NHS Resolution

31 July 2026

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Tel: 020 3928 2000
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REF: APL-4500 [SHA/26973]

APPEAL AGAINST COVENTRY AND WARWICKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY HEALTHCARE ASSOCIATES LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 33-34 HIGH STREET, RUGBY, WARWICKSHIRE, CV21 3BW 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 Healthcare Associates Ltd
PCSE, on behalf of Coventry and Warwickshire ICB
Community Pharmacy Arden
Rowlands Pharmacy

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1 The Application

By application dated 1 July 2025, Healthcare Associates Ltd ("the Applicant") applied to Coventry and Warwickshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 33-34 High Street, Rugby, Warwickshire, CV21 3BW 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:

1.1.1 "Drug Tarriff Part IX except items that require fitting or measuring"

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

1.2.1 "N/A Not applicable as no other pharmacy in the same or adjacent premises"

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

1.3.1 "Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list."

Pharmacy procedures

1.4 Please explain how the pharmacy procedures used within the premises will secure:

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

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

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

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

1.7 You must ensure that you provide sufficient information within this application form to satisfy NHS England or the relevant delegated integrated care board on the above points. You are not required to submit your standard operating procedures for the premises but if you do they will be circulated to interested parties unless NHS England or the relevant delegated integrated care board is satisfied that the full disclosure principle does not apply.

1.8 “Please see attached information – answers to the above section 7 questions.”

1.9 “**Section 7 – Addition** [sic] **information**

1.10 The pharmacy will comply with the premises standards set by NHS England. While these standards are not all directly applicable to distance-selling pharmacies, they will be followed where relevant, particularly when patients access non-essential services. As a designated Healthy Living Pharmacy, the pharmacy will adhere to criteria related to change management and organizational development, ensuring that its facilities and services are designed to engage effectively with the community. This will support the consistent delivery of high-quality health and wellbeing services.

1.11 To maintain accessibility, the pharmacy will be equipped with facilities that enable both telephone communication (or other live audio links) and live video interactions with patients, ensuring that patient confidentiality is always upheld.

1.12 The pharmacy will also operate in compliance with the General Pharmaceutical Council (GPhC) guidance for registered pharmacies providing pharmacy services at a distance, including online services. This guidance ensures the safety and effectiveness of pharmacy operations, with a strong focus on patient care and regulatory compliance. Before commencing operations, the pharmacy will implement a structured framework that includes key risk assessment measures and operational protocols.

1.13 A comprehensive Risk Assessment document and accompanying risk matrix will be developed to identify and effectively manage potential risks. This will evaluate any factors that could pose harm to patients and other users of pharmacy services. Additionally, it will outline measures to mitigate identified risks. The risk assessment will undergo quarterly reviews and will be updated whenever there are significant changes in business operations, service offerings, or regulatory requirements.

1.14 The pharmacy will establish a regular audit program as a critical component of its quality assurance process. The audit will assess various factors, including staffing levels, training, communication with patients and healthcare providers, the use of specialized equipment, and decision-making processes related to prescription services. Other areas of evaluation will include systems for processing electronic prescriptions (EPS), records of sale refusals, procedures for securely delivering medications, website compliance with security and data protection laws, and feedback from patients. Any concerns or complaints received will be reviewed and analysed as part of this ongoing process. The

audit and review system will also serve as a Project Plan, helping to implement continuous improvements in service delivery and staff training.

1.15 If an audit highlights concerns, or if specific triggers arise—such as changes in the law, an increase in patient numbers, a security breach, new technology implementation, or negative feedback from patients—a reactive review will be initiated. This ensures that corrective actions are taken promptly to address any issues.

1.16 A responsible pharmacist (RP) will always be on-site during operational hours, with clearly defined lines of accountability established by the superintendent pharmacist. This will ensure that all operations are effectively managed and comply with regulatory requirements.

1.17 All pharmacy records will be maintained in a secure IT system, including patient consent forms, queries, complaints, customer logs, and sale refusals. These records will be stored for a minimum of seven years or longer, depending on specific legal requirements.

1.18 To ensure the safe provision of pharmacy services, all staff members will receive appropriate training in accordance with GPhC guidance. The focus will be on developing a safe and effective team capable of providing medicines and other professional pharmacy services competently.

1.19 Before being added to the pharmaceutical list, the pharmacy premises will be officially registered with the GPhC to confirm compliance with all regulatory requirements.

1.20 The pharmacy's website will be designed to meet high security standards, ensuring compliance with data protection laws and information security management guidelines. Secure facilities will be used to collect, store, and process patient details, including a secure payment processing system for online transactions. The website will clearly display essential regulatory information, including:

1.20.1 The GPhC pharmacy registration number.

1.20.2 The name of the registered pharmacy owner.

1.20.3 The name of the superintendent pharmacist.

1.20.4 The name and address of the registered pharmacy responsible for supplying medicines.

1.20.5 Information on the pharmacy where medicines are prepared, assembled, dispensed, and labelled against prescriptions (if these activities take place at a different location).

1.20.6 Instructions on verifying the registration status of the pharmacy and the superintendent pharmacist.

1.20.7 A full list of available pharmacy services and how they can be accessed, including:

1.20.7.1 The procedure for returning unwanted medicines.

1.20.7.2 A Patient Lifestyle Questionnaire.

1.20.7.3 Instructions for registering exemptions from NHS charges.

1.20.7.4 Details on health promotion initiatives and campaigns.

1.20.7.5 Emergency supply procedures.

1.20.7.6 Guidelines on non-face-to-face patient interactions.

1.20.7.7 A Patient Information Leaflet.

1.20.8 Contact information, including an email address and phone number.

1.20.9 Clear procedures for submitting feedback or raising concerns.

1.20.10 The GPhC internet pharmacy logo, linked to the pharmacy's registry entry.

1.21 If the pharmacy offers medicines for sale online, it will be registered with the appropriate agency for online pharmacies. It will also display the required regulatory logos on every webpage where medicines are sold, even if the GPhC voluntary logo is already visible. The website will be regularly reviewed and updated to ensure accuracy, clarity, and compliance with GPhC guidance.

1.22 Public access to pharmaceutical services will be supported through the pharmacy's website, which will feature an interactive page providing access to up-to-date health-related materials. This will include resources promoting healthy lifestyles and addressing various health concerns. However, it is important to note that under the Regulations, this requirement only permits access to pharmaceutical services via the website. The premises itself will not facilitate face-to-face delivery of essential pharmaceutical services. The pharmacy will ensure ongoing compliance with these regulatory requirements, providing a safe, accessible, and high-quality service for all users.

1.23 Here is the revised and complete version, maintaining the original word count while ensuring clarity and completeness:

1.24 ---

1.25 The website and all promotional materials will clearly outline the nature and scope of services provided by the pharmacy, specifying who is responsible for delivering each service. In cases where pharmacy services are provided at multiple locations, users will receive clear and accurate information regarding where each stage of the service is conducted, ensuring full transparency in service delivery.

1.26 The pharmacy will operate under comprehensive Standard Operating Procedures (SOPs) designed to maintain the safe sale and supply of medicines while minimizing risks to patients. These procedures will be rigorously followed by all staff members to uphold patient safety and regulatory compliance.

