20 June 2025

REF: SHA/26568

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APPEAL AGAINST HERTFORDSHIRE AND WEST ESSEX ICB DECISION TO REFUSE AN APPLICATION BY OPTIOM HEALTH LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 126 QUEEN STREET, HITCHIN, SG4 9TH UNDER REGULATION 25

1 Outcome

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

1.2 The Committee determined that the application should be refused.

A copy of this decision is being sent to:

Optiom Health Ltd
Community Pharmacy Hertfordshire
PCSE on behalf of Hertfordshire and West Essex ICB

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1 The Application

By application dated 23 May 2025, Optiom Health Ltd ("the Applicant") applied to Hertfordshire and West Essex ICB ("the Commissioner") for inclusion in the pharmaceutical list at 126 Queen Street, Hitchin, SG4 9TH 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 "Appliances will be provided according to the order on electronic prescription only and delivered accordingly to patient. These include dressings and wound management products."

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

1.2.1 "This application should not be refused as it is for a distance selling pharmacy.

1.2.2 Essential services will not be provided to a person present at the pharmacy or in the vicinity of it.

1.2.3 There will be SOPs in place that clearly shows [sic] how essential services will be provided safely and effectively without face to face contact with any member of staff on the premises.

1.2.4 Advanced and Enhanced services will be provided on the premises, and any Essential services which forms part of the Advanced or Enhanced service is not to be provided to persons present at the premises."

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

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

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

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

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

1.5 "The pharmacy's procedures and SOPs will ensure uninterrupted provision of Essential services during the opening hours of the pharmacy to anyone in England who requests the service. Premises will have internet access, telephone, website and pharmacist active during opening hours.

1.6 Safe and effective provision of essential services without face to face will be achieved as Pharmacy's standard operating procedures (SOPs) for staff will stipulate that essential services can only be accessed digitally. Such as Discharge Medicine Services, consultation is via telephone or a video call. Prescription for medicines and appliances will be received via the NHS spine and delivered to patient addresses in England. All prescription enquiries will be done via telephone or video call. Disposal of unwanted medicine not accepted from patient on the premises but via opt in collection process. Where patient asks for essential services on premises, they will be advised to register and access NHS dispensing services online or via app. Only private prescriptions can be dispensed to patient on premises. Pharmacy will be registered under the General Pharmaceutical Council (GPHC), enabling sale of Pharmacy and General Sales List lines."

2 Comments to the Commissioner

In response to the representations received by the Commissioner, the Applicant submitted more information, including SOPs. As new information had been received, the Commissioner recommenced the circulation of the application including the SOPs. The SOPs provided are included at Appendix A.

3 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 27 February 2025 states:

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

3.1 "Hertfordshire and West Essex 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 "Decision wording"

3.2 "DS Application for inclusion in a pharmaceutical list: distance selling premises excepted application

3.3 Optiom Health Ltd, 126 Queen Street, Hitchin, SG4 9TH

3.4 The Pharmaceutical Services Regulations Committee (hereafter referred to as "the Committee") considers all pharmaceutical services applications for the 6 Integrated Care Boards (ICB) within the East of England footprint. NHS Hertfordshire & West Essex ICB (HWE ICB) hosts the meeting on behalf of the 6 ICBs, in accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended (hereafter referred to as "the Regulations").

3.5 The Committee considered this excepted application in respect of distance selling premises, which is determined under the following regulations:

Regulation 31: Refusal: same or adjacent premises

3.6 The Committee noted that the nearest pharmacies located within 1-mile to the proposed premises are detailed in the table below:

Pharmacy Name	Address	Distance to proposed premises (*source google maps)
NuCross Pharmacy	8 – 9 Hermitage Road, Hitchin	0.1 miles. 1 min by car. 2 min walk
Bell Chemist	21B Bancroft, Hitchin	0.2 miles. 2 min by car. 4 min walk
Boots	7 High Street, Hitchin	0.3 miles. 2 min by car. 6 min walk
Bancroft Pharmacy	41 Bancroft, Hitchin	0.3 miles. 2 min by car. 6 min walk
CareRx Pharmacy	Sainsburys, Unit 1 – 5 rear of 8 Bancroft, Hitchin	0.6 miles. 4 min by car. 6 min walk
Cross Chemist	8 Redhill Road, Hitchin	1 mile. 5 min by car. 22 min walk

3.7 The Committee noted that no NHS pharmacy exists or is said to exist at or adjacent to the proposed location. In addition, there is no person on the pharmaceutical list providing or undertaking to provide pharmaceutical services from or adjacent to the premises.

3.8 The Committee also noted that a private clinic and pharmacy exists at the proposed location and is owned by the same company. This pharmacy is not included in the relevant pharmaceutical list; therefore Regulation 31 does not apply.

3.9 The applicant stated in their application that in their view this application should not be refused pursuant to Regulation 31 for the following reasons [as per 1.2.1 to 1.2.4 above].

3.10 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25: Distance selling premises applications

Regulation 25(2)(a)

3.11 The Committee noted the nearest GP Practice is Portmill Surgery, 114 Queen Street, Hitchin, which is situated 61 feet from the proposed location and is less than a minute walk (*source Google maps). Although there is a very short distance between the GP practice and the premises in respect of which the application is made, it should be noted that it 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. See google maps aerial view embed ded below [see Appendix B]. The only access to Portmill Surgery from the applicant's premises is along the street.

3.12 The Committee noted that it is on the site of a private clinic which provides medical services.

3.13 The Committee were satisfied that the application is not refused under Regulation 25(2)(a).

Regulation 25(2)(b)

3.14 The Committee considered the information which has been provided by the Applicant. The Committee noted that in relation to its procedures for the provision of essential services, some Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises have been provided. These were shared with the Committee prior to the meeting.

3.15 The Committee noted that the core opening hours declared on the application form must and do total 40 core hours per week, and are listed as:

3.15.1 Monday to Friday 09:00 – 17.00.

3.15.2 There are 8.5 supplementary hours declared (Mon – Fri 17:00 – 17:30 and Sat 10:00 –16:00). Therefore, the total number of opening hours are 48.5.

3.16 The Committee noted the document provided by the applicant, namely: "Amended DS application 24.5.23". In support of their application the applicant states [as set out at paragraphs 1.5 to 1.6 above].

3.17 The Committee noted that the premises are currently registered with GPhC.

Representations

3.18 The Committee noted the representations/comments received from Boots NHS Contract Lead dated 29 September 2023, Community Pharmacy Hertfordshire (LPC) dated 27 September 2023 and Esoms Ltd dated 29 September 2023.

3.19 The Committee also noted the applicant's responses to the representations. The applicant's response included new information therefore the 45 days process was restarted, and this information was sent to the interested parties. Further responses were received from Boots NHS Contract Lead dated 20 November 2024 and Community Pharmacy Hertfordshire dated 28 November 2024.

3.20 The Committee considered each Essential Services in Paragraphs 3 to 22 of Schedule 4 Part 2 of the Regulations ("Terms of Service").

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

3.21.1 Dispensing of drugs and appliances

3.21.2 Urgent supply without a prescription

3.21.3 Preliminary matters before providing ordered drugs or appliances.

3.21.4 Providing ordered drugs or appliances

3.21.5 Refusal to provide drugs or appliances ordered.

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

3.21.7 Disposal service in respect of unwanted drugs

3.21.8 Promotion of healthy lifestyles

3.21.9 Prescription linked intervention.

3.21.10 Public health campaigns

3.21.11 Signposting

3.21.12 Support for self-care

3.21.13 Discharge medicines service

Dispensing of drugs and appliances

3.22 The Committee considered whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

3.23 The Committee noted the information provided by the applicant around how electronic prescriptions will be presented.

3.24 The Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2) & 5(3) of Schedule 4.

Urgent supply without a prescription

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

3.26 The Committee noted the information provided by the applicant relating to urgent supply without a prescription.

3.27 Based on the information before it, the Committee were satisfied that it has 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

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

3.29 The Committee noted the information provided by the applicant relating to preliminary matters before providing ordered drugs or appliances and their process for 'Verification of Declarations of Prescription Exemptions'.

3.30 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

3.31 The Committee considered whether the applicant has 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).

3.32 The Committee noted the information provided by the applicant relating to providing ordered drugs or appliances.

3.33 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance to this regard.

Refusal to provide drugs or appliances ordered

3.34 The Committee considered whether it is satisfied that when the applicant is 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 have been no changes to the patient's health, which may indicate the desirability of review of the patient's treatment.

3.35 The Committee noted the information provided by the applicant relating to 'refusal to provide drugs'.

3.36 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with 9(4) of Schedule 4.

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

3.37 The Committee considered whether the applicant has 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.

3.38 The Committee noted that the applicant has not provided any supporting information relating to further activities carried out in connection with the provision of dispensing services.

3.39 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with 10(1)(d) of Schedule 4.

Disposal service in respect of unwanted drugs

3.40 The Committee considered whether the applicant has explained how it will safely and effectively accept and dispose of unwanted drugs presented to it for disposal.

3.41 The Committee noted the information provided by the applicant relating to the disposal of unwanted medicines.

3.42 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 13 – 15 of Schedule 4.

Promotion of healthy lifestyles

3.43 The Committee considered whether the applicant has explained how it will safely and effectively promote healthy lifestyles.

3.44 The Committee noted the information provided by the applicant relating to the promotion of healthy lifestyles.

3.45 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 16 – 18 of Schedule 4.

Prescription linked intervention

3.46 The Committee considered whether the applicant has 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.

3.47 The Committee noted the information provided by the applicant relating to prescription linked intervention within their response.

3.48 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

Public health campaigns

3.49 The Committee considered whether the applicant has explained how it will safely and effectively participate in public health campaigns, if and to the extent required by the NHSCB.

3.50 The Committee noted the information provided by the applicant relating to public health campaigns within their response.

3.51 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 18 of Schedule 4.

Signposting

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

3.53 The Committee noted the information provided by the applicant relating to signposting patients.

3.54 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 19 – 20 of Schedule 4.

Support for self-care

3.55 The Committee considered whether the applicant has explained how it will provide advice and support to people caring for their families.

3.56 The Committee noted the information provided by the applicant relating to support for selfcare.

3.57 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 21 – 22 of Schedule 4.

Discharge medicines service

3.58 The Committee considered whether the applicant has explained how it will provide the discharge medicines service.

3.59 The Committee noted the information provided by the applicant relating to delivering a discharge medicines service.

3.60 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 22c of Schedule 4.

Decision

3.61 The Committee refused the application as the requirements set out in Regulation 25 were not met as, based on the information provided, there was no assurance that all aspects of essential services will be provided without interruption, to persons anywhere in England, in a safe and effective manner, without face to face contact as detailed in the considerations above.

3.62 The Committee agreed that the applicant, Optiom Health Ltd has a right to appeal."

4 The Appeal

In an email of 11 March 2025, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

4.1 "We have reviewed the decision wording from the committee and below is the summary of the committees decision with regards [sic] to level of satisfaction under the provisions of Regulation 31 and Regulation 25.

4.2 Regulation 31: Refusal: same or adjacent premises

4.2.1 The Committee agreed it was not required to refuse the application under the provisions of Regulation 31.

4.2.2 Hence the committee has not refused application based on this requirement.

4.3 Regulation 25: Distance selling premises applications.

4.3.1 The Committee were satisfied that the application is not refused under Regulation 25(2)(a).

4.3.2 Hence the committee has not refused application based on this requirement.

4.4 Regulation 25(2)(b)

4.5 Dispensing of drugs and appliances.

4.5.1 The Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2) & 5(3) of Schedule 4.

4.5.2 Hence the committee has not refused application based on this requirement.

4.6 Urgent supply without a prescription.

4.6.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 6 of Schedule 4.

4.6.2 Hence the committee has not refused application based on this requirement.

4.7 Preliminary matters before providing ordered drugs or appliances

4.7.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 7(3) of Schedule 4.

4.7.2 Hence the committee has not refused application based on this requirement.

4.8 Providing ordered drugs or appliances

4.8.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance to this regard.

4.8.2 Hence the committee has not refused application based on this requirement.

4.9 Refusal to provide drugs or appliances ordered

4.9.1 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with 9(4) of Schedule 4.

4.9.2 Hence the committee possibly refused application based on this requirement

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

4.10.1 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with 10(1)(d) of Schedule 4.

4.10.2 Hence the committee possibly refused application based on this requirement..

4.11 Disposal service in respect of unwanted drugs

4.11.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 13 - 15 of Schedule 4.

4.11.2 Hence the committee has not refused application based on this requirement.

4.12 Promotion of healthy lifestyles

4.12.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 16 – 18 of Schedule 4.

4.12.2 Hence the committee has not refused application based on this requirement.

4.13 Prescription linked intervention

4.13.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with paragraph 17 of Schedule 4.

4.13.2 Hence the committee has not refused application based on this requirement.

4.14 Public health campaigns

4.14.1 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 18 of Schedule 4.

4.14.2 Hence the committee possibly refused application based on this requirement.

4.15 Signposting

4.15.1 Based on the information before it, the Committee were not satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 19 – 20 of Schedule 4.

