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REF: SHA/26789

APPEAL AGAINST LANCASHIRE AND SOUTH CUMBRIA ICB DECISION TO REFUSE AN APPLICATION BY CURE CLINICS DISPENSING SERVICES LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 10 CABLE COURT, PITTMAN WAY, PRESTON PR2 9YW UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Cure Clinics Dispensing Services Ltd
Preston Pharmacy
Community Pharmacy Lancashire and South Cumbria
PCSE on behalf of Lancashire and South Cumbria ICB

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1 The Application

By application dated 17 June 2025, Cure Clinics Dispensing Ltd ("the Applicant") applied to Lancashire and South Cumbria ICB ("the Commissioner") for inclusion in the pharmaceutical list at 10 Cable Court, Pittman Way, Preston, PR2 9YW under Regulation 25. In support of the application it was stated:

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

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

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

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 “Services will be delivered remotely, supported by robust digital infrastructure, standardised workflows, and contingency planning.

1.9 Patients anywhere in England can access essential services through secure digital and telephone channels.

1.10 PMR systems manage prescription tracking, dispensing, and delivery, with workflow visibility for the whole team, reducing errors and ensuring continuity of care.

1.11 Trained pharmacy staff operate under defined escalation procedures. Cover arrangements and SOPs ensure business continuity in the event of absence or increased demand.

1.12 We use tracked signed for courier services to ensure reliable, nationwide medication delivery, including secure delivery confirmation protocols and contingencies for failed deliveries.

1.13 Activity is monitored digitally via Power Automate and PMR integration to identify delays or risks, which are escalated to the Responsible Pharmacist and/or Superintendent as required.

1.14 Our service model is designed to be fully remote and non-public-facing. We do not accept in-person visitors, and our SOPs reflect this.

1.15 All interactions occur via secure phone or email channels. For patients with accessibility needs, we offer alternative formats and can speak directly to parents/guardians where the patient is under 18.

1.16 All clinical checks, verifications, and prescription interventions are carried out via digital means. SOPs govern the safe supply of medicines, including controlled drugs, without the need for physical interaction.

1.17 Our team work from private, access-controlled areas. PMR access is role-specific with individual logins. Conversations about patient care occur confidentially and are never conducted in public or shared areas.

1.18 Our premises is on a secure business park with gated access (no public footfall). Should a patient attend the premises in person, a clear notice is displayed informing them that this is a non-patient-facing pharmacy.”

1.19 [A floor plan was submitted and this is included at Appendix A].

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 22 October 2025 states:

2.1 "Lancashire and South Cumbria 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."

Extract from the "Determination – Pharmaceutical Services Group – Wednesday 15 October 2025"

2.2 "The application is for distance-selling with no patient access to essential services face-to-face and gives assurances that:

2.2.1 the premises listed in the application are not on the same site or in the same building as a GP practice

2.2.2 the applicant is not seeking to restrict the provision of essential services in any way

2.2.3 there will be uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services

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

2.3 Using the NHS website, there are 3 other pharmacy contractors within 1 mile of the proposed premises. There is 1 GP practice currently listed within 1 mile of the proposed premises.

2.4 Using googlemaps, the proposed premises appears to be part of a commercial buildings. Access to the proposed premises is at street level.

2.5 It is not on the same site or in the same building as a provider of primary medical services with a patient list.

2.6 In representations, concerns raised included about the layout and security of the premises, cold chain and waste procedures and face-to face interactions.

2.7 The Applicant has provided evidence to maintain that granting of the application will support the provision of services and that they will be provided and accessible to patients. The Applicant supported this by providing the information regarding how it intends to carry on the provision of services.

2.8 All representations were considered, including from the Applicant.

2.9 Within the 45-days consultation period, representations were received from:

2.9.1 Boots

2.9.2 Community Pharmacy Lancashire and South Cumbria (CPLSC)

2.9.3 Preston Pharmacy

2.10 Outline of Representations

2.11 **Boots** trusts that the determining committee will consider all aspects of the relevant Regulations and its opinion is that this application should be refused.

2.12 **Boots** believes that there is limited information included within the application to satisfy the committee that the regulation will be met. There is limited information included on how the applicant will ensure there will be no face-to-face provision at the premises or how they will maintain a cold chain delivery or the supply of controlled drugs for example.

2.13 **CPLSC** opposes the application, questioning whether the services will be carried out in a professional way (e.g., dispensary layout and access/security) according to the 'generic' set of procedures submitted and whether there is a benefit of another pharmacy in the area, particularly when not opening on weekends.

2.14 **CPLSC** notes that:

2.14.1 The floorplan should be considered with regards to security.

2.14.2 The applicant has failed to demonstrate compliance with regulations, especially uninterrupted service provision along with safe and effective provision.

2.14.3 No supporting documentation or SOPs to support this. The application does not sufficiently explain how essential services will be delivered in a manner that meets the requirements of Regulation 25(2)(b), particularly the obligation to avoid face-to face contact at the pharmacy premises.

2.14.4 Given these deficiencies, CPLSC believes the application does not meet the regulatory standards and should therefore be refused.

2.14.1 Provides a summary of and a report from 2023 regarding DSPs and contractual obligations.

2.15 In summary, **CPLSC** submits that the application lacks sufficient detail on how essential services will be delivered uninterruptedly and safely without face-to-face contact, as required under Regulation 25(2)(b).

2.16 **Preston Pharmacy** objects and supports rejection of the application by noting:

2.16.1 The applicant does not mention how they would take prescription charges therefore they will not be able to deliver a safe and efficient service.

2.16.2 The applicant does not say how they would provide self-care advice across England, therefore the service provision will not be national.

2.17 There were no responses to the representations from interested parties.

2.18 **ICB Professional Advisor** – following assessment of the Application, the Professional Advisor has noted:

2.18.1 The ICB does not approve or authorise SOPs for any contractor.

2.18.2 It is observed that the SOPs provided are 'generic'.

2.18.3 No SOPs to cover essential services provision

2.18.4 Inadequate definition for cold chain arrangements

2.18.5 In any contractual or controlled drugs visit undertaken by the ICB, we will consider the observed pharmaceutical practices in line with the prevailing or most current SOPs available.

2.18.6 Overall, advise that the specific assertions are not adequate to assure the Group fully.

Regulation 31

2.19 The Group noted that Regulation 31 does not apply, as the applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide.

2.20 The Group therefore considered the application under Regulation 25, set out below, and took into account all information provided by the applicant and interested parties. The Group determined the following:

"Distance selling premises applications

25.— (1) Section 129(2A) of the 2006 Act(c) (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 also in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.

2.21 The application has been checked, and all relevant information is provided and meets the criteria of the Regulations, including Fitness to Practise. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

(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

2.22 The premises listed in the application are not on the same site or in the same building as a provider of primary medical services with a patient list. From the evidence provided in the application it is felt that the ICB can confirm that the applicant meets this element of the regulations.

(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

2.23 The applicant has stated the services and hours that will be provided at the new site, but this is not supported by procedures to evidence uninterrupted provision of services. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

(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."

2.24 Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain and the support of essential services (e.g., self-care). From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

2.25 **Decision – REFUSED.**

2.26 Appeal Rights to the Applicant."

3 The Appeal

In an online appeal form dated 19 November 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

"Introduction & Background

3.1 This application was submitted under Schedule 2, Paragraph 17 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as an exempt contract type—specifically a Distance Selling Pharmacy (DSP). Accordingly, the application should have been determined solely under Regulation 25, which sets the statutory test for DSPs and requires the decision-maker to be satisfied that the pharmacy's procedures will:

(i) secure the uninterrupted provision of essential services during opening hours to persons anywhere in England who request them; and

(ii) secure the safe and effective provision of those essential services without face-to-face contact between any recipient and the applicant or its staff.

Cure Clinics Dispensing Services Ltd (CCDS) respectfully appeals the decision dated 22 October 2025, by Lancashire & South Cumbria ICB, refusing our application for inclusion at 10 Cable Court, Preston solely on the basis that the ICB was "not satisfied that the procedures would secure uninterrupted and safe provision of essential services under Regulation 25(2)(b)".

3.2 The ICB's professional adviser concluded:

3.2.1 The ICB does not approve or authorise SOPs for any contractor.

3.2.2 It is observed that the SOPs provided are 'generic'.

3.2.3 No SOPs to cover essential services provision.

3.2.4 Inadequate definition for cold chain arrangements.

3.2.5 In any contractual or controlled drug visit undertaken by the ICB, we will consider the observed pharmaceutical practices in line with the prevailing or most current SOPs available.

3.2.6 Overall, advise that the specific assertions are not adequate to assure the Group fully.

3.3 In its refusal, the Integrated Care Board (ICB) concluded;

3.3.1 The applicant has stated the services and hours that will be provided at the new site, but this is not supported by procedures to evidence uninterrupted provision of services. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

3.3.2 Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., security of premises, cold chain and the support of essential services (e.g., self-care). From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations.

3.4 CCDS respectfully submits that this reasoning was procedurally and substantively flawed.

Application Guidance and Process Constraints

3.5 The NHS England DSP Application Form (Annex 1, Section 7.1) explicitly states:

"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."

3.6 CCDS complied exactly with that instruction. The Pharmacy Market Administration Services Market Entry Online Portal did not provide any mechanism for uploading SOP documents, and the response field for Section 7.1 was restricted to fewer than 350 words — insufficient to reproduce detailed procedural content covering six essential services, cold-chain governance, and controlled-drug processes.

3.7 Consequently, our narrative submission summarised those processes concisely, as required by the guidance—rather than attaching full SOPs. The refusal decision therefore mischaracterises the evidence: the ICB stated that "generic SOPs were provided" when none were submitted, and simultaneously that "no SOPs covering essential services were included." Both statements cannot be true.

3.8 The absence of attached SOPs was not an omission but compliance with NHS England's own instructions and a limitation of its online portal. It is disproportionate to penalise CCDS for adhering to the specified process.

New Evidence and Structure of This Appeal

3.9 In this appeal, CCDS provides a comprehensive and transparent evidential pack to address every concern raised and to demonstrate unequivocal compliance with Regulation 25(2)(b)(i) and (ii).

3.10 The document therefore contains:

3.11 A detailed narrative response mapping each element of the ICB's reasoning to the corresponding SOP, system, or procedure already operational at 10 Cable Court;

3.11.1 Standard Operating Procedures (SOPs)

3.11.2 Uninterrupted Nationwide Service Provision

3.11.3 Cold Chain Medicines Management

3.11.4 Controlled Drugs (CD) Handling and Disposal

3.11.5 Secure Delivery and Logistics

3.11.6 Non Face-to-Face Service Model (Remote Clinical Services & Patient Support)

3.11.7 Advanced Digital Infrastructure (Connect™, Titan, and PharmAppy)

3.12 SOP examples (attached to email) [see Appendix B] demonstrating site-specific and fully implemented procedures in the three domains the ICB questioned most:

3.12.1 Cold Chain Management – validated packaging, temperature monitoring, incident escalation, and courier audit trails.

3.12.2 Controlled Drug Governance – prescription handling, secure storage, witnessed destruction, patient-returned CD disposal, and audit reconciliation.

3.12.3 Remote Provision of Essential Services – Disposal of Unwanted Medicines (including Controlled Drugs)

3.13 A full SOP Index (Annex A) [see 3.78 below] covering all essential services, together with governance, clinical safety, and business-continuity protocols.

3.14 Floorplans of our GPhC registered pharmacy premises (attached to email). [Appendix C]

3.15 These inclusions go far beyond what the Regulations require. They evidence a live, GPhC-inspected, operational DSP already delivering safe, compliant, and uninterrupted services to private patients nationally—the same infrastructure proposed for NHS service delivery.

Operational Status and Compliance

3.16 CCDS is already a General Pharmaceutical Council–registered distance-selling pharmacy (Reg. No. 9012825) trading as Pharmacy by Cure Clinics.