1.27 SOPs concerning the delivery of medicines will provide detailed instructions on the secure and effective supply of medicines via the pharmacy's own delivery driver, Royal Mail, and other courier services. This process will involve:

1.27.1 Evaluating the suitability of supply methods, ensuring all medicines, particularly refrigerated medications and controlled substances, are dispatched and delivered using appropriate and timely procedures.

1.27.2 Implementing robust identity verification measures to ensure that dispensed medicines reach the intended recipient safely and securely.

1.27.3 Assessing packaging suitability, such as tamper-proof and temperature-controlled packaging, to maintain medication integrity throughout the delivery process.

1.28 The pharmacy will actively monitor third-party delivery services, analysing patient feedback to assess delivery efficiency, timeliness, and overall service satisfaction. Adjustments to delivery operations will be made as necessary to enhance the safety and reliability of medicine supply.

1.29 All equipment used within the pharmacy will be procured from reputable manufacturers that design equipment specifically for pharmacy use. Equipment will undergo annual performance testing and review, while specialized devices, such as temperature monitoring tools, will be checked on a monthly basis to ensure accuracy. IT systems will comply with the latest security specifications, with regular updates and encrypted communication networks for both wired and wireless connections. System access will be restricted based on each employee's authority level, as determined by the superintendent pharmacist, ensuring that sensitive information remains protected.

1.30 In instances where NHS England requires further information regarding any aspect of pharmacy operations, the relevant SOP will be provided upon request, ensuring full transparency and regulatory compliance.

1.31 All essential services provided by the pharmacy will align with the following regulatory frameworks:

1.31.1 Company Standard Operating Procedures.

1.31.2 NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

1.31.3 NHS Act 2006.

1.31.4 Human Medicines Regulations 2012.

1.31.5 GPhC Professional Standards and Guidance on Distance Selling Pharmacies.

1.31.6 Relevant Data Protection laws.

1.32 This structured regulatory framework will ensure the applicant delivers safe, effective, and uninterrupted access to essential services for patients across

England during the pharmacy's operating hours. Essential services will be provided without face-to-face contact between patients (or their representatives) and pharmacy staff.

1.33 The wholly Internet/Delivery Pharmacy will operate from secure premises with controlled entry to prevent unauthorized public access. If patients request essential services in person at the premises, they will be informed that these services are not available on-site. Instead, access to NHS Essential Services will be provided through various remote communication channels, including:

1.33.1 Telephone consultations.

1.33.2 Live video calls.

1.33.3 The pharmacy's website, offering clear, detailed guidance on accessing NHS Essential Services safely and efficiently without face-to-face interaction.

1.33.4 Email correspondence.

1.33.5 Postal services.

1.34 All NHS services will be provided free of charge, in accordance with the NHS Act 2006. Essential services may be delivered using multiple communication and delivery methods, including:

1.34.1 Telephone consultations, with text messaging available when appropriate.

1.34.2 The Electronic Prescription Service (EPS).

1.34.3 The pharmacy's website for information and service access.

1.34.4 Email correspondence for patient and prescriber communication.

1.34.5 Royal Mail postal services.

1.34.6 Courier services for timely medication delivery.

1.34.7 Specialist Waste Management Services for safe medication disposal.

1.34.8 Live video consultations to enhance accessibility and patient care.

1.34.9 Specialist cold chain courier services to ensure temperature-sensitive drugs remain effective throughout storage, transportation, and final delivery. These services will be fully monitored and temperature-controlled to maintain medication integrity.

1.35 **Provision of NHS Essential Services**

1.36 **Dispensing Services**

1.37 Prescriptions will be received through the Electronic Prescription Service (EPS), via postal services, or collected from a GP surgery with the patient's informed consent. Each prescription will undergo a clinical and legal review to determine its suitability for dispensing. If any clinical or legal concerns arise regarding a prescription, the pharmacist will follow Standard Operating Procedures to resolve the issue before dispensing the medication.

1.38 In cases where prescription concerns require further clarification, the pharmacist will promptly contact the prescriber to ensure that the patient receives their medication without unnecessary delays. If required, the pharmacist will discuss prescription interventions, such as potential drug interactions or concerns related to overprescribing or under prescribing, with both the prescriber and the patient before finalizing the dispensing and delivery of the medication.

1.39 The pharmacy will ensure that all prescribed medicines are supplied safely, efficiently, and in compliance with regulatory guidelines. By employing strict protocols, leveraging secure technology, and utilizing appropriate delivery mechanisms, the pharmacy will maintain a high standard of patient care while ensuring that NHS Essential Services remain accessible to all eligible individuals throughout England.

1.40 Here is the revised version of your passage, with the same word count and altered structure:

1.41 **Repeat Dispensing Services**

1.42 Pharmacy contractors must offer appropriate advice regarding the benefits of repeat dispensing to any patient who:

1.43 (i) has a long-term, stable medical condition that is unlikely to change in the short or medium term, and

1.44 (ii) requires regular medication for that condition. The advice provided will encourage discussions between the patient and their prescriber about the suitability of repeat dispensing.

1.45 The pharmacy will provide this guidance through permissible non face-to-face communication methods, ensuring the patient is fully informed about the process.

1.46 The dispensing of repeat NHS prescriptions, including those packaged in dosette boxes as required by the Equality Act 2010, will involve collaborative efforts between patients, caregivers, pharmacists, and prescribers. This collaboration extends beyond standard dispensing practices and includes the assessment of the patient's need for repeat supply. If any clinical issues arise, these will be communicated directly to the prescriber. If necessary, the pharmacist may contact the patient by telephone to provide additional verbal advice, supplementing the written information that accompanies their repeat prescriptions. Medicines will only be supplied when the pharmacist is confident that the patient is taking the medication appropriately and is not experiencing side effects that would necessitate a treatment review.

1.47 **Urgent Supply and Emergency Supply**

1.48 Although the pharmacy's distance selling nature may result in fewer urgent or emergency supply requests compared to a traditional retail pharmacy, all staff will be thoroughly trained in the correct procedures for managing such requests. Urgent supply requests may come from either a prescriber (Urgent Supply) or a patient (Emergency Supply). For prescriber requests, the following conditions must be met:

1.48.1 The pharmacist must verify that the request comes from an authorized prescriber.

1.48.2 The pharmacist must be convinced that a prescription cannot be provided immediately due to an emergency.

1.48.3 The prescriber must agree to provide a written prescription within 72 hours.

1.48.4 The medication must be dispensed according to the prescriber's instructions.

1.48.5 Emergency supplies cannot include Schedule 1, 2, or 3 controlled substances, except Phenobarbital for epilepsy prescribed by a UK-registered prescriber.

1.48.6 EEA prescribers are not authorized to request emergency supplies of controlled substances.

1.49 The pharmacy will maintain complete records of all emergency supplies as outlined in the relevant SOP.

1.50 For patient-initiated emergency supply requests:

1.50.1 The pharmacist must conduct an interview with the patient, which can take place via non-face-to-face communication methods, such as telephone or video call.

1.50.2 A record of the supply will be entered into the POM register on the day of supply, detailing all relevant information.

1.50.3 The medication label will include the term "Emergency Supply."

1.50.4 Faxed or scanned prescriptions are not considered legally valid because they lack the required signatures and are not written in indelible ink. While such documents may confirm the existence of a valid prescription, no medication should be dispensed until the original prescription is received. Pharmacists should follow emergency supply procedures instead of dispensing based on faxed prescriptions.

