NHS Resolution

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15 June 2026

REF: SHA/26895

APPEAL AGAINST HEREFORDSHIRE AND WORCESTERSHIRE ICB DECISION TO REFUSE AN APPLICATION BY AFIFY HEALTHCARE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT UNIT 3, LONG MEADOW INDUSTRIAL ESTATE, EWYAS HAROLD, HEREFORD, HR2 0UA UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be granted.

A copy of this decision is being sent to:

Rushport Advisory LLP on behalf of Afify Healthcare Ltd
Community Pharmacy Herefordshire & Worcestershire
PCSE on behalf of Herefordshire and Worcestershire ICB

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1 The Application

By application dated 20 June 2025, Afify Healthcare Ltd ("the Applicant") applied to Herefordshire and Worcestershire ICB ("the Commissioner") for inclusion in the pharmaceutical list at Unit 3, Long Meadow Industrial Estate, Ewyas Harold, Hereford, HR2 0UA under Regulation 25. In support of the application it was stated:

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

1.1.1 "Drug Tariff part IX*

1.1.2 *Except items that require measuring or fitting."

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

1.2.1 "Not applicable as no other pharmacy in same or adjacent premises."

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

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

Pharmacy procedures

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

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

(b) the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on

their own or someone else's behalf, and the applicant or the applicant's staff.

1.5 “All SOPS available upon request”

1.6 “A. Uninterrupted provision of essential services to any person in England

Multi-channel access throughout opening hours	• Patients anywhere in England can order prescriptions, request advice or nominate the pharmacy via freephone 0800 XXX XXX, NHSmail, secure webchat and the NHS App. • Channels are staffed 08:00–20:00 Monday–Saturday and 09:00–17:00 Sunday, exceeding the 40-hour core requirement so that every essential service is always reachable while the premises are open.
Resilient dispensing workflow	1. EPS messages are downloaded automatically to the PMR (Titan system) every 5 minutes. 2. Clinical check by a GPhC-registered pharmacist within 2 hours. 3. Barcode-driven assembly and independent accuracy check eliminate picking errors (SOP DSP-204). 4. Items leave the premises the same day if the prescription is cleared before 16:00.
Reliable nationwide delivery	• Royal Mail Tracked 24 for ambient lines; GDP-compliant courier for cold-chain items. • All parcels have unique tracking links sent to the patient by SMS/e-mail. • “Missed delivery” SOP triggers an automatic re-dispatch or local contingency supply.
Business continuity & stock security	Generator-backed UPS protects servers, fridges and automation for ≥ 12 hours. • A mirrored PMR in a Tier-3 UK datacenter allows order processing to switch to the superintendent’s remote workstation within 4 hours of a major incident (SOP BCP-001). • Forecast-driven stockholding (minimum 3 months’ demand) and two wholesale lines of supply maintain continuity during shortages.

B. Safe & Effective delivery without face to face contact

Clinical assessment & counselling	Telephone or video consultations (Accredited platform: AccuRx / Attend Anywhere/Signature RX or clinko). Written information leaflets e-mailed or posted; interpreter service available for >200 languages.
Identify verification	Patient identity confirmed through NHS login, SCR match or two-factor check (DOB + address) before any clinical discussion (SOP DSP-102).
Secure data handling	All patient data stored on ISO 27001-certified servers. Remote access via VPN with MFA; activity logs reviewed daily by the SIRO
Medicine safety once dispatched	Tamper-evident packaging, temperature indicators on cold-chain products, and courier chain-of-custody bar-coding. ADR and recall notices managed through the PMR with automatic patient notification
Preventing inadvertent face-to-face supply	Doors remain locked; reception vestibule and intercom allow staff to redirect walk-ins to remote channels (see Section 7.2). No counter, cash drawer or hand-over area exists inside the dispensary.

1.7 Conclusion – These procedures guarantee that every essential service is continuously available to any person in England during the stated opening hours, and that all dispensing, advice and clinical checks are carried out remotely, eliminating face-to-face contact while still meeting all safety and governance standards set by the NHS (Pharmaceutical Services) Regulations 2013.

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

1.8 “This procedure applies to any individual who presents at the distance-selling pharmacy (DSP) premises requesting the supply of one or more essential services. It ensures compliance with Regulation 25(3)(d) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which prohibits the provision of essential services face-to-face at DSP premises.

Step-by-step procedure

1.9 Access control – The entrance door remains locked. Visitors are greeted via a video intercom situated in the reception vestibule; CCTV records all interactions.

1.10 Initial triage – A trained dispenser confirms the visitor's name and reason for attendance. If the request is for urgent medical assistance, the staff member calls 999 or directs the person to the nearest Emergency Department.

1.11 Explain the DSP model – The staff member politely states: "We are an online-only pharmacy. By law we cannot dispense or hand out medicines on these premises."

1.12 Offer remote service channels – The visitor is given a printed leaflet containing the freephone 0800 XXX XXX number, NHS App nomination instructions, webchat QR code and service hours.

1.13 Signposting – If the visitor needs immediate supply (e.g. an urgent prescription), staff identify and telephone the nearest open community pharmacy or advise attendance at an NHS walk-in center [sic] as appropriate.

1.14 No on-site supply – No medicines, advice or records are provided on the premises. Payment facilities and a medicines counter are intentionally absent to prevent inadvertent supply.

1.15 Record keeping – The encounter is logged in the "DSP-VISIT Register" (date/time, initials of staff, nature of request, signpost action). Any safety concerns are escalated to the Responsible Pharmacist and documented in the Clinical Governance file.

1.16 Governance review – All DSP-VISIT entries are reviewed monthly by the Superintendent Pharmacist to identify trends and ensure adherence to this SOP (reference DSP-402).