3.17 The Superintendent Pharmacist, [BMK] (GPhC #[XXX]), oversees an experienced clinical and operational team from secure, non-public premises at 10 Cable Court. The site is fully equipped, inspected, and accessible to NHS England or the ICB for verification; no site visit was undertaken prior to refusal.

3.18 Our systems will integrate Titan PMR, PharmAppy, and Connect™ by Cure Clinics, enabling safe remote dispensing, ID verification (Veriff), automated exemption capture, temperature-logged cold-chain dispatch, and tracked delivery via Royal Mail Tracked 24 with signature capture. The same infrastructure already supports thousands of private prescriptions per month without a single service interruption or cold chain breach.

Conclusion

3.19 CCDS therefore submits that the original refusal:

3.19.1 was not based on a fair or accurate reading of the application,

3.19.2 assessed evidence that the process itself did not permit to be submitted, and

3.19.3 failed to apply the statutory test correctly under Regulation 25(2)(b).

3.20 We have now supplied the comprehensive evidence that the ICB did not review, clearly demonstrating that our procedures secure both the uninterrupted and safe remote provision of all essential services nationwide. Accordingly, CCDS respectfully requests that NHS Resolution uphold this appeal and direct that the application be granted.

Standard Operating Procedures (SOPs)

3.21 **Acknowledgement:** The decision letter noted that the SOPs provided were “generic” and did not cover essential services in sufficient detail. Elsewhere in the determination feedback it stated we didn’t provide SOPs to cover essential services provision. We accept that the narrative in our application, while outlining our approach, did not include the full context of our SOPs. We must however point out that, we did not in fact submit any SOPs as the online portal

did not provide an upload facility to do so. Unfortunately, this resulted in the Committee being unable to verify the depth of our procedures.

3.22 **Clarification:** CCDS has a complete, robust SOP portfolio governing every aspect of our pharmacy operations – from dispensing processes and clinical checks to cold-chain shipping, controlled drug handling, and remote patient counselling. These SOPs are company-specific (not off-the-shelf generics) and have been developed in line with GPhC standards and NHS contractual requirements. For example, we maintain SOPs for: Dispensing and accuracy checking, Data security and confidentiality, Pharmacist availability and oversight, Business continuity (unplanned downtime or staff absence), Cold Chain Management, Controlled Drug safe custody and destruction, Delivery and Failed Delivery handling, Essential Services delivery (each service area has a dedicated SOP), Complaints and Incident reporting, etc. Each SOP has been reviewed and approved by our Superintendent Pharmacist, has been internally tested during our existing private service operations and were available to the GPhC inspector during our pre-registration visit in July 2025.

3.23 To support this appeal, we have listed key SOPs and included them in Annex A (SOP Index) [see 3.78 and Appendix B]. These demonstrate, point-by-point, how our procedures align with the specific obligations of a DSP under Regulation 25(2)(b). We emphasise that had the application portal permitted multiple file uploads, we would have gladly provided this documentation at the outset. The lack of SOP or further detail attachments was a submission issue, not a procedural gap. We regret any confusion this caused. Moving forward, we are fully prepared to share our entire SOP set with NHS England or the Appeals Committee for verification. The comprehensive nature of our SOPs should assure reviewers that CCDS's procedures are likely to secure uninterrupted, safe services – the very test that Regulation 25(2)(b) requires.

Uninterrupted Nationwide Service Provision

3.24 One of the core requirements for a DSP is to provide essential services continuously during opening hours to any person in England who requests them. The ICB was not fully convinced that our application demonstrated how we would achieve "uninterrupted" service for all patients nationwide. We would like to reinforce how our operational model and contingencies already ensure continuity of service:

3.25 **Opening Hours & Capacity:** Our proposed NHS hours (09:00–17:00 Monday to Friday, 40 hours/week) are the same hours we currently operate privately. Within these hours, we always have pharmacists and trained staff on duty to promptly process prescriptions and respond to patient needs. We have surge capacity plans (detailed in our Business Continuity SOP) to handle peaks in demand – for instance, part-time staff and locum pharmacists can be called in if prescription volume spikes or if staff illness occurs. In our private service, we have successfully processed fluctuating prescription volumes without interruption or backlog. Our dispensing workflow (described under Digital Infrastructure below) is highly efficient and scalable, allowing us to comfortably expand throughput while maintaining safety.

3.26 **Nationwide Reach:** As a distance seller, we impose no geographic restrictions – any patient in England can access our services remotely. We have experience delivering to patients from Cornwall to Cumbria under our private provision. All essential services will be offered uniformly to all patients, regardless of location. This includes prompt dispensing and delivery of medicines, telephone/email access to our pharmacists for advice, and support services like signposting and self-care guidance. Our courier partnerships and IT systems are national in scope, ensuring that a prescription from a GP in London or Newcastle is handled with the same speed and efficiency as one from our local area. We are prepared for immediate EPS activation upon NHS contract award. Our chosen PMR system, Titan, is fully accredited for EPS and already deployed across other NHS pharmacies within the Cure Clinics Group. We will also use PharmAppy to support patient engagement, prescription tracking, and communications. While we are not currently receiving NHS prescriptions via EPS, given this is a new application for NHS market entry, we have established relationships and technical readiness with both Titan and PharmAppy. Our existing nationwide private dispensing operation demonstrates our proven capability to manage remote prescriptions safely, efficiently, and at scale, fully aligned with the expectations of an NHS DSP service.

3.27 **Continuous Workflow Monitoring:** Our clinical infrastructure supports real-time visibility across all prescription orders. Using a combination of Titan (PMR), PharmAppy (patient comms), and our proprietary Connect™ platform, we monitor each stage of the dispensing workflow, from prescription receipt through clinical check, assembly, final accuracy check, and dispatch. Any delays or workflow bottlenecks trigger automated internal alerts, which are escalated to the Responsible Pharmacist or Superintendent Pharmacist for immediate review. This system-driven oversight ensures that prescriptions are proactively managed, minimising risk and preventing delays in patient care. In parallel, our phone lines and email inbox are continuously monitored during core hours, with defined service standards in place. For example, all patient emails are responded to within 2 working hours, and urgent calls are triaged immediately. There is no point during contracted hours when a patient in England cannot reach our service or obtain essential pharmacy support.

3.28 **Contingency Planning:** We have robust contingency plans to prevent any interruption due to unforeseen events (e.g. IT failure, power outage). Should our registered premises become unavailable, we will implement a formal fallback arrangement with our affiliated NHS pharmacy, *H & A K Fletcher Ltd (trading as Broadway Pharmacy with Cure Clinics)*, located nearby. Under this arrangement, Broadway Pharmacy would temporarily act as the dispensing hub, enabling CCDS to maintain prescription processing, assembly, and delivery without disruption. All clinical responsibility, patient records, and communication would remain under the oversight of CCDS. This arrangement is consistent with the evolving hub-and-spoke regulatory framework, in which the fallback pharmacy functions as a licensed dispensing site under delegated authority, pending the full implementation of third-party hub-and-spoke permissions across legal entities. All data is cloud-hosted and backed up, and EPS prescriptions can be retrieved on any NHS-enabled device if our main systems fail. We also have arrangements for emergency courier services should our primary delivery network be disrupted (e.g., if a courier strike or

weather event occurs, we have accounts with alternative courier providers). These measures ensure that even in adverse scenarios, we can continue to fulfil prescriptions and serve patients without a break in service. We take our commitment to uninterrupted service seriously, and we have proven this capability in practice. The ICB's concern that our application only "stated the services and hours" but lacked evidence of procedures is understandable given the limited submission, but we trust that the above details now clearly demonstrate that uninterrupted nationwide service is assured in our model.

Cold Chain Medicines Management

3.29 **Issue Raised:** Representations and the ICB's assessment highlighted insufficient detail on how we will maintain a cold chain for temperature-sensitive medicines during storage and delivery. We acknowledge that our original application discussed using "tracked, signed-for courier services" for reliable delivery but did not explicitly describe our cold-chain protocols. We address that fully here.

3.30 **Cold-Chain SOP:** CCDS has a dedicated SOP for Cold Chain Handling and Delivery (attached in email) [see Appendix B]. This SOP covers end-to-end management of refrigerated items (e.g. insulin, certain vaccines, biologics) from the moment we receive them to the point they reach the patient. Key elements of our cold-chain protocol include:

3.31 **Facilities & Storage:** Our pharmacy is equipped with a purpose-built pharmaceutical refrigerator that is continuously temperature-monitored. We record fridge temperatures twice daily in accordance with GPhC standards, and the fridge is fitted with an alert system if temperatures stray out of 2–8°C. We also keep temperature data loggers on site and audits are run weekly. This ensures any cold-stock at our premises is stored correctly prior to dispatch.

3.32 **Packaging for Dispatch:** For refrigerated items sent out to patients, we use validated insulated packaging with frozen gel packs that maintain 2–8°C for a sufficient transit duration. In practice, our deliveries of cold items are sent on a next-day delivery service. Our SOP requires staff to pre-condition cool packs (as per manufacturer guidelines) and pack the medication with minimal head-space to preserve temperature. Each cold shipment is labelled "Keep Refrigerated" and "Urgent – perishable medicine" to alert the courier. Where a patient has a prescription for ambient and cold chain medications, accompanying items only requiring ambient provisions, will include a note to explain that fridge items will be delivered separately to the rest of their items to enable adequate cold chain to be maintained.

3.33 **Courier Arrangements**: All cold-chain parcels are sent via tracked next-day courier (Royal Mail) with priority handling, and patients are given the opportunity to select their preferred delivery day, and are also provided with tracking details immediately on handover to courier. We require a signature/confirmation on delivery for all items to ensure they aren't left unattended. The Royal Mail network covers all of England; if a remote location cannot be reached next-day by standard service, we will use a same day or dedicated courier to guarantee timely delivery. We have contingencies for failed delivery attempts. Where such an event occurs, Royal Mail are 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 redelivery of the items via Royal Mail or an alternative courier, and the return of the items that have failed to be delivered to the pharmacy by Royal Mail. Items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock.

3.34 **Patient Coordination:** We communicate with patients receiving cold-chain medicines to ensure they are prepared for the delivery. Patients are notified of the dispatch and given the tracking number and expected delivery date. We advise them to be available to receive it (and Royal Mail also sends a text on the day with a delivery window).

3.35 **Cold chain breaches**: It is the professional judgement of the RP on duty to determine if the cold chain has been breached to make supply of the medications inappropriate or unsafe. The length of time that the product has been out with the guideline temperature should be a factor in consideration. To establish this, the manufacturers of each medicine are contacted, for guidance on the stability of the medicine, to ensure suitability to supply to the patient. All breaches are documented incidents, and the details are shared during monthly team meetings.

Controlled Drugs (CD) Handling and Disposal

3.36 **Issue Raised:** The representations questioned how we would handle controlled drugs, including their secure supply and waste disposal, in a distance-selling model. The ICB's decision letter also implies that assurance was needed around controlled drug procedures (noting any future inspection would check our practices against SOPs). We want to affirm that CCDS has extensive protocols for controlled drugs management, leveraging our current experience dispensing privately (many of which are Schedule 2 or 3 CDs). Our processes meet all legal requirements for CDs and are tailored to the DSP setting, including arrangements for patient returns and disposal of unwanted medicines.

3.37 **Secure Storage and Records:** Our pharmacy premises has dedicated controlled drug safe cabinets that are compliant with the Misuse of Drugs (Safe Custody) Regulations, being bolted to the external wall. Our premises, and our facilities for the secure storage of CD's were all reviewed by the GPhC inspector during our pre-registration inspection. All Schedule 2 and Schedule 3 CDs (and others requiring safe custody) are kept secured in this cabinet when stored. We maintain a CD Register in which all receipts and supplies of Schedule 2 CDs are promptly entered. We conduct regular stock audits and reconciliations (at least weekly). These foundational measures ensure that CDs are stored and accounted for securely on-site.