1.51 **Delivery of Urgent Supplies**

1.52 When urgent supply requests are made, the pharmacy will prioritize medication delivery to the patient. For local deliveries, the driver will be notified that the

items are “URGENT.” For courier deliveries, couriers will be instructed to expedite the shipment using the fastest available route. The pharmacy will not charge patients additional fees for expedited delivery, even if the pharmacy incurs extra costs during the process. Standard delivery procedures will still apply, alongside the urgency of the delivery request.

1.53 **Disposal of Unwanted Medicines**

1.54 Patients will be offered multiple options for the safe disposal of unwanted medicines:

1.54.1 A specialist waste management company will collect unwanted medicines securely from patients and residential care homes.

1.54.2 Patients wishing to return unwanted medicines to the pharmacy can arrange for a courier service, which will be organized and paid for by the pharmacy.

1.54.3 Local patients can contact the pharmacy by phone or email to schedule a home or workplace collection of unwanted medicines by pharmacy staff. The pharmacy will provide appropriate packaging for returning medicines, and details about how to arrange this service will be available on the pharmacy’s website. Upon arrival at the pharmacy, returned medicines will be sorted and placed into disposal units for collection by a waste management service. The pharmacy’s disposal service will be promoted on its website and through various marketing materials.

1.55 **Promotion of Healthy Lifestyles**

1.56 Patients may be identified for lifestyle promotion either passively or actively. Active patients are those who access the pharmacy’s Lifestyle Questionnaire via the website or return it by post, allowing the pharmacy to identify them for follow-up support. Passive patients are identified during other pharmacy interactions, such as when they receive a prescription for medication related to conditions like high blood pressure.

1.57 All patients receiving prescriptions or purchasing medicines from the pharmacy will be encouraged to complete the Lifestyle Questionnaire, which collects information about their existing medical conditions, height, weight, and lifestyle habits, such as smoking and exercise frequency. Healthy lifestyle leaflets will be included with the patient’s medication. Patients identified as having conditions such as diabetes, coronary heart disease, COPD, asthma, or hypertension, or those at risk of developing such conditions, will be targeted with campaigns aimed at improving their knowledge and awareness of relevant health issues. The pharmacy’s website will also serve as a platform for promoting healthy lifestyles.

1.58 **Health Campaigns**

1.59 The pharmacy will participate in national health campaigns by delivering health messages to patients across England. During designated campaign periods, leaflets containing health information will be included with prescriptions, and

additional resources and guidance will be provided via the pharmacy's website. Patients will also be informed about relevant learning materials through email, text messages, and other remote communication methods.

1.60 Moreover, patients will be selected to participate in at least one clinical audit as mandated by the NHS Commissioning Board (NHSCB). This could involve:

1.61 (i) an audit conducted in compliance with NHSCB's data processing guidelines, or

1.62 (ii) an audit based on NHSCB policies to support the development of future commissioning strategies. Both types of audits will adhere to NHSCB data processing standards.

1.63 **Signposting and Support for Self-Care**

1.64 When appropriate, the pharmacy will refer patients to suitable healthcare or social care providers. The pharmacist will use the "Active and Passive" assessment method to determine whether patients would benefit from advice to reduce inappropriate use of health or social care services. If the pharmacist identifies that a patient could benefit from additional guidance in managing their condition, they will offer advice on treatment options, non-prescription medications, and lifestyle changes via remote communication methods.

1.65 If a patient:

1.66 (a) requires advice, support, or treatment not available from the pharmacy, but

1.67 (b) can be assisted by another healthcare or social care provider,

1.68 the pharmacy will provide the necessary contact details for the provider and, when needed, make a referral.

1.69 **Referral for Certain Appliances**

1.70 If the pharmacy receives a prescription for an appliance or stoma appliance customization that falls outside its usual services, the pharmacist will:

1.71 (a) Refer the prescription to another NHS pharmacist or appliance contractor with the patient's consent, or

1.72 (b) If the patient declines the referral, provide contact information for at least two NHS pharmacists or contractors capable of fulfilling the prescription.

1.73 The pharmacist will maintain records of any advice or referrals provided, ensuring proper auditing and follow-up care.

1.74 **Support for People with Disabilities**

1.75 The pharmacy will make reasonable adjustments for patients covered under the Equality Act 2010. A preliminary assessment will be conducted with the patient, caregiver, or representative to determine the necessary support for improving medication adherence. These assessments will be performed

remotely, eliminating the need for the patient to visit the pharmacy in person. Compliance aids such as dosette boxes and blister packs will be provided according to the service levels outlined in the Act.

1.76 **Clinical Governance**

1.77 Although clinical governance is not classified as an ‘essential service,’ the pharmacy will fully engage in and comply with all clinical governance requirements. This includes adherence to SOPs, reporting patient safety incidents, maintaining Continuing Professional Development (CPD) records for pharmacists and pharmacy technicians, conducting clinical audits, workforce surveys, and managing medication recalls. Information on how to submit complaints or compliments will be readily accessible on the pharmacy’s website or available upon request through phone or post.

1.78 All pharmacy staff members will either be fully qualified or undergoing nationally accredited training. They will demonstrate competency in upholding the highest clinical governance standards. Staff will receive ongoing training and development through internal programs and accredited external providers. Each team member will participate in an annual appraisal process and feedback mechanisms to support continuous professional growth and development.

1.79 Here’s the passage without the headings but with all the exact details preserved:

1.80 ---

1.81 The pharmacy will strictly adhere to the Data Protection Act, General Data Protection Regulation (GDPR), and the Access to Health Records Act 1990. The pharmacy’s Freedom of Information Act Publication Scheme will be posted on the website, with physical copies available on request. Patient data will be handled confidentially and securely in accordance with NHS and legal obligations for data protection and security. The PMR provider will ensure continuous access to the Electronic Prescription Service.

1.82 During operational hours, at least two staff members will have access to the PMS system. The NHS mail system will be checked daily for emails, including those related to the Discharge Medicines Service (DMS).

1.83 Community pharmacies, when required, may provide a three-stage service related to medication changes for NHS patients discharged from the hospital or transferred between NHS service providers. Stages two and three of this service are linked to the first prescription presented after discharge or transfer. Medication concerns can be raised with the patient, their carer, or their general practitioner.

1.84 The DMS requires pharmacies to assist NHS patients who have recently:

1.85 (a) been discharged from a hospital and referred by hospital staff for advice on medication, or

1.86 (b) been referred for support with medication management by NHS trust personnel during care transitions.

1.87 The DMS involves three stages, providing continuous support to the patient or their carer as required. Clinical judgment will guide the pharmacist's decisions, and patient confidentiality will be maintained during discussions with carers.

1.88 If the DMS referral specifies that the service should not be provided, or should stop, under conditions such as patient readmission, the pharmacy will comply.

1.89 The pharmacy will supply medicines requested under any PTP arrangements. The RP must:

1.89.1 Provide an estimate for when the medication will be ready and delivered.

1.89.2 If the medication isn't ready by the estimated time, provide a revised estimate and inform the patient of any changes.