1.17 This procedure guarantees that essential services and advanced service NMS are not provided face-to-face, while ensuring that every visitor receives clear information on how to access services remotely or obtain urgent care if required"

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.

1.18 The following advanced services will be provided entirely by remote means so that no element of the essential services (dispensing, supply, disposal, etc.) occurs during the advanced-service encounter. This fulfils Regulation 25(3)(e) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which was amended with effect from 23 June 2025

Advanced Service	Remote delivery method	Separation from essential services
New Medicine Service (NMS)	Procedure (14 Stages) 1 Eligibility Detection: System rules flag qualifying new medicine; 'NMS_ELIGIBLE' set. the Titan PMR 2 Clinical Check & Flag Confirmation: RP completes clinical check (dose, interactions). If unsuitable for NMS,	The medicines have already been clinically checked, dispensed and dispatched (see 7.1). The NMS discussion occurs after receipt, so

	selects exclusion reason (mandatory field). 3 Offer Preparation: generates templated offer text + digital leaflet link in PMR task queue. 4 Initial Offer & Consent Request: Within X working days technician/RP phones patient; verifies identity (name, DOB, address, NHS number) and reads offer script emphasising remote-only model; sends leaflet. 5 Consent Capture: RP secures explicit consent (verbal recorded OR e-sign). Logs date/time, method and call ID; status changes to 'NMS Active'. 6 Baseline Consultation: RP conducts structured assessment (indication understanding, baseline adherence score, barriers, early side effects) via phone/video; completes mandatory PMR fields. 7 Risk Stratification: System algorithm assigns risk tier (Low/Moderate/High) based on adherence score, polypharmacy, cognitive risk; RP may override with reason. 8 Follow-Up Scheduling: Admin schedules FU1 (Day 7–14) and FU2 (Day 21–35). Automated confirmations include 'REMOTE ONLY – DO NOT ATTEND PREMISES'. 9 Follow-Up 1 (FU1): RP reassesses adherence, side effects, barriers; updates adherence score; records interventions and safety net advice. Escalate clinically significant issues via NHSmail. 10 Prescriber Liaison (If needed): RP drafts structured NHSmail (Issue | Recommendation | Clinical Rationale). Logs 'Pending Intervention'. Implements change ONLY upon receipt of new EPS script. 11 Interim / Unscheduled Contacts: Any patient-initiated contact logged; minor issues resolved with education; major issues escalate (GP / urgent care). Never invite patient to premises. 12 Follow-Up 2 (FU2): Final adherence assessment and outcome classification (Continue / Adjust / Discontinue).	no dispensing or supply takes place during the consultation. …… Eligibility is auto flagged from EPS data. Identity and consent are captured remotely. Structured baseline consultation and two follow ups are conducted via phone/video. Risk stratification informs scheduling. Interventions are actioned through prescriber liaison (NHSmail) and only new EPS prescriptions initiate therapy changes. All documentation and KPIs are recorded electronically. No step permits or requires face-to-face Attendance detailed SOPs are available upon request

	Reinforce long-term management, document final adherence delta. 13 Outcome & KPI Coding: System auto-derives metrics (offer, consent, completion, adherence improvement, intervention acceptance). Dashboard refreshes daily. 14 Audit & Closure: Governance Lead samples ≥5% episodes monthly. Non-conformities graded; CAPA raised; closure verification logged. Episodes then archived as 'Closed'. detailed SOPs are available upon request."	

Supporting information with the application form

1.19 "Regulation 25 –

1.20 Further to your letter requesting additional information under the amended Regulation 25, I write to provide our definitive remote-only clarification.

1.21 Limited-Service Undertaking (for determination):

1.22 Afify Healthcare Ltd confines its undertaking at this stage to:

1.22.1 Provision of all Essential Services nationwide on a wholly remote basis; and

1.22.2 Provision, remotely only, of one Advanced Service – the New Medicine Service (NMS).

1.23 We withdraw any previous indication of undertaking other Advanced, National Enhanced, or Locally Commissioned Enhanced (Directed) Services (including CPCS, DMS, vaccinations, physical clinical measurements, supervised consumption, etc.).

Face-to-Face Prohibition:

1.24 No pharmaceutical service will involve face-to-face contact at, or in the vicinity of, the proposed DSP premises. The premises in a remote industrial area have no public access or collection facility; any attempted arrival is politely redirected and logged. Access to premises via access cards for staff and a reception individual recording access and visitor log. There is no pathway for patient collection or on-site consultation.

Procedural Assurance:

1.25 The attached Comprehensive.Remote_Only.Addendum details:

1.25.1 End-to-end remote Essential Services workflow (EPS retrieval → clinical check →assembly → accuracy → counselling → tracked dispatch → monitoring).

1.25.2 Fully remote NMS lifecycle (eligibility flag → offer & e-consent → baseline assessment → scheduled remote follow-ups → outcomes).

1.25.3 Safeguarding escalation (remote recognition → 999 / GP / local authority referral—never on-site assessment).

1.25.4 Information governance, business continuity (dual ISPs, UPS, courier contingency), and KPI / audit framework (zero face-to-face verification, incident trend analysis, adherence outcomes).

1.26 These layered controls demonstrate that our procedures are likely to secure the safe and effective remote provision of pharmaceutical services in accordance with the amended Regulation 25.

1.27 Please find enclosed our consolidated submission relating to the determination of our Distance Selling Pharmacy application (submitted prior to 23 June 2025). This pack formalises a limited remote-only service undertaking and evidences the procedures by which Afify Healthcare Ltd will secure the safe and effective provision of pharmaceutical services without any face-to-face contact at or near the proposed premises.

Executive Summary

1.28 This Addendum consolidates and supersedes previous submissions. For determination, Afify Healthcare Ltd now confines its service undertaking to: (a) provision of all Essential Services nationwide on a wholly remote basis; and (b) provision, remotely only, of ONE Advanced Service – the New Medicine Service (NMS). All other Advanced, National Enhanced or Locally Commissioned Enhanced (Directed) Services referenced previously are formally withdrawn at this stage.

1.29 No pharmaceutical service involves, or will involve, any face-to-face contact at, or in the vicinity of, the proposed Distance Selling Pharmacy (DSP) premises. Procedures set out below demonstrate that our systems and controls are likely to secure the safe and effective remote provision of pharmaceutical services in line with the amended Regulation 25 wording.

Limited Service Undertaking & Explicit Withdrawals

1.30 Undertaking: Essential Services + ONE Advanced Service -Remote-only New Medicine Service (NMS). Withdrawn: CPCS, DMS

Remote-Only Model – Overarching Principles

1.31 Zero Public Access (staff access with access card and finger print sign in): Locked entrance; no counter or waiting area; signage and website wording dissuade attendance.

1.32 Visitor Management SOP: Any arrival (patient/representative) is politely redirected; reason recorded; no service episode provided.

1.33 Remote Channel Exclusivity: All clinical interactions via authenticated telephone, video, secure portal/chat or NHSmail – never in person.

1.34 Segregated Workflows: Clinical consultations and dispensing physically separate from any potential public interface; no handover point.

1.35 No Collection Pathway: PMR, patient communications and SOPs contain no option for collection; tracked courier (royal mail) dispatch is mandatory.

1.36 Auditability: All steps time/user-stamped in PMR; exception reports monitor access, delivery status, incidents, safeguarding referrals.

New Medicine Service (NMS) – Fully Remote Lifecycle (more detailed SOPs available upon request)

1.37 Eligibility Auto-Flag: Rule engine identifies new qualifying medicine immediately after clinical check.

1.38 Offer & Information: Phone/SMS/email offer containing remote-only disclaimer; digital leaflet supplied.

1.39 Identity Re-Verification: Name, DOB, address, NHS number (where available) reconfirmed; representative authority confirmed if applicable.

1.40 Digital Consent: E-signature or recorded verbal consent (stored in PMR) .

1.41 Baseline Assessment: Remote (phone/video) evaluation of understanding, adherence barriers, concerns, initial side-effect review.

1.42 Risk Stratification: Template assigns Low/Moderate/High adherence risk to tailor follow-up intensity.

1.43 Personalised Adherence Plan: Strategies (reminders, aids, packaging solutions) documented; all deliverable remotely via royal mail.

1.44 Initial Consultation Record Finalisation: Structured fields (issues, interventions, counselling points) saved; timestamped.

1.45 Follow-Up Scheduling: Automated booking windows (Day 14 & Day 28); confirmations reiterate 'All consultations remote – do not attend premises'.

1.46 Follow-Up 1 (≈ Day 14): Remote review of adherence, side effects, unresolved concerns; escalate to prescriber electronically if needed.

1.47 Prescriber Liaison: NHSmail summary of intervention request; any therapy modification via new EPS prescription processed through standard remote dispensing.

1.48 Follow-Up 2 (≈ Day 28): Final adherence score, outcome classification (continue/adjust/discontinue) recorded; reinforce self-management.

1.49 Unscheduled Contacts: Patient may request additional remote discussion; triaged by pharmacist; outcome documented.

1.50 Outcome & KPI Coding: System calculates adherence improvement %, intervention acceptance, outstanding issues for monthly dashboard.

1.51 Monthly NMS Audit: Sample (≥5%) checked for documentation completeness, consent evidence, zero face-to-face references; corrective action logged if deviation found.

Essential Services – Detailed Remote Procedures (more detailed SOPs available upon request)

1.52 EPS Retrieval: Automated EPS polling queues prescriptions – no paper acceptance.

1.53 Integrity & Fraud Screening: System flags duplicate supplies or unusual quantities; pharmacist resolves remotely with prescriber.

1.54 SCR/PMR Review (Titan): Pharmacist accesses Summary Care Record and patient history remotely to inform clinical check.

1.55 Clinical Check: Dose, interactions, contraindications, therapeutic duplication, and safeguarding cues assessed; clarifications via NHSmail/phone.

1.56 Intervention Logging: Structured PMR note with intervention code and prescriber communication record.

1.57 Stock & Cold Chain Verification: Staff-only process verifying batch, expiry and temperature data; no patient presence.

1.58 Assembly: Barcode-driven selection and label application; controlled access.

1.59 Accuracy Check: Independent check recorded with user ID and timestamp.

1.60 Counselling Flag & Scheduling: System prompts remote counselling for new/changed/high-risk therapy; appointment arranged by phone/video; message includes 'Do NOT attend premises'.

1.61 Packaging: Tamper-evident, plain outer pack; cold-chain validated packaging with temperature logger if required.

1.62 Manifest & Tracking: Unique internal manifest ID linked to PMR; tracking number autocommunicated to patient.

1.63 Tracked Courier Dispatch: Handover scanned; no collection alternative exists in SOPs.

1.64 Delivery Monitoring: Dashboard polls tracking; exceptions (delay, failed attempt, temperature alert) trigger remote contact only.

1.65 Failed Delivery Protocol: Re-attempt, address verification, potential re-dispatch; never converted to collection.

1.66 Post-Dispatch Queries: Managed via remote channels; no face-to-face slots offered.

1.67 Adverse Event & Side Effect Reporting: Patient reports through phone/video/secure form; pharmacist records and (where applicable) submits Yellow Card electronically.