3.38 **Prescription Handling:** For the supply of controlled drugs on prescription, we follow all NHS and legal protocols. Electronic prescriptions for Schedule 2 and 3 CDs come to us via EPS as any prescription would. Our PMR (Titan) is configured to flag and require additional checks for CD items. Pharmacists verify the prescription's legitimacy (appropriate prescriber, valid dates, etc.) and perform a thorough clinical check as per our SOP. Before dispatch, a

second trained individual performs an accuracy check on all CD items. We also implement AI-driven clinical screening via our Titan system to catch any potential interactions or dosage anomalies for CDs (e.g., high dose alerts for opioids), adding an extra layer of safety.

3.39 **Delivery of CDs:** We recognise that delivering controlled drugs requires careful security to prevent misuse or loss. Royal Mail are instructed not to leave the package with anyone except the addressee or a trusted adult at the address. For Schedule 2–5 Controlled Drugs we dispatch via Royal Mail Tracked 24 with Signature. Each order is verified: the patient confirms and reconfirms their delivery address through our Connect™ system before dispatch. If the parcel is not signed for on the first attempt, a card is left and a second delivery attempt is made the next day. Should the second attempt also fail, our internal system triggers manual intervention within 12 hours – the item is returned to our pharmacy and we contact the patient to arrange a secure redelivery. We monitor tracking and delivery status using our Royal Mail account management function and will escalate to return to sender or alternate delivery pathways if required. This protocol ensures we maintain chain of custody, meet our regulatory responsibilities and manage patient access without unnecessary delay. Our SOP also covers the reporting process for any lost or stolen CD prescriptions (https://www.cdreporting.co.uk/). These precautions ensure that patients receive their controlled medicines safely and that the chain of custody is maintained.

3.40 **Patient Advice & Monitoring:** When supplying CDs, especially those prone to abuse or dependence, our pharmacists provide appropriate counselling remotely. For certain medications, we schedule follow-up calls to monitor adherence and any issues. By maintaining a close pharmacist-patient dialogue, we uphold safe use of CDs despite the distance. All interactions are documented in the patient's record on our system.

3.41 **Disposal of Unwanted Medicines (Including CDs):** Safe disposal of unwanted medicines is a critical component of the Essential Services framework, and CCDS has adopted a deliberately conservative, safety-first model. To ensure absolute regulatory compliance and patient safety, all unwanted medicines are treated as potentially hazardous and are managed through a single, high integrity courier (PHS) collection and destruction pathway.

Single Secure Returns Process

3.42 Patients who wish to dispose of unwanted medicines, whether Controlled Drugs, cytotoxic or cytostatic agents, or any other prescription or OTC items, contact CCDS by telephone, secure web form, or email. Our pharmacy team triages each request and arranges a courier collection through PHS from the patient's address at no cost to them. We do not use postal services for any medicine returns.

3.43 Each return is:

3.44 **Collected by a Licensed Hazardous Waste Courier (PHS)** – operating under an Environment Agency waste carrier permit and trained in the handling of pharmaceuticals and controlled substances.

3.45 **Accompanied by Secure Packaging and Handover Protocols** – patients are instructed to retain original packaging where possible and hand the item directly to the courier.

3.46 **Delivered to the Pharmacy Premises** – all returns are logged upon arrival and stored in a designated, locked returns area pending destruction.

Governance and Oversight

3.47 **Standard Operating Procedures:** Detailed SOPs cover every stage; patient communication, courier handover, logging, segregation, denaturing, and waste contractor interface.

3.48 **Audit Trail:** Every movement is documented with date, time, staff initials, and courier reference. Monthly audits are completed by the Responsible Pharmacist; quarterly reviews by the Superintendent Pharmacist.

3.49 **Training:** All staff handling returned medicines receive annual training in CD destruction, hazardous waste handling, and environmental compliance.

3.50 **Documentation:** Copies of the Waste Carrier License, Hazardous Waste Registration, Consignment Notes, and CD Denaturing Log are held for inspection.

Patient Accessibility and Safety

3.51 Patients are never required to physically attend the premises. Our national courier arrangement ensures equitable access across England, including remote and rural areas. Where a patient prefers to return unwanted medicines locally, we provide clear signposting to nearby NHS community pharmacies while maintaining our own responsibility for the safe management of returns initiated through CCDS.

3.52 In summary, by treating all unwanted medicines as hazardous and managing them through a single, specialist courier based return and destruction process, CCDS exceeds the minimum requirements of Regulation 25(2)(b) and the Essential Service specifications. This approach removes any potential for misclassification, prevents unsafe stockpiling or disposal, and ensures that all patients, regardless of location, have a safe, compliant, and convenient route to return and destroy unwanted medicines.

Secure Delivery and Logistics

3.53 **Issue Raised:** The refusal letter and representations questioned how we would ensure secure, reliable delivery of medicines given the absence of a face-to-face handover. Ensuring medications reach patients safely is indeed a linchpin of the DSP model, and we have designed our logistics with security as a top priority.

3.54 **Delivery Service Overview:** As noted, we use tracked courier services for all medication deliveries nationwide. Every parcel dispatched from CCDS is assigned a tracking number, and its progress can be monitored by both our team and the patient in real time. We use Royal Mail next-day delivery services (Tracked24) to reduce transit time.

3.55 **Security Measures:** All medication parcels are packed in tamper-evident packaging. We use robust mailing boxes or padded bags which are then sealed with security tape; if a parcel were interfered with, it would be evident on arrival. The exterior label shows our return address but gives no indication that the contents are medicines or from a pharmacy, for discretion. For all prescription deliveries, we opt for "signed for" service. This ensures that there is an accountable handover at the point of delivery. If a patient isn't home, the package will not be left unattended; instead, it will be taken back to the depot or local post office and the patient can arrange redelivery or collection with identification. This policy is explained to patients to avoid any misunderstanding.

3.56 **Address and Recipient Verification:** Our systems capture the patient's exact delivery address and any specific instructions on every single prescription order. We cross verify new addresses against the Royal Mail Postcode Address File (PAF) to reduce errors. If delivering to workplaces or alternative addresses, we confirm the details with the patient. In addition, at the initial registration stage the patient completes a full identity verification via Veriff, which uses biometric and document checks to confirm identity before we dispatch any controlled or high risk medicines.

3.57 **Failed Delivery Protocol:** Despite best efforts, failed deliveries can happen. We recognise that delivering medications requires careful security to prevent misuse or loss. Royal Mail are instructed not to leave the package with anyone except the addressee or a trusted adult at the address. All prescriptions are dispatched via Royal Mail Tracked 24 with Signature. Each order is verified: the patient confirms and reconfirms their delivery address through our systems before dispatch. If the parcel is not signed for on the first attempt, a card is left and a second delivery attempt is made the next day. Should the second attempt also fail, our internal system triggers manual intervention within 12 hours – the item is returned to our pharmacy and we contact the patient to arrange a secure redelivery. We monitor tracking and delivery status using our Royal Mail account management function and will escalate to return to sender or alternate delivery pathways if required. This protocol ensures we maintain chain of custody, meet our regulatory responsibilities and manage patient access without unnecessary delay.

3.58 **Delivery Network Resilience:** To further ensure reliability, we maintain accounts with multiple courier providers. If Royal Mail has a service disruption in a certain area, we can switch to another provider. We stay updated on any logistics issues nationally (weather, strikes, peak times such as national holidays) and will communicate with patients in advance if any anticipated delays could occur, with advice to reorder medicines slightly earlier if needed.

3.59 In summary, our secure delivery processes guarantee that medicines reach patients intact, on time, and securely across England. The ICB highlighted

premises security as well, we note that our premises is in a secure business park with controlled access, and all dispatches occur from within a locked facility accessible only to authorised staff, minimising any risk of theft before courier handover. Additionally, we have CCTV and alarm systems in our building as part of our premises security protocols, ensuring the medicine stock is secure prior to dispatch. Again, this has been approved by the GPhC when they came to undertake our pre-registration inspection in July 2025.

3.60 **Non Face-to-Face Service Model (Remote Clinical Services & Patient Support) Issue Raised:** The fundamental nature of a DSP is that no essential services are provided face-to face at the premises, and the ICB must be satisfied that services will still be provided safely and effectively in this remote manner. The feedback from the Committee and representations indicated that our application did not sufficiently explain how we would deliver certain clinical aspects – for example, providing self-care advice nationally and handling patient interactions without in-person contact. We address this by describing our remote service model, which leverages technology and proactive patient engagement to fulfil all obligations typically met in a bricks-and-mortar setting.

3.61 **No Public Access Policy:** First and foremost, we reiterate that our premises has no public access or walk-in facility, as required for DSPs. We have a clear policy (and signage on the door) stating that we do not serve patients face-to-face at the pharmacy. If a patient or member of the public were to visit the location, they would find a notice directing them to contact us via telephone or online for service. Our staff are trained never to dispense or provide any pharmacy service inperson at the door – even if someone comes in, we politely explain we are a distance pharmacy and arrange to assist them remotely. This ensures full compliance with the letter of the DSP regulations.

3.62 **Patient Communication Channels:** We provide multiple convenient channels for patients to interact with our pharmacists and team remotely. These include: a dedicated pharmacy phone line (with local-rate or free call), a secure email address for inquiries, the option for requesting a video consultation (to support visual inspection if required), and a web messaging portal (through our website and PharmAppy app). During opening hours, a pharmacist or trained pharmacy technician is always available to speak to patients on the phone. We do not operate an automated call centre – patients get through to a staff member who can help or escalate to the pharmacist. For out-of hours, our phone line has a recorded message advising on alternative sources of urgent help (such as calling NHS 111 or using the NHS pharmacy finder to locate an open pharmacy), which is standard practice. Emails received after hours are answered first thing the next working day. In effect, patients can receive counselling and answers to medicines-related questions much like they would by walking up to the pharmacy counter, except it is done via a phone call or message.

3.63 **Essential Services Delivered Remotely:** Each of the community pharmacy Essential Services is delivered by CCDS through remote methods:

3.64 **Dispensing & Repeat Dispensing***:* Prescriptions are received electronically, dispensed and checked with care, and delivered to the patient as detailed. Any clinical concerns (e.g. interactions, adherence issues) that a pharmacist would

normally discuss across the counter are instead discussed via a remote consultation. We contact patients if we need to clarify any clinical queries, or to give important counselling. We will make use of the Connect/PharmAppy platform to message patients about their prescription status and any actions required. For repeat dispensing (eRD), our system automatically processes batch issues and we use in-app notifications to prompt patients when a new supply is being sent or to ask them to confirm need – effectively mirroring the engagement they'd get in person by coming for a refill.

3.65 **Clinical Advice & Self-Care***:* We robustly provide self-care support and healthy lifestyle advice at a distance. During any interaction (phone or app message), our pharmacists are attentive to advising on diet, exercise, smoking cessation, or other lifestyle factors when relevant – just as they would in person. Additionally, we proactively send out public health information to our patient base in line with NHS campaigns. The team will include trained Health Champions who will oversee these campaigns. For *Support for Self-Care*, our pharmacists will respond with advice on over-the-counter options or general care measures. If a patient needs an OTC medicine, we will arrange to sell and dispatch it or direct them to a nearby pharmacy if urgent.

3.66 **Signposting**: When a patient has a need outside our pharmacy scope, we use NHS Service Finder and our curated directory to signpost them appropriately. For example, if someone contacts us needing a service we cannot provide (such as a vaccination or an urgent supply when we are closed), our team will locate the nearest appropriate provider for them (whether that's advising on a local walk-in center [sic], their GP, or a late night pharmacy in their area). We then communicate the information via text or email immediately. In complex cases, we will even phone ahead to that service to hand over information if appropriate (with patient consent). We document signposting instances in our records as part of clinical governance. Geography is not a barrier, using the patient's postcode, we can find services all over England. We already do this in practice for our private patients. This fulfils the signposting essential service requirement effectively.