1.89.3 Notify the patient when the medication is dispatched.

1.90 Along with standard requirements, the dispensing label will also display the applicable protocol's name.

1.91 The pharmacy has the right to refuse the supply of drugs under a PTP order if:

1.91.1 (a) The RP believes it is not a legitimate request.

1.91.2 (b) Supplying it would contradict the RP's clinical judgment.

1.91.3 (c) The RP or staff are subjected to threats or violence by the individual or their companions.

1.91.4 (d) The individual or companions threaten or commit criminal acts.

1.92 Any refusal to supply under a PTP order will be documented in the patient and/or pharmacy records.

1.93 The Responsible Pharmacist (RP) will ensure secure and timely delivery of medicines with proper instructions. Local deliveries will be handled by the pharmacy's driver, while refrigerated items will be sent via courier. National deliveries, excluding refrigerated items, will be done through Royal Mail's special delivery or courier services, requiring a signature from the patient, carer, or authorized representative.

1.94 Medicines will be packaged, transported, and delivered to maintain their integrity and ensure they reach the patient safely. A verifiable audit trail will be established from the time of request to delivery, or return in case of delivery failure. Packaging will maintain patient confidentiality, and the nature of the items will determine how they are packed to avoid damage.

1.95 Local deliveries of non-fragile items will be packed in standard pharmacy bags for prescription items. Non-toxic, non-flammable medicines will be securely

sealed in leak-proof containers, such as polythene bags for liquids or sift-proof containers for solids. Items will be placed in sturdy outer packaging with enough cushioning for protection. For postal or courier items, padded envelopes will be used to protect the manufacturer's packaging, and bubble wrap or polystyrene filler will be used inside reinforced boxes if necessary.

1.96 Fragile or large medicines will be packed in cardboard boxes with bubble wrap and protective filler. A receipt will be signed by the patient, carer, or authorized representative upon successful delivery. If the patient is unavailable at the time of delivery, a non-delivery notice will be left, and a new delivery time will be arranged.

1.97 A list of approved cold chain couriers will be maintained for cold chain items, which will be packed in styrofoam boxes marked "FRAGILE" and "FRIDGE LINE." No additional packaging will be required since the couriers use vehicles with cold chain facilities to preserve the contents. Temperature-sensitive products will not come into contact with ice packs to avoid damage.

1.98 The courier service will provide full monitoring and temperature-controlled delivery. Any cold chain breach will trigger a notification to the driver, who will follow the failed delivery protocol and inform the pharmacy for re-delivery. Products affected by a cold chain breach will not be reused.

1.99 Controlled drugs (CD) delivery will comply with legislative provisions regarding third-party possession of controlled drugs during transit between authorized individuals. The pharmacy will use specialized couriers who meet healthcare product standards, including Home Office-approved storage for controlled drugs.

1.100 Patients will be provided with packaging and instructions for returning unwanted medications. The superintendent pharmacist will decide the appropriate collection method, considering the patient's location. Patients may also be directed to alternate pharmacies if necessary. Returned controlled drugs will not be reused and will be denatured promptly. Destruction will be witnessed by another staff member, and if immediate destruction isn't possible, the drugs will be securely stored and labeled [sic] as 'Patient Returns' to avoid accidental use. A record of the destruction will be maintained in the CD Destruction Register.

1.101 A second pharmacist will cover the RP's breaks and assume responsibility for RP duties during that time.

1.102 The applicant will establish accounts with pharmaceutical manufacturers and wholesalers to improve stock availability and manage shortages. Contingency plans will address disruptions such as medication shortages, postal strikes, and EPS system failures.

1.103 The reverse side of the prescription must be completed (except for age-exempt patients) in black ink. Patients can provide exemption evidence via delivery drivers or mail, and the PMR system will be updated accordingly. Exemptions will be recorded, and payments for non-exempt patients will be processed securely online.

1.104 The pharmacy's profile will be accurately maintained in the NHS Digital Directory of Services.

1.105 The pharmacy's NHS mail address will be used to access the MHRA Central Alerting System, which will be checked daily.

1.106 Once the NHS contract is approved, the pharmacy will apply for registration with the GPhC, with an inspection conducted before services commence.

1.107 The practice leaflet will not suggest that essential services are limited to certain parts of England or imply services may be refused outside the outlined terms.

1.108 Only remotely deliverable services, which do not require physical visits to the premises, will be provided by the pharmacy."

2 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that the second comments made by the Applicant to the representations on the application, had not been circulated or seen by parties.

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

2.1 "Thank you for your response and for setting out the ICB's position. We write further to provide a clear and definitive clarification of the company's position, as requested, in order to ensure the application is considered on an accurate and lawful basis.

2.2 The documents provided during the 14-day consultation period were not submitted as Standard Operating Procedures, nor were they presented, described, or relied upon as such. They consisted of informal working material of mixed content, prepared solely to respond to specific matters raised by interested parties during consultation. They did not form part of the core application documentation and were not intended to evidence operational readiness, governance structures, or regulatory compliance in the manner required of formal SOPs.

2.3 For clarity the documents were not finalised SOPs, they had not been approved, adopted, or implemented operationally. They were not submitted for determination by the Pharmaceutical Services Regulations Committee. They were provided exclusively for explanatory and contextual purposes in response to consultation representations, and for no other purpose.

2.4 While certain sections may have resembled procedural descriptions, the documents differ materially in status, purpose, and evidential weight from SOPs formally submitted in support of a distance-selling pharmacy application.

2.5 For completeness, and to ensure the material is assessed within the correct statutory framework, we further confirm that the application relates solely to the provision of pharmaceutical services as a distance-selling pharmacy in

accordance with Regulation 64 of the Human Medicines Regulations 2012 and the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The pharmacy does not provide face-to-face services, does not operate a walk-in model, and does not supply patients on the basis of proximity to the pharmacy premises. The service is national in scope and does not compete for local pharmaceutical services.

2.6 Any references within the explanatory material to delivery arrangements, including the possible use of a delivery driver, were included only to describe limited and non-routine contingency measures to support service continuity. The pharmacy's primary operating model relies on established third-party courier services. These references were not intended to suggest, evidence, or imply the operation of a local or neighbourhood pharmacy service, and do not alter the distance-selling nature of the application.

2.7 For the avoidance of doubt, the company's sole regulated activity is the operation of a pharmacy and the lawful supply of medicines in accordance with applicable medicines and pharmacy legislation. The company does not operate, and does not propose to operate, as a GP practice, specialist medical service, nursing home, or residential care facility.

2.8 We also confirm that the "nature of business" information recorded for the company is being aligned to ensure it accurately and transparently reflects pharmacy activity, and to ensure consistency across regulatory and public records. This exercise is undertaken solely in the interests of accuracy and transparency and does not affect the substance of the application, the proposed operating model, or the company's compliance arrangements.

2.9 We recognise the ICB's duties in relation to procedural fairness and disclosure. Our concern arises from the characterisation of the consultation documents as SOPs, which risks conferring a formal status and evidential significance that they do not possess. It is this mischaracterisation that we seek to correct.

2.10 For the avoidance of doubt, we are not seeking to withhold information or depart from established process. Our position is simply that the additional material should be understood as contextual and explanatory, and not as SOPs forming part of the application evidence base.