4.15.2 Hence the committee possibly refused application based on this requirement.

4.16 Support for self-care

4.16.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraphs 21 – 22 of Schedule 4.

4.16.2 Hence the committee has not refused application based on this requirement.

4.17 Discharge medicine service

4.17.1 Based on the information before it, the Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 22c of Schedule 4.

4.17.2 Hence the committee has not refused application based on this requirement.

4.18 Decision:

4.18.1 The Committee refused the application as the requirements set out in Regulation 25 were not met as, based on the information provided, there was no assurance that all aspects of essential services will be provided without interruption, to persons anywhere in England, in a safe and effective manner, without face-to-face contact as detailed in the considerations above.

4.19 It is noted that the Committee were not satisfied, that the information provided were not sufficient to show that there would be compliance with Regulation 25 in the following four areas:

4.19.1 Refusal to provide drugs or appliances ordered

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

4.19.3 Public health campaigns

4.19.4 Signposting

4.20 We therefore expand on the information relating to these areas with reference to respective Standard Operating Procedures, to demonstrate compliance to Regulation 25 in these four specific areas.

4.21 As the committee has expressed satisfaction in other areas of Regulation 25, these will not be included within this appeal document.

Refusal to provide drugs or appliances ordered.

4.22 The Committee requires additional information to show compliance with 9(4) of Schedule 4.

9(4) of Schedule 4 states that:

Where a patient requests the supply of drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), P must only provide the drugs or appliances ordered if P is satisfied—

(a)that the patient to whom the prescription relates—

(i)is taking or using, and is likely to continue to take or use, the drug or appliance appropriately, and

(ii)is not suffering from any side effects of the treatment which indicates the need or desirability of reviewing the patient's treatment;

(b)that the medication regimen of, or manner of utilisation of the appliance by, the patient to whom the prescription relates has not altered in a way which indicates the need or desirability of reviewing the patient's treatment; and

(c)there have been no changes to the health of the patient to whom the prescription relates which indicate the need or desirability of reviewing the patient's treatment.

Response 1

4.23 Process: Dispensing subsequent Electronic Repeat Prescriptions (ERP)

4.24 When supplying drugs or appliances ordered on a repeatable prescription (other than on the first occasion that the patient makes such a request), the Pharmacist will ensure that the ERP patient request form is completed and satisfied with patient responses.

4.25 The ERP patient request form is completed either by patient digitally or on the phone with a qualified pharmacy team. Dispensing of subsequent electronic repeatable prescription can only be triggered following the completion of the ERP patient request form.

4.26 The ERP patient request form collects necessary information to enable the pharmacist to be satisfied and make an informed decision.

4.27 Content of the form include the following:

4.27.1 Are you taking or using your current medication or appliance appropriately?

4.27.2 Are you likely to continue taking or using your current medication or appliance appropriately?

4.27.3 Have you started taking any new medicines (including over the counter products, herbal products, supplements or alternative therapies)?

4.27.4 Have you experienced any issues or side effects with your medicine(s)?

4.27.5 Have your dose regimen or the way you use your appliance changed since your last GP appointment?

4.27.6 Do you require all the items on the prescription? If not, please choose only items you need on this prescription.

4.27.7 Have there been any changes to your health since your last request? If so, please give details.

4.28 The Pharmacist reviews the form and must only supply if satisfied. Refusal of order and prescriber review on patients' treatment is considered in the following scenarios:

4.28.1 Where patient is not taking the medication or using appliance appropriately.

4.28.2 Where patient experiences issues or side effect(s)

4.28.3 Where there has been changes to regimen of, or manner of utilisation of the appliance

4.28.4 Where there are changes to the health of the patient

4.29 SOP reference attachment: SOP-DIS-103 - Dispensing Electronic Repeat Prescription

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

4.30 The Committee requires provision of information to show compliance with 10(1)(d) of Schedule 4.

10(1)(d) of Schedule 4.

(d)when providing appliances to patients in accordance with a prescription form or repeatable prescription—

(i)provide appropriate advice in particular on the importance of only requesting those items which they actually need, and

(ii)for those purposes, have regard to the details contained in the records maintained under paragraph (f) in respect of the provision of appliances and prescribing pattern relating to the patient in question;

Paragraph (f)

keep and maintain records—

(i) of drugs and appliances provided, in order to facilitate the continued care of the patient;

(ii) in appropriate cases, of advice given and any interventions or referrals made (including clinically significant interventions in cases involving repeatable prescriptions), and

(iii) of notes provided under sub-paragraph (e);

Paragraph (e)

provide a patient with a written note of any drug or appliance which is owed, and inform the patient when it is expected that the drug or appliance will become available;

Response 2

4.31 When supplying drugs or appliances in accordance with an electronic prescription or electronic repeat prescription, patients are prompted to request items which they need.

4.32 The ERP patient request form for repeat dispensing ensures this step is done by patient or approved carer.

4.33 Records of all items dispensed and prescribing pattern for patient are kept and maintained in the PMR system (Patient Medical Record System) to facilitate continued care of the patient.

4.34 All advice and any clinically significant intervention or referrals made for both electronic prescription and electronic repeat prescription is recorded in the PMR system.

4.35 Where an item is not in stock, but will be available later, a notification on affected item(s) owed is sent and informed when the item is expected to become available.

4.36 SOP reference attachment: SOP-DIS-101 - Dispensing Electronic Prescription Service

Public health campaigns

4.37 The Committee requires provision of information to show compliance with Paragraph 18 of Schedule 4.

18 of Schedule 4.

An NHS pharmacist (P) must, at the request of the NHSCB, ensure that—

(a)P (including P's staff) participates, in the manner reasonably requested by the NHSCB, in up to 6 campaigns in each calendar year to promote public health messages to users of P's pharmacy;

(b)where requested to do so by the NHSCB, P records the number of people to whom P (including P's staff) has provided information as part of one of those campaigns.

Response 3

4.38 At the request of NHSCB, the pharmacy will utilise the campaign feature on the system to end up to 6 campaigns in each calender [sic] year to registered users of the pharmacy.

4.39 The Pharmacist and the pharmacy team will participate, in the manner reasonably requested by the NHSCB.

4.40 We will utilise various campaign delivery initiatives depending on the type of campaign. Such campaign deliveries to users include:

4.40.1 Email campaigns

4.40.2 SMS campaigns

4.40.3 Leaflets placed in delivery packages to users

4.40.4 Within the client portal.

4.41 We would also record as requested by NHSCB the number of people to whom Pharmacist has provided information as part of one of those campaigns.

4.42 SOP reference attachment: SOP-PP-189 Mandatory Annual Campaign to Pharmacy Users

Signposting

4.43 The Committee requires provision of information to show compliance with Paragraphs 19 – 20 of Schedule 4.

4.44 19-20 of Schedule 4.

19. An NHS pharmacist must, to the extent paragraph 20 requires and in the manner set out in that paragraph, provide information to users of the NHS pharmacist's pharmacy about other health and social care providers and support organisations.

4.45 Service outline in respect of signposting

20.—(1) Where it appears to an NHS pharmacist (P), having regard to the need to minimise inappropriate use of health and social care services and of support services, that a person using P's pharmacy—

(a)requires advice, treatment or support that P cannot provide; but

(b)another provider, of which P is aware, of health or social care services or of support services is likely to be able to provide that advice, treatment or support,

P must provide contact details of that provider to that person and must, in appropriate cases, refer that person to that provider.

(2) Where, on presentation of a prescription form or repeatable prescription, P is unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within P's normal course of business, P must—

(a)if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and

(b)if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation (as the case may be), if these details are known to P.

(3) Where appropriate, a referral under this paragraph may be made by means of a written referral note.

(4) P must, in appropriate cases, keep and maintain a record of any information given or referral made under this paragraph and that record must be in a form that facilitates—

(a)auditing of the provision of pharmaceutical services by P; and

(b)follow-up care for the person who has been given the information or in respect of whom the referral has been made.

Response 4

4.46 Below is the extract from our Signposting procedure:

4.47 Procedure

4.48 Identifying Signposting Needs:

4.49 During enquiries online or over the phone:

4.49.1 Pharmacy Technician/ Assistants: During enquiries for over-the-counter medicines, pharmacy technicians/ assistants must refer to the responsible pharmacists for certain conditions. See Table 1 below for example of referrals.

4.49.2 Pharmacists: Pharmacist should actively assess patient needs, including medical history, current medications, and any concerns or questions raised by the patient. Identify red flags and refer appropriately, if required.

4.50 During Online Consultations:

4.50.1 Pharmacist/Technician: During online consultations, pharmacists should actively assess patient needs, including medical history, current medications, and any concerns or questions raised by the patient.

4.50.2 Red Flags: Identify potential red flags, such as:

4.50.2.1 Patients requiring urgent care or medical advice that cannot be provided remotely.

4.50.2.2 Patients with complex medical conditions or medications that require specialized management.

4.50.2.3 Patients expressing concerns about their health or well-being that are beyond the scope of the pharmacy services.

4.50.2.4 Patients who may benefit from social support or community resources.

4.51 During Electronic Prescription/ Repeat Prescription Processing:

4.51.1 Pharmacist/Technician: Review the patient's prescription and medical history to identify any potential issues or concerns that may require signposting.

4.51.2 Red Flags: Identify potential red flags, such as:

4.51.2.1 Prescriptions for medications that require close monitoring or specialized knowledge.

4.51.2.2 Patients with a history of adverse drug reactions or medication interactions.

4.51.2.3 Unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within Tabi Health's normal course of business, if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation.

4.52 Signposting process:

4.52.1 Patient Information: Obtain relevant patient information, including name, contact details, and the nature of their need. Record this into the PMR system.

4.52.2 Service Details: Gather information about the specific service or organization to which the patient needs to be signposted.

4.52.3 Clear and Concise Communication: Communicate the signposting clearly and concisely, explaining the reason for the referral and the benefits of seeking support from the recommended service.

4.52.4 Contact Information: Provide the patient with clear contact information for the recommended service, including phone number, website, and address.

4.53 Documentation: Document the signposting in the patient's record, including the reason for the referral, the recommended service, and the date and time of the signposting. Where appropriate, a referral under this paragraph may be made by means of a written referral note.

4.54 Follow-Up:

4.54.1 Patient Confirmation: Ensure the patient understands the signposting and has received the necessary information.

4.54.2 Feedback: Set up a follow up task to follow up with the patient to ensure they have accessed the recommended service and received the necessary support.

4.55 Resources and Support:

4.55.1 Signposting Resources: As Tabi Health is a distance selling pharmacy, hence it will have access to database of both local and regional healthcare providers support organizations, and community resources. This will be accessed by Tabi Health's staff when signposting patients accordingly.

4.55.2 These include:

4.55.2.1 Find local services on NHS UK - Click https://www.nhs.uk/ and search by GP, Urgent Care, Hospitals or Dentists or click the link to view a Full A-Z list.

4.55.2.2 NHS Service Finder - https://servicefinder.nhs.uk/landingPage

4.55.2.3 NHS 111

4.55.2.4 Relevant useful links for referral embedded on the website e.g. NHS talking therapies, Live Well, Find a pharmacy.

4.55.3 Staff Training: All staff will be training annually on staff on signposting procedures, including identifying needs, providing information, and documenting referrals.

4.55.4 Pharmacist Consultation: Pharmacists must be available to provide expert advice and guidance on signposting decisions.

4.56 Monitoring and Evaluation:

4.56.1 Regular Audits: The superintendent pharmacist must conduct regular audits of signposting procedures to ensure compliance and identify areas for improvement.

4.56.2 Feedback: Feedback mechanism from patient and staff is set up following signposting to identify areas for improvement in the signposting process.

4.56.3 Continuous Improvement: Implement changes to the SOP based on audit findings and feedback to ensure the process remains effective and efficient.

4.57 SOP reference attachment: SOP-PP-126 Signposting Procedure

4.58 Attached documents for the appeal process

4.58.1 SOP-DIS-103 - Dispensing Electronic Repeat Prescription

4.58.2 SOP-DIS-101 - Dispensing Electronic Prescription Service

4.58.3 SOP-PP-189 Mandatory Annual Campaign to Pharmacy Users

4.58.4 SOP-PP-126 Signposting Procedure"

5 Summary of Representations

This is a summary of representations received on the appeal.

5.1 THE COMMISSIONER

5.1.1 "Thank you for your letter dated 24 March 2025 advising us that Optiom Health Ltd (the Appellant) have submitted an appeal against the decision by Herts and West Essex Integrated Care Board (HWE ICB) to refuse their application for a distance selling pharmacy.

5.1.2 The Appellant notes that as set out in the decision wording, some of the requirements of regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) were not met. The decision wording sets out 4 areas where there was insufficient evidence to demonstrate compliance with the Regulations. The Appellant has reviewed these four areas and provided additional information that was not available to the Pharmaceutical Services Regulations Committee (PSRC).