3.67 **Medicine Disposal***:* As detailed in Section 4, CCDS provides a fully remote medicine disposal service through secure courier collection from patients' homes. This ensures that all unwanted or expired medicines, including Controlled Drugs and hazardous items are safely returned, logged, and destroyed under our supervised procedures. By removing unused medicines from patients' homes nationwide, we uphold the highest standards of safety and environmental responsibility within a distance-selling model.

3.68 **Remote Clinical Services (Advanced Services):** In addition to essential services, we intend to provide certain Advanced Services remotely – for instance, the New Medicine Service (NMS) and the NHS Pharmacy Contraception Service. For example, an NMS follow-up for a patient starting a new medication will be done as a scheduled phone call at a convenient time, with the pharmacist using a structured interview template just as they would in a face-to-face meeting (and documenting the outcomes to claim the service). We have already trialed [sic] this approach privately for some medicines and found patients actually appreciate the phone call approach – it can be more flexible for them than coming into a pharmacy. We will likewise conduct the

Contraception Service consultations by video/phone and arrange supply via postal methods in line with service specs (noting that all such services will comply with the new NHS England guidance that from October 2025 DSPs must only deliver Advanced services remotely). We are fully aligned with providing all our services without requiring the patient's physical presence.

3.69 In summary, our non-face-to-face model is comprehensive, patient-centered [sic], and technologically supported. It addresses every facet of care that an in-person pharmacy would, but through remote means. The initial decision suggested that our assurances were "not adequate" regarding safe and effective provision without face-to-face contact. We trust that the detailed explanations above, alongside evidence of our existing operations, now make it clear that CCDS can safely extend the pharmacy care model beyond the premises walls. We are also able to capture prescription charge exemptions and payments through our platform, addressing the concern that we didn't mention this in the application. In practice, our system prompts patients to declare their exemption status or pay the NHS charge via a secure online checkout; records of exemptions are then sent with our prescription claims.

Advanced Digital Infrastructure (Connect™, Titan, and PharmAppy)

3.70 A major strength of CCDS – underpinning all the points above – is our technology infrastructure. We want to highlight how our Connect™, Titan PMR, and PharmAppy stack supports our clinical workflow, messaging, exemption capture, and NHS integration, enabling us to meet the DSP requirements reliably.

3.70.1 **Titan PMR:** We use the Titan Pharmacy Management System, which is an NHS accredited PMR platform known for its innovative, fully paperless workflow. Titan allows us to manage the entire dispensing process digitally – from receiving an electronic prescription to generating labels, picking stock, performing clinical checks, and recording the supply – without the traditional manual steps that can introduce delays or errors. This significantly enhances patient safety, as every prescription gets an automated "second look" before pharmacist approval. Titan also uses barcode validation in the dispensing process, meaning we scan product barcodes to verify the correct medicine and strength for the correct patient, virtually eliminating picking errors. The system provides a clear audit trail and real-time dashboard of workload – our pharmacists can see how many scripts are in queue, in progress, or dispatched at a glance. Because Titan is cloud-based, our operation is highly resilient and accessible, where we could operate from a secondary location if needed without disruption, as all data is online and secure. With Titan, we seamlessly connect to the NHS Spine for prescription downloads and Electronic Prescription Service uploads. It also handles electronic reporting for services and will aid us in submitting claims digitally. In short, Titan forms the clinical and operational backbone of our pharmacy, ensuring efficient prescription handling and workflow management. Its advanced capabilities give us confidence in scaling our service while maintaining accuracy and safety.

3.70.2 **PharmAppy Patient App:** On the patient-facing side, we will partner with PharmAppy, a cutting-edge pharmacy patient app that is fully embedded into the Titan system. PharmAppy provides our patients with a user-friendly mobile (and web) application through which they can order prescriptions, manage their medications, and communicate with us. Notably, the app is integrated with NHS login, allowing patients to easily request their NHS repeat prescriptions from their GP to be sent to us. It also sends us those requests via the Connect interface so we can facilitate the EPS flow. Patients can track their prescription status in real time (they receive updates like "order received," "dispensed," "out for delivery") – this transparency greatly improves their experience and reduces anxiety about when their medicine will arrive. The app also includes a secure messaging feature: patients can message our pharmacists with questions or for advice, and our team can reply through our dashboard. This bidirectional messaging is encrypted and keeps a record in the patient's profile, effectively creating a virtual consultation room. PharmAppy also supports sending reminders to patients (for instance, to take their medication or reorder a repeat); this helps us help patients with adherence. Because the app is tied into Titan, any communications or actions the patient takes are reflected in our pharmacy system instantly. For example, if a patient marks that they have an exemption (e.g., NHS prepayment or age exemption) in the app, Titan receives that info and we capture it for our dispensing and reporting – thereby facilitating exemption capture digitally. If a patient needs to pay an NHS charge, the app can process secure payments online. All of these features address the logistical challenges of a distance model (no physical signature for exemption – instead we have a digital record, no cash payments – instead online in application card payments).

3.70.3 **Connect™ by Cure Clinics:** "Connect™" is our integrated digital platform (developed by Cure Clinics) that ties together our systems and patient interface. In essence, Connect is the glue between Titan and PharmAppy, along with additional workflow tools. It powers our secure web portal and authentication system.

3.71 The synergy of **Titan + Connect + PharmAppy** is a modern solution that gives us capabilities beyond a traditional pharmacy, which is crucial for a DSP. Many potential failure points of a distance model (missed phone calls, unclear patient needs, lack of real-time communication) are solved by this integrated tech stack. Our use of these systems should give the Committee confidence that CCDS has the infrastructure to deliver all services seamlessly and in full alignment with NHS digital initiatives. We are not attempting to run a mail-order pharmacy with ad-hoc processes; rather, we have invested in a proven platform that many pharmacies are using to integrate clinical workflow with patient-facing tech. This is the backbone that ensures all our good intentions (as described in earlier sections) are executed reliably day-to-day.

Conclusion

3.72 The decision of the ICB's Pharmaceutical Services Committee found that our application did not evidence certain requirements to their satisfaction. We have

now supplied that evidence: CCDS has the necessary SOPs, systems, and experience in place to ensure uninterrupted, safe, and effective pharmaceutical services to all patients without face-to-face contact. The shortcomings identified were a result of an administrative limitation in our original submission, not an actual deficiency in our operations.

3.73 We ask the Appeals Body to recognise that CCDS is not a speculative startup with merely a proposal – we are an established pharmacy provider, already operating to high standards under GPhC oversight as a fully remote service. We have demonstrated our capabilities in the private sector and now seek to bring them into NHS service, expanding patient choice and accessibility.

3.74 Our model aligns with NHS England's digital transformation goals and the need to innovate pharmacy services while maintaining quality. We fully appreciate the commissioner's duty to ensure any new DSP will meet all contractual requirements. Through this appeal submission, we have shown in detail how we meet those requirements in practice.

3.75 Ultimately, we believe granting our application will pose no risk to service standards and will in fact add a valuable service for patients – particularly those who prefer or require remote access to pharmacy care such as individuals with mobility issues, those in rural areas, or the neurodiverse patients we specialise in, who often benefit from our simplified, calm approach. The refusal, we feel, was rooted in a misinterpretation that we lacked operational depth, we hope we have corrected that misinterpretation with this appeal.

3.76 We therefore kindly request NHS Resolution to allow this appeal. We seek a decision that the requirements of Regulation 25(2)(b) are satisfied by CCDS's procedures (now evidenced), and that our application for inclusion in the pharmaceutical list be granted. We are eager to begin providing NHS pharmaceutical services and to uphold the trust placed in us as a distance selling contractor.

3.77 Thank you for considering this appeal and the accompanying documents. We are prepared to answer any further questions the Committee may have."

3.78 "**Annex A:** The following table presents the Standard Operating Procedures at Cure Clinics Dispensing Services Ltd (CCDS). This SOP suite governs operational, clinical, and governance processes relevant to our private dispensing activity, and is immediately applicable to NHS dispensing in the distance-selling model. These SOPs (which include ready versions for NHS contractual activity), demonstrate preparedness to deliver all Essential Services remotely and to comply fully with Regulation 25(2)(b). Each SOP has been authored internally and approved by the Superintendent Pharmacist. SOPs are regularly reviewed and updated in line with regulatory requirements, internal audit findings, and service developments.

SOP Code	SOP Title	Key Domains Covered
DSOP-01	Receiving a Prescription	Core workflow, prescription validation, labelling, supply

DSOP-02	Professional or Clinical Assessment of a Prescription	Clinical judgement, red flags, referral triggers
DSOP-03	Barcode-Guided Dispensing including CDs – labelling and assembly	Barcode verification (incl CDs), label generation, assembly process
DSOP-04	Final Check for Prescriptions	Accuracy check, basket segregation, audit trail
DSOP-05	Packing, dispatch and Delivery of Prescription Medicines including Controlled Drugs	Packing standards, courier handover, delivery verification (incl. CDs)
DSOP-06	Procurement and Supply of Specials – Unlicensed Medicines	Ordering specials, supplier governance, documentation and labelling
DSOP-07	Repeat dispensing	eRD
DSOP-08	Public Health Campaign Delivery	DHSC led messaging, structured outreach monitoring
DSOP-09	Provision of Self Care	Self-care guidance, escalation, signposting
DSOP-10	NHS Signposting and Service Delivery	Referrals to NHS services, ICB services and fallback to local pharmacy
DSOP-11	Discharge Medicines Services	Safe medicines management post hospital discharge
RPSOP-01	Responsible Pharmacist	RP log, duty delegation, shift handover
RPSOP-02	Absence of the Responsible Pharmacist	RP absence log, permitted activities, escalation process
RPSOP-03	Roles and Responsibilities	Role boundaries, task delegation, accountability
RXSOP-01	Disposal of Unwanted Medicines (including controlled drugs)	Stock write off, denaturing CDs, waste contractor handover
CDSOP-01	Goods in including Schedule 2 and 3 Controlled Drugs	CD delivery checks, stock entry, discrepancy management
CDSOP-02	Storage and Security of Controlled Drugs (Schedules 2,3 and Relevant Schedule 4)	Cabinet standards, access controls, key holding
CDSOP-03	Weekly balance Checks for Schedule 2 Controlled Drugs, Liquids and Non-Liquids	Balance checks, discrepancy investigation, record keeping
CDSOP-04	Destruction and Disposal of Controlled Drugs and Unwanted Medicines	Authorised destruction, denaturing process, witness and record keeping

CDSOP-05	Controlled Drug Incident Reporting	Near-miss logging, CD discrepancies, governance reporting
CDSOP-06	Failed, Delayed or Lost Prescription Deliveries for Controlled Drugs	Delivery exception handling, CD risk assessment, notification and follow-up
IGSOP-01	Information Governance, Data Protection, and Cybersecurity Response	GDPR, DSP Toolkit, patient record confidentiality
LGSOP-01	Cold Chain Medicines Handling, Packaging and Delivery	Temperature-sensitive packaging, failed delivery SOP
OSOP-01	Clinical Governance – Dispensing Errors, Near Misses and Incident Management	Error logging, root cause analysis, learning and feedback
OSOP-02	Complaints Management Policy	Complaint log, response SLAs, patient comms
OSOP-03	Expiry Date Management and Stock Rotation	Expire date checks, FEFO stock rotation, write off process
OSOP-04	Adverse Drug Reactions ADRS – Identification, Reporting and Learning	ADR detection, MHRA Yellow Card reporting, shared learning
OSOP-05	lack Triangle Medicines – Identification, Monitoring and Reporting	Identifying enhanced-monitoring medicines and ensuring appropriate patient counselling and reporting
OSOP-06	Failed, Delayed or Lost Prescription Deliveries (non-Controlled Drugs)	Delivery exception handling, investigation, patient communication
OSOP-07	Safeguarding Vulnerable Adults and Children	Risk recognition, referral pathways, documentation
BCSOP-01	Business Continuity and Disaster Recovery	Outage scenarios, staffing cover, power failure contingencies

Review and Maintenance:

3.79 All SOPs are reviewed annually or following any significant operational change. CCDS's SOP set is fully auditable and subject to internal and external governance processes, including GPhC inspections and independent audit."