2.11 Given that the 45-day consultation period has now commenced and cannot be revisited, we note your position. We respectfully request that, when the application is presented to the Pharmaceutical Services Regulations Committee, it is clearly recorded that:

2.11.1 The documents were not SOPs not meant to be shared with local competitors.

2.11.2 They were not submitted as SOPs.

2.11.3 They were provided solely in response to consultation concerns and do not constitute operational commitments.

2.12 We are content for this clarification to be placed before the Committee alongside the documents, to ensure they are interpreted fairly, accurately, and

within the correct regulatory context applicable to a distance-selling pharmacy application.

2.13 Should the ICB require formal SOPs to be submitted for determination at a later stage, these would be provided explicitly as such, clearly labelled, and in accordance with the established process, including any agreed redactions.

2.14 We trust this clarifies the company's position and assists the Committee in its consideration. We would be grateful if you could confirm that this clarification will be recorded and presented accordingly."

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 17 March 2026 states:

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

3.1 "NHS Coventry and Warwickshire ICB has considered the above application and I am writing to confirm that it has been refused. Please see the enclosed report for the full reasoning.

3.2 You have a right of appeal to the Secretary of State against NHS Coventry and Warwickshire 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:

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

Decision report

3.4 "**Decision:**

3.5 **Regulation 31** – refusal: same or adjacent premises

3.6 **Regulation 31(1)** A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.

3.7 **Regulation 31(2)(a)(i)(ii)** There is no pharmacy providing pharmaceutical services at the same or adjacent premises.

3.8 As **Regulation 31(2)(a)** does not apply, the Committee is not required to consider Regulation **31(2)(b)**

3.9 Therefore, the Committee concluded that it was not required to refuse the application under the provisions of Regulation 31.

3.10 The Committee then went on to consider Regulation 25.

3.11 **Regulation 25** – Distance Selling Premises Applications

3.12 **Regulation 25(2)(a)** – The NHSCB must refuse an application to which paragraph 1 applies-

3.13 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.

3.14 The Committee was satisfied that the proposed 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.

3.15 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.1 mile away.

3.16 Therefore, the Committee concluded that it is not required to refuse the application under Regulation 25(2)(a).

3.17 **Therefore**, **this regulation is deemed to have been met.**

3.18 **Regulation 25(2)(b)(i) –**

3.19 The Committee noted that the applicant provided a 186-page response to the representations received which resulted in the application being recirculated for a second 45-day consultation to interested parties as the material provided significant changes to the original application received.

3.20 The Committee noted the applicant response stating that the 186-page response were not submitted for determination by the Pharmaceutical Services Regulations Committee.

3.21 They were provided exclusively for explanatory and contextual purposes in response to consultation representations, and for no other purpose.

3.22 The Committee determined that the lack of detail contained within the documents presented to them, did not provide assurance that the premises are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.

3.23 **Therefore, this Regulation is deemed to have not been met.**

3.24 **Regulation 25(2)(b)(ii) –**

3.25 The Committee noted that the applicant provided a 186-page response to the representations received which resulted in the application being recirculated for a second 45-day consultation to interested parties as the material provided significant changes to the original application received.

3.26 The Committee noted the applicant response stating that the 186-page response were not submitted for determination by the Pharmaceutical Services Regulations Committee.

3.27 They were provided exclusively for explanatory and contextual purposes in response to consultation representations, and for no other purpose.

3.28 The Committee concluded that the limited level of detail remaining in the documents presented to them, did not provide sufficient assurance that pharmaceutical services could be delivered safely without face to face contact at the pharmacy premises between the applicant or their staff and any person receiving services, whether for themselves or on behalf of someone else.

3.29 **Therefore, this Regulation is deemed to have not been met.**

3.30 **Regulation 66**: The applicant has not undertaken to provide any directed services if the application is granted.

3.31 The Committee **refused** the application. Regulation 25(2)(a) is met. Regulations 25 (2)(b)(i) and 25 (2)(b)(ii) are not met.

3.32 The Committee determined that appeal rights to go the applicant.

3.33 **Who has right of appeal Applicant**

3.34 **Actioned for - PCSE to notify the applicant and interested parties of the decision**"

4 The Appeal

In a letter dated 8 April 2026, the Applicant, through its representative Rushport Advisory LLP, appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "I act for Healthcare Associates Limited and have been instructed by my client to submit this appeal against the attached decision of the Commissioner to refuse the above application.

4.2 As a preliminary point I note that Well Pharmacy objected to this application on the basis that it was submitted on 1 July 2026, ie after the deadline of 23 June 2026. In fact my client's application was submitted well before the deadline however PCSE requested some missing information. When my client provided the missing information they also updated the date on their application form. The initial application was submitted well before the 23 June 2026 deadline and PCSE had already allocated the case reference number by 11 June 2026 (see below email trail to confirm).

4.3 [Screenshot of email trail provided]

4.4 As the Committee will note from the Decision Report, the Commissioner's does not provide any intelligible reasons for refusing the application. Instead, the Commissioner has simply repeats [sic] parts of the legal test and then simply stated that the legal test has not been met.

4.5 As the Commissioner provides no intelligible reasons for the refusal of my client's application, this appeal focusses instead on demonstrating that my client's application meets all parts of the legal test and should be approved.

4.6 Since my client submitted its application, it has prepared a floor plan and for the sake of completeness this is attached along with this appeal. My client's premises will have a consultation room for the provision of private video and phone consultations and their premises will operate with a controlled entry system. Members of the public will not be able to access the premises.

4.7 In addition, my client has instructed me to submit the attached SOPs that have been approved by my client for use at the proposed pharmacy and we trust that these provide the Committee with sufficient detail to allow the appeal. These SOPs include a number of changes compared to the SOPs that my client submitted with its original application and the previous version of the SOPs should now be disregarded.

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

4.9 [Supporting information and updated SOPs at Appendix A for Committee]

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 Community Pharmacy Arden

5.1.1 "Thank you for your letter dated 21st April 2026, Community Pharmacy Arden would like to reiterate the representations made in our letter dated 8th December 2025 regarding the original application.

5.1.2 An application for a Distance Selling Premises (DSP) is made in accordance with regulation 25 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which includes the following:

25 (2) The NHSCB 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 the NHSCB 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 essential services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff.

5.1.3 We assume that the original application came in before the amendment regulation changes to the NHS (Pharmaceutical and Local

Pharmaceutical Services) Regulations 2013 (the PLPS regulations) agreed in the recent 2024/25 and 2025/26 negotiations between the Department of Health and Social Care (DHSC), NHS England (NHSE), and Community Pharmacy England. The DSP market entry exemption closed on 23rd June 2025.

5.1.4 The application appears to cover requirements. The only point of concern is the location being in the high street which is not usual for a DSP – efforts must be made to ensure that patients do not confuse this pharmacy with that of a local bricks and mortar community pharmacy. There are several community pharmacies in Rugby near the proposed location, some of which are within a few minutes walk."

5.2 The Commissioner

5.2.1 "When PSRC considered the application, the applicant stated that the information provided were not to be considered as SOPs. PSRC considered the information presented by the applicant and the views of a clinical adviser who reviewed the applicant's information. PSRC decided that they did not meet the criteria to be approved.

5.2.2 Rushport Advisory on behalf of the applicant have submitted a suite of SOPs which were not available to PSRC at the time of its decision. Had these SOPs been submitted with the application PSRC might have reached a different conclusion."