5.1.3 The HWE ICB was required to make a decision based on the information available to it at the time. When the PSRC made the determination, it did not have the information now supplied on appeal by the Appellant. It is recognised

that had this information been available to PSRC, a different determination may have been made.

5.1.4 Noting the above, on receipt of the appeal and in reviewing all documents prior to sending to NHS Resolution, the ICB has noted an error in the PSRC minutes and decision wording letter. The minutes are used as the basis to form the decision letter. In the Committee Report (enclosed) presented to PSRC, the following was noted on page 5:

5.1.5 “Dispensing of drugs and appliances

5.1.6 The Committee is to consider whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

5.1.7 The Committee is to note the information provided within the application states how electronic prescriptions will be presented.

5.1.8 The Committee may not be satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2) & 5(3) of Schedule 4.”

5.1.9 Unfortunately, in the minutes and decision letter there was an error and it was noted that the Committee was satisfied. The following was noted on page 5 of the minutes (enclosed) and replicated in the decision letter (enclosed as part of the appeal, page 38):

5.1.10 “Dispensing of drugs and appliances

5.1.11 The Committee considered whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided.

5.1.12 The Committee noted the information provided within the application states how electronic prescriptions will be presented.

5.1.13 The Committee were satisfied that it has been provided with information sufficient to show that there would be compliance with Paragraph 5(2) & 5(3) of Schedule 4.”

5.1.14 The ICB would like to apologise to all parties for this oversight.

5.1.15 The ICB notes that the Appellant has made no reference to Paragraph 5(2) of Schedule 4 in their appeal as the appeal focuses on the four areas outlined in the decision letter as “not met.” Having reviewed all information, the ICB is unclear on how the Appellant will manage the presentation of non-electronic prescriptions.

5.1.16 We note that NHS Resolution will have regard to all information provided to date including the additional information submitted by the Appellant as part of this appeal.”

5.2 COMMUNITY PHARMACY HERTFORDSHIRE

5.2.1 “Community Pharmacy Hertfordshire (CPH) acknowledges the appeal made by Optiom Health Ltd, as detailed in their letter dated 11 March 2025, and has

reviewed the supporting information provided. Our position, as outlined in our original letter dated 28 November 2024, remains unchanged.

5.2.2 However, we would like to emphasise the following points in light of the applicant's appeal:

5.2.3 That the Standard Operating Procedures (SOPs) provided by the applicant do not compromise the provision of essential services to any person in England requesting or receiving those services. This is in accordance with Regulation 25(2) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

5.2.4 We reiterate our request whether the procedures and SOPs detailed in the application adequately ensure the safe and effective provision of essential services, as mandated by Regulation 25(2).

5.2.5 We maintain that the provision of commissioned services by the applicant is contingent on commissioner agreement and cannot be guaranteed. We also highlight that some listed services are not commissioned within Hertfordshire.

5.2.6 We again request that the proposed floor plan and operational procedures do not compromise the delivery of essential services without face-to-face contact and to individuals across England, as required for a Distance Selling Pharmacy.

5.2.7 It is crucial to note that the regulatory direction for Distance Selling Pharmacies (DSPs) is towards reinforcing the distance-selling model. There are proposed regulatory changes that will restrict enhanced or advanced services from being delivered face-to-face on DSP premises. Current and emerging regulations, including Regulation 25 and 64, emphasize that DSPs should not be structured or operated in a way that implies or facilitates the provision of advanced or enhanced services on physical premises. This principle underpins the very definition of a DSP and the core requirements for service delivery without face-to-face contact.

5.2.8 CPH trusts that these points will be thoroughly considered and the information provided in the applicant's appeal when making its final decision. We would appreciate being kept informed of the progress of this appeal."

In a letter to the Commissioner dated 28 November 2024 Community Pharmacy Hertfordshire stated:

5.2.9 "Thank you for your letter dated 18 October 2024 notifying Community Pharmacy Hertfordshire (CPH) of this application which is made under Regulation 25 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

5.2.10 CPH would respectfully ask that when considering the application, NHS England is satisfied that the pharmacy procedures for the pharmacy premises will ensure:

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

5.2.10.2 the safe and effective provision of essential services without face-to-face contact between any person receiving the services, whether on

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

5.2.11 NHS England should additionally be satisfied that:

5.2.11.1 the applicant's practice leaflet and publicity material does not suggest that essential services are only available to patients living in a particular area;

5.2.11.2 should the applicant commence offering directed services, the applicant does not appear to offer pharmaceutical services other than directed services, to patients who are present at, or in the vicinity of, the proposed premises;

5.2.11.3 there will be arrangements in place to monitor the opening hours offered in the application.

5.2.12 NHS England should be assured that the evidence put forward in the form of Standard Operating Procedures (SOPs), do not focus on local provision and compromise the proposed pharmacy in providing services to anyone in England requesting or receiving their services.

5.2.13 CPH would ask that NHS England, when considering the application, decide if the procedures set out in the application supported by the SOPs can deliver the safe and effective provision of essential services as required by Regulation 25(2).

5.2.14 CPH notes that the ability to provide most of the commissioned services offered would depend on whether commissioners agreed to commission them from this pharmacy and the commissioning of proposed services from this pharmacy could not be guaranteed. It should also be noted that a few of the commissioned services listed are not commissioned within Hertfordshire.

5.2.15 CPH has noted the floor plan layout provided by the applicant. CPH would request that NHS England is satisfied that the suggested operations of the pharmacy and the proposed floor plan does not compromise that essential services are made without face-to-face contact and are available to anyone in England."

6 Comments to the Commissioner

On reviewing the paperwork provided by PCSE, it was noted that whilst the additional SOPs provided by the Applicant were circulated to parties and the initial consultation period was recommenced, the comments made by the Applicant in response 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 to circulate these comments to parties for them to make observations on them if they so wished.

6.1 OPTIOM HEALTH LTD

6.1.1 "Further to your letter dated 6th October 2023, please find below responses to the representations from interested parties.

Response Overview

6.1.2 Optiom Health Limited was born out of a vision and passion to embrace the changing face of pharmaceutical services delivery to patients. As part of the NHS long term plan, there is an ambition for Community Pharmacies to be more clinically focused, to help provide accessible and convenient healthcare to patients.

6.1.3 There is a recognition within the current Community Pharmacy Contractual Framework that for community pharmacies to deliver this bold ambition, pharmacists time must be released from high degree of focus on dispensing.

6.1.4 Setting up as a distance selling pharmacy would allow us to support this bold vision for pharmaceutical service delivery to patients.

6.1.5 As a distance selling pharmacy, we will have the opportunity to deliver NHS Essential Pharmaceutical services completely remotely, freeing up valuable time saved from walk ins or face to face contact to deliver clinical services. The details of how we will ensure delivery of essential services without the need for face-to-face contact are outlined in below responses to representations made to this application.

6.1.6 The NHS pharmaceutical services also include enhanced and advanced services, which distant selling pharmacies can deliver face to face, without compromising essential services by means of complete segregation of the premises. Recognising the regulatory requirement to deliver essential services without face-to face contact, we will have a complete wall to ceiling partition between the dispensary, where these services can be delivered compliantly and the OTC medicines & clinical area, where clinical services can be delivered. We recognise that there are some clinical services that are not commissioned by the NHS that pharmacies can deliver privately through private patient group directives. We are also positioned to deliver these services to those patients willing to pay. For example, we note that the NHS flu vaccination is not available to patients under the age of 65, some of these patients may want to receive flu vaccination.

6.1.7 We are able to deliver these privately to those patients.

6.1.8 We are passionate about healthcare and delivery of quality conveniently accessible healthcare. We are ready and willing to embrace the future of digital healthcare delivery which will be at the heart of the efficiency savings the NHS wishes to make in the face of increasing demand for healthcare.

6.1.9 This digital transformation is well underway with ~96% of prescriptions issued electronically according to NHS Business Services Authority General Pharmaceutical Services 2022/23 report.

6.1.10 We also note in this report that since 2015, there has been a year on year decrease in the number of Community pharmacies (535 less in 2022/23 vs. 2015/16) whilst the number of dispensed items has increased by 84 million in the same period. There is a need for new ways of delivering pharmaceutical services to patients in the face of growing demand, and the distance selling model will enable us to contribute to addressing this demand.

6.1.11 Recognising that some interested parties consulted on this application have made representation, we have responded to each of these below.

Interested Party 1: LPC

6.1.12 *CPH would respectfully ask that when considering the application, NHS England is satisfied that the pharmacy procedures for the pharmacy premises will ensure*:

6.1.13 *the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services*.

Response 1

6.1.14 The pharmacy's operational procedures are designed to ensure the seamless provision of essential services to individuals throughout England. These procedures are specifically tailored to guarantee uninterrupted access to NHS essential services following approval of NHS pharmaceutical distance selling premises application.

6.1.15 Our active online presence will be accessible through our website with details of our opening hours on the 'contact us' page.

6.1.16 To further enhance accessibility, our website features a chat function, which will be available during our specified opening hours, to address any enquiries. Additionally, a contact form, email address and telephone number are conveniently located on our website header and footer.

6.1.17 The internet service will always be available as it is backed up in additional servers to ensure smooth running of the services. Its functionality and accessibility are checked 24/7 by the website hosting company, Hostinger.

6.1.18 Additionally, through telephone and online services, patients can request medications and access all essential services as detailed further in Response 2 below.

6.1.19 All our standard operating procedures emphasize the crucial presence of a qualified pharmacist and a dedicated pharmacy team during our operational hours to ensure the uninterrupted delivery of NHS essential services during the opening hours of the premises.

6.1.20 See SOP-RP-123: Assuming and ceasing duties and changeover of the responsible pharmacist.

6.1.21 *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*.

Response 2

6.1.22 Safe and effective provision of essential services.

6.1.23 We have provision in place to deliver all essential services safely and effectively without face to- face contact.

Discharge Medicines Service

6.1.24 Discharge Medicines Service will be delivered remotely to those in need following approval of the NHS pharmaceutical distance selling premises application. Upon referral and completion of initial checks, consultation will happen remotely via telephone or video and any follow up prescription from the new regimen will be received electronically from the GP, item dispensed

and delivered for free to patient. We will be using approved courier services Royal Mail and DPD that would allow us to deliver to patients across England.

6.1.25 Therefore, a face-to-face contact is not required to deliver this service safely and effectively as outlined in our SOPs. See

6.1.26 SOP-DIS-135: Delivering Discharge Medicines Services

6.1.27 SOP-DIS-134 Preparing for Discharge Medicines Services

6.1.28 SOP-DIS-150- Communicating Non-Supply of NHS Essential Services

Dispensing of Medicines

6.1.29 Regarding the dispensing of medicines, majority of prescriptions are now transmitted electronically through the NHS spine with ~96% of items in 2022/23 dispensed via electronic prescription service (EPS) according to NHS Business Services Authority Report.

6.1.30 There will be provision for any patient in England to register for free prescription dispensing and delivery service online through our website, via phone, or email to nominate our pharmacy following approval of this application. Upon nomination, we will liaise with their GP to facilitate electronic prescription fulfilment. We already have an account opened with Royal Mail and plan to open an account with DPD. Both couriers ensures tracked delivery service to the whole of England free to all patients.

6.1.31 All prescribed items will be delivered using a tracked delivery system, communicated to patients via email. For patients that are identified as vulnerable for example elderly, we will add another means of communication, that is calling them to confirm date and time of delivery to ensure they are home. In case of inquiries or questions related to their medicines, patients can reach out to us through online chat, phone, or the contact form on our website.

6.1.32 For fridge line items, these will be packed using quality assured ice packs and insulated shipping systems by HydroPac, an established manufacturer and supplier of pharmaceutical grade shipping systems that supplies many pharmaceutical businesses. These items will delivered [sic] within 24 hours using a 24-hour tracked system. Prior to despatching, the patient will receive communication that they will be receiving a fridge item to ensure that they are available to receive the item. In case of missed delivery, the item will be sent back to the pharmacy for destruction.

6.1.33 Controlled drugs will also be sent via tracked courier service. For enhanced security, the patient or authorised representative will be sent a unique pin code. The item will be delivered within 24 hours and the delivery driver will deliver the package after confirmation of the pin code by the patient or authorised representative and obtain signature. In case of missed delivery, CD items will be returned immediately to the pharmacy. The details on handling of delivery can be found in our SOP. See:

6.1.33.1 SOP-DIS-101: Dispensing Electronic Prescriptions

6.1.33.2 SOP-DIS-108 Packing & Delivery of prescription orders.

6.1.33.3 SOP-DIS-114-Packing & Delivery of fridge items.

6.1.33.4 SOP-DIS-122- Packing & Delivery of Schedule 2 & 3 CDs

Support for self-care

6.1.34 We believe that it is important for patients to take charge of their own healthcare and we are equipped to support patients to manage their own health. For all patients we will be providing prescription delivery service upon approval of this application. We will include a leaflet in each parcel delivered to patients informing them to contact our pharmacy team if they have questions regarding their healthcare. As the pharmacist sees fit, where it appears that a patient would benefit from advice on their medical condition, the pharmacist will contact the patient to offer appropriate advice and counselling. This can be recorded on the PMR.

6.1.35 We will also send out regular email communication to patients registered with our pharmacy with self-care advise including seasonal conditions such as cold & flu and hay fever, to reduce the demand on health and social care services.

Disposal service in respect of unwanted drugs

6.1.36 To simplify the disposal of unwanted medicines under the provision of essential service following NHS approval, customers can contact the pharmacy team to request for return of their medicines. Additionally, we will incorporate a "Disposal of unwanted medicines" form on our website, for customers to complete. Upon completion of the form and confirmation that the returns do not contain sharps or other items that cannot be accepted as noted on the return of medicines cue card, a tracked pre-paid plastic bag will be sent to the patient with instructions, so they can return their medicine via post, eliminating the need for in-person face to face visits. Details can be found in our draft SOP. SOP-DIS-128 Disposal of unwanted medicines.

Urgent supply without a prescription

6.1.37 An emergency supply request via Pharmaoutcomes for example, will be received digitally, that is no face-to-face contact required. Patient will be contacted via phone or video for consultation and item dispensed as required.

6.1.38 Urgent request via a patient will have to be individually assessed as per our procedure. The request can only be done remotely, via online form or phone call. We would in all cases speak and interview the patient. Should there be a need for medication supply, this will be confirmed with their GP, and supply upon agreement as per the direction of the prescriber – pending receipt of a prescription. The prescription will be dispensed and delivered to the patient using Royal Mail tracked delivery service.

Promotion of healthy lifestyles and Health campaigns

6.1.39 This will be available on the health and advice section of our website; we will also include leaflets in patients' delivery pack promoting healthy lifestyles encouraging them to visit our health and advice page for more information; as well as sending out periodic email communications to patients in support of NHS public health campaigns.

Prescription linked intervention.

6.1.40 We will perform legal and clinical checks of all prescriptions. Where pharmacist intervention or advice is required, the pharmacist will call the patient, discuss

and counsel accordingly. If required, provide additional information within the parcel to be delivered.

Signposting

6.1.41 When contacted about a service not provided by the pharmacy, via phone or contact form or email, patients can be referred to relevant services as needed.

Refusal to provide drugs ordered.

6.1.42 We will perform legal and clinical check of all prescriptions, additionally ensuring that prescribed items are not on the NHS blacklist. Should there be a reason that a drug cannot be supplied, the patient and their doctor will be contacted by phone, email to explain the reason about the non-supply. The prescription can be released back to spine.

Preliminary matters before providing ordered drugs.

6.1.43 We will undertake legal and clinical checks of all prescriptions. Upon reviewing the prescription or request, if such supply cannot be completed for legal and clinical reasons, or due stock availability issues, we will inform the patient as soon as possible by telephone. If a specific advice or request is needed, the patient will also be contacted by phone or email.

6.1.44 Follow up contact will be done until patient is reached.

Providing ordered drugs.

6.1.45 Drugs can be ordered by phone, website, and following patient verification, these can be dispensed and delivered with a prescription following the relevant SOPs.

Websites and health promotion zones.

6.1.46 Our website is for use by the public providing public access to up-to-date information that will promote healthy lifestyles by addressing a range of health issues. We have an agreement with Sky Business who will manage our telephone system and internet. We will use the internet, telephone and video calling as required to communicate with patients. Once approved we will insert a login section and registration section for patients to request their medicines, forms to contact us, for complaints and for all other essential services.

Repeat Dispensing

6.1.47 Repeat dispensing request will be initiated remotely through the nomination of our pharmacy via website, phone, chat, or email. Upon receipt of nominations, we will facilitate communication and prescription delivery to patients across England, as outlined in our SOPs.

6.1.48 In summary, as highlighted both above and within the relevant Standard Operating Procedures, our pharmacy is committed to delivering NHS essential services seamlessly, catering to the needs of those who request these services, and ensuring they can be provided without the necessity of face-to-face contact.

6.1.49 If a patient attends the premises asking for essential service to be provided face to face, we will explain that it is not permissible for it to be done as we are a distance selling pharmacy.

6.1.50 All staff will be trained accordingly.

Additional Information

6.1.51 To further enhance the segregation of the essential services from other services, we will have a subdomain online to our website, dedicated to providing the NHS essential services, which will be created as essentialservices.ourwebsite.com.

6.1.52 This will enlist all NHS essential services to further separate this from other services.

6.1.53 *NHS England should additionally be satisfied that*:

6.1.54 *the applicant's practice leaflet and publicity material does not suggest that essential services are only available to patients living in a particular area*.

Response 3

6.1.55 Upon the approval of an NHS application, our marketing guidelines, will clearly specify that it is imperative that leaflets and all public materials refrain from implying that essential services are restricted solely to patients residing within a specific geographical area. We will ensure that our communication is clear that essential services is available to all patients in England and details of how these services can be accessed remotely.

6.1.56 *should the applicant commence offering directed services, the applicant does not appear to offer pharmaceutical services other than directed services, to patients who are present at, or in the vicinity of, the proposed premises*.

Response 4

6.1.57 Should there be directed services provided by the pharmacy, which are commissioned by the NHS, these will exclusively cater to patients located in the immediate vicinity of our proposed premises.

6.1.58 To uphold this practice, we will rigorously follow our procedure, which entails the compilation of an approved list of services designated for local patients. Locally commissioned services will be advertised to local customers only via leaflet or digitally. We will include the requirement to list the covered areas on our online platform as well as within the pharmacy. Furthermore, a secondary checklist will be accessible and must be signed by all members of the pharmacy team to verify the patient's address prior to the delivery of such services.

6.1.59 *there will be arrangements in place to monitor the opening hours offered in the application*.

Response 5

6.1.60 The premises will consistently be staffed by a Responsible Pharmacist during our intended opening hours. Our registration with the General Pharmaceutical Council (GPHC) mandates this requirement, and we are unable to operate

without one. Both the Responsible Pharmacist and our pharmacy team are contractually obligated to function within the specified opening hours, which are also in alignment with our GPHC registration details, as outlined in our procedures.

6.1.61 *NHS England should be assured that the evidence put forward in the form of Standard Operating Procedures (SOPs), which we have not seen, do not focus on local provision and compromise the proposed pharmacy in providing services to anyone in England requesting or receiving their services*.

Response 6

6.1.62 As previously discussed, and outlined in Response 1 and 2, along with the relevant Standard Operating Procedures (SOPs), NHS essential services will be intentionally designed to have a broader reach beyond local provision, that is, to anyone in England.

6.1.63 CPH would ask that NHS England, when considering the application, decide if the procedures set out in the application supported by the draft SOPs can deliver the safe and effective provision of essential services as required by Regulation 25(2).

Response 7

6.1.64 I would like to direct your attention to the information previously presented in Response 1 and 2. It comprehensively outlines the procedures, as detailed within our Standard Operating Procedures (SOPs), that govern the safe and effective provision of NHS essential services without necessitating face-to-face interaction between the service recipient, whether acting on their own behalf or representing someone else, and our team members.

6.1.65 The proposed premises in the 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.

6.1.66 *CPH would like it noted that the applicant is already advertising its services despite its application not yet being approved. In addition, CPH has evidence that the applicant is applying for services that are only open to those on the NHS pharmaceutical list before its application has been approved*.

Response 8

6.1.67 We have recently been registered as a pharmacy, by the General Pharmaceutical Council (GPHC). We are currently advertising services that can be obtained privately by patients wishing to do so under appropriate private patient group directives. We are NOT advertising NHS services.

6.1.68 In response to the comment regarding the assertion that we are seeking services only available to those on the NHS pharmaceutical list before our application has been approved, we wish to clarify that we have indeed applied for inclusion on the NHS pharmaceutical list and we have not offered, nor delivered NHS services available only to those on the NHS pharmaceutical list, as it is not possible for us to do so. We strongly refute this assertion. The provision of NHS services will be initiated only upon the approval of our application. For reference, we possess both case numbers, denoted as ' CAS-214782-K1W5Y8 ' and ' CAS- 216272-Z3P7T8,' related to this application process.

6.1.69 *CPH notes that the ability to provide most of the commissioned services offered would depend on whether commissioners agreed to commission them from this pharmacy and the commissioning of Chair Chief Officer Rachel Solanki Helen Musson proposed services from this pharmacy could not be guaranteed. It should also be noted that a few of the commissioned services listed are not commissioned within Hertfordshire*.

Response 9

6.1.70 It is important to highlight that we are fully equipped to offer some pharmacy services on a private basis under private PGDs. As outlined in the response overview above, there are clinical services pharmacies can deliver which are not commissioned by the NHS community pharmacy contractual framework. There will be some locally commissioned services we may wish to deliver upon approval of this application. If these are not commissioned, we will not deliver them. The introduction of additional locally commissioned services will extend the accessibility of services to local patients without the need for direct payment.

6.1.71 *CPH has noted the floor plan layout provided by the applicant and query whether the applicant has made a correct application under the regulations for which it has applied. CPH would request that NHS England is satisfied that the suggested operations of the pharmacy and the proposed floor plan does not compromise that essential services are made without face-to-face contact and are available to anyone in England*.

Response 10

6.1.72 The application made is for inclusion in a pharmaceutical list in respect of distance selling premises. As such, the dispensary will be entirely away from direct customer access with a floor-to-ceiling wall to prevent public access and view of the dispensary. Unlike traditional pharmacies, where patients can observe the display of Prescription-Only Medicines (POM), the pharmacist at work, or signage indicating "PRESCRIPTIONS" this is NOT the case in our premises.

6.1.73 We appreciate the expressed concern regarding the imperative to maintain essential services without face-to-face contact. Importantly, no face-to-face interaction occurs during the provision of essential services in the dispensary area as detailed in response 1 & 2. We have clearly outlined in our procedure, that NHS prescriptions cannot be received onsite, and staff will be trained accordingly. All patients will only be able to access NHS essential services by requesting such services on our website upon approval of this application, or calling, emailing the pharmacy.

6.1.74 All services, including the dispensing of NHS-prescribed medicines, will be delivered using the designated rear door of the building for daily collection by an approved courier service.

6.1.75 Consequently, the services delineated in Response 1 are accessible to individuals throughout England, as they are primarily digital in nature. The physical aspects and preparations are carried out exclusively within the dispensary, utilizing the space at the rear for this purpose.

6.1.76 The front area is designated for the provision of non-essential NHS services and privately directed PGDs. The regulation does not prohibit the provision of such services on the premises. Additionally local customers wishing to

purchase GSL and Pharmacy medicine may do so as we are an approved pharmacy under the GPHC regulations.

6.1.77 To further address the concerns raised by CPH, upon approval of the application, the front area will largely be a reception area with consultation room(s) for patients wishing to use our private clinical services and designated area for OTC medicines sales. We have enclosed a revised floor plan. [see Appendix C].

6.1.78 Revised Floor Plan (attached to the response for the application [see Appendix C]: the green wall is the floor to ceiling wall to ensure NO face-to-face contact for essential services. The consultation room will be available for advance, enhanced and PGD directed services.

Interested Party 2: Boots

6.1.79 Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application.

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

> *(a)for inclusion in a pharmaceutical list by a person not already included; or*
>
> *(b)by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.*

(2) The NHSCB must refuse an application to which paragraph (1) applies— (

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

Response 11

6.1.80 Below are criteria set out in Regulation 25 and responses on how this is met.

6.1.81 An application for inclusion in a pharmaceutical list has been made. Here are relevant case references - CAS-214782-K1W5Y8 and CAS-216272-Z3P7T8. The applications are done concurrently.

6.1.82 Optiom health is NOT on the same site or in a building of a provider of a primary medical services with a patient list.

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

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

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

6.1.83 I would like to draw attention to the information provided in Response 1 and 2 above. It outlines the specific procedures detailed within our Standard Operating Procedures (SOPs) governing the safe and efficient provision of services without the need for face-to-face contact. These protocols ensure that services can be administered securely to individuals, whether they are receiving them personally or on behalf of someone else, without direct physical interaction.

6.1.84 Regulation 64 [quoted in full]

Response 12

6.1.85 Below are criteria set out in Regulation 64 and responses on how this is met.

6.1.86 We have submitted applications for inclusion in the pharmaceutical list, and we can provide the relevant case references for your records: ' CAS-214782-K1W5Y8' and 'CAS-216272- Z3P7T8.' These applications have been concurrently processed.

6.1.87 Should any directed services be offered by our pharmacy, that are for commissioning by the NHS, they will be exclusively extended to patients residing in the vicinity of our proposed premises.

6.1.88 To ensure stringent compliance with our procedures, we will implement a comprehensive approach. This approach involves compiling a catalogue of all services earmarked for local patients within an approved list accessible to the pharmacy team. Furthermore, in all our digital forms and correspondence, we will explicitly indicate that these services are solely intended for patients within the local area, clearly listing the eligible regions. We will also provide a second checklist available to all members of the pharmacy team, serving to verify the patient's address prior to the delivery of these services.

(c)the listed chemist 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.

See response 11.

6.1.89 Regulation 64 (d) – (e) [quoted in full]

Please see responses 1 and 5

6.1.90 Our practice leaflet and publicly available material will NOT indicate provision of drugs or appliances to only certain category of patients. Upon approval of this application, we will offer NHS essential services to all patients in England according to the regulatory requirement terms of service.

Interested Party 3: Esom's Ltd

6.1.91 *Hitchin already has six pharmacies trying to survive in the current economic climate. We provide an excellent service to the patients of Hitchin opening six*

full days every week from 8.30am to 6pm weekdays and until 5pm on Saturdays.

Response 15

6.1.92 As stipulated in the Regulation 2013, Section 64 about 'Distance Selling Premises'

6.1.92.1 - nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that—

6.1.92.2 (i)the essential services provided at or from the premises are only available to persons in particular areas of England, or..'

6.1.93 As previously outlined in our earlier responses, it is imperative to emphasize that the services rendered by our dispensary are entirely distinct from those offered in the OTC and clinical area. NHS essential services, governed by our Standard Operating Procedures (SOPs), are not restricted to any specific geographical area within England but are intended to benefit individuals across the entire country. Upon approval of this application, we have a comprehensive marketing plan that covers the entirety of England.

6.1.94 *The applicant is not providing any extra long hours of opening nor are they offering any services that the other pharmacies, we also offer a free delivery service to all patients. The current PNA has not identified any need for a new pharmacy (I do understand that his is a distance selling pharmacy) why does the government then have to incur the cost of yet another pharmacy?*

6.1.95 The application is for inclusion in a pharmaceutical list in respect of distance selling premises for provision to the whole of England, therefore, a pharmaceutical needs assessment is not warranted. As previously outlined in our earlier responses, it is imperative to emphasize that the NHS essential services will be delivered in the dispensary away from public view. These essential services, governed by our Standard Operating Procedures (SOPs), are not restricted to any specific geographical area within England but are intended to benefit individuals across the entire country, England.

6.1.96 *We believe the applicants have every intention of only operating locally and will only deliver nationally when forced to do so. They have a shop area how can this be a distant selling pharmacy*.

6.1.97 We strongly refute this false accusation. We have outlined in above responses our plans to deliver NHS essential services without face-to-face contact, as well as having marketing plan to ensure we are able to reach all geographical areas in England.

6.1.98 See below for responses to the rest of the representation.

6.1.99 Patients will not be required to enrol in a delivery service. We proudly offer free delivery services to all individuals in England. This approach facilitates our capacity to deliver essential services to the entirety of England by leveraging the services of approved courier providers that conducts daily pickups.

6.1.100 It is important to underscore that there is no temptation or allowance within our in-house procedures to provide essential services within the OTC and reception area. This separation is intentionally maintained to create an environment conducive to the provision of pharmacy private clinical services as well advanced services and locally commissioned services upon approval of this application and commissioning of the latter.

6.1.101 This distinction and separation better positions us to focus on supporting customers wishing to access private clinical services and in future upon approval of this application, clinical enhanced and advanced services, as well as locally directed services in alignment with the evolving NHS plan, which encourages pharmacies to expand their service offerings. Providing essential services in the OTC and clinical area would hinder our ability to achieve and support these objectives.

6.1.102 There are few private clinics, a medical centre, a private hospital within our vicinity and a short distance away. Our location does not violate any regulatory requirements. We have diligently adhered to all the conditions stipulated within the regulation.

Future NHS Strategy and Plan

6.1.103 Future NHS plan describes the expectations of community pharmacy teams to deliver consistent, high-quality care of patients with minor illnesses and support the public to live healthier lives.

6.1.104 For community pharmacy, part of the plan states:

6.1.104.1 NHS England will work with Government to make greater use of community pharmacists' skills and opportunities to engage patients.

6.1.104.2 NHS England will work with community pharmacists and others to provide opportunities for the public to check their health, through tests for high blood pressure and other high-risk conditions; and

6.1.104.3 From 2019, NHS 111 will start direct booking into GP practices across the country, as well as referring on to community pharmacies who can support urgent care and promote patient self-care and self-management.

6.1.104.4 Pharmacists may be involved in helping to identify and treat people with high-risk conditions, undertaking a range of medicine reviews, including educating patients on the correct use of inhalers, and offering medicine reviews to care home residents.

6.1.104.5 (Reference - https://cpe.org.uk/our-work/negotiations/the-nhs-long-term-plan/)

6.1.105 This is why it is important for us to separate the NHS essential services as a stand-alone department, working independently and providing its services to the whole of England. Whilst the advanced and enhanced services support the future NHS plan with pharmacists providing opportunities for the public to check their health, through tests for high blood pressure and other high-risk conditions; identify and treat people with high-risk conditions, undertaking a range of medicine reviews, including educating patients on the correct use of inhalers, and other services.

Conclusion

6.1.106 We are a passionate team committed to delivering quality pharmaceutical services to patients. We are ready to embrace the changing landscape of healthcare provision in the UK and upon approval of this application support delivery of the NHS long term plan. We have procedures in place that will help us in ensuring consistent compliance to all applicable laws and regulations. The SOPs supplied with this response is not the exhaustive list of SOPs we have drafted to date but helps to demonstrate our ability to adhere to the relevant regulations of the NHS Pharmaceutical List for distant selling premises.

References

6.1.107 The NHS Long Term Plan

6.1.108 The Community Pharmacy Contractual Framework 2019-2024 supporting delivery for NHS long term plan

6.1.109 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

6.1.110 The National Pharmacy Services: https://cpe.org.uk/national-pharmacy-services/

6.1.111 Flu vaccination programme 2023-2024: information for healthcare practitioners:

https://www.gov.uk/government/publications/flu-vaccination-programme-information-forhealthcare-practitioners

6.1.112 NHS Business Services Authority General Pharmaceutical Services England 2015/16 to 2022/23 Report."

6.1.113 The SOPs are included at Appendix A

6.2 OPTIOM HEALTH LTD

6.2.1 “Following the email sent on 3rd December 2024 with response to comments received.

Interested Party 1: Boots

6.2.2 *Thank you for your letter dated 18th October 2024 informing us of the above application. Boots UK Ltd would like to respectfully request that members of the deciding committee are satisfied that this application fully meets the criteria set out in Regulation 25 and the conditions set out in Regulation 64 when determining this application. I would be grateful if you would inform us of the outcome of this application*.

Response 1

6.2.3 Below are criteria set out in Regulation 25 and responses on how this is met.

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

(a)for inclusion in a pharmaceutical list by a person not already included; or (b)by a person already included in a pharmaceutical list for inclusion in that list also in respect of premises other than those already listed in relation to that person, in respect of pharmacy premises that are distance selling premises.

(2) The NHSCB must refuse an application to which paragraph (1) applies— (a)if the premises in respect of which the application is made are on the same site or in the same building as the premises of a provider of primary medical services with a patient list; and

6.2.4 An application for inclusion in a pharmaceutical list has been made. Here are relevant case references - CAS-214782-K1W5Y8 and CAS-216272-Z3P7T8. The applications are done concurrently.

6.2.5 Tabi health [sic] is not on the same site or in a building of a provider of a primary medical service with a patient list.

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

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

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

6.2.6 Our active online presence, accessible through our website, Details of our opening hours, please refer to our "Contact Us" page.

6.2.7 To further enhance accessibility, our website features a chat function, available during our specified opening hours, to address any inquiries. Additionally, a contact form, email and phone are conveniently located on our website's "Contact Us" page website header for those seeking our services and once approved NHS essential services.

6.2.8 The internet service will always be available as it is backed up in another server to ensure smooth running of the services.

6.2.9 Additionally, through telephone and online services, patient can request medications.

6.2.10 All our standard operating procedures emphasize the crucial presence of a qualified pharmacist and a dedicated pharmacy team during our operational hours to ensure the uninterrupted delivery of NHS essential services as outlined in our Standard Operating Procedures.

6.2.11 Our Standard Operating Procedures (SOPs) governs the safe and efficient provision of essential services without the need for face-to-face contact. These protocols ensure that services can be administered securely to individuals, whether they are receiving them personally or on behalf of someone else, without direct physical interaction.

Response 2

6.2.12 Below are criteria set out in Regulation 64 and responses on how this is met.

64.—(1) If an application in respect of distance selling premises—

(a)to which regulation 25(1) applies is granted;

(b)to which regulation 25(1) of the 2012 Regulations (distance selling premises applications) applied was granted; or

(c)to which regulation 13(1)(d) of the 2005 Regulations (exemption from the necessary or expedient test) applied was granted, paragraph (2) applies.

(2) The inclusion in the pharmaceutical list of the person (X) listed in relation to—

(a)those distance selling premises; or

(b)if there has been a relocation of the retail pharmacy business or appliance contractor business at those distance selling premises to other premises, those other premises,

is subject to the conditions set out in paragraph (3).

(3) Those conditions are—

(a) X must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises;

6.2.13 Tabi Health will not offer to provide essential pharmaceutical services. Services provided to persons who are present at (which includes in the vicinity of) the listed premises will include:

6.2.13.1 Directed services; and

6.2.13.2 Private services.

6.2.14 To ensure stringent compliance with our procedures, we will implement a comprehensive approach.

6.2.15 This approach involves compiling a catalogue of all services earmarked for local patients within an approved list accessible to the pharmacy team.

6.2.16 Pharmacy team will be trained only to provide essential services digitally, as per distance selling service requirements.

(b) how X provides pharmaceutical services, other than directed services, must be such that any person receiving those services does so otherwise than at the listed chemist premises.

6.2.17 Other services other than directed services will only be available for persons receiving those services otherwise than at the listed chemist premises.

(c) the listed chemist 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.

6.2.18 See response 1.

(d)in the case of pharmacy premises, the pharmacy procedures for the premises must be such as to secure—

(i)the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and (ii)the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and X or X's staff; and

Discharge Medicines Service

6.2.19 We have put provision in place to be able to deliver Discharge Medicines Service remotely to those in need following approval of the NHS pharmaceutical distance selling premises application. Referrals for this service involve completing necessary details online, followed by remote contact with patients via phone or video to complete all required stages, as outlined in our SOPs.

Dispensing of Medicines

6.2.20 Regarding the dispensing of medicines, majority of prescriptions are now transmitted electronically through the NHS spine. Patients will register with us online through our website, via phone, or email to nominate our pharmacy.

6.2.21 Upon nomination, we liaise with their GP to facilitate electronic prescription fulfilment. We already have an account opened with an approved courier service that ensures tracked delivery service to the whole of England.

6.2.22 All prescribed items are then delivered using a tracked delivery system. In case of inquiries or questions related to their medicines, patients can reach out to us through online chat, phone, or the contact form on our website https://tabihealth.com/contact/

Support for self-care

6.2.23 We will include contact details in each parcel delivered to patient to encourage them to contact us for support for self-care. Our correspondence email will also include this. So they know how to reach us when this is required.

Disposal service in respect of unwanted drugs

6.2.24 To simplify the disposal of unwanted medicines under the provision of essential service following NHS approval, we will incorporate a form section on our website, allowing patients to express their interest in returning unwanted medicines to the premises via post, eliminating the need for in-person face to face visits.

Urgent supply without a prescription

6.2.25 An urgent supply without prescription can be requested via phone or website.

6.2.26 Patient details once verified on our system, prescription can be requested electronically from their GP and dispensed and delivered as usual, making a

note of the supply. Payment if required can be requested digitally using customers' details on record.

Promotion of healthy lifestyles and Health campaigns

6.2.27 This will be available on out healthy and advice section on the website. Some of which can be advertised as well.

Prescription linked intervention.

6.2.28 Where pharmacist intervention or advice is required, depending on the type of advice, the pharmacist will call the patient following checking process, provide additional information within the parcel to be delivered and for general information about a medicine, can be communicated via email. All intervention will be recorded on patient medical records.

Signposting

6.2.29 When contacted about a service not provided by the pharmacy, via phone or contact form or email, they can be referred to relevant services as needed.

Refusal to provide drugs or appliances ordered.

6.2.30 Should there be a reason that a drug cannot be supplied patient will be contacted by phone, email to explain the reason and their doctor informed about the non-supply. The prescription can be uploaded back to spine so patient can obtain from another pharmacy.

Preliminary matters before providing ordered drugs.

6.2.31 The pharmacist or pharmacy team upon reviewing the prescription or request, realise that such supply cannot be complete, will contact patient. If a specific advice or request is needed, patient will also be contacted by phone or email.

6.2.32 Follow up contact will be done until patient is reached.

Providing ordered drugs.

6.2.33 Drugs can be ordered by phone, website, and following patient verification, these can be dispensed and delivered with a prescription following the relevant SOPs.

Refusal to provide drugs ordered.

6.2.34 If there is a reason for refusing to provide drugs ordered, patient will be contacted via phone, email or text, reason for refusal stated and if there is prescription involved, this is returned to spine and the surgery contacted.

Websites and health promotion zones.

6.2.35 Our website is for use by the public providing public access up to date information that will promote healthy lifestyles by addressing a range of health issues. Our telephone/IT provider will manage our telephone system, IT connectivity and efficiency. We will use the internet, telephone and Video calling as required.

6.2.36 Once approved we will insert a login section and registration section for patient to request their medicines, forms to contact us, for complaints and for all other essential services.

Repeat Dispensing

6.2.37 Is initiated remotely through the nomination of our pharmacy via website, phone, chat, or email. Upon receipt of nominations, we facilitate communication and prescription delivery to the patient across England, as outlined in our SOPs.

6.2.38 In summary, as highlighted both above and within the relevant Standard Operating Procedures, our pharmacy is committed to delivering NHS essential services seamlessly, catering to the needs of those who request these services, and ensuring they can be provided without the necessity of face-to-face contact.

6.2.39 All communication by the pharmacy will indicate that essential services are provided to all areas of England and not a particular location. as we are a distance selling pharmacy.

(e)nothing in X's practice leaflet, in X's publicity material in respect of the listed chemist premises, in material published on behalf of X publicising services provided at or from the listed chemist premises or in any communication (written or oral) from X or X's staff to any person seeking the provision of essential services from X must represent, either expressly or impliedly, that—

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

(ii)X is likely to refuse, for reasons other than those provided for in X'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 (for example, because the availability of essential services from X is limited to other categories of patients).

(4) The NHSCB may not vary or remove the conditions set out in paragraph (3).

6.2.40 Please see responses 1 and Response 2.5

6.2.41 All practice leaflet and marketing materials with respect to Tabi Health premises, including all oral or written communication with regards to essential services will NOT expressly imply that all essential services provided at or from the premises are only available to the persons in a particular area of England.

6.2.42 Tabi Health practice leaflet and publicly available material will NOT indicate that Tabi Health is likely to refuse the provision of drugs or appliances to any categories of patient.

Interested Party 2: Community Pharmacy Hertfordshire

6.2.43 *CPH would respectfully ask that when considering the application, NHS England is satisfied that the pharmacy procedures for the pharmacy premises will ensure:*

6.2.43.1 *the uninterrupted provision of essential services during the opening hours of the premises, to persons anywhere in England who request those services.*

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

6.2.44 See response 2.4

6.2.45 *NHS England should additionally be satisfied that:*

6.2.45.1 *the applicant's practice leaflet and publicity material does not suggest that essential services are only available to patients living in a particular area;*

6.2.45.2 should the applicant commence offering directed services, the applicant does not appear to offer pharmaceutical services other than directed services, to patients who are present at, or in the vicinity of, the proposed premises;

6.2.46 See response 2.5

6.2.47 *There will be arrangements in place to monitor the opening hours offered in the application*.

Response 2.6

6.2.48 The premises will consistently be staffed by a Responsible Pharmacist during our intended opening hours. Our registration with the General Pharmaceutical Council (GPHC) mandates this requirement, and we are unable to operate without one. Both the Responsible Pharmacist and our pharmacy team are contractually obligated to function within the specified opening hours, which are also in alignment with our GPHC registration details, as outlined in our procedures.

6.2.49 *NHS England should be assured that the evidence put forward in the form of Standard Operating Procedures (SOPs), which we have not seen, do not focus on local provision and compromise the proposed pharmacy in providing services to anyone in England requesting or receiving their services*.

6.2.50 *CPH would ask that NHS England, when considering the application, decide if the procedures set out in the application supported by the draft SOPs can deliver the safe and effective provision of essential services as required by Regulation 25(2)*.

Response 2.7

6.2.51 Please find listed below int eh [sic] appendix all relevant Standard Operating Procedures (SOPs) designed not to focus on local provision of essential services but to the whole of England.

6.2.52 Our procedures comprehensively outline the procedures, that govern the safe and efficient provision of our services without necessitating face-to-face interaction between the service recipient, whether acting on their own behalf or representing someone else, and our team members.

6.2.53 In addition, that the pharmacy can also deliver safe and effective provision of essential services.

6.2.54 *CPH notes that the ability to provide most of the commissioned services offered would depend on whether commissioners agreed to commission them from this pharmacy and the commissioning of proposed services from this pharmacy could not be guaranteed. It should also be noted that a few of the commissioned services listed are not commissioned within Hertfordshire*.

Response 2.8

6.2.55 It is important to highlight that we are fully equipped and currently offer private services. The pharmacy will not provide any proposed advanced/enhanced services that is not currently commissioned. The listed services in the application simply represents the services we can offer when commissioned by the local authority.

6.2.56 If certain services are not eligible for local commissioning, we can provide these on a private Patient Group Directions (PGDs) or simply not provide the service.

6.2.57 CPH has noted the floor plan layout provided by the applicant and query whether the applicant has made a correct application under the regulations for which it has applied. CPH would request that NHS England is satisfied that the suggested operations of the pharmacy and the proposed floor plan does not compromise that essential services are made without face-to-face contact and are available to anyone in England.

Response 2.9

6.2.58 The Dispensary department is entirely segregated to the back of the building away from direct customer access with a floor-to-ceiling wall.

6.2.59 Unlike traditional pharmacies, where patients can observe the display of Prescription-Only Medicines (POM), the pharmacist at work, or signage indicating "PRESCRIPTIONS" within the store, this is not the case in the premises.

6.2.60 We genuinely appreciate the expressed concern regarding the imperative to maintain essential services without face-to-face contact. Importantly, no face to-face interaction occurs during the provision of services in the dispensary area.

6.2.61 When enquiries are made by patient on essential services, we currently advise we do not offer such services, and they are directed to nearby pharmacy that offers such essential services.

6.2.62 The public accessible part of the premises and procedures have been designed not to accommodate or provide any essential services.

6.2.63 Consequently, essential services delineated above are accessible to individuals throughout England, as they are primarily digital in nature.

6.2.64 Appendix 1 [see SOPs in Appendix A]

6.2.64.1 SOP-DIS-135: Delivering Discharge Medicines Services

6.2.64.2 SOP-DIS-134 Preparing for Discharge Medicines Services

6.2.64.3 SOP-DIS-150- Communicating Non-Supply of NHS Essential Services

6.2.64.4 SOP-DIS-101: Dispensing Electronic Prescriptions

6.2.64.5 SOP-DIS-108 Packing & Delivery of prescription orders.

6.2.64.6 SOP-DIS-114-Packing & Delivery of fridge items.

6.2.64.7 SOP-DIS-122- Packing & Delivery of Schedule 2 & 3 CDs"

7 Summary of Observations

This is summary of observations received.

7.1 THE COMMISSIONER

7.1.1 "Thank you for your letter dated 30 April 2025. We acknowledge receipt of the representations that were provided from:

7.1.1.1 Optiom Health Ltd

7.1.1.2 Community Pharmacy Hertfordshire

7.1.1.3 Boots

7.1.2 Upon review of the representation submitted by the Appellant, we observe that it still remains unclear how the Appellant will manage the presentation of non-electronic prescriptions.

7.1.3 The ICB maintains that as this is not clear, the requirements of paragraph 5(2) and 5(3) of schedule of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, are not met and the application should be refused."

7.2 OPTIOM HEALTH LTD

7.2.1 "Thanks for your response and Optiom Health Ltd acknowledges receipt of your letter dated 30th April 2025.

7.2.2 This final observation is divided into three main sections:

7.2.2.1 Feedback on the Hertfordshire and West Essex ICB Appeal Response

7.2.2.2 Feedback on Community Pharmacy Hertfordshire Appeal Response

7.2.2.3 Optiom Health Ltd Feedback

7.2.3 As clearly stated in your letter 'You should restrict yourself to rebuttal of the information already provided; no new matters should be raised at this stage', we will simply highlight key areas that may have been overlooked or not clarified properly during the application and appeal process. The initial application did not mandate the supply of full standard operating procedures,

therefore some of the requirements were addressed as an overview of operations.

7.2.4 Therefore, do consider the supported clarification on how the activities will be implemented to ensure compliance to the required regulation.

Section 1: Feedback on the Hertfordshire and West Essex ICB (HWE ICB) Appeal

Response

7.2.5 As mentioned in the letter presented by the HWE ICB, the 4 areas indicated in the decision wording letter was clarified with more comprehensive information and standard operating procedures (see attachment) as part of documentation provided in the appeal process.

7.2.6 The HWE ICB also confirmed it recognised that had this information been available to PSRC, a different determination may have been made.

7.2.7 Hence, do endeavour to review the documentation provided in these 4 key areas as Optiom Health believes that information provided during the application and appeal process ensures the requirements set out in Regulation 25 are met, and that all essential services will be provided without interruption, to persons anywhere in England, in a safe and effective manner, without face-to-face contact.

7.2.8 The ICB has noted an error in the PSRC minutes and decision wording letter. The ICB has apologised to all parties for this oversight.

7.2.9 The error as stated in the letter, confirmed that the requirement 'Dispensing of drugs and appliances of the regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations) were not satisfied in the Committee Report Minutes (enclosed) presented to PSRC but indicated in the decision letter that the Committee were satisfied.

7.2.10 The ICB noted that Optiom Health Ltd has made no reference to Paragraph 5(2) of Schedule 4 in their appeal as the appeal focused on the four areas outlined in the decision letter as "not met." And having reviewed all information, the ICB was unclear on how Optiom Health Ltd will manage the presentation of non-electronic prescriptions.

7.2.11 Optiom Health Ltd had not address [sic] or made reference to Paragraph 5(2) of Schedule 4 in the appeal as this was not indicated as not satisfied in the decision letter and were under the impression that the Committee had been satisfied with this requirement.

7.2.12 Considering the HWB ICB error, we would like to take this opportunity to provide further clarification on this requirement.

Dispensing of drugs and appliances

7.2.13 The Committee's minutes states "The Committee considered whether the applicant has explained how non-electronic prescriptions will be presented by the patient and how products will be provided. The Committee noted the information provided within the application states how electronic prescriptions will be presented. The Committee were satisfied that it has been provided with

information sufficient to show that there would be compliance with Paragraph 5(2) & 5(3) of Schedule 4."

7.2.14 To clarify how Optiom Health Ltd will manage the presentation of non-electronic prescriptions.

7.2.15 Please see SOP-DIS-151 - Handling Non-Electronic Repeatable Prescriptions in a Distance Selling Pharmacy. [see Appendix E].

7.2.16 Extract from SOP

Receipt of Non-electronic Prescription

7.2.17 Patients or representatives must post the repeatable prescription to the pharmacy's registered address.

7.2.18 On arrival, prescriptions must be:

7.2.18.1 Logged in the PMR software

7.2.18.2 Date-stamped.

7.2.18.3 Placed in a secure, designated location for processing.

7.2.19 Process: New patient on Non-electronic Repeat Prescription Service

7.2.19.1 Discuss with patient if they want to join the Electronic Repeat Prescription Service

7.2.19.2 If patient agrees, discuss the nomination process for future repeat prescriptions – see SOP-DIS-150 - Dispensing Electronic Repeat Prescription

Dispense the first repeat prescription

7.2.20 Carry out legal and clinical check of the prescription - Refer to SOP-DIS-100 on Prescription legal & clinical check

Prescription Validation

7.2.21 The Responsible pharmacist must:

7.2.21.1 Check the prescription for validity and repeatability.

7.2.21.2 Confirm the number of repeats remaining.

7.2.21.3 Contact the prescriber if clarification is needed.

Communication with Patient

7.2.22 The pharmacy dispenser/technician must contact the patient via web-portal (via phone, email, or web portal) to:

7.2.22.1 Confirm delivery address.

7.2.22.2 Discuss any medication queries.

7.2.22.3 Obtain consent for delivery and data handling.

7.2.23 Therefore, posting of the non-electronic prescriptions and communicating with patients or representatives via email, phone or web-portal will ensure the requirements set out in Regulation 25 Paragraph 5(2) & 5(3) of Schedule 4 are met, and the essential services will be provided without interruption, to persons anywhere in England, in a safe and effective manner, without face-to-face contact.

Section 2: Feedback on Community Pharmacy Hertfordshire Appeal Response

7.2.24 Letter dated 15th April 2025

7.2.25 *We maintain that the provision of commissioned services by the applicant is contingent on commissioner agreement and cannot be guaranteed. We also highlight that some listed services are not commissioned within Hertfordshire*.

7.2.26 As mentioned on previous documentation, Optiom Health Ltd will only provide commissioned services that is available (i.e. advanced or enhanced services (if any). We do not require or request that such services be guaranteed by the Community Pharmacy Hertfordshire. We again request that the proposed floor plan and operational procedures do not compromise the delivery of essential services without face-to-face contact and to individuals across England, as required for a Distance Selling Pharmacy.

7.2.27 As mentioned on previous documentation, operational procedures for the essential services will be provided in the allocated section of the floor plan. See response 10.3 in this documentation.

7.2.28 It is crucial to note that the regulatory direction for Distance Selling Pharmacies (DSPs) is towards reinforcing the distance-selling model. There are proposed regulatory changes that will restrict enhanced or advanced services from being delivered face-to-face on DSP premises. Current and emerging regulations, including Regulation 25 and 64, emphasize that DSPs should not be structured or operated in a way that implies or facilitates the provision of advanced or enhanced services on physical premises. This principle underpins the very definition of a DSP and the core requirements for service delivery without face-to face contact.

7.2.29 Optiom Health Ltd is aware of this and would update operational procedures accordingly when such proposed regulatory changes are initiated and confirmed.

Letter dated 28th November 2024

7.2.30 Please find responses in this response letter previously submitted that addresses these issues.

Section 3 - Optiom Health Ltd Feedback

7.2.31 Optiom Health Ltd has provided detailed information of operations and how it intends to comply with the Regulation 25(2)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. The documentation provided in the appeal process further clarifies in detail how such operational procedures do not compromise the delivery of essential services without face-to-face contact and to individuals across England, as required for a Distance Selling Pharmacy.

7.2.32 As mentioned above, we would have clarified the issue with 'Dispensing of drugs and appliances' requirement in the appeal documentation, if we were aware of the 'not met' decision.

7.2.33 Please do also take into consideration the following statement from HWE ICB and Community Pharmacy Hertfordshire.

7.2.34 The HWE ICB confirmed 'It recognised that had this information been available to PSRC, a different determination may have been made'.

7.2.35 Community Pharmacy Hertfordshire (CPH) acknowledges 'the appeal made by Optiom Health Ltd, as detailed in their letter dated 11 March 2025, and has reviewed the supporting information provided. Our position, as outlined in our original letter dated 28 November 2024, remains unchanged. However, we would like to emphasise the following points in light of the applicant's appeal: - That the Standard Operating Procedures (SOPs) provided by the applicant do not compromise the provision of essential services to any person in England requesting or receiving those services. This is in accordance with Regulation 25(2) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013'.

7.2.36 We hope the NHS Resolution team will consider all procedures and clarifying responses accordingly. Do not hesitate to reach out to Optiom Health Ltd should you need any additional information."

8 Consideration

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

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

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

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

Regulation 31

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

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

(2) This paragraph applies where -

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

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

(ii) adjacent premises; and

(b) NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing

services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).

8.6 The Committee noted the response from the Applicant as to why the application should not be refused under Regulation 31 as "*it is for a distance selling pharmacy*" and that the Applicant then goes on to confirm that essential services will not be provided to persons present at the pharmacy and confirms that there will be SOPs in place. The Committee was of the view that the Applicant had not provided information in the application form that was relevant to the question of Regulation 31, however the Committee noted that the wording of the application form only requires the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor. The Committee was mindful that an application for a distance selling pharmacy does not negate the requirement for the application to be initially considered under the provisions of Regulation 31.

8.7 The Committee noted the information from the Commissioner with regard to the nearest pharmacies to the proposed site as well as confirmation that "*a private clinic and pharmacy exists at the proposed location which is owned by the same company. This pharmacy is not included in the relevant pharmaceutical list, therefore Regulation 31 does not apply*". The Committee also noted the conclusion of the Commissioner that "*no NHS pharmacy exists or is said to exist at or adjacent to the proposed location*" therefore it was not required to refuse the application under the provisions of Regulation 31. The Committee noted that this had not been disputed either on appeal or in subsequent correspondence.

8.8 The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

8.9 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 essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff."*

8.10 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)

8.11 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)

8.12 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list.

8.13 The Committee noted the comments from the Commissioner that "*a private clinic and pharmacy exists at the proposed location and is owned by the same company".* The Committee was mindful that a private clinic is not considered a "*provider of primary medical services with a patient list*" in line with the Regulations.

8.14 The Committee also noted the comments from the Commissioner with regard to the nearest GP surgery which is confirmed as being "*61 feet from the proposed location*"

however the Commissioner goes on to state "*Although there is a very short distance between the GP practice and the premises in respect of which the application is made, it should be noted that it is not on the same site or in the same building as the premises of a provider of primary medical services with a patient list*". The Committee noted that this had not been disputed by parties either on appeal or in subsequent representations and further noted the photographs provided showing the location of the GP practice and the proposed location of the pharmacy.

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

Regulation 25(2)(b)

8.16 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, including its Standard Operating Procedures (SOPs) that it intends to use at the proposed pharmacy premises.

8.17 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, in a safe and effective way, across England, and without face to face contact.

8.18 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.

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

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

8.21 The Committee noted the references from the Applicant to prescriptions being received electronically through the NHS spine and that services would be provided to anyone in England who requests the service. The Committee noted that the Applicant had confirmed that there would be:

8.21.1 "*Provision for any patient in England to register for free prescription dispensing and delivery services online through our website, via phone or email to nominate our pharmacy … we already have an account open with Royal Mail and plan to open an account with DPD. Both couriers ensures tracked delivery service to the whole of England free to all patients*."

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

8.23 The Committee noted references throughout the application form, appeal and additional information to essential services being provided other than by face to face; that this would be reiterated in training to all staff and that "*all patients will only be able to access NHS essential services by requesting such services on our website upon approval of this application, or calling, emailing the pharmacy.*"

8.24 The Committee noted the comments about the layout of the pharmacy and also noted the floor plan as submitted by the Applicant. Whilst the Committee noted that there were "waiting areas" and a "consultation room" on the floor plan, the Applicant had confirmed that they were also offering some commissioned services as well as private prescriptions, which could be delivered on a face to face basis.

8.25 The Committee noted the information contained within the SOPs, appeal and subsequent correspondence which sets out how the Applicant intends to provide essential services without face to face contact but using permissible methods of communication with patients, including by email and telephone.

8.26 In the appeal, the Applicant states:"*…patients can reach out to us through online chat, phone or the contact form on our website".*

8.27 The Applicant confirmed in the application form that "*Essential services will not be provided to a person present at the pharmacy or in the vicinity of it*" and further that "*there will be SOPs in place that clearly shows [sic] how essential services will be provided safely and effectively without face to face contact with any member of staff on the premises*."

8.28 The Committee also noted SOP-DIS-150- Communicating non-supply of NHS Essential Services which states:

8.28.1 *"Below are services that fall within the NHS Essential Service category.*

Discharge Medicines Service

Dispensing of Medicines

Disposal service in respect of unwanted drugs

Healthy Living Pharmacy

Urgent supply without a prescription

Promotion of healthy lifestyles and Health campaigns

Signposting

Repeat Dispensing

All NHS Essential Service must be provided on a REMOTE only basis.

If a patient or a representative contact the pharmacy, requests made from premises or on phone or email, below is the guidance on response that must be provided to ensure compliance with the NHS distance selling pharmacy regulation requirement:

Should a patient or patient representative attends or contacts the premises asking for NHS essential services, all pharmacy team must respond clearly and accurately that 'We DO NOT provide any for NHS essential services face to face directly to patient or patient representative on the premises. We are a distance selling pharmacy and as part of our contract and regulation we are prohibited to offering such services'."

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

8.30 The Committee was satisfied that the provision of services would be without face to face contact.

8.31 The Committee noted the references by the Applicant to the pharmacy "*…consistently staffed by a Responsible Pharmacist during our intended opening hours*" and "*Both the Responsible Pharmacist and our pharmacy team are contractually obligated to function within the specified opening hours…*"

8.32 The Committee also noted the Applicant had confirmed throughout the SOPs under 'Guidance' that "*The RP must be signed in to be able to undertake the steps involved…"* and further that SOP-RP-123: Assuming and ceasing duties and changeover of the responsible pharmacist states:

8.32.1 *"A pharmacist and another member of the pharmacy team must be present at all times, during opening hours on the premises."*

8.33 However, it was noted that the SOP under "Process: Ceasing duties of an RP" goes on to state:

8.33.1 "*Convey necessary handover notes, instructions of information for the next RP and if relevant, leave contact details for the next RP*

Refer to relevant SOP if the next RP is not immediately available to assume the duties of the RP and the current RP is not able to remain as the RP."

8.34 The Committee noted that it had not been provided with any other SOPs or other information regarding the absence of the Responsible Pharmacist and how the Applicant would ensure there was a second pharmacist available to provide that there would be uninterrupted provision of essential services at the pharmacy, should they be required, during the absence of the Responsible Pharmacist.

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

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

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

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

8.38.1 Dispensing of drugs and appliances

8.38.2 Urgent supply without a prescription

8.38.3 Preliminary matters before providing ordered drugs or appliances

8.38.4 Providing ordered drugs or appliances

8.38.5 Refusal to provide drugs or appliances ordered

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

8.38.7 Disposal service in respect of unwanted drugs

8.38.8 Promotion of healthy lifestyles

8.38.9 Prescription linked intervention

8.38.10 Health campaigns

8.38.11 Signposting

8.38.12 Support for self-care

8.38.13 Discharge medicines service

8.38.14 Websites and health promotion zones

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

Preliminary matters before providing drugs or appliances

8.40 The Committee considered if the Applicant had explained how evidence will be sought and provided about the patient's entitlement to exemption or remission from NHS charges.

8.41 The Committee noted SOP-DIS-101: Dispensing Electronic Prescriptions under Part B: Labelling, stage 3 which states:

8.41.1 *"Log on to Be Well System to update patient order status to "preparing" and check patient exemption status on record.*

You can also check RTEC on Rx Web to check and verify patients' exemption status."

8.42 The Committee noted that the SOP goes on to state in Appendix 1: Guidance:

8.42.1 *"EPS Tokens*

Dispensing token (white) – these are printed by the nominated pharmacy after downloading electronic prescription, this could be used to capture patient exemption."

8.43 Whilst the Committee noted that the Applicant would be checking patient records for exemption status before issuing the prescription, the Committee noted that there was

no information provided as to how the Applicant was going to obtain the evidence initially from the patient regarding their exemption status.

8.44 The Committee was of the view that the Applicant had not provided sufficient information for it to be satisfied that there would be compliance with paragraph 7(3) of Schedule 4.

Providing ordered drugs or appliances

8.45 The Committee considered whether the Applicant had explained how drugs/appliances will be provided to the patient (including to ensure that (1) 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).

8.46 The Committee noted SOP-DIS-114-Packing Fridge items for Delivery states:

8.46.1 *"This SOP sets out the process for packaging of prescription orders for safe delivery of prescription to patient or representative's address including:*

Packaging of fridge items

This SOP does not cover the process for handling of unsuccessful delivery. See SOP-PP-115 on Handling of unsuccessful delivery."

…

NOTE: Pack orders with fridge items between 3.00-3.30pm. Please note that courier will arrive between 3.40-4.00pm. All items must be packed and placed in courier bag before he/she arrives

Packaging process for fridge items

…

Go to fridge and pick up plastic bag. Check bag label on plastic bag matches with the bag label on the checklist. Open freezer and take two ice packs.

Return to packing area. Remove items from plastic bag and wrap in bubble wrap. Take an insulated envelope and place the wrapped item in the envelope. Put the ice packs inside the envelope on either side of the fridge item. Seal the envelope.

Take appropriately sized flat delivery box and assemble box. If standard items also in plastic bag, remove items from plastic bag and place them in the box with marketing materials.

Place the foil envelope in a delivery box (fold if necessary, using cello tape to hold it in place).

Place the item on weighing scale

Go to courier click & drop site.

Enter customer details to generate delivery labels.

a. Enter the weight of the parcel

b. Select "Tracked 24" delivery service.

c. Select obtain signature upon delivery

d. Select "Apply and generate labels"

e. Print two delivery labels.

f. Apply one delivery label on the package, apply the second on packing delivery checklist

g. Seal box and place in Tracked 24 courier bag"

8.47 The Committee noted that in subsequent correspondence, the Applicant had stated:

8.47.1 "*For fridge line items, these will be packed using quality assured ice packs and insulated shipping systems by HydroPac, an established manufacturer and supplier of pharmaceutical grade shipping systems that supplies many pharmaceutical businesses. These items will delivered [sic] within 24 hours using a 24-hour tracked system. Prior to despatching, the patient will receive communication that they will be receiving a fridge item to ensure that they are available to receive the item. In case of missed delivery, the item will be sent back to the pharmacy for destruction."*

8.48 The Committee noted the use of "ice packs" for cold chain delivery but no information had been provided as to how these would ensure that a consistent temperature was maintained and would not compromise the integrity of the medication. The Committee further noted that the fridge lines, once packaged with the ice packs were then to be put in the "Tracked 24 courier bag". .

8.49 The Committee noted the references to "24-hour tracked system" however it appeared that this was with regard to tracing the location of the items with the courier rather than a system which tracked the temperature of the fridge lines. The Committee noted that the Applicant had not provided any information as to how the courier would ensure that the cold chain was maintained or, if there was a breach in the cold chain, how they would become aware of this and what the process was for the return of any medication where the integrity of the cold chain had been breached.

8.50 In the SOP-DIS-122-Packaging & Delivery Schedule 2 & 3 Controlled Drug it states:

8.50.1 *"Packaging and delivery of CDs*

Pick one plastic bag from packing box

Remove prescription from plastic bag and check delivery address against bag label on checklist.

Go to CD cupboard and pick up plastic bag. Check bag label on plastic bag matches with the bag label on the checklist.

Return to packing area. Take appropriately sized flat delivery box and assemble box. If standard items also in plastic bag, remove items from plastic bag and place them in the box with marketing materials.

Place the item on weighing scale

Go to courier DPD site.

Enter customer details to generate delivery labels.

a. Enter the weight of the parcel

b. Select "Tracked 24 and signed delivery service.

c. Select "Apply and generate labels"

d. Print two delivery labels.

e. Apply one delivery label on the package, apply the second on packing delivery checklist

f. Seal box and return to CD cupboard

Review and sign checklist. Return prescription and checklist back into the plastic bag and place in basket next to CD delivery tray.

Upon arrival of the courier,

Take plastic bags with the prescription from CD basket and collect these items from the CD cupboard. Place these boxes in Tracked 24 courier bag one by one and sign handed out by section of the checklist and ask courier to sign collected by section of the checklist

Return checklist into plastic bag with prescription and place bag into CD collected tray.

As soon as courier has left, take prescriptions from the CD collected tray and record CDs collected into CD register.

Also see SOP-DIS-133 on Handing out orders to courier."

8.51 The Committee also noted in subsequent correspondence that the Applicant had stated:

8.51.1 "*Controlled drugs will also be sent via tracked courier service. For enhanced security, the patient or authorised representative will be sent a unique pin code. The item will be delivered within 24 hours and the delivery driver will deliver the package after confirmation of the pin code by the patient or authorised representative and obtain signature. In case of missed delivery, CD items will be returned immediately to the pharmacy. The details on handling of delivery can be found in our SOP.*"

8.52 The Committee noted that whilst the Applicant had provided some information regarding the various delivery methods, including the use of couriers for fridge lines and controlled drugs, and had made reference to SOP-PP-115 on handling unsuccessful delivery, it had not been provided with this SOP. The Committee was of the view that there was limited information provided as to what would happen for a missed or failed delivery of a controlled drug.

8.53 Taking all of the information before it into account, the Committee was of the view that the Applicant had not provided sufficient information for it to be satisfied that there would be compliance with paragraph 8(1) of Schedule 4.

8.54 The Committee noted that the Applicant had stated "*Appliances will be provided according to the order on electronic prescription only and delivered accordingly to*

patient. These include dressings and wound management products". Therefore the Committee considered whether the Applicant had explained the arrangements that it will have in place to ensure that for appliances which require fitting/measuring, a registered pharmacist measures/fits them.

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

8.55.1 *"Unable to provide an appliance or stoma appliance customisation because the provision of the appliance or customisation is not within Tabi Health's normal course of business, if the patient consents, refer the prescription form or repeatable prescription to another NHS pharmacist or to an NHS appliance contractor; and if the patient does not consent to a referral, provide the patient with contact details of at least 2 people who are NHS pharmacists or NHS appliance contractors who are able to provide the appliance or stoma appliance customisation."*

8.56 The Committee was of the view that it was ambiguous as to whether or not the Applicant would or would not be providing appliances which require measuring and/or fitting, given the conflicting information contained within the application form and the appeal. The Applicant had not explained which appliances were within its 'normal course of business'.

8.57 If it was the Applicant's intention to provide appliances that require measuring and fitting, then there was no information provided to explain how a registered pharmacist would measure or fit an appliance which needed to be measured/fitted.

8.58 Based on the information before it, the Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(4) of Schedule 4.

8.59 The Committee considered if the Applicant had explained what containers will be suitable for posted/delivered items.

8.60 The Committee noted SOP-DIS-108: Packaging of Prescription Order for Delivery which states:

8.60.1 "*Take appropriately sized flat delivery box and assemble box. Remove items from plastic bag and place them in the box with relevant informational materials.*"

8.61 Whilst the Committee noted the comments with regard to the use of carboard boxes, it had no information as to how the Applicant would ensure that the integrity of the medicines remained intact during delivery, for example, bubble wrapping medicines or how would liquid medicines which were in bottles are appropriately packed.

8.62 The Committee was not satisfied that the Applicant had provided information sufficient to show that there would be compliance with paragraph 8(15) of Schedule 4.

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

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

8.64 The Commissioner had not been satisfied that paragraph 10(1) would be fully complied with effectively.

8.65 The Committee noted the comments from the Applicant on appeal with regard to repeat dispensing which stated:

8.65.1 *"When supplying drugs or appliances in accordance with an electronic prescription or electronic repeat prescription, patients are prompted to request items which they need.*

The ERP patient request form for repeat dispensing ensures this step is done by patient or approved carer.

Records of all items dispensed and prescribing pattern for patient are kept and maintained in the PMR system (Patient Medical Record System) to facilitate continued care of the patient.

All advice and any clinically significant intervention or referrals made for both electronic prescription and electronic repeat prescription is recorded in the PMR system.

Where an item is not in stock, but will be available later, a notification on affected item(s) owed is sent and informed when the item is expected to become available.

SOP reference attachment: SOP-DIS-101 - Dispensing Electronic Prescription Service."

8.66 The Applicant, in subsequent correspondence went on to state:

8.66.1 *"Repeat Dispensing*

Repeat dispensing request will be initiated remotely through the nomination of our pharmacy via website, phone, chat, or email. Upon receipt of nominations, we will facilitate communication and prescription delivery to patients across England, as outlined in our SOPs."

8.67 The Committee also noted the comments from the Applicant with regard to the "non electronic repeat prescription service" which states:

8.67.1 "*Discuss with patient if they want to join the Electronic Repeat Prescription Service*

If patient agrees, discuss the nomination process for future repeat prescriptions – see SOP-DIS-150 - Dispensing Electronic Repeat Prescription."

8.68 The Committee noted that SOP-DIS-103: Dispensing Electronic Repeat Prescription states:

8.68.1 *"Check NHS Spine for eRDs that has been issued to Tabi Health following patient nomination; see SOP-DIS-144 on EPS Nomination*

Explain the eRD service to the patient if they are a new patient

Inform the patient that information may be shared with their GP

Inform the patient that they can change their nominated pharmacy at any time

Check that the patient has an EPS nomination - see SOP-DIS-144 on EPS Nomination."

8.69 The Committee was of the view that whilst the Applicant had provided assurances that any interaction would not be via face to face contact as well as confirming how repeat dispensing would be undertaken, there was no information provided by the Applicant as to how it would give advice about the benefits of repeat dispensing to a patient who was not currently receiving this service, but had a long term, stable medical condition that would benefit from this service.

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

Other considerations

8.71 The Committee noted that the Commissioner had refused the application on the basis that they were not satisfied that the Applicant had provided information to show that there would be compliance with the Terms of Service. The Committee, taking into account the additional information provided by the Applicant on appeal, considered these areas of the Terms of Service in more detail.

Dispensing of drugs and appliances

8.72 The Committee noted that there was some confusion as to whether or not the Commissioner had been satisfied that the Applicant would comply with paragraph 5(2) and (3) of Schedule 4 safely and effectively.

8.73 The Committee noted that the Commissioner, in subsequent representations had confirmed that they were not satisfied that there would be compliance with paragraph 5(2) of Schedule 4.

8.74 In response, the Committee noted the further information provided by the Applicant in the form of SOP-DIS-151 "Handling Non-Electronic Repeatable Prescriptions in a Distance Selling Pharmacy".

8.75 The Committee noted that under "Purpose" the SOP stated "*to ensure safe, efficient and compliant handling of paper-based repeatable prescriptions received at the Distance Selling Pharmacy, without any face to face interaction."*

8.76 The SOP goes on to state:

8.76.1 "*Receipt of Non-electronic Prescription*

Patients or representatives must ***post the repeatable prescription*** *to the pharmacy's registered address*

…"

8.77 The Committee noted that the Applicant had quoted the SOP in its observations and had gone on to state ""*Therefore, posting of the non-electronic prescriptions and communicating with patients or representatives via email, phone or web portal will ensure the requirements as set out in Regulation 25 Paragraph 5(2) & 5(3) of Schedule 4 are met …".*

8.78 The Committee noted that this was with reference to a repeatable prescription, however it was of the view that the receipt of an initial repeatable prescription was the same as a one-off paper prescription.

8.79 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 5(2) and (3) of Schedule 4.

Refusal to provide drugs or appliances

8.80 The Commissioner had not been satisfied that the Applicant had provided sufficient information regarding how it would assess appropriate use, side effects or the need or desirability to review treatment and was of the view that paragraph 9(4) of Schedule 4 had not been met.

8.81 The Committee noted in the SOPs as well as the supporting information from the Applicant it states:

8.81.1 *"Check that it is appropriate to make the supply*

Check and review the ERP patient request form completed with the new order,

Answers to the following questions must be reviewed by pharmacist:

Are you taking or using your current medication or appliance appropiately? [sic]

Are you likely to continue taking or using your current medication or appliance appropiately? [sic]

Have you started taking any new medicines (including over the counter poducts, herbal products, supplements or alternative therapies)? [sic]

Have you experienced any issues or side effects with your medicine(s)?

Have your dose regimen or the way you use your appliance changed since your last GP appointment?

Do you require all the items on the prescription? If not, please tick only items you need on this prescription.

Have there been any changes to your health since your last request? If so, please give details.

Pharmacist must refuse order and speak to prescriber fo [sic] review if an intervention is required in the following scenarios:

Where patient is not taking the medication or using appliance appropriately.

Where patient experiences issues or side effect(s)

Where there has been changes to regimen of, or manner of utilisation of the appliance

Where there is changes to the health of the patient."

8.82 The Committee was satisfied that the Applicant had provided sufficient information to show that there would be compliance with paragraph 9(4) of Schedule 4.

Health Campaigns

8.83 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraph 18 of Schedule 4.

8.84 The Committee noted SOP-PP-189 "Mandatory Annual Campaign to Pharmacy Users" which stated:

> *"At the request of NHSCB, the pharmacy will utilise the campaign feature on the system to send up to 6 campaigns in each calender year to registered users of the pharmacy. [sic]*
>
> *The Pharmacist and the pharmacy team will participates, in the manner reasonably requested by the NHSCB. [sic]*
>
> *The pharmacy will utilise various campaign delivery initiatives depending on the type of campaign. Such campaign deliveries to users include:*
>
> *Email campaigns*
>
> *SMS campaigns*
>
> *Leaflets placed in delivery packages to users*
>
> *With the client potal. [sic]*
>
> *The pharmacy would also record as requested by NHSCB the number of people to whom Pharmacist has provided information as part of one of those campaigns."*

8.85 The Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraph 18 of Schedule 4.

Signposting

8.86 The Committee noted that the Commissioner had not been satisfied that the Applicant would comply with paragraphs 19 – 20 of Schedule 4 safely and effectively.

8.87 The Committee noted SOP-PP-126 "Signposting Procedure" as provided by the Applicant which states:

8.87.1 *"The conditions / symptoms / requests listed in table 1 should always be referred to the pharmacist; this list is not exhaustive.*

> ***Purpose***
>
> *To inform or advise people who require assistance, which cannot be provided by the pharmacy, of other appropriate health and social care providers or support organisations. 2.2 To enable people to contact and/or access further care and support appropriate to their needs.*
>
> *To minimise inappropriate use of health and social care services.*

Identifying Signposting Needs:

During enquiries online or over the phone:

Pharmacy Technician/ Assistants: During enquiries for over the counter medicines, pharmacy technicians/ assistants must refer to the responsible pharmacists. See Table 1 below for example of referrals.

Pharmacists: Pharmacist should actively assess patient needs, including medical history, current medications, and any concerns or questions raised by the patient. Identify red flags and refer appropriately.

…

Resources and Support:

Signposting Resources: As Tabi Health is a distance selling pharmacy, hence it will have access to database of both local and regional healthcare providers support organizations, and community resources. This will be accessed by Tabi Health's staff when signposting patients accordingly.

These include:

Find local services on NHS UK - Click https://www.nhs.uk/ and search by GP, Urgent Care, Hospitals or Dentists or click the link to view a Full A-Z list.

NHS Service Finder - https://servicefinder.nhs.uk/landingPage

NHS 111

Relevant useful links for referral embedded on the website e.g. NHS talking therapies, Live Well, Find a pharmacy"

8.88 Based on the information before it, the Committee was of the view that the Applicant had provided sufficient information for it to be satisfied that there would be compliance with paragraphs 19 – 20 of Schedule 4.

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

Summary

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

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

8.91.1 confirm the Commissioner's decision;

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

8.91.3 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.

8.92 In those circumstances given that the Committee had additional information which was not available to the Commissioner and that the Commissioner had made an error in its decision, the Committee determined that the decision of the Commissioner must be quashed.

8.93 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.

8.94 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.

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

9 Decision

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

9.2 Accordingly, the Committee:

9.2.1 quashes the decision of the Commissioner; and

9.2.2 redetermines the application as follows -

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

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

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

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

9.2.2.5 the Committee was not satisfied that all essential services were likely to be secured in a safe and effective manner,

9.2.2.6 the Committee was satisfied that all essential services were likely to be secured without face to face contact.

9.2.3 The application is refused.

Case Manager
Primary Care Appeals