4 Summary of Representations

This is a summary of representations received on the appeal.

Representations were also sought from the Applicant on the amendments to Regulation 25 as the Commissioner considered the application against the previous regulatory test.

4.1 THE APPLICANT

"Purpose of this Addendum

4.1.1 This Addendum is submitted further to NHS Resolution's confirmation that the appeal will be determined by way of redetermination of the application, applying the amended Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which came into force on 23 June 2025.

4.1.2 Its purpose is to:

4.1.2.1 demonstrate Cure Clinics Dispensing Services Ltd's (CCDS) explicit understanding of the amended statutory test;

4.1.2.2 confirm full alignment with post-June 2025 DSP regulatory changes, including service delivery constraints effective from 1 October 2025; and

4.1.2.3 assist NHS Resolution in substituting a fresh decision, applying the correct legal framework to the evidence already before it.

4.1.3 This Addendum should be read alongside the substantive appeal submission and supporting evidence pack previously provided.

The Amended Regulation 25 Test (Post-23 June 2025)

4.1.4 As amended, Regulation 25(2)(b) requires the decision-maker to be satisfied that the applicant's arrangements secure:

i. The uninterrupted provision of pharmaceutical 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 behalf or another's) and the applicant or its staff.

4.1.5 The amendments are material in that they:

4.1.5.1 expressly refer to pharmaceutical services as a whole (not solely "essential services"); and

4.1.5.2 reinforce the policy intent that distance-selling pharmacies operate as remote service providers, not walk-in or on-site clinical service hubs.

Application of the Amended Test to CCDS

4.1.6 **Uninterrupted provision of pharmaceutical services**

4.1.7 CCDS demonstrably satisfies Regulation 25(2)(b)(i).

4.1.8 As set out in the appeal bundle, CCDS is already an operational, GPhC-registered distance-selling pharmacy delivering pharmaceutical services nationally within defined opening hours, using the same premises, staff, systems, and governance arrangements proposed for NHS service delivery.

4.1.9 Key assurances include:

4.1.9.1 **Operational maturity and scale**: CCDS is not a speculative proposal; it is an established remote dispensing operation already providing uninterrupted pharmaceutical services across England.

4.1.9.2 **Nationwide accessibility**: Services are available to patients anywhere in England without geographic restriction, supported by national courier coverage and remote pharmacist access.

4.1.9.3 **Business continuity and resilience**: Documented contingency arrangements exist for staffing, systems, premises unavailability, and delivery disruption, ensuring continuity of service.

4.1.9.4 **System-enabled oversight**: Titan PMR, PharmAppy, and the Connect™ platform provide real-time workflow visibility, escalation of exceptions, and auditable clinical oversight by the Responsible and Superintendent Pharmacists.

4.1.10 These arrangements exceed the evidential threshold required to demonstrate uninterrupted provision under Regulation 25.

Safe and effective provision without face-to-face contact at the pharmacy premises

4.1.11 CCDS fully satisfies Regulation 25(2)(b)(ii).

4.1.12 The CCDS operating model is expressly designed to ensure that pharmaceutical services are not provided face-to-face at the distance-selling premises, while maintaining high standards of safety, effectiveness, and governance.

4.1.13 This is achieved through:

4.1.13.1 **Closed-premises DSP model**: The premises at 10 Cable Court have no public access. Policies, staff training, and physical controls ensure that no services are delivered face-to-face at the premises.

4.1.13.2 **Remote clinical interaction**: Medicines advice, counselling, and clinical services are delivered via structured telephone or

video consultations, with full documentation and escalation pathways.

4.1.13.3 **Robust clinical governance**: Including professional assessment of prescriptions, incident and near-miss reporting, safeguarding procedures, complaints handling, and Superintendent Pharmacist oversight.

4.1.13.4 **High-risk area controls**: Enhanced SOPs and risk assessments govern controlled drugs, cold-chain medicines, and delivery failures, supported by secure storage, tracked delivery, and audit trails.

Coverage of Pharmaceutical Services

4.1.14 CCDS confirms that all pharmaceutical services capable of lawful provision by a distance-selling pharmacy are governed by approved SOPs, risk assessments, and audit mechanisms, under the oversight of the Superintendent Pharmacist.

A. Essential Services

4.1.15 Dispensing of NHS prescriptions (acute, repeat, and electronic repeat dispensing)

4.1.16 Dispensing of private prescriptions

4.1.17 Discharge Medicines Service (DMS)

4.1.18 Disposal of unwanted medicines, including Schedule 2–5 Controlled Drugs

4.1.19 Support for self-care

4.1.20 Public health promotion of healthy lifestyles

4.1.21 NHS signposting

4.1.22 Clinical governance requirements associated with Essential Services

B. Advanced Services

4.1.23 Where permitted by national service specifications and DSP guidance, CCDS has governance arrangements in place to support remote or off-site delivery of Advanced Services, including:

4.1.23.1 New Medicine Service (NMS)

4.1.23.2 Pharmacy Contraception Service

4.1.23.3 Pharmacy First Service

4.1.23.4 Hypertension Case-Finding Service

4.1.23.5 Smoking Cessation Service

4.1.23.6 Flu Vaccination Service

4.1.23.7 COVID-19 Vaccination Service

4.1.23.8 Appliance Use Reviews (AUR)

4.1.23.9 Stoma Appliance Customisation (SAC)

4.1.24 Activation of Advanced Services is subject to accreditation, commissioning arrangements, and compliance with DSP-specific delivery rules.

SOP Governance and Service Mapping

4.1.25 Each Essential and Advanced pharmaceutical service listed above is governed by one or more Standard Operating Procedures (SOPs) approved by the Superintendent Pharmacist.

4.1.26 For clarity and completeness, Annex A (Revised) [see 4.1.41 below] to this Addendum provides an explicit mapping between individual pharmaceutical services and the SOPs that govern their safe, effective, and compliant delivery within the distance-selling pharmacy model.

Regulatory Alignment: DSP Service Delivery Changes from 1 October 2025

4.1.27 CCDS expressly confirms its understanding of, and compliance with, the regulatory changes to DSP service delivery arising from the June 2025 amendments to the PLPS Regulations.

4.1.28 In particular, CCDS recognises that:

4.1.29 From 1 October 2025, DSP pharmacies are no longer permitted to provide Directed services (Advanced, National Enhanced, or Enhanced services) face-to-face at the distance-selling premises.

4.1.30 Accordingly, CCDS's service model ensures that:

4.1.30.1 Directed services are delivered remotely from the DSP premises (e.g. telephone or video consultation), where the service specification allows; or

4.1.30.2 face-to-face off-site, where explicitly permitted by the service specification and commissioning arrangements.

4.1.31 COVID-19 and Influenza Vaccination Services may continue to be delivered on-site at the DSP premises only until 31 March 2026, in accordance with the transitional provisions.

4.1.32 All relevant SOPs and risk assessments explicitly incorporate these constraints, ensuring that no Directed service is delivered face-to-face at the DSP premises outside the permitted exception.

Governance, Safety, and Risk Control

4.1.33 Across all service categories, CCDS maintains documented governance arrangements covering:

4.1.33.1 Controlled drug management and CDAO-aligned incident reporting

4.1.33.2 Cold-chain handling and temperature-sensitive medicines

4.1.33.3 Clinical incident and near-miss reporting

4.1.33.4 Safeguarding of vulnerable adults and children

4.1.33.5 Complaints handling and patient feedback

4.1.33.6 Business continuity and disaster recovery

4.1.33.7 Information governance, data protection, and cybersecurity

4.1.34 Each service area is supported by a documented SOP and associated risk assessment, indexed in Annex A (Revised) [see 4.1.41 below].

4.1.35 The structured disclosure of SOP coverage within this Addendum, and in Annex A (Revised) [see 4.1.41 below], reflects a proportionate, risk-based evidential approach, aligned with NHS Resolution's role as a decision-substituting body rather than an inspection authority.

4.1.36 Full SOP documents are live, operational, routinely audited, and available for inspection should NHS Resolution require further verification.

Satisfaction of Regulation 25 as Amended

4.1.37 Applying the amended Regulation 25 test to the evidence before NHS Resolution, CCDS clearly secures:

4.1.37.1 the uninterrupted provision of pharmaceutical services to persons anywhere in England during opening hours; and

4.1.37.2 the safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises, in full compliance with post-June 2025 DSP regulations.

4.1.38 Had the amended Regulation 25 been applied at first instance, the application could not reasonably have been refused on the grounds cited by the ICB.

Conclusion and Invitation to Substitute Decision

4.1.39 In light of:

4.1.39.1 the amended statutory framework;

4.1.39.2 CCDS's explicit alignment with post-June and post-October 2025 DSP regulatory requirements; and

4.1.39.3 the comprehensive evidence already submitted,

4.1.40 CCDS respectfully invites NHS Resolution to consider the Addendum as a whole, together with Annex A (Revised), and to substitute a positive decision granting the application for inclusion in the pharmaceutical list as a distance-selling pharmacy at 10 Cable Court, Preston.

Annex A (Revised) Standard Operating Procedure (SOP) Index and Service Mapping

4.1.41 This Annex provides a consolidated index of the Standard Operating Procedures (SOPs in force at Cure Clinics Dispensing Services Ltd) and explicitly maps SOP coverage to each Essential and Advanced pharmaceutical service referenced in this Addendum.

4.1.42 It is provided to evidence compliance with Regulation 25(2)(b) (as amended June 2025).

4.1.43 A. SOP Index – Core, Essential and Governance Services

SOP Code	SOP Title	Service(s) Governed
DSOP-01	Receiving a prescription	Essential – Dispensing (NHS & Private)
DSOP-02	Professional / Clinical Assessment of a Prescription	Essential – Dispensing; Clinical Governance
DSOP-03	Barcode-Guided Dispensing incl. CDs – Labelling & Assembly	Essential – Dispensing; CD Governance
DSOP-04	Final Check for Prescriptions	Essential – Dispensing; Patient Safety
DSOP-05	Packing, Dispatch & Delivery of Prescription Medicines incl. CDs	Essential – Dispensing; Secure Delivery
DSOP-06	Procurement & Supply of Specials (Unlicensed Medicines)	Essential – Dispensing (Specials)
DSOP-07	Repeat Dispensing (eRD)	Essential – Repeat Dispensing
DSOP-08	Public Health Campaign Delivery	Essential – Public Health
DSOP-09	Provision of Self-Care Advice	Essential – Support for Self-Care
DSOP-10	NHS Signposting & Service Directory Use	Essential – NHS Signposting
DSOP-11	Discharge Medicines Service (DMS)	Essential - DMS

RPSOP-03	Roles and responsibilities	Essential – Clinical Governance
RXSOP-01	Disposal of unwanted medicines (including Controlled Drugs)	Essential – Patient returned medication

4.1.44 B. Advanced Services – SOP Governance

4.1.45 (Delivered remotely or off-site only, in accordance with DSP regulations effective 1 October 2025)

SOP Code	SOP Title	Service(s) Governed
OSOP-01	Clinical Governance – Dispensing errors, Near Misses & Incident Management	All advance services
OSOP-07	Safeguarding Vulnerable Adults & Children	All Advanced services
RPSOP-01	Responsible Pharmacist	Oversight of Advanced Services
RPSOP-02	Absence of Responsible Pharmacist	Continuity of Advanced Services
LGSOP-01	Cold chair Medicines Handling, Packaging and Delivery	Flu & Covid-19 Vaccination Services

4.1.46 Note

4.1.47 In line with post-June 2025 PLPS amendments, CCDS does not provide Directed services face-to-face at the DSP premises (with the sole transitional exception of Flu and Covid-10 vaccinations until 31 March 2026). All Advanced Services are governed by SOPs explicitly designed for remote or permitted off-site delivery.