5.3 Rowlands Pharmacy

5.3.1 "Thank-you for the opportunity to comment on the above appeal. If the NHSR decide to convene an oral hearing, we are willing to attend under the provisions of Paragraph 8 of schedule 3 of the regulations.

5.3.2 We wish to express our concern regarding the submission of a new set of SOPs at this late stage of the process, after the application has been determined. These documents appear to provide additional assurances that the proposed pharmacy will operate in accordance with regulatory requirements; however, given their timing, we consider them insufficient to change the original outcome.

5.3.3 We respectfully request that NHSR inform us of the outcome in due course."

6 Summary of Observations

This is summary of observations received.

6.1 Community Pharmacy Arden

6.1.1 "Thank you for your letter of 27th May 2026 regarding the above. Community Pharmacy Arden have nothing to add to our previous response of 22nd April 2026 but would like to reiterate the point of concern regarding the location being in the high street which is not usual for a DSP. Efforts must be made to ensure that patients do not confuse

this pharmacy with that of a local bricks and mortar community pharmacy. We wish to be kept informed of any further correspondence or updates."

7 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

7.6 The Committee noted the Applicant had stated "*N/A Not applicable as no other pharmacy in the same or adjacent premises*" in the application and the Commissioner had determined that "*…it was not required to refuse the application under the provisions of Regulation 31.*" The Committee saw no dispute on the matter from other parties.

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

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.11 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application is 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 Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied 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)

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

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

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

7.15 The Committee has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case,

that evidence put forward has taken the form of SOPs provided on appeal which the Applicant has prepared or commissioned.

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

7.17 The Committee first considered how the Applicant would provide essential services without interruption and noted the Commissioner had determined that "*…the lack of detail contained within the documents presented to them, did not provide assurance that the premises are likely to secure the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services.*"

7.18 The Committee noted the following information in the Applicant's SOPs:

7.19 SOP 1: 'Introduction and Background to SOPs'

7.19.1 "*1.3 Overriding provisions Applicable to All SOPs*

… In order to comply with our terms of service, this pharmacy will provide;

The uninterrupted provision of pharmaceutical services, during the opening hours of the premises, to persons anywhere in England who request those services."

7.20 SOP 33: 'The Responsible Pharmacist'

7.20.1 "33.9 *Absence of the RP*

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]

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."

7.21 With regard to essential services being available to persons anywhere in England, the Committee noted the following information in the Applicant's SOPs:

7.22 SOP 1: 'Introduction and Background to SOPs'

7.22.1 "*1.3 Overriding Provisions Applicable to All SOPs*

In order to comply with our terms of service, this pharmacy will provide… to persons anywhere in England who request those services."

7.23 SOP 3: 'Procedures for NHS Pharmaceutical Services'

7.23.1 "*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.*"

7.24 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact and noted the Commissioner had determined that "*…the limited level of detail remaining in the documents presented to them, did not provide sufficient assurance that pharmaceutical services could be delivered safely without face to face contact at the pharmacy premises between the applicant or their staff and any person receiving services, whether for themselves or on behalf of someone else.*" The Committee also had regard to Community Pharmacy Arden's comment that "*The only point of concern is the location being in the high street which is not usual for a DSP – efforts must be made to ensure that patients do not confuse this pharmacy with that of a local bricks and mortar community pharmacy.*"

7.25 The Committee noted the following information in the Applicant's SOPs:

7.26 SOP 1: 'Introduction and Background to SOPs'

7.26.1 "*1.3 Overriding Provisions Applicable to All SOPs*

… In order to comply with our terms of service, this pharmacy will provide; …

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.

… 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.

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."

7.27 SOP 3: 'Procedures for NHS Pharmaceutical Services'

7.27.1 "*3.1 Communication Channels*

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 using the pharmacy's secure system.

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."

7.27.2 "*3.2 Request for face-to-face service provision*

OUR PHARMACY OPERATES FROM SELF-CONTAINED PREMISES THAT USE A CONTROLLED ACCESS SYSTEM. MEMBERS OF THE PUBLIC ARE NOT ABLE TO ATTEND THE PREMISES TO RECEIVE ANY NHS SERVICES [Emphasis in SOPs]

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;

Inform the person that, we cannot provide any face to face NHS services

Refer the person to the Responsible Pharmacist if they require any further explanation."

7.28 The Committee was mindful of the regulatory changes as of 1 October 2025 and 31 March 2026, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services) face to face with the patient at the pharmacy premises. As a result of this amendment, the Committee noted that the Applicant would not be able to provide any pharmaceutical services to patients present at its premises.

7.29 The Committee noted the Applicant had indicated in the application form that it does not propose to provide any directed services.

7.30 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

7.30.1 "*3.3 Provision of Advanced or Enhanced Services*

The Pharmacy does not provide advanced or enhanced services to patients on the premises. NMS will be conducted remotely with no patients accessing the service at the premises (see NMS SOP).

Pharmacy First will be provided remotely if the pharmacy has been approved to provide the service (see Pharmacy First SOP)."

7.31 The Committee also noted SOP 7 'The New Medicine Service ("NMS")' which states "*The service must be provided remotely by phone or video call*" and also SOP 8 'The Pharmacy First Service' which states "*Patients may not attend the premises to receive the service and the service must be provided remotely*".

7.32 The Committee was aware that if 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.

7.33 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 provided without face to face contact. The Committee went on to consider whether the safe and effective provision of pharmaceutical services was likely to be secured.

7.34 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

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

7.36 The Committee noted SOP 3 'Procedures for NHS Pharmaceutical Services' states:

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

7.37 SOP 6 'Prescription Receipt & Exemption Checking' states:

7.37.1 "*6.2 Scope*

All online services including the following:

… NHS Prescriptions."

7.37.2 "*6.7 Administration Checks*

Check all prescriptions received in the post against printed and written prescription reception forms. Check the corresponding prescription has been received in the post…"

7.38 SOP 19 'Order Delivery' states:

7.38.1 "*19.6 Choice of Delivery Method*

*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 must 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 (see below).*" [Emphasis in SOPs]

7.39 On the basis of the information supplied, 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.

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

Urgent supply without a prescription

7.41 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.

7.42 The Committee noted SOP 16 'Emergency Supply and Urgent Supply' which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means 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.

7.43 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

7.44 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.

7.45 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking states:

7.45.1 "*6.9 Exempt NHS Prescriptions*

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, but see NOTE below) 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."

7.46 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.

7.47 The Committee considered whether the Applicant had explained how charges will be paid.

7.48 The Committee noted SOP 6 'Prescription Receipt & Exemption Checking' states:

7.48.1 "*6.12 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

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

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

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."

7.49 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

7.50 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).

7.51 The Committee noted SOP 19 'Order Delivery' states:

7.51.1 "*19.10 Transfer to the Delivery Driver*

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

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

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

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

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

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.

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."

7.51.2 "*19.11 Delivery of prescription to patient or representative address*

… Ask the patient/representative for their name and address.

Check the patient name and address against the prescription and the bag label. Patient confidentiality should be maintained at all times, especially if delivering to a representative.

Where appropriate ask the patient or representative to complete the reverse of the prescription.

Hand the medication to the patient or representative.

Ask the patient or representative to sign their details on the delivery sheet. If they are unable to sign the delivery sheet the delivery driver should sign on their behalf with their consent and write a note explaining the reason the patient or representative could not sign.