1.68 Pharmacovigilance & Incident Trend Review: Monthly analysis of interventions, incidents, delivery exceptions for continuous improvement.

Declaration

1.69 I confirm that for determination purposes Afify Healthcare Ltd undertakes only Essential Services and the New Medicine Service (remote-only). All procedures above are active or will be before service commencement, ensuring safe and effective pharmaceutical service provision without any face-to-face contact at, or in the vicinity of, the premises. Any attempted patient or representative attendance is redirected and logged; no in person consultation or supply occurs.

1.70 Signed: [MA] Date: 19/07/2025

1.71 Name: [MA]

1.72 (GPhC 2234860) – Afify Healthcare Ltd

1.73 I have attached to this email 4 attachments

1.73.1 amended Application

1.73.2 corrected Fitness to practice

1.73.3 SOPs for NMS .

1.73.4 Comprehensive remote only addendum

1.74 Please confirm receipt. I would be pleased to provide any further clarification or supply redacted SOP excerpts and templates referenced in the Addendum."

1.75 [SOPs provided with the application form have now been superseded]

2 Comments to the Commissioner

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

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

2.1 THE APPLICANT

2.1.1 “Cover letter to PCSE / ICB (responding to LPC comment)

2.1.2 Subject: Afify Healthcare Ltd (DSP) – Clarification & updated documents (Regulation 25 compliance)

2.1.3 Dear Sir/Madam,

2.1.4 Thank you for the LPC comments dated 13 August 2025 regarding our DSP application (Unit 3, Long Meadow Industrial Estate, Ewyas Harold, HR2 0UA; CAS-370746-T6F6F4).

2.1.5 We now confirm our service undertaking is limited to Essential Services (nationwide) and a single Advanced Service: the New Medicine Service (NMS), delivered remotely only. All previous references to CPCS, DMS, vaccinations, BP monitoring, or any service requiring in-person contact are withdrawn.

2.1.6 We reiterate compliance with Regulation 25 (as amended):

2.1.6.1 We are not on the same site or in the same building as a provider of primary medical services with a patient list.

2.1.6.2 All essential services are provided without any face-to-face contact with patients or representatives.

2.1.6.3 Services are delivered from the designated registered premises during contracted opening hours, with uninterrupted access for people anywhere in England via remote channels.

2.1.7 Enclosed: updated Annex-1 (Application Form) sections and our consolidated Comprehensive Remote-Only Addendum and NMS (Fully Remote) SOP.”

2.1.8 “Annex-1 Application Form – Section 4 (replace the whole block)

2.1.9 Pharmaceutical services to be provided at these premises

2.1.9.1 Essential Services: Yes – provided nationwide during opening hours without any face-to-face contact; all interactions are by telephone/video/secure digital channels; no collection from premises.

2.1.9.2 Appliances: Drug Tariff Part IX except items requiring measuring/fitting.

2.1.10 Advanced services to be provided (remote-only):

Service	Accredited to provide (Y/N/NA)	Premises accredited to provide (Y/N/NA)	Consultation area (Y/N/NA)

New Medicine Service (NMS) remote only	Y	Y	Y - (privacy room used solely for remote phone/video consultations; no face-to-face service is offered or permitted at the premises)

2.1.11 Withdrawn: CPCS, DMS, vaccinations, BP monitoring, supervised consumption, and any other service requiring or implying face-to-face contact. (These were listed in earlier drafts and are now withdrawn.)

2.1.12 Floor plan note: “A private staff-only room is available solely to conduct remote telephone/video consultations in privacy. It is not used for any in-person patient contact or supply.”

2.1.13 Annex-1 – Section 7.1 (add this opening paragraph before your existing detail) Regulation 25 assurance (summary statement):

2.1.14 “The pharmacy’s procedures secure uninterrupted provision of essential services during opening hours to persons anywhere in England and secure the safe and effective provision of essential services without any face-to-face contact between patients/representatives and the applicant or staff. All services are provided from the designated registered premises during contracted hours; the model precludes onsite collection or in-person consultations.”

2.1.15 “Annex-1 – Section 7.2 (keep as is; it already bans F2F and logs redirections)”

2.1.16 7.2 “Visitor Management/Signposting” text is compliant: locked door, intercom, no onsite supply, signposting + logging. (Just ensure the staff script explicitly says, “By law we cannot provide services in person at these premises.”)

2.1.17 “Annex-1 – Section 7.3 (replace with concise NMS-only wording)

2.1.18 Advanced service: New Medicine Service (NMS) – remote-only NMS is delivered entirely by phone/video with digital consent. The NMS consultation takes place after dispensing and after the item has been dispatched/received; therefore no element of essential services occurs during the NMS encounter.

2.1.19 Workflows (eligibility flag → baseline consult → FU1 → FU2 → outcome) and prescriber liaison are described in the attached SOP and Addendum; no step allows or requires face-to-face contact. (Full SOP available on request.)

2.1.20 Comprehensive Remote-Only Addendum – final confirmation

2.1.21 Addendum already limits the undertaking to Essential Services + remote-only NMS and explicitly withdraws CPCS/DMS/etc. Please just:

2.1.21.1We added one sentence in Section 1: “This Addendum supersedes any prior references to CPCS, DMS or ‘Pharmacy First’ within the application bundle.”

Annex-1 (Application Form) – UPDATED SECTIONS

2.1.22 “Afify Healthcare Ltd – Distance Selling Pharmacy

2.1.23 The following text replaces Section 4 and Section 7.3, and is inserted as the opening paragraph to Section 7.1.

2.1.24 Section 4 – Pharmaceutical services to be provided at these premises

2.1.25 Essential Services: Yes – provided nationwide during opening hours without any face-to-face contact; all interactions are by telephone/video/secure digital channels; no collection from premises.

2.1.26 Appliances: Drug Tariff Part IX except items requiring measuring/fitting.

Service	Accredited (Y/N/NA)	Premises accredited (Y/N/NA)	Consultation area (Y/N/NA)
New Medicine Service (NMS) – remote only	Y	Y	Y (privacy room used solely for …

2.1.27 Withdrawn: CPCS, DMS, vaccinations, blood pressure monitoring, supervised consumption, and any other service requiring or implying face-to-face contact. (These were listed in earlier drafts and are now withdrawn.)

2.1.28 Floor plan note: A private staff-only room is available solely to conduct remote telephone/video consultations in privacy. It is not used for any in-person patient contact or supply.

2.1.29 Section 7.1 – Regulation 25 assurance (opening paragraph to insert)

2.1.30 The pharmacy’s procedures secure uninterrupted provision of essential services during opening hours to persons anywhere in England, and secure the safe and effective provision of essential services without any face-to-face contact between patients/representatives and the applicant or staff. All services are provided from the designated registered premises during contracted hours; the model precludes on-site collection or in-person consultations.

2.1.31 Section 7.3 – Advanced service: New Medicine Service (NMS) – remote-only (replacement text)

2.1.32 NMS is delivered entirely by phone/video with digital consent. The NMS consultation takes place after dispensing and after the item has been dispatched/received; therefore no element of essential services occurs during the NMS encounter. Workflows (eligibility flag → baseline consult → FU1 → FU2 → outcome) and prescriber liaison are described in the attached SOP and Addendum; no step allows or requires face-to-face contact.

2.1.33 Comprehensive Remote-Only Addendum – Confirmation

2.1.34 Afify Healthcare Ltd – Distance Selling Pharmacy

2.1.35 Date: 13 October 2025

2.1.36 This confirmation note accompanies the existing Comprehensive Remote-Only Addendum and should be filed with it. It adds the following sentence to Section 1:

2.1.37 “This Addendum supersedes any prior references to CPCS, DMS or ‘Pharmacy First’ within the application bundle.”

2.1.38 Please sign below to confirm adoption and immediate effect across the organisation.

2.1.39 NMS (Fully Remote) SOP – Confirmation

2.1.40 Afify Healthcare Ltd – Distance Selling Pharmacy

2.1.41 Date: 13 October 2025

2.1.42 This confirmation note accompanies the existing SOP titled “NMS – Fully Remote”. Add the following line to Section 1 (Purpose):

2.1.43 “This SOP is specific to Distance Selling Pharmacy operations and prohibits any face-to-face contact at or in the vicinity of the premises.”

2.1.44 Please sign below to confirm adoption and immediate effect across the organisation.”

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 30 January 2026 states:

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

3.1 “Herefordshire and Worcestershire 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 Pharmacy Services Regulations Committee minutes dated 17 December 2025:

3.2 "Distance Selling Premises – excepted application

3.3 CAS-370746-T6F6F4

3.4 Afify Healthcare Limited

3.5 Unit 3 Long Meadow Industrial Estate, Ewyas Harold, Hereford, HR2 0UA

3.6 Regulation 31 – refusal: same or adjacent premises [quoted in full]

3.7 Regulation 31(2)(a) (i) (ii) The Committee were satisfied that there is no pharmacy providing pharmaceutical services at the same or adjacent premises.

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

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

3.10 The Committee then went on to consider Regulation 25.

3.11 Regulation 25 – Distance Selling Premises Applications

3.12 Regulation 25(2)(a) – The NHSCB must refuse an application to which paragraph 1 applies – If the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.13 The Committee was satisfied that the proposed premises are not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.14 This is confirmed with information available on the NHS.UK website where the nearest general practice is located 0.7 miles away.

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

3.16 Regulation 25(2)(b)(i) – The pharmacy procedures indicate that it does not meet the standard required to satisfy the regulatory requirements of the provision of essential services.

3.17 There is nothing documented on having a pharmacist available during opening hours

3.18 Therefore, this regulation is deemed to have not been met

3.19 Regulation 25(2)(b)(ii) – The pharmacy procedures does not meet the standard required to satisfy the regulatory requirements of the provision of pharmaceutical services without face to face contact.

3.20 Applicant is proposing to provide the New Medicine Service (NMS) and has provided a response following the regulation changes in June 2025, with regards to safe and effective provision of NMS

3.21 The Committee considered the supporting information provided for New Medicine Service (NMS) and concluded that the process is not detailed enough on how the service will be delivered without face to face contact. Furthermore the applicant has not demonstrated the necessary procedures to ensure safe and effective delivery of the services e.g. disposal of unwanted medicines.

3.22 Therefore, this regulation is deemed to not have been met

3.23 Regulation 66

3.24 The applicant has undertaken to provide directed services. If the application is to be granted, and the inclusion of the applicant and the pharmacy premises in the pharmaceutical list for the area of Herefordshire HWB, would be subject to the relevant conditions set out in Regulation 66.

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

3.26 The Committee determined that appeal rights are to be granted to the applicant

3.27 Who has right of appeal – Applicant only

3.28 Actioned for: PCSE to notify the applicant and interested parties of the decision

3.29 Specific conditions – Distance Selling Premises

3.30 “As the application is in respect of distance selling premises, by virtue of Regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of Herefordshire Health and Wellbeing board in respect of the premises included in the application, that inclusion will be subject to the following conditions:

3.30.1 The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises.

3.30.2 The means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises.

3.30.3 The proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

3.30.4 The pharmacy procedures for the premises must be such as to secure:

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

3.30.4.2 the safe and effective provision of pharmaceutical services without face-to-face contact at the proposed 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; and

3.30.5 Nothing in the applicant's practice leaflet, in the applicant's publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant's staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:

3.30.5.1 the essential services provided at or from the premises are only available to persons in particular areas of England, or

3.30.5.2 the applicant is likely to refuse, for reasons other than those provided for in the applicant's terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (eg because the availability of essential services from the applicant is limited to other categories of patients)."

4 The Appeal

In a letter dated 11 February 2026, Rushport Advisory LLP on behalf of the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

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

4.2 As the Committee will note, the Commissioner's states that the application was refused due to my client not providing sufficient information in a number of areas including;

4.2.1 disposal of unwanted medicines

4.2.2 New Medicine Service and

4.2.3 "The pharmacy procedures indicate that it does not meet the standard required to satisfy the regulatory requirements of the provision of essential services"

4.3 My client has reviewed their SOPs and provides an updated copy with this appeal [see Appendix A]. These SOPs replace all previous information provided in support of my client's application and deal with the omissions

identified by the Commissioner. The new SOPs have been approved by my client for use at the proposed pharmacy.

4.4 Since my client submitted its application, it has prepared a floor plan and for the sake of completeness this is attached along with this appeal [see Appendix B]. The premises will operate using a controlled entry system and patients will not be able to attend the premises for any service."

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 COMMUNITY PHARMACY HEREFORDSHIRE & WORCESTERSHIRE

5.1.1 "Thank you for your letter dated 24 February 2026 regarding the above appeal.

5.1.2 Further to our letter of 13th August 2026 [sic], Herefordshire and Worcestershire LPC note the amendments made. We note that the responses appear to be in line with the proposed changes to regulations in October restricting face-to-face services provisions for Advanced and Enhanced as well as the current Essential Services. Services offered remotely should be from the designated registered site during contracted opening hours. We have nothing to add other than the assurance that SOPs will be in place and the pharmacy website, and any advertising, meet relevant national regulations.

5.1.3 Please keep us informed of any updates on this application and Oral Hearings arranged."

5.2 THE COMMISSIONER

5.2.1 "The suite of pharmacy procedures now provided from the applicant to NHS Resolution was not available to the Committee at the time the decision was made .

5.2.2 If that information had been available, the Committee may have come to a different decision."

6 Summary of Observations

No observations were received by NHS Resolution in response to the representations received on appeal.

7 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

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

7.6 The Committee noted that the Applicant had stated "*not applicable as no other pharmacy in same or adjacent premises"* in response to the question of Regulation 31. The Commissioner had stated that it was "*satisfied that there is no pharmacy providing pharmaceutical services at the same or adjacent premises"* and had gone on to conclude that it "*was not required to refuse the application under Regulation 31*" and this had not been disputed either on appeal or in subsequent representations. Based on the information provided, the Committee determined that it was not required to refuse the application under the provisions of Regulation 31

Regulation 25

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

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

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

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

in respect of pharmacy premises that are distance selling premises.

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

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

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

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

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

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

Additional information to be included with excepted applications

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

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

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

Nature of details to be supplied

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

Regulation 25(1)

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

Regulation 25(2)(a)

7.10 As far as Regulation 25(2)(a) is concerned, the Committee had regard to the application form in which the Applicant states "*Application is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*." The Commissioner in its decision report had concluded that as the nearest GP is located over 0.7 miles away it was not required to refuse the application under the provisions of Regulation 25(2)(a). The Committee noted that this had not been disputed and that it had not been provided with any information to persuade it otherwise. The Committee was therefore satisfied that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

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

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

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

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

7.15 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 revised SOPs

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

7.16 The Committee first considered how the Applicant would provide essential services without interruption.

7.17 The Committee noted the conclusion of the Commissioner that "*there is nothing documented on having a pharmacist available during opening hours*"

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

7.19 SOP 1: "Introduction and Background to SOPs"

7.19.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises."

7.20 SOP 33: "The Responsible Pharmacist"

7.20.1 "*33.9 Absence of the RP*

As a Distance Selling pharmacy, we must provide uninterrupted service throughout the opening hours of the pharmacy. Whilst the GPhC permits the absence of the RP from the pharmacy in particular situations, the NHS Terms of Service still require a pharmacist to be present so that services are not interrupted. [Applicant's emphasis]

If, for any reason, the RP wishes to leave the premises or wishes to take a break then the second pharmacist must sign in as the RP and arrangements must be made for this prior to one RP leaving the premises and another RP signing in."

7.21 Based on the information before it, the Committee was of the view that the Applicant had provided information regarding having a pharmacist available during opening hours and that the provision of essential services would be without interruption.

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

7.23 SOP 1: "Introduction and Background to SOPs"

7.23.1 "*1.3 Overriding Provisions Applicable to All SOPs*

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

7.24 SOP 3: "Procedures for NHS Pharmaceutical Services"

7.24.1 "*NHS Pharmaceutical Services will be provided to any patient living in England who requests such services, this is made clear on the website and in the Practice leaflet.*"

7.25 As well as the assertions in the "overriding provisions" in SOP 1, as set out above with regard to pharmaceutical services being available to patients anywhere in England, the Committee noted references throughout the rest of the SOPs to delivery being made by couriers and Royal Mail as well as the Applicant's own delivery driver.

7.26 The Committee was of the view, based on all of the information before it, that essential services would be provided to persons anywhere in England, who requested those services.

7.27 The Committee next considered how the Applicant would provide pharmaceutical services without face to face contact.

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

7.29 SOP 1: "Introduction and Background to SOPs"

7.29.1 "1.3 Overriding Provisions Applicable to All SOPs

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

…

The safe and effective provision of pharmaceutical services without face-to-face contact between any person receiving the services, whether on their own or on someone else's behalf, and the owner of this pharmacy or any member of staff either on or in the vicinity of the premises.

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

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

7.30 SOP 3: "Procedures for NHS Pharmaceutical Services"

7.30.1 "3.1 Communication Channels

All communication regarding NHS Pharmaceutical Services should be carried out using the most suitable non face to face method for the

patient and the service being provided with particular consideration to maintaining confidentiality. This may be telephone, email, video-conferencing or other types of non face to face communications such as text messages.

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

7.30.2 "*3.2 Request for face-to-face service provision*

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

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

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

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

7.31 The Committee was of the view that there was nothing provided in the information submitted by the Applicant, which demonstrated that pharmaceutical services would be provided by face to face contact at, or in the vicinity of, the pharmacy premises.

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

7.33 In its application the Applicant stated that it intended to provide the New Medicine Service. In its decision letter the Commissioner had stated "*The Committee considered the supporting information provided for New Medicine Service (NMS) and concluded that the process is not detailed enough on how the service will be delivered without face to face contact."*

7.34 The Committee noted SOP 7 'The New Medicine Service ("NMS")', contained within the revised suite of SOPs provided on appeal, which states "*The service must be provided remotely by phone or video call*" and had gone on to provide details on how NMS would be provided without face to face contact.

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

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

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

Dispensing of drugs and appliances

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

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

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

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

7.40.1 "*6.2 Scope*

All online services including the following:

… NHS Prescriptions."

7.40.2 "*6.7 Administration Checks*

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

7.41 SOP 19 'Order Delivery' states:

7.41.1 "*19.6 Choice of Delivery Method*

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

7.42 The Committee was satisfied as to how patients throughout England would present their prescriptions and that the Applicant was proposing to offer products and services to all of England, as per the information contained in the SOPs.

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

Urgent supply without a prescription

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

7.45 The Committee noted the information in the Applicant's SOPs under the heading 'Emergency Supply and Urgent Supply' (SOP 16) which describes how the Applicant will process such a request. The Committee noted that the SOPs refer to pharmaceutical services being delivered by several means of non-face to face communication including telephone and email, and considered that it was reasonable to infer that these methods would be used to receive requests from prescribers for the urgent supply of drugs.

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

Preliminary matters before providing ordered drugs or appliances

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

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

7.48.1 "*6.9 Exempt NHS Prescriptions*

…

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

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

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

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

7.51.1 "*6.12 Paid NHS Prescription*

Check the prescription to confirm how many charges are due.

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

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

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

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

Providing ordered drugs or appliances

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

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

7.54.1 "*19.10 Transfer to the Delivery Driver*

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

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

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

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

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

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

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

7.54.2 "*19.11 Delivery of prescription to patient or representative address*

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

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

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

Hand the medication to the patient or representative.

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

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

7.54.3 "*19.12 Successful delivery*

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

7.54.4 "*19.13 Unsuccessful Delivery*

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

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

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

DO NOT:

Post the medication through the letter/post box.

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

Leave the medication at an unauthorised address."

7.54.5 "*19.14 Delivery of a prescription via Royal Mail (Not for Cold Chain or CDs)*

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

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

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

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

7.54.6 "19.15 Unsuccessful Delivery via Royal Mail

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

7.54.7 "19.16 Cold chain delivery via courier

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

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

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

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

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

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

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

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

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

Confirm details of all prescriptions to be delivered.

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

7.54.8 "*19.17 Unsuccessful cold chain delivery via courier*

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

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

7.54.9 "*19.18 Breach of Integrity of Cold Chain*

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

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

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

7.55 SOP 23 'Controlled Drugs: Delivery' states:

7.55.1 "*23.5 Delivery of Schedule 2 & 3 CDs*

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

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

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

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

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

The delivery driver/courier must check the identity of the person accepting the delivery to ensure that it is the patient or authorised representative (passport, driving licence or government approved photo ID card are acceptable forms of ID). A delivery cannot be left with anyone who is not the patient or their authorised representative.

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

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

7.55.2 "*23.7 Successful Schedule 2 & 3 Delivery*

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

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

7.55.3 "*23.8 Unsuccessful Schedule 2 & 3 Delivery via pharmacy driver*

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

7.55.4 "*23.9 Unsuccessful Schedule 2 & 3 Delivery via courier*

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

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

7.55.5 "*23.10 Note re Use of Couriers for Controlled Drugs Deliveries*

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

7.56 Based on the information before it, the Committee was satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(1) of Schedule 4.

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

7.58 The Committee noted that in the application form, in response to the question as to whether they were undertaking to provide appliances, the Applicant had stated "Drug Tarif part IX* *Except items that require measuring or fitting".

7.59 The Committee noted the Applicant's SOPs state:

7.60 SOP 9 ‘Pharmaceutical & Legal Assessment’:

7.60.1 “*9.9 Items Requiring Measuring and Fitting*

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

7.61 SOP 26 ‘Support for Self-Care, Signposting and Health Promotion’:

7.61.1 “*26.14 Items Requiring Measuring and Fitting*

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

7.62 The Committee was of the view that it had been provided with information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

7.63 The Committee considered whether the Applicant had explained what containers will be “suitable” for posted/delivered items.

7.64 The Committee noted that SOP 18 ‘Bagging-Up’ states:

7.64.1 “*18.7 Choice of Packaging*

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

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

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

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

For postal items, either:

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

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

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

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

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

Refusal to provide drugs or appliances ordered

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

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

7.67.1 "*34.10 Prescription reception*

…

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

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

7.67.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.70.1 "*34.10 Prescription Reception*

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

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

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

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

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

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

7.70.2 "*34.11 Pharmaceutical & Legal Assessment*

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

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

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

Disposal service in respect of unwanted drugs

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

7.73 The Commissioner had stated "*Furthermore, the applicant has not demonstrated the necessary procedures to ensure safe and effective delivery of the services e.g. disposal of unwanted medicines."*

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

7.74.1 "*24.5 Patient Returned Medication*

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

Patients or their representatives may not return and medicines directly to the pharmacy and must follow the procedures set out in this SOP. [Applicant's emphasis]

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

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

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

Each return will be made by booking an appointment for the pharmacy's driver to visit the patient's home to collect the returned medication or by sending the appropriate packaging to the patient to arrange for return by Royal Mail – Note the Royal Mail website refers to a prohibition on carrying "controlled drugs" but this refers only to illicit controlled drugs and not those supplied under the direction of a physician."

7.74.2 "*24.7 Return by Royal Mail*

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

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

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

Contact the patient to ensure that the packaging has been received

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

7.74.3 "*24.8 Handling Patient-Returned CDs from Delivery Driver*

Drivers need to:

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

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

Pharmacy staff need to:

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

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

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

7.75.1 "*25.6 Process for Patients to Return Medication*

Patient Returned Medication

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

This service is available to all patients living in England.

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

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

Patients may

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

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

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

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

Explaining the Process to Patients

Check which patient or patients the medication belonged to.

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

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

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

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

7.75.2 "*25.7 Process for accepting patient returns by the Driver*

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

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

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

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

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

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

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

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

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

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

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

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

7.75.3 "*25.9 Return by Royal Mail*

The pharmacist must

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

Assess the items for suitability for return by Royal Mail

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

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

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

Contact the patient to ensure that the packaging has been received

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

7.75.4 "*25.10 Disposal of returned medicines*

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

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

7.76 Based on all of the information before it, the Committee was satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 13 - 15 of Schedule 4.

Promotion of healthy lifestyles

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

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

7.78.1 "*27.3 Identification of patients for promotion of Healthy Lifestyles*

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

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

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

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

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

7.78.2 "*27.4 Health Campaigns & Community Engagement Exercise*

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

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

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

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

Prescription linked intervention

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

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

7.81.1 "*27.6 Long Term Conditions*

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

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

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

7.81.2 "*27.7 Identification of patients for Support with Long Term Conditions*

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

Active patients will be those who have chosen to access the Lifestyle Questionnaires via the website or returned them by post and who are then identified from the results as patients to whom further information should be sent, or who should be called to follow up on the results and offer additional support and information. All patients who have prescriptions dispensed or purchase medicines from the pharmacy will be asked to fill in the Lifestyle Questionnaire which will ask for details such as existing medical conditions, height, weight and also lifestyle

questions such as whether a patient is a smoker and how much exercise they normally have on a weekly basis.

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

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

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

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

Health campaigns

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

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

7.84.1 "*27.4 Health Campaigns & Community Engagement Exercise*

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

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

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

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

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

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

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

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

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

Signposting

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

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

7.87.1 "*26.10 Other Provider Organisations and Support Details*

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

7.87.2 "*26.12 Signposting*

Service Description

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

7.87.3 "*26.13 Patient Identification*

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

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

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

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

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

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

Support for self-care

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

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

7.90.1 "*26.8 Patient Identification*

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

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

on changes to the patient's lifestyle."

7.90.2 "*26.9 Service outline*

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

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

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

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

Discharge medicines service

7.92 The Committee considered whether the Applicant had explained how it will provide advice, assistance and support to and in respect of a health service patient – (a) recently discharged from hospital who is referred to P for advice, assistance and support in respect of the patient's medication regimen by the staff of the hospital in which the patient stayed; or (b) who is otherwise referred to P for advice, assistance and support in respect of the patient's medication regiment by the staff of an NHS trust and NHS foundation trust as part of arrangements linked to the transfer of care between different providers of NHS services.

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

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

7.94.1 "*28.3 Process*

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

7.94.2 "*28.4 Consent*

Obtain and record the informed consent from the patient prior to provision of the service using the consent form. As part of obtaining

consent discuss the requirements for data sharing. Inform the patient that any information discussed as part of the service may be shared with their GP."

7.94.3 "*28.5 DMS Stages*

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

7.94.4 "*28.6 DMS Stage 1 (within 72 hours of referral excluding times when the pharmacy is not open)*

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

7.94.5 "*28.7 Considering the appropriateness of any medication changes prior to discharge*

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

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

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

For actions that are considered appropriate the pharmacist must;

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

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

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

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

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

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

REQUIRED ACTIONS AS PER NHS GUIDANCE"

7.94.6 "*28.8 DMS Stage 2*

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

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

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

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

Then the pharmacist must:

Review / perform a further review of any prescription

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

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

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

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

7.94.7 "*28.9 DMS Stage 3*

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

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

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

Websites and health promotion zones

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

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

7.97.1 "*26.11 Health promotion zone on our website*

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

Explaining the Interactive Page to Patients

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

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

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

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

Summary

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

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

7.100.1 confirm the Commissioner's decision;

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

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

7.101 In those circumstances, given that the Committee has reached a different conclusion to the Commissioner, it determined that the decision of the Commissioner must be quashed.

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

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

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

8 Decision

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

8.2 The Committee:

8.2.1 quashes the decision of the Commissioner; and

8.2.2 redetermines the application as follows -

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

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

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

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

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

8.2.3 The application is granted.

Case Manager
Primary Care Appeals