4.1.48 C. Controlled Drugs and High-Rish Medicines

SOP Code	SOP Title	Service(s) Governed
CDSOP-01	Goods in incl. Schedule 2 & 3 Controlled Drugs	Controlled Drugs Receipt & Verification
CDSOP-02	Storage & Security of Controlled Drugs (Schedules 2,3 and relevant Schedule 4)	Safe custody
CDSOP-03	Weekly Balance Checks for Schedule 2 Controlled Drugs, Liquids and non-liquids	Controlled Drugs Audit & Reconciliation
CDSOP-04	Destruction & Disposal of Controlled Drugs and Unwanted medicines	Controlled drug disposal
CDSOP-05	Controlled Drugs Incident Reporting	Governance & Reporting
CDSOP-06	Failed / Delayed / Lost prescriptions for Controlled Drugs Deliveries	Controlled Drugs Delivery Risk Management

4.1.49 D. Information Governance, Safety and Business Continuity

SOP Code	SOP Title	Service(s) Governed
IGSOP-01	Information Governance, Data Protection & Cybersecurity response	GDPR, DSP, Toolkit
OSOP-02	Complaints Management	Patient Feedback
OSOP-03	Expiry Date Management & Stock Rotation	Medicines Safety
OSOP-04	Adverse Drug Reactions (ADRs) – Identification, reporting and learning	MHRA Reporting
OSOP-05	Black Triangle Medicines – Identification, monitoring and reporting	Enhanced Monitoring
OSOP-06	Failed / Delayed or lost prescription Deliveries (Non-Controlled Drugs)	Delivery Governance
BCSOP-01	Business Continuity & Disaster Recovery	Uninterrupted Service Provision

Assurance Statement

4.1.50 Each Essential and Advanced pharmaceutical service referenced in the Regulation 25 Addendum is governed by one or more SOPs listed above.

4.1.51 All SOPs:

4.1.51.1 are approved by the Superintendent Pharmacist,

4.1.51.2 are operational and actively used within CCDS's existing distance-selling pharmacy, and

4.1.51.3 are subject to routine audit, review, and regulatory inspection.

4.1.52 The structured disclosure of this SOP Index reflects a proportionate, risk-based evidential approach, aligned with NHS Resolution's role as a decision-substituting body rather than an inspection authority."

4.2 PRESTON PHARMACY

4.2.1 "Thank you for sending me a copy of this appeal. I maintain that the application should be refused.

4.2.2 Cure Clinics have submitted completely new evidence to be considered at the appeal stage and blames the online application portal for not providing all of this evidence at an earlier stage. Now Cure Clinics say, "*In this appeal, CCDS provides a comprehensive and transparent evidential pack to address every concern raised and to demonstrate unequivocal compliance with Regulation 25(2)(b)(i) and (ii)*.". When

submitting an appeal, Cure Clinics was required to provide all the evidence that they rely on and they are not permitted to keep adding more evidence at later stages, or if they do, the additional evidence should be disregarded.

4.2.3 Cure Clinics has provided only a very limited number of SOPs. The statement under "Operational Status and Compliance" suggests that Cure Clinics believe their application should be approved simply because they have provided assurances that they will comply with the Regulations and because they are already "*a General Pharmaceutical Council–registered distance-selling pharmacy*". However, Cure Clinics has not said how they will comply with all parts of regulation 25 and even the limited SOPs they have provided show that pharmaceutical services would not be provided in a safe and effective way. There are many examples such as those listed below.

4.2.4 Cure Clinics says "*Packaging for Dispatch: For refrigerated items sent out to patients, we use validated insulated packaging with frozen gel packs that maintain 2–8°C for a sufficient transit duration. In practice, our deliveries of cold items are sent on a next-day delivery service*". However, Cure Clinics cannot control how quickly an item is delivered and there is no procedure to monitor the cold chain delivery. The SOP itself says "*Insert pre-conditioned frozen gel packs (as per manufacturer instructions) above and below the product to maintain 2–8 °C for at least 48 hours in ambient conditions*.". There is no process described for non-ambient conditions and Cure Clinics is relying on ambient conditions without being able to check if those conditions actually exist for the delivery process.

4.2.5 Cure Clinics says "*Delivery of CDs: We recognise that delivering controlled drugs requires careful security to prevent misuse or loss. Royal Mail are instructed not to leave the package with anyone except the addressee or a trusted adult at the address. For Schedule 2–5 Controlled Drugs we dispatch via Royal Mail Tracked 24 with Signature*." Cure Clinics does not mention anything about checking the ID of a person who accepts a controlled drug delivery and will simply allow it to be signed for by any person. The lack of any ID checking is confirmed in the SOP that has been provided.

4.2.6 It is also not possible to ascertain how Cure Clinics will provide a service like the Discharge Management Service remotely as no information is provided about the service at all. Whilst Cure Clinics provide a list of their SOPs at page 16 of their appeal document, these do not even include SOPs for Discharge Management.

4.2.7 Regulation 25(2)(b)(ii) says.

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

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

(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.

4.2.8 Cure Clinics say they will provide,

4.2.8.1 NMS

4.2.8.2 NHS Pharmacy Contraception Service

4.2.8.3 Lateral Flow Test Supply

4.2.8.4 Pharmacy First

4.2.9 These are all pharmaceutical services. It is not possible to decide that there will be "*safe and effective provision of pharmaceutical services without face to face contact*" when no information is provided about the services.

4.2.10 As there is not enough information provided to allow the application to be approved it should be refused."

4.3 COMMUNITY PHARMACY LANCASHIRE AND SOUTH CUMBRIA

4.3.1 "On behalf of Community Pharmacy Lancashire and South Cumbria I enclose a copy of our original letter arguing against the granting of this contact and politely ask that it is considered as part of the appeal."

In a letter to PCSE dated Community Pharmacy Lancashire and South Cumbria stated:

4.3.1 "Thank you for informing Community Pharmacy Lancashire and South Cumbria (CPLSC) the name adopted by Lancashire and South Cumbria Local Pharmaceutical Committee, of the above application.

4.3.2 We note that this is a Distance Selling Application, and we would be willing to attend an oral hearing if it were to be deemed necessary.

4.3.3 Community Pharmacy Lancashire and South Cumbria have had the opportunity to consider the application and with input from the whole committee CPLSC would like to make the following comments;

4.3.4 The 2023 CCA Report on the Impact of "pseudo" distance selling pharmacies Concluded with evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk.

"Failure to regulate rogue businesses is leading to pharmacy closures."

4.3.4.1 Public data shows that there were 372 active DSP Contracts in England at the end of 2022. The prescriptions by each were analysed to determine which GP Surgery prescribed them.

4.3.4.2 268 (72%) are not following their NHS DSP contractual requirements. More than 50% of their prescriptions come from GP's in a single postcode area that is located within 10 miles of the pharmacy.

4.3.4.3 28 (72%) are not following their NHS DSP requirements. More than 50% of their prescriptions come from GP's in a single postcode area. However more than 50% of their prescriptions come from more than 10 miles from the pharmacy.

4.3.4.4 15 (4%) receive up to 50% of their prescriptions come from GP's in a single postcode area. However fewer than 50% of their prescriptions come from more than 10 miles from the pharmacy.

4.3.4.5 Only 63 (16%) receive prescriptions from across the country and provide the service expected of DSP's

4.3.5 There are three other pharmacies within 1 mile of the pharmacies proposed location (NHS Services Website).

4.3.6 We note the lack of a set of SOP's.

4.3.7 We note the minimum 40 hours of pharmacy coverage (wholly during the daytime when other pharmacies are open) and ask what benefit that brings to the local or national population.

4.3.8 We note the comprehensive floorplan and would ask that consideration to adequate security is looked at, an issue that has been a problem in pharmacies previously in Lancashire and South Cumbria.

4.3.9 There is no lack of DSP pharmacies already operating in Lancashire and South Cumbria.

4.3.10 We would ask that it is noted, that this application will in no way cause any loss of pharmaceutical cover.

4.3.11 In summary, there is evidence that the majority of DSP (Distance Selling Pharmacies) are operating in breach of their NHS Contracts putting brick and mortar pharmacies and therefore local care at risk and we urge the ICS to ensure that if this pharmacy is approved that it is audited to ensure its does not operate in breach of its contract."

5 Summary of Observations

This is a summary of observations received.

5.1 THE APPLICANT

5.1.1 “This rebuttal is submitted further to NHS Resolution’s letter dated 8 January 2026, enclosing third party representations and inviting a response limited to rebuttal of matters already raised.

5.1.2 Cure Clinics Dispensing Services Ltd (“CCDS”) confirms that this response:

5.1.2.1 is confined strictly to rebuttal of the third-party representations provided;

5.1.2.2 raises no new evidence, services, or factual assertions beyond those already contained within the appeal submission and subsequent Addendum; and

5.1.2.3 is intended to assist the Pharmacy Appeals Committee by clarifying why the representations do not undermine satisfaction of Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended in June 2025.

5.1.3 CCDS notes the representations submitted by Community Pharmacy Lancashire and South Cumbria (CPLSC) dated 2 January 2027. While the representations express general concerns regarding distance-selling pharmacies, they are generic, speculative, and not probative of the application under appeal. CPLSC relies on broad assertions regarding:

5.1.3.1 national compliance issues attributed to some distance-selling pharmacies;

5.1.3.2 perceived sector-wide risks; and

5.1.3.3 anecdotal concerns not linked to CCDS.

5.1.4 These submissions are not specific to CCDS and do not engage with the statutory test under Regulation 25. It is well established that an application cannot lawfully be refused on the basis of generalised concerns about a category of provider, rather than the applicant’s own arrangements.

5.1.5 The Committee is respectfully invited to place no weight on such generalised assertions.

5.1.6 CPLSC suggests that distance-selling pharmacies may lack sufficient Standard Operating Procedures or governance arrangements. Insofar as this assertion is intended to apply to CCDS, it is factually incorrect and is directly contradicted by material already before the Committee, including:

5.1.6.1 the original appeal submission; and

5.1.6.2 the Addendum, including Annex A (Revised), which explicitly maps each Essential and Advanced pharmaceutical service to the SOPs governing its delivery.

5.1.7 The existence and scope of SOP governance for CCDS is therefore already evidenced, and no further rebuttal is required beyond directing the Committee to that material.

5.1.8 CPLSC makes reference to local pharmacy provision and implied market impact. Such considerations are legally irrelevant to a distance-selling pharmacy application. Regulation 25 is concerned solely with whether the applicant's arrangements secure:

5.1.8.1 uninterrupted provision of pharmaceutical services during declared opening hours; and

5.1.8.2 safe and effective provision of pharmaceutical services without face-to-face contact at the pharmacy premises.

5.1.9 Local market impact is not a lawful ground for refusal and should be disregarded.

5.1.10 CPLSC appears to suggest that CCDS's opening hours may be less convenient than those of local pharmacies. Regulation 25 does not require parity of opening hours or comparative convenience. The test is whether pharmaceutical services are provided uninterrupted during the applicant's declared opening hours, a matter which is fully addressed in the appeal and Addendum. No contrary evidence has been presented.

5.1.11 CCDS notes the representations submitted by Preston Pharmacy dated 15 December 2025. Preston Pharmacy suggests that information not before the Commissioner at first instance should not be considered on appeal. This position is inconsistent with NHS Resolution's own published guidance and correspondence, which expressly confirms that appeals may be determined by way of redetermination, including consideration of information not available to the original decision-maker.