If necessary, collect any medication returns. Always use the Patient Returned Medication Tray that is available in the delivery vehicle. Refer to the Patient Returned Medicines SOP for further guidance."

7.51.3 "*19.12 Successful delivery*

Once the deliveries are completed, return the delivery sheets to the pharmacy on the same day. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years."

7.51.4 "*19.13 Unsuccessful Delivery*

If the patient or representative is not able to receive the delivery of their medication, complete the 'attempted delivery' form and post it through the letterbox. The form will have details for arranging re-delivery.

The prescription and medication must be returned to the pharmacy on the same day and the pharmacist informed of the unsuccessful delivery.

The pharmacy must follow up the unsuccessful delivery by contacting the patient to arrange a second delivery time.

DO NOT:

Post the medication through the letter/post box.

Leave the medication in the porch or any other out building.

Leave the medication at an unauthorised address."

7.51.5 "*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

Follow preparation for delivery process. The pharmacist must contact any patients for whom there are relevant messages or counselling required.

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

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

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

Confirm details of all prescriptions to be delivered.

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

Ensure Royal Mail driver signs Delivery Log sheet for all prescriptions being accepted for delivery. The delivery sheets must be scanned into the pharmacy IT system and kept for a minimum period of 7 years.

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

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

7.51.6 "*19.15 Unsuccessful Delivery via Royal Mail*

In the event of an unsuccessful delivery, Royal Mail will leave a 'Sorry We Missed You' card, stating the date and time of the attempted delivery. The patient can then either choose to collect and sign for their medicines at their local post office, or rearrange delivery for a convenient time by telephone or email."

7.51.7 "*19.16 Cold chain delivery via courier*

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.

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.

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.

… 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.

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

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

7.51.8 "*19.17 Unsuccessful cold chain delivery via courier*

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.

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."

7.51.9 "*19.18 Breach of Integrity of Cold Chain*

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

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.

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."

7.52 SOP 23 'Controlled Drugs: Delivery' states:

7.52.1 "*23.5 Delivery of Schedule 2 & 3 CDs*

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.

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

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.

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

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

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.

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'.

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."

7.52.2 "*23.7 Successful Schedule 2 & 3 Delivery*

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 their authorised representative.

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."

7.52.3 "*23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

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."

7.52.4 "*23.9 Unsuccessful Schedule 2 & 3 Delivery via courier*

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.

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."

7.52.5 "*23.10 Note re Use of Couriers for Controlled Drugs Deliveries*

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."

7.53 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.

7.54 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.

7.55 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated "*Drug Tarriff Part IX except items that require fitting or measuring*". The Committee noted the Applicant's SOPs state:

7.56 SOP 9 'Pharmaceutical & Legal Assessment':

7.56.1 "*9.9 Items Requiring Measuring and Fitting*

Where a prescription is received for an item that requires measuring or fitting the patient should be contacted and informed that these items are not available from this pharmacy as we do not provide a measuring and fitting service. Patients should be signposted to at least two other providers of the service in their area, or if they consent the prescription can be referred directly to another NHS pharmacist or appliance contractor. (see signposting SOP)"

7.57 SOP 26 'Support for Self-Care, Signposting and Health Promotion':

7.57.1 "*26.14 Items Requiring Measuring and Fitting*

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)"

7.58 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.

7.59 The Committee considered whether the Applicant had explained what containers will be "suitable" for posted/delivered items.

7.60 The Committee noted that SOP 18 'Bagging-Up' states:

7.60.1 "*18.7 Choice of Packaging*

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

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

Medicine for local delivery which is 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.*

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

For postal items, either:

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

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

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

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 in SOPs]

7.61 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(15) of Schedule 4.

Refusal to provide drugs or appliances ordered

7.62 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 regime has not changed in any way and there has been no changes to the patient's health, which may indicate the desirability of review the patients treatment.

7.63 The Committee noted SOP 34 'Repeat Dispensing' states:

7.63.1 "*34.10 Prescription Reception*

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

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."

7.63.2 "*34.11 Pharmaceutical & Legal Assessment*

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.

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

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

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

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

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

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

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

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.

The prescriber must have signed the RA. The RDs will not be signed but will be numbered as appropriate. The RA will detail the specific number of issues and, if appropriate, the dispensing interval."

7.64 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

7.65 The Committee considered whether the Applicant had explained how appropriate advice about the benefits of repeat dispensing is given to any patient who (i) has 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.

7.66 The Committee noted SOP 34 'Repeat Dispensing' states:

7.66.1 "*34.10 Prescription Reception*

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

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

requires regular medicine in respect of that medical condition, including, where appropriate, advice that encourages the patient to discuss repeat dispensing of that medicine with a prescriber at the provider of primary medical services whose patient list the patient is on.

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

On receipt of a repeatable prescription from the patient, 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. Contact the patient to discuss the service and confirm if they wish to access the information leaflet online, by email or by post.

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."

7.66.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

7.67 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

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

7.69 The Committee noted SOP 24 'Controlled Drugs: Collection and Disposal of Patient Returns' states:

7.69.1 "*24.5 Patient Returned Medication*

This service is available to <u>all</u> patients living in England.

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

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

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.

The process for returning medication must be explained to the patient.

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 – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

7.69.2 "*24.7 Return by Royal Mail*

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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)

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.

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

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.69.2.1"24.8 Handling Patient-Returned CDs from Delivery Driver

Drivers need to:

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.

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.

Pharmacy staff need to:

If CDs have been identified, immediately on receipt from the driver, secure them in a bag, clearly marking on 'Patient-returned CDs for destruction' and include the date of return; place the bag in the CD cabinet away from pharmacy stock until they can be destroyed.

As soon as possible, Refer to the 'Returned medicines form' to make the entry in the 'Patient returned CD register', to record the CD that require destruction at a later date."

7.69.3 SOP 25 'The Safe and Effective Receipt and Disposal of Medicines' states:

7.69.3.1"25.6 Process for Patients to Return Medication

Patient Returned Medication

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

This service is available to all patients living in England.

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

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

Patients may

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

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,

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

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).

Explaining the process to patients

Check which patient or patients the medication belonged to.

Check the relevant PMR to identify any hazardous / dangers drugs or items that have been dispensed and could potentially form part of the return.

Ask the patient to identify the type of medication being returned.

If there is any item considered dangerous, such as a cytotoxic, inform the patient that we will collect items using the specialist waste management contractor and arrange for that collection to take place at a convenient time.

Go through the "unwanted medicines card" (available from the CPE website) over the phone with the patient"

7.69.4 "*25.7 Process for accepting patient returns by the Driver*

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.

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

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

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'.

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.

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

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

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.

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

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

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

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

7.69.5 "*25.9 Return by Royal Mail*

*The pharmacist mus**t***

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

Assess the items for suitability for return by Royal Mail

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)

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.

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

Contact the patient to ensure that the packaging has been received

Provide signposting via phone or email to other pharmacies where the patient prefers to dispose of unwanted medicines locally."

7.69.6 "*25.10 Disposal of returned medicines*

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.

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."

7.70 Based on all of the information before it, 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

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

7.72 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.72.1 "*27.3 Identification of patients for promotion of Healthy Lifestyles*

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

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

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

As part of repeat dispensing process (or during any other interaction with a patient) 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.

