be sought and provided about the patients' entitlement to exemption or remissions from NHS Charges.

10.57 The Committee noted SOP 6 "Online Order Receipt & Exemption Checking" under the heading 'Exempt NHS Prescriptions' point 6.11 states:

10.58 *"… Where no satisfactory evidence of exemption has been provided patients should be informed that checks to prevent and detect fraud are routinely undertaken by the NHS. …*

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

10.60 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

10.61 The Committee noted Lobley Hill Pharmacy's representative, in its appeal states "*Information about collecting the prescription charge appears to be inconsistent*." Further, throughout its appeal and in its observations states "*that it would be inappropriate for NHS Resolution to simply disregard all the previous information given by this applicant in support of its application as that would undermine the integrity of the application process and would lead to an entirely inaccurate assessment of this application*". The Committee agreed that this was confusing. However, the Committee is mindful the Applicant provided it's most up to date SOPs in response to NHS Resolutions request for comments on the amendment to Regulation 25 and it is this document which should be reviewed. With this in mind, the Committee considered whether the Applicant had explained how charges will be paid.

10.62 The Committee noted SOP 6 under the heading at point 6.14 'Paid NHS Prescription' states:

10.63 *"Check the prescription to confirm how many charges are due.*

10.64 *Check to see if any fees have been paid and if so, was the correct amount paid?*

10.65 *Contact the patient to arrange payment using the secure payments system using the "customer not present" option.*

10.66 *If no fees have been paid or there is a discrepancy between fees paid and those due, the patient should be contacted and directed to pay the appropriate fees via the online payment system."*

10.67 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

10.68 The Committee noted that both Appellants raise concerns regarding this term of service. Namely:

10.68.1 "*how risks will be managed in respect of failed delivery of controlled drugs."*

10.68.2 *"No information is provided generally in respect of measures to deal with failed deliveries when patients are not at home."*

10.68.3 "*In relation to the delivery of dispensed medicines, the information provided by the applicant is confusing and contradictory*."

10.68.4 "*SOP for "Running a prescription delivery service*""

10.68.5 "*the delivery SOP makes no mention of using a courier service at all and only refers to deliveries using the pharmacy's delivery driver*."

10.68.6 "*It is not clear exactly how the applicant intends to supply cold chain medicines to patients anywhere in England, and how the applicant can assure itself that the integrity of the cold chain supply will be maintained*."

10.68.7 "*the SOP for "delivery via cold chain" refers to cold chain items being placed in a "cool bag" for delivery. The SOP makes no mention of packaging or deliveries via courier and is entirely inconsistent with the information given in the "pharmacy procedures" document*."

10.68.8 "*In relation to controlled drugs, the "pharmacy procedures" document states that all CD deliveries will be made by "City Sprint", but the SOP for controlled drugs only refers to CDs being delivered by the pharmacy's delivery driver and makes no mention of a courier or City Sprint*."

10.69 The Committee is mindful that some of the comments above from the two Appellants representatives were based on previous iterations of the Applicant's SOPs. However, the Committee has been provided with the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which should be reviewed.

10.70 Lobley Hill Pharmacy's representative lists further concerns in its observations:

10.70.1 *"The "SOPs" refer to the use of a cold chain courier for supplies of all cold chain items, but the "SOPs" do not state which cold chain courier has been identified by the pharmacy (presumably because of the generic nature of the SOPs). NHS Resolution cannot, therefore, be satisfied that an appropriate cold chain courier has been identified and will be used*.

10.70.2 *The "SOPs" refer to the use of a specialist controlled drugs courier, but no detail is provided about the identity of the courier to be used. NHS Resolution cannot, therefore, be satisfied that an appropriate courier has been identified and will be used*.

10.70.3 *In relation to the supply of CDs, the "SOPs" (at page 83) state that delivery will be via courier outside the delivery driver's radius, but the "SOPs" then refer to the "driver" (presumably the delivery driver) with no mention of the "nominated controlled drugs courier", for example*:

10.70.3.1 At page 96 in relation to obtaining a signature for schedule 2 and 3 CDs

10.70.3.2 At page 97 in relation to making entries in the CD register "as soon as possible when issuing to a delivery driver."

10.71 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, Regulations 14 and 16, are met).

10.72 The Committee noted that SOP 20 'Order Delivery' under the heading 'Transfer to the Delivery Driver' at point 20.10 states:

10.73 *"Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.*

10.74 *Ensure that any special instructions for the delivery are included with the packaging.*

10.75 *Ask the delivery driver to check the details on the delivery sheet correspond to the deliveries.*

10.76 *Ensure the delivery driver completes all the sections on the delivery sheet including their name and the date.*

10.77 *Ensure the delivery driver is notified of any messages for the patient or representative.*

10.78 *Make and retain a copy of the delivery sheet until the original has been returned by the delivery driver. The original must be returned to the pharmacy on the same day.*

10.79 *Ensure the deliveries are placed in the delivery vehicle and are stored securely and out of sight. The delivery vehicle must be locked at all times when left unattended.*

10.80 *At hand-over to the driver / courier ensure that any current falsified medicines regulation or guidance is followed."*

10.81 Further, SOP 20 at point 20.14, under the heading 'Delivery of a prescription via Royal Mail (Not for cold chain or CDs) states:

10.82 *"Follow preparation for delivery process. The pharmacist should contact any patients for whom there are relevant messages or counselling required.*

10.83 *Ensure that the pharmacist on duty is available to supervise the handing over of all items for delivery.*

10.84 *Print and attach relevant Royal Mail Signed For delivery labels using the Royal Mail online business account and attach securely to outer packaging.*

10.85 *Ensure a return address is printed clearly on the outer packaging.*

10.86 *Confirm details of all prescriptions to be delivered.*

10.87 *Make a note of all Tracking numbers for prescriptions being delivered by Royal Mail on Delivery Log sheet.*

10.88 *Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. Store Delivery Log sheet for a minimum of 3 months from dispatch date.*

10.89 *Email patients dispatch confirmation with their Tracking number when the prescriptions have left the premises.*

10.90 *All deliveries will require a signature from the patient to confirm receipt of their prescription."*

10.91 The Committee noted that the SOP then, under the heading 'Cold chain delivery via courier', at point 20.16 states:

10.92 *"All cold chain deliveries must be carried out by couriers with verified and approved cold chain procedures. A list of approved cold chain couriers is available within the Pharmacy and will be updated from time to time. Each approved courier meets stringent criteria to ensure a fully monitored and dedicated cold chain service.*

10.93 *Specialist cold chain courier service will ensure the integrity of the cold chain and the maximum stability of thermo-liable drugs by packing, transporting and delivering in such a way that their integrity, quality and effectiveness are always preserved. This is a dedicated, fully monitored and temperature controlled delivery service.*

10.94 *Any breach of cold chain conditions will be notified to the driver and any affected delivery will be cancelled with the pharmacy informed of the cold chain breach. …*

10.95 *Ensure any items for cold chain delivery via courier are stored in the fridge and accompanying items are appropriately marked with a fridge line sticker. Accompanying items must include a note to explain that fridge items will be delivered separately to the rest of their items to enable the cold chain to be maintained. ….*

10.96 *A delivery must be booked using the couriers specified Cold Chain Services (refer to booking procedure with courier in the "cold chain courier" folder),*

10.97 *Select a delivery maintaining 2– 8°C unless the item requires shipping at a different temperature.*

10.98 *The cold chain item must be kept in the fridge until the courier arrives to accept the delivery.*

10.99 *Confirm with the courier that the delivery will be maintained at the booked temperature range.*

10.100 *Confirm details of all prescriptions to be delivered.*

10.101 *The courier must scan a barcode sticker for each item. The pharmacy retains a copy of the barcode which is also the tracking number.*

10.102 *Make a note of all Tracking numbers for prescriptions being delivered by the courier on Delivery Log sheet.*

10.103 *Ensure courier signs Delivery Log sheet for all prescriptions being accepted for delivery.*

10.104 *Remove items from the DELIVERY FRIDGE and match against the delivery log and place a copy of the barcode sticker on the packaging.*

10.105 *At hand-over to courier scan the aggregated FMD code [NOTE THAT A NEW FMD PROCESS HAS YET TO BE AGREED POST BREXIT] (the system will disaggregate the unique identifiers and forward them to the NMVS for decommissioning)*

10.106 *Give all fridge line deliveries to the courier.*

10.107 *Store Delivery Log sheet for a minimum of 3 months from dispatch date.*

10.108 *Contact the patient and dispatch confirmation with their Tracking number when the prescriptions have left the premises. Live tracking with estimated ETA is available via the courier website.*

10.109 *All deliveries will require a signature from the patient to confirm receipt of their prescription."*

10.110 The Committee noted SOP 20.17 under the heading '*Unsuccessful cold chain delivery via courier'* states:

10.111 *"In the event of an unsuccessful delivery, the courier will leave a 'Missed Delivery' card, stating the date and time of the attempted delivery along with details of how to contact the courier to arrange the redelivery. The patient can then rearrange delivery for a convenient time by telephone or Internet.*

10.112 *We operate to a 48 hour maximum window for cold chain deliveries and the courier will keep the cold chain intact until successful delivery for up to 48 hours. After 48 hours the items will be returned to the pharmacy and the pharmacy will contact the patient to rearrange delivery."*

10.113 The Committee noted SOP 20.18 under the heading 'Breach of Integrity of Cold Chain' states:

10.114 *"The courier ensures temperature integrity throughout the supply chain, from point of collection & goods-in to pharmaceutical storage to final delivery.*

10.115 *The cold chain service is a dedicated, fully monitored and temperature controlled delivery service. However, in the event of any breach in the integrity of this service, the system automatically alerts the delivery driver that the cold chain has not been kept intact.*

10.116 *Where such an event occurs, the courier is instructed to leave a 'Missed Delivery' card and also inform the pharmacy that the delivery was unsuccessful due to a breach of the cold chain. The pharmacy must arrange for immediate re-delivery of the items via courier and the return of the items that have failed to be delivered to the pharmacy by the courier. Items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."*

10.117 The Committee noted that SOP 24 'Controlled Drugs: Delivery' under the heading 'Delivery of Schedule 2 & 3 CDs' at point 24.5 states:

10.118 *"A robust audit trail is essential when controlled drugs are involved. The delivery can be made to a person who is not the patient (the patient must have given authorisation for a representative to take receipt of CDs on their behalf). A Controlled Drugs Delivery Sheet must also be filled in for CD deliveries in addition to the Delivery Log sheet.*

10.118.1 *CDs must be in a separate bag to any other medication being delivered and the bags should be attached together.*

10.118.2 *CDs and any other medicines on that patient's delivery must be stored in the lockable compartment of the delivery van and out of sight.*

10.118.3 *The delivery van must be kept locked at all times when the driver is not in the vehicle.*

10.118.4 *The delivery driver/courier must sign the back of the prescription as the representative when accepting the CD for delivery.*

10.118.5 *The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of*

ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

10.118.6 *Any falsified medicines rules introduced by the UK must be followed.*

10.118.7 *All entries in the CD register must be made when the medication leaves the pharmacy premises. The delivery driver/courier must be entered as the 'person collecting'.*

10.118.8 *The prescription must be retained in the pharmacy until the delivery driver returns the appropriate paperwork signed by the patient or representative to confirm successful delivery or the patient signature is confirmed online if delivered by courier."*

10.119 The Committee noted SOP 24.6 under the heading 'Successful Schedule 2 & 3 Delivery' states*:*

10.120 *"The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative. A delivery cannot be left with anyone who is not the patient or authorised representative.*

10.121 *For all successful deliveries the Controlled Drug delivery sheet signed by the patient or online courier delivery record should be cross-referenced with the prescription and CD register prior to the prescription being processed as part of the end of day procedure."*

10.122 The Committee noted SOP 24.7 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver' states:

10.123 *"Unsuccessful deliveries sent with a pharmacy driver must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate."*

10.124 The Committee noted SOP 24.8 under the heading 'Unsuccessful Schedule 2 & 3 Delivery via courier' states:

10.125 *"Unsuccessful deliveries sent with a courier must be returned to the pharmacy on the same day and entered back into the CD register where appropriate with an explanation. These must then be secured in the CD cabinet where appropriate. Where the time of attempted delivery means that the return cannot be made on the same day, the courier will store the drugs at their approved warehouse overnight.*

10.126 *When a failed delivery occurs, the tracking service will notify the pharmacy and the patient of the failed delivery so that delivery can be re-arranged for the patient at the next convenient time or returned to the pharmacy. …"*

10.127 The Committee noted SOP 24.9 under the heading 'Note re Use of Couriers for Controlled Drug Deliveries' states

10.128 *"The Courier has pharma grade specialist facilities to meet specific quality and validation requirements for healthcare products. This includes Home Office licensed controlled drug stores."*

10.129 Lobley Hill Pharmacy's representative states in its observations that "*In relation to deliveries made by Royal Mail, the applicant fails to explain how these supplies will be made "with reasonable promptness" in accordance with paragraph 5 of the terms of service*" The Committee was satisfied that the Applicant had demonstrated this as per paragraph 9.71 to 9.128 above.

10.130 The Committee was also of the view that the Applicant was not required to specify which courier it would use. Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

10.131 The Committee considered whether the Applicant had explained the arrangements which ensure that, for appliances which require fitting / measuring, a registered pharmacist measures / fits them.

10.132 The Committee noted that in its application form, the Applicant had left this section blank.

10.133 The Committee noted SOP 27 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Items Requiring Measuring and Fitting' at point 27.14 states:

10.134 "*Where a prescription is received for an appliance or stoma appliance customisation or any item that requires measuring or fitting the patient must be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients must be signposted to at least two other providers of the service in their area. (see signposting SOP)*."

10.135 In the event that the application is granted, the Applicant would not therefore, be able to provide to patients any appliances that require measuring or fitting.

10.136 Based on the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

10.137 The Committee noted the Lobley Hill Pharmacy's representative, in its appeal stated "*the applicant refers to using certain packaging and packing material but does not explain how the applicant can be sure that this packaging will be sufficient to maintain the integrity of the cold chain and how this can be monitored and audited*." The Committee has been provided with the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which should be reviewed. The Committee considered whether the Applicant had explained what containers would be suitable for posted/delivered items.

10.138 The Committee noted that SOP 19 'Bagging Up' under the heading 'Choice of Packaging' at point 19.7 states:

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

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

10.141 *Medicine for local delivery which is not fragile and to be delivered by the delivery driver can be packaged in the [sic] using the pharmacy bags supplied for standard prescription items.*

10.142 *DO NOT use normal cardboard boxes. When cardboard boxes are required ALWAYS use the re-enforced boxes that are purchased for delivery purposes.*

10.143 *For postal items, either:*

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

10.143.2 *For most items - bubble wrap and where necessary, polystyrene filler, placed within a cardboard box. **use the re-enforced cardboard boxes***

10.144 *Large or any fragile medicines should be packed into the re-enforced cardboard boxes with bubble packaging and filling material to protect from damage.*

10.145 *Coldchain items should be bubble wrapped and placed in Styrofoam filled re-enforced cardboard boxes and kept in the DELIVERIES FRIDGE (rather than the storage fridge) with the "FRAGILE" and "FRIDGE LINE" stickers attached. The courier company will transport the boxes in vans with cold chain sections that protect the integrity of the box ("cold ship" packaging) and are fully monitored – typically at 2 to 8 degrees Celsius range- (see delivery SOP). Pharmacy staff should be aware that some thermolabile products can be damaged by excessive cold as well as heat. Items such as ice packs can cause freezing in medicines which is damaging to them and such items must not be used."* [Emphasis added by the Applicant.]

10.146 Based on the information placed before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

10.147 The Committee asked itself how the Applicant will be satisfied that when dispensing a repeatable prescription other than on the first occasion, that the patient is still using the medication, is not suffering from any side effects, the medicine regimen has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of reviewing the patients treatment.

10.148 The Committee noted that SOP 35 'Repeat Dispensing' states under the heading 'Pharmaceutical & Legal Assessment' at point 35.11:

10.149 *"Terms of Service states that a pharmacy must, when providing drugs in accordance with a repeatable prescription the importance of only requesting those items which they need. Patients should be so advised either by phone or through the inclusion of written information with delivered medication.*

10.150 *The pharmacist should telephone and speak with the patient before issuing a repeat and ensure:*

10.150.1 *They are taking or using, and likely to continue to take or use the medicine or appliances appropriately*

10.150.2 *Advise the patient that they should only order items that they need*

10.150.3 *Check that the patient is not suffering any side effects which may suggest they need a review of their medication*

10.150.4 *Check that the patient's regimen has not been changed since the prescriber authorised the repeatable medication.*

10.150.5 *Check that there has not been any change to the patient's health since prescription was authorised*

10.150.6 *Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber.*

10.151 *Any interventions, referrals (to the patient's GP or otherwise) or refusal to supply decisions which are deemed to be clinically significant should be recorded on the Intervention and Referral Form which must be shared with the patient's GP."*

10.152 The Committee further noted SOP 35 under the heading 'Prescription Reception' at point 35.10 states:

10.153 *"Check to confirm if the patient has a long term, stable medical condition that requires regular medicine in the short to medium term and ensure relevant patients have the scheme explained to them.*

10.154 *The pharmacy record card must be completed and attached to a RA and an entry made on each occasion a dispensing takes place.*

10.155 *Any amendments to the RD, e.g. items not issued or change to expected interval must be recorded in the comment section of the pharmacy copy of the card.*

10.156 *When a RA is accepted the details should be checked thoroughly to ensure that there are no omissions or errors which could prevent the dispensing of all the batch prescriptions.*

10.157 *The RA should be retained in the pharmacy although it is the patient's choice whether they leave the RD with the pharmacy or retain them."*

10.158 The Committee was therefore satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

10.159 Lobley Hill Pharmacy's representative states in its appeal that "*the applicant does not explain how it intends to meet the requirements of paragraphs 10(1)(d) and 10(1)(da) of the terms of service*." The Committee has been provided with the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which should be reviewed.

10.160 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing to be given to any patient who (i) has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

10.161 The Committee noted SOP 35 'Repeat Dispensing' under the heading 'Prescription Reception' at point 35.10 states:

10.162 "*Appropriate advice about the benefits of repeat dispensing must be given to any patient who:*

10.162.1 *has a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term); and,*

10.162.2 *requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing*

of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

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

10.164 *On receipt of a repeatable prescription from the patient, either in the post or collected from the surgery for the first time, the pharmacy staff should ensure that the patient fully understands the Repeat Dispensing Process and is provided with a patient information leaflet that outlines the benefits of the service.*"

10.165 Further, the Committee noted SOP 35 goes on under 'Pharmaceutical and Legal Assessment' at point 35.11 to states:

10.166 "*Provide advice and encourage patients with long term, stable medical conditions to discuss repeat dispensing of their medicine with their prescriber*."

10.167 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Disposal service in respect of unwanted drugs

10.168 Lobley Hill Pharmacy's representative states in its appeal that "*In relation to the return of unused medication, again it is not clear how the applicant intends to provide this service, and the information given is contradictory*." The Committee has been provided with the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which should be reviewed.

10.169 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

10.170 For the return of controlled drugs, the Committee noted that in SOP 25 'Controlled Drugs: Collection and Disposal of Patient Returns', particularly under the heading 'Patient Returned Medication', at point 25.5 states:

10.171 "*This service is available to <u>all</u> [Applicants emphasis] patients living in England.*

10.172 *Patients or their representatives <u>may not [</u>Applicants emphasis<u>]</u> return and [sic] medicines directly to the pharmacy and must follow the procedures set out in this SOP*.

10.173 *Patients should be referred to the 'Returning unwanted medication' page on the website for information.*

10.174 *To arrange the return of unwanted medicines to the Pharmacy the patient must telephone and speak to a member of the dispensary team. For controlled drugs this must always be the pharmacist on duty.*

10.175 *The process for returning medication should be explained to the patient.*

10.176 *Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail…"*

10.177 The Committee noted that SOP 25 goes on under the heading 'Return by Royal Mail' to state at point 25.7:

10.178 *"The pharmacist must*:

10.178.1 *Speak to the patient about the return and clarify the items being returned*.

10.178.2 *Assess the items for suitability for return by Royal Mail*

10.178.3 *If items are suitable for return by Royal Mail then make a note on the PMR and arrange to send the appropriate packaging to the patient for safe return (refer to bagging up SOP for appropriate packaging)*

10.178.4 *If items are not suitable for return by Royal Mail (eg clinical or contaminated waste) then provide the patient with details of their local procedures for disposal*.

10.178.5 *Send the packaging to the patient along with the instructions for appropriate packing of the goods*

10.178.6 *Contact the patient to ensure that the packaging has been received*

10.178.7 *Provide signposting to other pharmacies where the patient prefers to dispose of unwanted medicines locally*."

10.179 The Committee noted that SOP 25 under the heading 'Handling Patient-Returned CDs from Delivery Driver' states at point 25.8:

10.180 *"Drivers need to*:

10.180.1 *Be aware that they cannot accept patient returns from patients without prior arrangement. The driver must notify the patient to follow the "returning unwanted medication" process as set out on the website*.

10.180.2 *Ensure that appropriate packaging is within the van prior to starting the journey as the patient may not have requested the correct type or there may be a requirement for additional packaging.*"

10.181 The Committee noted that SOP 26 'The Safe and Effective Receipt and Disposal of Medicines' under the heading 'Process for Patients to Return Medication' at point 26.6 states:

10.182 *"Patient Returned Medication*

10.182.1 *Patients or their representatives MAY NOT return and medicines directly to the pharmacy and must follow the procedures set out in this SOP*.

10.182.2 *This service is available to all patients living in England*.

10.182.3 *Patients can be referred to the 'Returning unwanted medication' page on the website for information*.

10.182.4 *To arrange sending medication back to the Pharmacy the patient must telephone and speak to a member of the dispensary team*.

10.183 *Patients may*

10.183.1 *Arrange collection by the Pharmacy driver at an appointed time, or*

10.183.2 *Send unwanted medication back to the Pharmacy via courier (at the pharmacy's cost), or Royal Mail (subject to risk assessment of contents by the RP in advance) or*,

10.183.3 *The Pharmacy can arrange for medication to be collected by our specialist waste management contractor*.

10.183.4 *Advise patient of their other options to dispose of unwanted or expired medication if none of these options is suitable for them (signposting to local pharmacies)*."

10.184 The Committee noted that SOP 26 goes on under the heading 'Process for accepting patient returns by the Driver' at point 26.7 to state:

10.185 *"Confirm that a collection of unwanted medication for disposal has been booked. Returns without a booking should only happen in exceptional circumstances as this increases the chance that the proper process for segregation of medicine has not been followed*.

10.186 *Ensure you are fully equipped with the utensils in your vehicle to accept unwanted medication as patients may have placed unwanted medication into incorrect bags*.

10.187 *Wear appropriate protective clothing where there is a requirement to handle any returned waste*.

10.188 *Identify any controlled drugs (check with the pharmacist if necessary); segregate these and place in a labelled clear bag for the pharmacist for denaturing and disposal. For further guidance read SOP Controlled Drugs: Disposal of Patient returned medication'*

10.189 *Identify any sharps and ask the customer to take these back if it safe to do so, signposting to the most appropriate route of disposal*.

10.190 *Identify any cytotoxic or other hazardous waste (check with the pharmacist where necessary)*.

10.191 *Identify any flammable waste and store separately until this can be removed by the waste contractor*.

10.192 *Where large quantities of the same medicine are being returned, then report this to the pharmacist as this could indicate a compliance issue requiring intervention.*

10.193 *Complete the 'Patients Returns Sheet' detailing the patients name and address, also if relevant their representatives name*.

10.194 *Store returned medicines in the quarantine area of the van for transport.*

10.195 *The returnable items can be taken back to the pharmacy for destruction.*

10.196 *Ensure medicines are not visible in the vehicle at all times*"

10.197 The Committee noted SOP 26 under 'Disposal of returned medicines' at point 26.10, states:

10.198 *"Use the specialist waste management company to provide safe and secure disposal of unwanted medicines by collection of unwanted medicines from patients and residential homes*.

10.199 *Unwanted medicines collected by the driver must be sorted and placed in disposal units / containers provided by the NHSCB or a waste contractor retained by the NHSCB ready for waste management services to collect*."

10.200 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

10.201 The Committee considered whether the Applicant had explained how it will safely and effectively promote healthy lifestyles.

10.202 The Committee noted that SOP 28 'Promotion of Healthy Living, Lifestyles & Health Campaigns' under the heading 'Health Campaigns and Community Engagement Exercise' states at point 28.4:

10.203 *"Terms of Service require participation in up to 6 campaigns per financial year, but you should agree to take part in all campaigns where practicable.*

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

10.205 *The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health living each financial year*.

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

10.207 *Patients should also be assessed for participation in at least one clinical audit and whichever of the following that the NHSCB* [sic] *specifies—*

10.207.1 *a clinical audit carried out in a manner which is compatible with the NHSCB's* [sic] *arrangements for the receiving and processing of data from the audit, or*

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

10.208 *We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times*."

10.209 Further, in SOP 28, under the heading 'Identification of patients for promotion of Healthy lifestyles' states at point 28.3:

10.210 *"Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease, COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone*."

10.211 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

10.212 The Committee considered whether the Applicant had explained how it will assess whether persons require prescription linked intervention advice because they have diabetes, are at risk of coronary heart disease, smoke or are overweight.

10.213 The Committee noted SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' at point 28.3 under the heading 'Identification of patients for promotion of Healthy Lifestyles' states:

10.214 "*Identification can take three forms, namely, passive, active, or as part of the repeat (or normal) dispensing process*.

10.215 ***Active patients*** [Applicants emphasis] *will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis*.

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

10.217 *As part of repeat dispensing process (or during any other interaction with a patient)* [Applicants emphasis] *staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from promotion of healthy lifestyles they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided*.

10.218 *Leaflets will be delivered to patients with their medication. Those identified as having medical conditions such as diabetes, coronary heart disease COPD, Asthma, high blood pressure, smokers, overweight individuals, etc. or being at risk from them or other conditions will also receive targeted campaigns. The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone*."

10.219 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

10.220 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will safely and effectively participate in health campaigns, if and to the extent required by the Commissioner.

10.221 The Committee noted that in SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Health Campaigns & Community Engagement Exercise', at point 28.4 states:

10.222 "*The Pharmacy will take part in national health campaigns to promote public health messages to patients across England. This will be achieved by sending out leaflets*

with prescriptions during specific targeted campaign periods and providing additional advice and learning resources via the website on the health promotion zone.

10.223 *The pharmacy will also take part in at least one approved community engagement exercise in relation to the promotion of health* [sic] *living each financial year*.

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

10.225 *We will also offer help and support on our website and direct patients to appropriate links for the health campaigns. This will ensure that patients across the UK are able to easily access information about health campaigns at all times*.

10.226 *The Pharmacy will use the opportunity when dispensing prescriptions for patients who have conditions such as diabetes, heart disease, obesity and high blood pressure, to offer health advice over the phone or provide them with leaflets about their conditions. Patients will also be able to speak to the pharmacist regarding information about the campaigns. Advice and help will be available to patients during opening hours of the pharmacy and patients can access information on our pharmacy website at all times. This ensures the uninterrupted provision of the service to patients across England*."

10.227 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

10.228 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide information to users of its pharmacy about other health and social care providers and support organisations.

10.229 The Committee noted that in SOP 27 'Support for Self-Care, Signposting and Health Promotion' under the heading 'Patient Identification' at point 27.13, states:

10.230 "*Identification can take place during any interaction that the patient has with the pharmacy staff. In particular, staff should consider the results from the identification of patients for the promotion of healthy lifestyles and those who have filled in the Lifestyle Questionnaire on the website*.

10.231 *Staff should always consider that in order to minimise inappropriate use of health and social care services and of support services and [sic] person who*:

10.231.1 *requires advice, treatment or support that we cannot provide; but*

10.231.2 *we are aware of another provider of health services who is likely to be able to provide that advice, treatment or support.*

10.232 *We must provide the patient with contact details of that provider and, where appropriate, refer the person to the provider. At least two providers should be identified if this is possible*."

10.233 The Committee noted that in SOP 27 under the heading 'Other Provider Organisations and Support Details' at point 27.10 states:

10.234 *"Details of local health and social care providers to whom patients can be referred as well as contact details for local patient and support groups can should [sic] be provided to patients via written mailshots, flyers, sent with prescription deliveries, our website and by telephone or email."*

10.235 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for Self-Care

10.236 The Committee considered whether the Applicant had explained or otherwise demonstrated how it will provide advice and support for people caring for their families

10.237 The Committee noted the Applicant's SOP 27, point 27.9 the heading 'Service outline' states:

10.238 *"Upon receipt of a request for help with the Support for Self-Care, including treatment of minor illness and long-term conditions, pharmacy staff should consider available resources and provide general information and advice on how to manage illness.*

10.239 *If appropriate, access the patient's Summary Care Record/National Care Records Service to see if it assists in delivery of the service. ….*

10.240 *The pharmacist should provide advice on the appropriate use of non-prescription medicines which can be used in the self-care of the relevant minor illness and / or long-term conditions."*

10.241 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 21 – 22 of Schedule 4.

Discharge Medicines Service

10.242 The Committee noted that in its decision the Commissioner was not satisfied with regard to the provision of DMS in the application. The Committee was mindful that the Applicant has now provided a new suite of SOPs. The Committee considered whether the Applicant had now explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

10.243 Further, the Committee considered whether the Applicant had explained what procedures it has in place for checking referrals for the discharge medicines service.

10.244 The Committee noted SOP 29 'Discharge Medicines Service ("DMS"). At point 29.3 the heading 'Process' states:

10.245 *"Every day the RP must check the pharmacy's NHS mail system, PharmOutcomes and Refer to Pharmacy for referrals to the DMS. Pharmacy contractors must consider any communication in the following form and manner as constituting a referral: "Any written patient information received by a community pharmacy via secure electronic message from an NHS trust or other provider of NHS services concerning a patient's discharge to usual primary care services and their medicines regimen."*

10.246 The Committee noted point 29.5 the heading 'DMS Stages' states:

10.247 *"It is expected that all patients referred to the pharmacy will receive all three stages of the service. Note that stages 1, 2 and 3 of the service may occur in parallel and first contact with the patient (as defined in the NHS Discharge Medicines Service toolkit) could happen at any stage in the process."*

10.248 The Committee noted point 29.10 under the heading 'Additional Advice assistance and support' states:

10.249 *"When the pharmacy either receives a prescription (in whatever form) or has been made aware via a referral to the DMS that a prescription is the first prescription for a medicine that has been made following the patient's discharge from hospital, or where the patient's care has been transferred from another NHS service provider, the following steps must be followed:*

10.249.1 *Summary Care Record/National Care Records Service Access….. - If appropriate, access the patient's Summary Care Record/National Care Records Service ….. to see if it assists in providing the service*

10.249.2 *Arrange a live video call or audio call with the patient (or where appropriate and bearing in mind the duty of confidentiality their carer to; [sic]*

10.249.2.1 *Assess the patient / carer understanding of the medicines that the patient should be taking*

10.249.2.2 *The patient should have received a copy of the prescribed medication from the hospital which lists the medication you are taking. This must match the discharge prescription when written.*

10.249.2.3 *If changes have been made to the patient's medication regimen, clearly explain the changes.*

10.249.2.4 *Offer such advice, assistance and support as is appropriate in your clinical judgement in respect of the medicines being taken and the medication regimen overall.*

10.249.2.5 *Think about high risk medicines or those where the treatment is more complex and where extra advice and support should be provided – e.g. anticoagulants*

10.249.2.6 *Discuss common or expected side effects*

10.249.2.7 *Discuss the use of medication apps which can be downloaded and may help the patient stick to their treatment plan.*

10.249.2.8 *If injectables have been prescribed and the patient is considered to be able to self-administer these, then have they received appropriate training from their GP practice nurse or hospital?*

10.249.2.9 *Inform the patient/carer*

10.249.2.9.1 *The disposal service offered in respect of unwanted drugs (see separate SOP). This is particularly relevant to medicines which may still be in the patient's home but may no longer be prescribed.*

10.249.2.9.2 *Any other pharmaceutical services that the patient or their carer may benefit from following their stay in hospital and / or the transfer of care from another NHS pharmacy.*

10.250 *Follow up*

10.250.1 Where you identify any areas of concern then to the extent it is appropriate to do so in your clinical judgement, contact the patient's GP to discuss the concerns and consider any appropriate action plan to deal with the concerns.

10.251 *In every case it is important to keep and maintain records of the above discussions, concerns and actions taken as part of providing this service and these will also assist in service evaluation processes."*

10.252 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Websites and health promotion zones

10.253 Lobley Hill Pharmacy's representative states in its appeal that "*The applicant refers to the pharmacy's proposed website but does not provide information as to how the website will comply with paragraph 28C of the terms of service*." The Committee has been provided with the Applicant's most up to date SOPs since the amendment to Regulation 25 and it is this latest document which should be reviewed.

10.254 The Committee considered whether the Applicant had explained how it will ensure that it has a website for use by the public for the purpose of accessing pharmaceutical services from those premises, on which there is an interactive page, clearly promoted to any user of the website when they first access it, which provides public access to a reasonable range of up to date materials that promote healthy lifestyles by addressing a reasonable range of health issues.

10.255 The Committee noted SOP 27 'Support for Self-care, signposting and health promotion' states under the heading 'Health Promotion Zone on our website' at point 27.11:

10.256 *"The website allows patients to access pharmaceutical services via our interactive page.*

10.257 *The interactive page is promoted on the website so that when a patient first visits the website they are signposted to a range of up to date materials that promote healthy lifestyles.*

10.258 *The Superintendent Pharmacist is responsible for ensuring that a reasonable range of materials are accessible via the interactive page and that they address a reasonable range of health issues.*

10.259 *The health promotion zone may also includes [sic] details of current health campaigns and other information to promote healthy lifestyle choices as well as providing access to the Lifestyle Questionnaire that is used to target health information to patients."*

10.260 The Committee also noted further mention of health promotion zones is made in SOP 28 'Promotion of Healthy Living, Lifestyle & Health Campaigns' under the heading 'Identification of patients for promotion of healthy lifestyles' at point 28.3 which states:

10.261 *"… The website, app and email newsletters will also be used to promote healthy lifestyles via the health promotion zone."*

10.262 The Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 28C of Schedule 4.

Other matters

10.263 Lobley Hill Pharmacy's representative states in its observations that "*The "SOPs" appear to suggest that the applicant's compliance with GPhC guidance for providing pharmaceutical services at a distance is not relevant to NHS Resolution's consideration of this application (see the text in bold and capitals at page 14). This is, of course, incorrect, since paragraph 29 of the Terms of Service provides that "An NHS pharmacist must provide pharmaceutical services and exercise any professional judgement in connection with the provision of such services in conformity with the standards generally accepted in the pharmaceutical profession."*

10.264 The Committee noted the statement to which Lobley Hill Pharmacy's representative referred is in SOP 1 'Introduction and Background to SOPs' and states:

10.264.1"*IMPORTANT NOTE RE GPHC GUIDANCE*

10.264.2*THESE SOPS COVER THE PROVISION OF PHARMACEUTICAL SERVICES UNDER THE NHS (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) REGULATIONS 2013 (AS AMENDED). GPHC GUIDANCE ON THE PRESCRIBING AND DISPENSING OR CERTAIN CLASSES OF MEDICINES TO PATIENTS WILL BE RELEVANT TO ANY PRESCRIBING OR SUPPLY VIA PRIVATE PRESCRIPTION OR VIA ONLINE CONSULTATIONS, BUT THIS DOES NOT FORM PART OF THE REGULATIONS FOR THE DISPENSING OF NHS PRESCRIPTIONS AND IS NOT INCLUDED WITHIN THESE SOPS*."

10.265 The Committee further noted that above this statement the SOP states:

10.266 "*The GPhC has set out principles for the purpose of creating and maintaining the right environment for Pharmacy staff to abide by, to ensure Pharmacies are safe and effective in their practice*.

10.267 ***Principle 1:*** *The governance arrangements safeguard the health, safety and wellbeing of patients and the public*.

10.268 ***Principle 2:*** *Staff is empowered and competent to safeguard the health, safety and wellbeing of patients and the public*.

10.269 ***Principle 3:*** *The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and wellbeing of patients and the public*.

10.270 ***Principle 4:*** *The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and wellbeing of patients and the public*.

10.271 ***Principle 5:*** *The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients and the public*."

10.272 The Committee was mindful that GPhC is the regulatory body for pharmacists, pharmacy technicians, and registered pharmacies in Great Britain. The Committee was of the view then when reviewing the SOPs as a whole, the Applicant demonstrated it was following these five principles with regard to NHS prescriptions.

10.273 Lobley Hill Pharmacy's representative states in its observations that "*The "SOPs" refer to Clinical Commissioning Groups (or CCGs) at page 130, but these were abolished in 2022*."

10.274 The Committee noted that this was in relation to SOP 31 'Customer Complaints' which states "*The complaint has been referred from the CCG, Health Board or another HSC organisation following a complaint which they received directly from the affected person or representative*." The Committee accepted that CCGs were abolished in 2022 and was likely a typographical error given that other SOPs refer to ICBs which replaced the CCGs in 2022. The Committee was of the view that this did not have an effect on any of the criteria which would persuade the Committee to refuse this application.

10.275 Lobley Hill Pharmacy's representative states in its observations that "*In relation to the Pharmacy First "SOP" (pages 39 to 48) there is reference (at pages 43 and 47) to confirming the "delivery time" with the patient and ensuring that "this delivery time is suitable" or "still meets the need for the emergency supply". However, the applicant fails to identify what delivery method will be used for the provision of this service and what will happen if the delivery time is not suitable*". The Committee considered SOP 8 'The Pharmacy First Service' in conjunction with other SOPs including SOP 17 'Emergency Supply and Urgent Supply' which states at point 17.11 "*Given the nature of a request of this type, the Pharmacy should prioritise delivery of the medication to the patient. For local deliveries the driver should be specially informed of the fact that the items are "URGENT" and for any items delivered by courier, the company must be informed that items must be delivered ASAP by the quickest route possible*." The Committee was satisfied that the Applicant's SOPs covered this aspect adequately.

10.276 Lobley Hill Pharmacy's representative states in its observations that "*The applicant provides a "sample of delivery note" at page 27. The wording is confusing, however, stating "Please refer to the Product Information Leaflet Rushport sops enclosed with each product". Is the applicant intending to provide a copy of the "Rushport sops" with each delivery and, if so, why?*"

10.277 The Committee was mindful that this example is referred to as a "sample" and it states underneath "*Sample of a delivery notes (details TBC)*". In any event, the Committee did not consider this to be a relevant factor.

10.278 Lobley Hill Pharmacy's representative states in its observations that "*The section in the "SOPs" in relation to insulin supplies (page 61) is unclear, since it fails to provide sufficient information about how the appropriate records will be checked and discussed with the patient.*"

10.279 The Committee is mindful that paragraph 12.17 'Additional Procedures Re Insulin" should be read as in addition to supporting SOPs rather than a standalone paragraph. For example, SOP 9 'Intervention and Problem Solving', SOP 19 'Bagging Up' and SOP 20 'Order Delivery' which adequately show how the Applicant will contact patients regarding prescriptions.

10.280 Lobley Hill Pharmacy's representative states in its observations that "*It does not appear that the "SOPs" for prescription reception includes providing information to the patient about a time estimate for the delivery of the dispensed medication as required by paragraph 7 of the Terms of Service*".

10.281 The Committee was of the view that SOP 20 'Order Delivery' as considered above adequately covered this aspect of the pharmaceutical provision.

Summary

10.282 On the information before it, the Committee could be satisfied that there are procedures likely to secure safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

10.283.1 confirm the Commissioner's decision;

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

10.283.3 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.

10.284 The Committee noted the Commissioner had not given reasons in its decision, other than assessing that the application had met each strand of the Regulations. So, whilst the Committee has reached the same conclusion as the Commissioner, it is also mindful that Regulation 25 was amended part way through the appeal period. Further, the Applicant, provided new SOPs then an updated suite of SOPs in response to the amendments to Regulation 25. In those circumstances the Committee determined that the decision of the Commissioner must be quashed.

10.285 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.

10.286 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.

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

11 Decision

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

11.2 The Committee:

11.2.1 quashes the decision of the Commissioner; and redetermines the application as follows -

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

11.2.1.2 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;

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

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

11.2.1.5 the Committee was satisfied that pharmaceutical services were likely to be secured in a safe and effective manner; and

11.2.1.6 the Committee was satisfied that pharmaceutical services were likely to be secured without face to face contact.

11.2.2 The application is granted.

Case Manager
Primary Care Appeals