5.1.12 The Committee is therefore invited to disregard this assertion.

5.1.13 Preston Pharmacy raises assertions regarding potential safety or delivery risks associated with distance-selling pharmacies. These assertions are unsupported, speculative, and not specific to CCDS. They are also contradicted by the documented governance, controlled drug management, cold chain arrangements, and delivery procedures already contained within the appeal bundle and Addendum. No evidence has been provided that challenges CCDS's ability to provide pharmaceutical services safely and effectively in accordance with Regulation 25.

Conclusion

5.1.14 None of the third-party representations raise matters that undermine satisfaction of Regulation 25 (as amended June 2025) in relation to CCDS. In summary:

5.1.14.1 The representations are largely generic, non-specific, or legally irrelevant to a distance-selling pharmacy application;

5.1.14.2 Assertions regarding governance and SOPs are demonstrably contradicted by material already before the Committee; and

5.1.14.3 No evidence has been presented that challenges CCDS's ability to provide uninterrupted pharmaceutical services, or to do so safely and effectively without face-to-face contact at the pharmacy premises.

5.1.15 CCDS respectfully invites the Pharmacy Appeals Committee to proceed to determination of the appeal on the papers."

5.1 PRESTON PHARMACY

5.1.1 "Thank you for your letter of 8th January 2026. My previous comments still apply in this case. In addition I note that the Applicant has provided information about how they will carry out appliance customisation and appliance reviews. In their original application the Applicant was silent about whether Appliances would be provided or not. As the new evidence confirms that Appliances will be provided the Applicant is required to show how the service can be provided remotely and has not done so."

6 Consideration

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

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

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

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

Regulation 31

6.5 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).

6.6 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises.

6.7 The Committee noted, that whilst the Commissioner had misquoted Regulation 31, it had reached the conclusion that Regulation 31 does not apply, as the Applicant is not undertaking to provide pharmaceutical services from the same or adjacent premises to existing services they provide. The Committee noted that this had not been disputed by any party either on appeal or in subsequent representations. On the basis of the information before it the Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

6.8 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."

6.9 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)

6.10 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)

6.11 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner it is decision report stated that "*The premises listed in the application are not on the same site or in the same building as a provider of primary medical services with a patient list*" and had gone on to conclude "*…it is felt that the ICB can confirm that the application meets this element of the regulations*." Based on the information available to it, which has not been disputed, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

6.12 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.

6.13 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.

6.14 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.

6.15 The Committee noted the comments from the Applicant with regard to the portal not being able to "provide any mechanism for uploading SOP documents" and further that the response section at 7.1 has a word limit. Whilst the Committee considers each application on its own merits, it was mindful of other applications which did not appear to encounter these difficulties and were able to submit all relevant information to support the initial application. In any event, the Committee was of the view that there is no such restriction when submitting an appeal.

6.16 The Committee noted the comments from the Applicant that "*no evidence has been presented that challenges CCDS's ability to provide uninterrupted*

pharmaceutical services, or to do so safely and effectively without face-to-face contact at the pharmacy premises." The Committee was mindful that it was not for other parties to provide evidence to challenge the assertions made by the Applicant.

6.17 It is a matter for the Applicant to provide the relevant information required, either in the first instance to the Commissioner or on appeal, to demonstrate that there would be compliance with Regulation 25. The Committee is of the view that this does not have to be in the form of SOPs (as they may contain matters not relevant to the Committee's consideration) as there are many ways an applicant can choose to organise itself in order to comply with the various requirements of the Regulations.

6.18 The Committee noted the comments from the Applicant, on appeal, that "*These inclusions go far beyond what the Regulations require. They evidence a live, GPhC-inspected, operational DSP already delivering safe, compliant, and uninterrupted services to private patients nationally—the same infrastructure proposed for NHS service delivery*." The Committee was mindful that each application is considered on its own merits, based on the information that it has before it and, whilst the Applicant may already be operating a private pharmacy that has been GPhC inspected, it would be unfair to treat the Applicant differently to those applicants who are not currently an "operational DSP".

6.19 The Committee therefore proceeded to consider the instant application which was before it and has asked itself whether it has sufficient information and documentation which would address the criteria in Regulation 25(2)(b). If the Committee is to be satisfied of the matters in that paragraph, the Committee must be provided with evidence to demonstrate these matters. In this case, that evidence put forward has taken the form of the original application, the appeal and three SOPs which the Applicant has provided.

6.20 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 application, appeal and SOPs in order to satisfy itself that it is appropriate to grant the application, the absence of which would require it to reject it.

6.21 In respect of uninterrupted provision of services, the Committee noted that the Commissioner had concluded "*The applicant has stated the services and hours that will be provided at the new site, but this is not supported by procedures to evidence uninterrupted provision of services. From the evidence provided in the application it is felt that the ICB cannot confirm that the applicant meets this element of the regulations"*.

6.22 The Committee noted that the Applicant, on appeal, had provided information regarding the "Opening hours and Capacity" of the pharmacy as well as the "Nationwide Reach" and further "Continuous Workflow Monitoring" as well as "Contingency Planning". The Committee noted the statement from the Applicant "*Within these hours, we always have pharmacist and trained staff on*

duty to promptly process prescriptions and respond to patients needs. ..." but noted that the Applicant had not expanded upon this further.

6.23 The Committee was mindful that the uninterrupted provision of services was greater than patients being able to communicate with the pharmacy. Whilst the Committee noted the SOPs "RPSOP-01 – Responsible Pharmacist" and "RPSOP-02 – Absence of the Responsible Pharmacist" for which the 'key domain' was "*RP absence log, permitted activities, escalation process*" it had not been provided with these SOPs and there was no further information provided by the Applicant with regard to the Responsible Pharmacist and how they would ensure that essential services would be available without disruption, for example during any absence of the Responsible Pharmacist.

6.24 Based on the lack of information before it, the Committee was not satisfied that the provision of services would be without interruption.

6.25 The Committee noted the statement from the Applicant that "*Services will be delivered remotely…"* and further "*Patients anywhere in England can access essential services through secure digital and telephone channels."* The Applicant had further stated "*We use tracked signed for courier services to ensure reliable, nationwide medication delivery …"*

6.26 The Applicant, on appeal, had further stated:

6.26.1 "*Nationwide Reach: As a distance seller, we impose no geographic restrictions – any patient in England can access our services remotely. We have experience delivering to patients from Cornwall to Cumbria under our private provision. All essential services will be offered uniformly to all patients, regardless of location …"*

6.27 The Committee further noted the references throughout the application and appeal to services being provided on a national basis with the use of Royal Mail as well as a courier. Based on the information before it, the Committee was satisfied that the provision of essential services would be available to persons anywhere in England.

6.28 The Committee noted the comments from the Applicant with regard to the location of the premises and what would happen if a member of staff received a query requesting the provision of essential services face to face or in the vicinity of the premises. The Applicant, in its application had stated "*Our service model is designed to be fully remote and non-public facing. We do not accept in-person visitors, and our SOPs reflect this."*

6.29 The Applicant had gone on to state:

6.29.1 *"All interactions occur via secure phone or email channels. For patients with accessibility needs, we offer alternative formats and can speak directly to parents/guardians where the patient is under 18.*

…

Our team work from private, access-controlled areas. PMR access is role-specific with individual logins. Conversations about patient care occur confidentially and are never conducted in public or shared areas.

Our premises is on a secure business park with gated access (no public footfall). Should a patient attend the premises in person, a clear notice is displayed informing them that this is a non-patient-facing pharmacy."

6.30 The Committee noted that on appeal the Applicant had gone on to state:

6.30.1 *"**No Public Access Policy:** First and foremost, we reiterate that our premises has no public access or walk-in facility, as required for DSPs. We have a clear policy (and signage on the door) stating that we do not serve patients face-to-face at the pharmacy. If a patient or member of the public were to visit the location, they would find a notice directing them to contact us via telephone or online for service. Our staff are trained never to dispense or provide any pharmacy service in person at the door – even if someone comes in, we politely explain we are a distance pharmacy and arrange to assist them remotely. This ensures full compliance with the letter of the DSP regulations."*

6.31 The Committee was mindful of the regulatory changes as of 1 October 2025, that distance selling pharmacies can no longer provide Directed services (Advanced, National Enhanced and Enhanced Services, with the exception of Covid-19 and Flu vaccination services) face-to-face with the patient at the pharmacy premises.

6.32 The Committee noted the comments with regard to Advanced services that the Applicant was proposing to offer "where permitted" and that the offer of advanced services "*was subject to accreditation, commissioning arrangements and compliance with DSP-specific delivery rules"*. The Committee was of the view that whilst it had not been provided with information as to how the Applicant would be providing such services, based on the information provided, the Applicant would not be able to provide any pharmaceutical services at the premises.

6.33 The Committee was mindful that when the pharmacy opens, it will be the responsibility of the Commissioner, in keeping with Regulation 64, to ensure that services are provided other than with face to face contact.

6.34 The Committee was of the view, based on the information before it, that the provision of pharmaceutical services would be without face to face contact.

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

6.36 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.

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

6.37.1 Dispensing of drugs and appliances

6.37.2 Urgent supply without a prescription

6.37.3 Preliminary matters before providing ordered drugs or appliances

6.37.4 Providing ordered drugs or appliances

6.37.5 Refusal to provide drugs or appliances ordered

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

6.37.7 Disposal service in respect of unwanted drugs

6.37.8 Promotion of healthy lifestyles

6.37.9 Prescription linked intervention

6.37.10 Health campaigns

6.37.11 Signposting

6.37.12 Support for self-care

6.37.13 Discharge medicines service

6.37.14 Websites and health promotion zones

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

Dispensing of drugs and appliances

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

6.40 Whilst the Committee noted the comments from the Applicant with regard to the electronic prescriptions and the use of EPS, no information had been provided by the Applicant as to how non-electronic prescriptions would be presented at the pharmacy. Therefore, the Committee was not 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

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

6.42 The Committee noted that the Applicant had made no reference, either in its original application form or on appeal or subsequent correspondence as to how it would safely and effectively receive requests from prescribers for urgent supplies of drugs and appliances.

6.43 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 6 of Schedule 4.

Providing ordered drugs or appliances

6.44 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 Misue of Drugs Regulations 2001 and, in particular, Regulations 14 and 16, are met).

6.45 The Committee noted that the Commissioner had concluded that "*Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., … cold chain …*"

6.46 The Committee noted that, on appeal, the Applicant had provided further information with regard to cold chain delivery which stated:

6.46.1 "***Packaging for Dispatch:*** *For refrigerated items sent out to patients, we use validated insulated packaging with frozen gel packs that maintain 2–8°C for a sufficient transit duration. In practice, our deliveries of cold items are sent on a next-day delivery service. Our SOP requires staff to pre-condition cool packs (as per manufacturer guidelines) and pack the medication with minimal head-space to preserve temperature. Each cold shipment is labelled "Keep Refrigerated" and "Urgent – perishable medicine" to alert the courier. Where a patient has a prescription for ambient and cold chain medications, accompanying items only requiring ambient provisions, will include a note to explain that fridge items will be delivered separately to the rest of their items to enable adequate cold chain to be maintained.*

Courier Arrangements*: All cold-chain parcels are sent via tracked next-day courier (Royal Mail) with priority handling, and patients are given the opportunity to select their preferred delivery day, and are also provided with tracking details immediately on handover to courier. We require a signature/confirmation on delivery for all items to ensure they aren't left unattended. The Royal Mail network covers all of England; if a remote location cannot be reached next-day by standard service, we will use a same day or dedicated courier to guarantee timely delivery. We have contingencies for failed delivery attempts. Where such an event occurs, Royal Mail are 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 redelivery of the items via Royal Mail or an alternative courier, and the return of the items that have failed to be delivered to the pharmacy by*

Royal Mail. Items subject to a cold chain breach may not be re-used and must be segregated from the pharmacy stock."

6.47 The Applicant went on to state:

6.47.1 *"**Cold chain breaches**: It is the professional judgement of the RP on duty to determine if the cold chain has been breached to make supply of the medications inappropriate or unsafe. The length of time that the product has been out with the guideline temperature should be a factor in consideration. To establish this, the manufacturers of each medicine are contacted, for guidance on the stability of the medicine, to ensure suitability to supply to the patient. All breaches are documented incidents, and the details are shared during monthly team meetings.*

6.48 The Committee noted that whilst the Applicant had referred to a "courier" it had clarified that they were proposing to use "*tracked next-day courier (Royal Mail) with priority handling"*. The Committee was of the view that whilst the items may be tracked, there was nothing provided to demonstrate the monitoring of the cold chain and if this had been compromised during transit, that Royal Mail would know prior to the medication being delivered to the patient. The Committee noted the comment "*It is the professional judgement of the RP on duty to determine if the cold chain has been breached"* however there was nothing provided as to how the pharmacist on duty would be aware of a breach of cold chain once the medication left the premises and was in the custody of Royal Mail.

6.49 The Committee noted that the pharmacy was to be notified if there was a "missed delivery" by Royal Mail and that there were contingencies in place for such an event, however this was different to the temperature of the medication being compromised, of which Royal Mail nor the pharmacist would be aware.

6.50 The Applicant had also provided a SOP entitled "LGSOP-01 Cold Chain Medicines Handling, Packaging and Delivery" which states:

6.50.1 *"Scope*

This SOP applies to all cold chain medicines dispensed and delivered. It covers receipt, storage, assembly, packing, and dispatch using validated insulated containers and Royal Mail Tracked 24™ or City Sprint refrigerated courier services, with protocols in place for delivery coordination, failed delivery, cold chain breach, and waste.

Procedure

Packaging Protocol

Use validated insulated mailing kits comprising a rigid outer carton and foil-lined or phase-change insulation sleeve.

Insert pre-conditioned frozen gel packs (as per manufacturer instructions) above and below the product to maintain 2–8 °C for at least 48 hours in ambient conditions.

Minimise headspace and ensure medication remains upright.

Seal the carton securely with tamper-evident tape. Label clearly: "Keep Refrigerated", "Perishable Medicines", and "Urgent Delivery Required".

Courier Dispatch

Dispatch of cold-chain medicines is normally scheduled Monday–Thursday to maintain validated temperature control and avoid weekend/public-holiday transit. This packaging method forms part of our patient-safety assurance, maintaining a validated 2–8 °C environment for up to 48 hours to ensure product integrity throughout delivery; Friday dispatch risks extended depot storage and potential excursion.

Service availability during all opening hours: Clinical processing (clinical check, labeling, [sic] *packaging preparation), patient coordination, and dispatch planning continue every working day. Patients anywhere in England can request and receive essential services throughout opening hours, with cold-chain consignments queued for the next safe dispatch window where appropriate.*

Exceptional authorisation: In exceptional clinical circumstances (e.g., urgent initiation where delay poses clinical risk), the Responsible Pharmacist (RP) may authorise a Friday dispatch using a guaranteed next-day service to qualifying postcodes, following a documented risk assessment and confirmation of patient availability.

Royal Mail service: Use Royal Mail Tracked 24™ (Signature) as default with SMS/email alerts and proof of delivery. Where Royal Mail cannot guarantee next-day to a location, an approved medical courier (CitySprint Refrigerated Service) is used. CitySprint offers validated temperature-controlled vehicles with real-time GPS and thermal monitoring. Dispatches via CitySprint are prioritised for urgent clinical supply where Royal Mail service limitations exist.

Tracking numbers for all consignments (Royal Mail or CitySprint) are logged in the PMR. Patients are notified of expected delivery, the need to refrigerate immediately on receipt, and the requirement for someone to be present to sign.

Failed Delivery Handling

Royal Mail or CitySprint will leave a 'Missed Delivery' card and return the item to sender if delivery fails.

Returned cold chain items are quarantined immediately upon arrival.

RP assesses item integrity with reference to:

Internal SOP.

Manufacturer guidance.

Time out of cold chain (based on dispatch/return timestamps).

Items deemed compromised are segregated and disposed of as clinical waste.

Re-dispensing is arranged with patient after clinical reassessment."

6.51 The Committee accepted that if City Sprint was to be used then a *"validated temperature controlled vehicle with real-time GPS and thermal monitoring*" would be used, however the Committee was mindful that the use of City Sprint Refrigerated Service was only to be used "*Where Royal Mail cannot guarantee next-day to a location."*

6.52 There was some ambiguity over which courier service was going to be used for cold chain deliveries however the Committee was of the view, from the information before it that Royal Mail was the preferred choice. As the Committee must be satisfied that the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that the 'cold chain' is maintained), the Committee considered that the wording and processes provided creates sufficient ambiguity as to the Applicant's intentions.

6.53 Therefore, the Committee could not be satisfied, as it was required to be, that during transit, the cold chain would be monitored throughout, or what would happen in the event of a breach in cold chain delivery by Royal Mail.

6.54 Based on the information before it, the Committee was not satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

6.55 The Committee noted that the Applicant had not provided a response to the question on the application form as to whether they were undertaking to provide appliances. The Committee noted that the Applicant had stated in further representations:

6.55.1 "*B. Advanced Services*

Where permitted by national service specifications and DSP guidance, CCDS has governance arrangements in place to support remote or off-site delivery of Advanced Services, including:

…

Appliance Use Reviews (AUR)

…

Activation of Advanced Services is subject to accreditation, commissioning arrangements, and compliance with DSP-specific delivery rules."

6.56 However, the Applicant had not provided any further information with regard to appliances and the Appliance Use Reviews and had provided no information regarding signposting for those patients who did require an appliance which may require measuring or fitting. Based on the lack of information before it, the Committee was of the view that it had not been provided with sufficient information to show that there would be compliance with paragraph 8(4) of Schedule 4.

Refusal to provide drugs or appliances ordered

6.57 The Committee asked itself how the Applicant will be satisfied that, when dispensing a repeating 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 to review the patients treatment.

6.58 The Committee noted the reference in the appeal to "Dispensing & Repeat Dispensing" which stated:

6.58.1 *"**Dispensing & Repeat Dispensing**: Prescriptions are received electronically, dispensed and checked with care, and delivered to the patient as detailed. Any clinical concerns (e.g. interactions, adherence issues) that a pharmacist would normally discuss across the counter are instead discussed via a remote consultation. We contact patients if we need to clarify any clinical queries, or to give important counselling. …"*

6.59 The Committee further noted the reference in Annex A to SOP "DSOP-02 – Professional or Clinical Assessment of a Prescription" but noted that this had not been provided. Further the Applicant had not explained how it would assess that the patient was still using the medication, was not suffering from any side effects and that the medicine regime has not changed.

6.60 Therefore, the Committee was not 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

6.61 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 a long term, stable medical condition (that is, a medical condition that is unlikely to change in the short to medium term), and (ii) requires regular medicine in respect of that medical condition.

6.62 The Applicant had made reference to "Dispensing & Repeat Dispensing" in the appeal which stated:

6.62.1 *"**Dispensing & Repeat Dispensing**: Prescriptions are received electronically, dispensed and checked with care, and delivered to the patient as detailed. Any clinical concerns (e.g. interactions, adherence issues) that a pharmacist would normally discuss across the counter are instead discussed via a remote consultation. We contact patients if we need to clarify any clinical queries, or to give important counselling. We will make use of the Connect/PharmAppy platform to message patients about their prescription status and any actions required. For repeat dispensing (eRD), our system automatically processes batch issues and we use in-app notifications to prompt patients when a new supply is being sent or to ask them to confirm need – effectively mirroring the engagement they'd get in person by coming for a refill."*

6.63 Whilst the Committee noted reference to SOP "DSOP-07 Repeat Dispensing" this had not been provided. Further there was no mention in the application form or on appeal with regard to how they would provide appropriate advice about the benefits of repeat dispensing.

6.64 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 10(1) of Schedule 4.

Promotion of Healthy Lifestyles

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

6.66 The Committee noted that apart from the heading "Public health promotion of health lifestyles" under "A Essential Services" and stating that this was contained within "DSOP-09 Public Health Campaigns" no information on this had been provided by the Applicant either in the original application form, on appeal or in subsequent representations.

6.67 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 16-18 of Schedule 4.

Prescription Linked Intervention

6.68 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.

6.69 Whilst the Committee noted the comment from the Applicant that "*During any interaction (phone or app message), our pharmacists are attentive to advising on diet, exercise, smoking cessation, or other lifestyle factors when relevant*" there was no information provided as to how the Applicant would assess whether persons required prescription linked intervention.

6.70 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Health Campaigns

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

6.72 The Committee noted the comment from the Applicant on appeal that "*we proactively send out public health information to our patient base in line with NHS campaigns*" and further the reference to SOP "DSOP-08 Public Health Campaign Delivery" however it noted that it had not been provided with the SOP and that the Applicant had not expanded further upon how it would participate in health campaigns.

6.73 Based on the information before it, the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

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

6.75 Whilst the Committee noted the comments from the Applicant in the original application form with regard to signposting, it noted that this was specifically with regard to finding suitable service providers for patients who had attended the pharmacy and were requesting the provision of essential services in a face to face setting. The Committee noted that no further information regarding signposting in the context of a distance selling pharmacy and paragraphs 19-20 had been provided by the Applicant on appeal.

6.76 The Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 19-20 of Schedule 4.

Discharge Medicine Service

6.77 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 regimen by the staff of an NHS trust or NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

6.79 The Committee noted that the Applicant had provided no information in its original application form with regard to the Discharge Medicines Service. On appeal, the Applicant had listed a SOP in Annex A entitled "DSOP-011 Discharge Medicine Service (DMS)" however this had not been provided and no other information had been provided by the Applicant. Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22B and 22C of Schedule 4.

Other considerations

Support for self-care

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

6.81 The Committee noted that the Commissioner had concluded "*Specific assertions/procedures are not adequate to assure the Group fully that safe and effective provision of essential services will be maintained, e.g., … and the support of essential services (e.g., self-care)*."

6.82 The Committee noted that on appeal, the Applicant had stated:

6.82.1 "***Clinical Advice & Self-Care****: We robustly provide self-care support and healthy lifestyle advice at a distance. During any interaction (phone or app message), our pharmacists are attentive to advising on diet, exercise, smoking cessation, or other lifestyle factors when relevant – just as they would in person. Additionally, we proactively send out public health information to our patient base in line with NHS campaigns. The team will include trained Health Champions who will oversee these campaigns. For Support for Self-Care, our pharmacists will respond with advice on over-the-counter options or general care measures. If a patient needs an OTC medicine, we will arrange to sell and dispatch it or direct them to a nearby pharmacy if urgent."*

6.83 The Committee was of the view that it had been provided with information sufficient to show that there would be compliance with paragraphs 21-22 of Schedule 4.

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

Summary

6.85 On the information before it, the Committee could not be satisfied that there are procedures likely to secure the safe and effective provision of pharmaceutical services as required by Regulation 25(2)(b).

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

6.86.1 confirm the Commissioner's decision;

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

6.86.3 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.

6.87 Although the Committee reached the same conclusion as the Commissioner, it did so for different reasons therefore the Committee determined that the decision of the Commissioner must be quashed.

6.88 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.

6.89 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.

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

7 Decision

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

7.2 The Committee:

7.2.1 quashes the decision of the Commissioner; and

7.2.2 redetermines the application as follows -

7.2.2.1 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;

7.2.2.2 the Committee was not satisfied that all essential services were likely to be secured without interruption during the opening hours;

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

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

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

7.2.3 The application is refused.

Case Manager
Primary Care Appeals