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."

7.72.2 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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.

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."

7.73 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

7.74 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.

7.75 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.75.1 "*27.6 Long Term Conditions*

If it is appropriate to provide advice the pharmacist should provide any advice necessary and within their area of competency. Where advice is provided it should be recorded on an Intervention & Referral form. Any advice given should always aim to include counselling on healthy lifestyle as well as management of the long-term condition.

If it is not appropriate to provide advice the patient should be referred to the appropriate health or social care provider or support organisation (see Signposting SOP). Where advice cannot be provided it should be recorded on an Intervention & Referral form along with the referral organisation.

For specific groups of patients (those with diabetes, at risk of coronary heart disease, especially those with high blood pressure, and patients who smoke or who are overweight) the pharmacists must provide advice without face-to face interaction (eg telephone, Live video, via the website). Such advice should be backed up, as appropriate, by the provision of written material such as leaflets."

7.75.2 "*27.7 Identification of patients for Support with Long Term Conditions*

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

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

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

As part of repeat dispensing process (or during any other interaction with a patient) 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.

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."

7.76 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

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

7.78 The Committee noted SOP 27 'Promotion of Healthy Living, Lifestyle & Health Campaigns' states:

7.78.1 "*27.4 Health Campaigns & Community Engagement Exercise*

Terms of Service require participation in a maximum of 2 campaigns per financial year, but you should agree to take part in all campaigns where practicable.

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.

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.

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

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

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

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

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.

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."

7.79 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

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

7.81 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.81.1 "*26.10 Other Provider Organisations and Support Details*

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.*"

7.81.2 "*26.12 Signposting*

Service Description

To minimise inappropriate use of health and social care services and support services, patients who require further support, advice or treatment which cannot be provided by the pharmacy, on other health and social care providers or support organisations who may be able to assist the person must be given sufficient information to enable them to access those services. Where appropriate, this may take the form of a referral."

7.81.3 "*26.13 Patient Identification*

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.

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

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

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

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."

7.82 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

7.83 The Committee considered whether the Applicant had explained how it will provide advice and support to people caring for their families.

7.84 The Committee noted SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.84.1 "*26.8 Patient Identification*

As part of repeat dispensing process / medicine sale or during any other interaction with a patient staff should record the information provided by patients on the PMR system. Where a patient provides information that indicates that they would benefit from support for self-care they should be recorded as a 'target patient' and the appropriate information that is relevant to them should be provided and should include:

treatment options, including advice on the selection and use of appropriate drugs which are not prescription only medicines; and

on changes to the patient's lifestyle."

7.84.2 "*26.9 Service outline*

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.

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

… 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."

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

Discharge medicines service

7.86 The Committee considered whether the Applicant had 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.

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

7.88 The Committee noted SOP 28 'Discharge Medicines Service ("DMS")' states:

7.88.1 "*28.3 Process*

Every day the RP must check the pharmacy's NHS.net Connect 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"."

7.88.2 "*28.4 Consent*

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

7.88.3 "*28.5 DMS Stages*

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."

7.88.4 "*28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)*

The community pharmacy receives a discharge referral. A clinical review is undertaken by a community pharmacist following receipt of a patient referral. The community pharmacy team may contact the referring NHS trust contact or the PCN pharmacy team to discuss any concerns (eg an important medicine the patient usually takes is omitted on the discharge referral) and to seek clarification about the discharge referral."

7.88.5 "*28.7 Considering the appropriateness of any medication changes prior to discharge*

DMS requests will not necessarily all be in the same form.

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

The pharmacist must review the actions requested in the DMS and consider whether the actions requested are, in the pharmacists clinical judgement, appropriate.

For actions that are considered appropriate the pharmacist must;

Use the information in the referral, to compare (as far as possible) the patient's medicines at discharge to those they were taking before admission to hospital.

Check any prescriptions issued to be dispensed to assess whether any changes are appropriate and identify any areas of concern.

Where necessary, discuss changes that may be appropriate or raise any issues of concern identified, to the extent that in accordance with the pharmacist's clinical judgement, it appropriate to do so with—

(i) the staff of the hospital or other provider of NHS services that made the referral, and

(ii) any provider of primary medical services on whose patient list the patient is; and

keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stages 2 and 3 of the service)."

7.88.6 "*28.8 DMS Stage 2*

The community pharmacy receives the first prescription following discharge. The pharmacist or pharmacy technician will ensure medicines prescribed post-discharge take account of the appropriate changes made during the hospital admission. If there are discrepancies, the pharmacy team will try to resolve them with the general practice, utilising existing communication channels. Alternatively, the community pharmacist may refer the patient to the PCN pharmacy team for a Structured Medication Review or other intervention.

If the pharmacy receives either a written or electronic prescription (or repeatable prescription) or EPS token and the pharmacy as received a request for Stage 2 of the DMS service either from Stage 1 or

Even without a referral to Stage 2, the pharmacy receives such a prescription as described above and the pharmacy is aware as a result of an earlier referral to Stage 2 or Stage 3 that this is the first prescription for a medicinal product following the patient's discharge from hospital, or a transfer of the patient's care from another NHS service provider, AND

The pharmacy is aware that either the patient, or their carer wishes the pharmacy to provide Stage 2 of the DMS service then the pharmacy must provide the following service as part of Stage 2

Then the pharmacist must:

Review / perform a further review of any prescription

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.

Specifically consider if in your clinical judgement appropriate account has been taken to any changes in the medication regimen during the patient's stay in hospital or prior to the transfer of the DMS from another pharmacy.

Where you see areas of concern, raise those issues as appropriate with the patient's GP

Keep and maintain records of the DMS referrals received and of any actions taken, as appropriate (in particular, to support delivery of stage 3 of the service)."

7.88.7 "*28.9 DMS Stage 3*

The NHS Discharge Medicines Service should also be used as an opportunity to engage with patients about their medicines on a shared decision-making basis. Whether the patient or their carer makes contact themselves for advice, a referral is received from an NHS trust on discharge or a prescription is received following prescribing changes, the pharmacist or pharmacy technician should take the opportunity to establish the patient's understanding of their condition(s), their associated medications and how each medicine can be best administered to get optimum benefit and reduce unwanted side effects.

The community pharmacy checks the patient's understanding of their medicines regimen. The pharmacist or pharmacy technician will hold a discussion, adopting a shared decision-making approach, with the patient (or the carer if appropriate) to check their understanding of their post-discharge medicines' regimen. The pharmacist or pharmacy technician will identify any adherence, clinical issues, outstanding questions or needs the patient may have regarding their medicines."

7.89 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

7.90 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.

7.91 The Committee noted that SOP 26 'Support for Self-Care, Signposting and Health Promotion' states:

7.91.1 "*26.11 Health promotion zone on our website*

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

Explaining the Interactive Page to Patients

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.

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.

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.*"

7.92 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.

Summary

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

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

7.94.1 confirm the Commissioner's decision;

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

7.94.3 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.

7.95 The Committee was mindful that it had been provided with additional information which was not available to the Commissioner at the time it made its decision. Given that it had reached a different decision to that of the Commissioner, the Committee determined that the decision of the Commissioner must be quashed.

7.96 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.

7.97 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.

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

8.2.2.1 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;

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

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

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

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals