8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

28 August 2024

REF: SHA/26230

APPEAL AGAINST NHS HUMBER AND NORTH YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY CLINICAL SERVICES YORKSHIRE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 16 CLARO COURT, CLARO ROAD, HARROGATE, HG1 4BA 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:

Clinical Services Yorkshire Ltd
Humber and North Yorkshire ICB

NHS Resolution

8th Floor
10 South Colonnade
Canary Wharf
London
E14 4PU

Tel: 0203 928 2000
Email: nhsr.appeals@nhs.net

REF: SHA/26230

APPEAL AGAINST NHS HUMBER AND NORTH YORKSHIRE ICB DECISION TO REFUSE AN APPLICATION BY CLINICAL SERVICES YORKSHIRE LTD FOR INCLUSION IN THE PHARMACEUTICAL LIST AT 16 CLARO COURT, CLARO ROAD, HARROGATE, HG1 4BA UNDER REGULATION 25

1 The Application

By application dated 14 November 2023, Clinical Services Yorkshire Ltd ("the Applicant") applied to Humber and North Yorkshire ICB ("the Commissioner") for inclusion in the pharmaceutical list at 16 Claro Court, Claro Road, Harrogate, HG1 4BA 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 The Applicant left this section of the application form blank.

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

1.2.1 The Applicant left this section of the application form blank.

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

1.3.1 The Applicant left this section of the application form 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 NHS Essential Services will be provided to any patient living in England who requests such services, this information will be made clear on our patient leaflets and website. However, what will also be made clear is that these NHS Essential Services will not be made face-to-face due to NHS Regulations of our contract.

1.6 All communication regarding NHS Essential Services will be carried out via telephone, email, videoconferencing and text messages. The pharmacy will have provision for both live audio and live video communication with patients and this will be carried out only in private areas of the pharmacy e.g. the consultation room, so that we maintain patient confidentiality at all times.

1.7 If any member of staff receives a query from any member of the public, or patient or their carers that requests the provision of any NHS Essential Service face-to-face on or in the vicinity of the premises, then they will be informed that this is not possible due to NHS Regulations. Instead, the staff members will refer them to our website of provide the person with a copy of our patient information leaflet: both explain what services the pharmacy provides and why they cannot be carried out face-to-face. If they require any further information, then they will be referred to the Responsible Pharmacist.

1.8 If the member of the public, or patient or their carers, that requests the provision of any NHS Essential Service face-to-face is still not satisfied with our response, the staff member as a duty of care will use the NHS Choices website to find suitable service providers near to the patient and offer them their details to contact them.

1.9 Access to the premises for NHS Advanced and Enhanced services is permitted as long as no NHS Essential Service is provided during the same visit. All NHS Advanced and Enhanced will, where necessary/possible, be provided in the private consultation room. If during this time an NHS Essential Service is requested, we will follow the steps mentioned above."

2 The Decision

The Commissioner considered and decided to refuse the application. The decision letter dated 4 June 2024 states:

2.1 "Humber and North Yorkshire 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.

2.2 You have a right of appeal to the Secretary of State against Humber and North Yorkshire ICB's decision. Should you choose to appeal then you should either complete the online form available on the NHS Resolution website or send a concise and reasoned statement of the grounds for you appeal within 30 days of the date of this letter to nhsr.appeals@nhs.net or: Primary Care Appeals, NHS Resolution, 8th Floor South Colonnade, Canary Wharf, London, E14 4PU."

The Commissioner's decision report

2.3 "Humber and North Yorkshire ICB has considered the above application, and I am writing to inform you that it has not been supported as it did not meet all the regulations which are applicable for this application.

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

2.5 Regulation 25(2)(a) was met as no primary care provider with a patient list is present within the same premises as the proposed site.

2.6 Regulation 25(2)(b) was not met as the Applicant had not fully demonstrated how services will be provided remotely, and without interruption throughout the given opening hours.

2.7 Information provided by the Applicant did not fully demonstrate how the specific conditions within Regulation 64 would be met.

2.7.1 The Applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are present or in the vicinity of the pharmacy premises.

2.7.2 The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises.

2.7.3 The pharmacy 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.

2.7.4 The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff.

2.7.5 The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular area of England [sic] or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

2.8 Appeal rights are granted to the applicant.

2.9 Dispensing Practices to be informed of the decision: [The decision letter left this section blank.]"

3 **The Appeal**

In an email dated 5 June 2024, the Applicant appealed against the Commissioner's decision. The grounds of appeal are:

3.1 "I am writing to you to appeal against a decision made by Humber & North Yorkshire ICB. They have refused my application for a distance selling pharmacy:

3.1.1 ME3036/CAS-260399-T1Y0H4 – Distance Selling

3.1.2 Applicant name: Clinical Services Yorkshire Ltd

3.1.3 Proposed premises: 16 Claro Court, Claro Road, Harrogate, North Yorkshire, HG1 4BA

3.2 I have attached the letter received with the reasons for refusal from the Humber & North Yorkshire ICB. I have also attached the standard operating procedures for my proposed distance selling pharmacy [Appendix A provided for Committee]. These SOPs address all the concerns the ICB have raised as reason for refusal and I would like to address them individually.

3.3 The ICB states: *"Regulation 25(2)(b) was not met as the applicant has not fully demonstrated how services will be provided remotely, and without interruption throughout the given opening hours".* This concern is addressed specifically in the attached SOPs on pages 3, 5, 6, 29, 30, 31, 33, 44, 45, 55, 57, 60 – for all parts of providing NHS essential services remotely.

3.4 The ICB states: "*Information provided by the applicant did not fully demonstrate how the specific conditions within Regulation 64 would be met specifically the one highlighted in red. The Applicant must not offer to provide pharmaceutical services, other than directed services, to persons who are presents or in the vicinity of the pharmacy premises. The means by which persons receive services from the pharmacy must be otherwise than at the pharmacy premises."* These points raised by the ICB should only concern NHS Essential services. We have demonstrated how we will only provide these services remotely in the attached SOPs on pages 3, 5, 6, 29, 30, 31, 33, 44, 45, 55, 57, 60.

3.5 "*The pharmacy 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."* This point is not

valid as it is addressed by the ICB themselves in the same attached letter: "*Regulation 25(2)(a) was met as no primary care provider with a patient list is present within the same premises as the proposed site.*"

3.6 "*The pharmacy procedures must ensure the uninterrupted provision of essential services, during the pharmacy opening hours, to persons anywhere in England who request the services and must ensure the safe and effective provision of essential services without face-to-face contact between the person receiving the services and the pharmacy staff*". This concern is addressed specifically in the attached SOPs on pages 3, 5, 6, 29, 30, 31, 33, 44, 45, 55, 57, 60 for all parts of providing NHS essential services remotely.

3.7 "*The pharmacy must not produce any practice leaflet, publicity material or any other communication, which expressly or impliedly states that access to the essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.*" This point raised by the ICB is not valid as we have not produced any practice leaflet, public material or any other communication which would expressly or impliedly state that access to NHS essential services provided by the pharmacy are only available to persons in particular areas of England or that the pharmacy is likely to refuse to provide essential services or prescribed drugs or appliances to particular categories of patients.

3.8 We have addressed the point of accessibility in our attached SOPs on page 43 and we also demonstrate how we will deliver to patients anywhere in England on pages 29 & 31 as well as providing the other NHS essential services to patients throughout England remotely on pages 3,5, 5, 33, 44, 45, 55, 57, 60.

3.9 By addressing specifically all the points of concern raised by the ICB in there [sic] attached letter, I hope you will overturn the decision to refuse our application for a distance selling pharmacy as I believe we have demonstrated that we will meet all the required regulations, specifically regulations 25, 31 and 64.

3.10 If you require any further information then please do not hesitate to contact me."

4 Summary of Representations

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

5 Consideration

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

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

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

Regulation 31

5.4 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).

5.5 The Committee noted that the Applicant had not provided any information in the application form on this point but the Committee noted that the wording of the application form only required the Applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee considered it reasonable to determine that the lack of information in the application form on this point when read with the wording of the application form allowed it to be reasonably satisfied that the Applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Commissioner in its decision report states that "*Regulation 31 does not apply as there is no pharmacy at the same or adjacent premises to the proposed site", which had not been disputed by any party.* The Committee therefore determined that it was not required to refuse the application under the provisions of Regulation 31.

Regulation 25

5.6 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."

5.7 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)

5.8 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)

5.9 The Committee noted that the Applicant had not included any information in the relevant section of the application form that deals with this point. The Committee noted that the application form states that the relevant section should only be completed if the proposed premises are on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Committee considered that, where the Applicant did not include any information in this section, it was reasonable to consider that the Applicant was indicating that the proposed premises were not on the same site or in the same building as the premises of a provider of primary medical services with a patient list. The Commissioner in its decision report stated that "*Regulation 25(2)(a) was met as no primary care provider with a patient list is present within the same premises as the proposed site*". Based on the information available to it, the Committee therefore determined that the proposed premises were not on the same site as, or in the same building as the premises of a provider of primary medical services with a patient list.

Regulation 25(2)(b)

5.10 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.

5.11 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.

5.12 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.

5.13 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.

5.14 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.

5.15 The Committee noted that the Applicant had not included information in the application form, or later on appeal, to indicate that they were proposing to offer appliances which require measuring or fitting. The Committee was of the view that if the application was granted the Applicant would not therefore be able to provide these services to patients.

5.16 The Committee noted that within the SOPs provided there was a statement that the Applicant's pharmacy would provide "uninterrupted essential services to individuals across England during operational hours". The Committee considered how the Applicant would provide essential services without interruption and noted the SOP titled 'Responsible Pharmacist' states:

5.16.1 "*The Responsible Pharmacist can be absent for a maximum of 2 hours during operational working time.*

Total absence in 24 hours must not exceed 2 hours.

Absence should only occur if confident pharmacy operations can continue safely and effectively.

Ensure contractability [sic] and leave notice indicating location, mode of contact and expected absence duration.

Be prepared to return promptly if issues arise.

Arrange for another Responsible Pharmacist to be available if not contactable during absence.

…

If absent over 2 hours with no second pharmacist available, ensure restrictions are enforced.

If a second pharmacist is available, normal duties can continue."

5.17 The Committee considered that the statement "***If a second pharmacist is available**, normal duties can continue"* [emphasis added] could cast doubt on whether uninterrupted provision would be available to patients. On the basis of the limited

information provided to the Committee in this regard, the Committee was not satisfied that the provision would be provided without interruption.

5.18 With regard to services being available to persons anywhere in England the Committee noted the application form states “NHS Essential Services will be provided to any patient living in England who requests such services, this information will be made clear on our patient leaflets and website”. The Committee was of the view that this was further demonstrated in the SOPs provided which details the Applicant’s use of not only a local delivery driver but the use of Royal Mail and couriers for controlled drugs and specialised couriers for fridge lines.

5.19 There was nothing to conclude that the Applicant would not be providing essential services to persons anywhere in England.

5.20 The Committee noted the SOPs provided state that “it is strictly prohibited to engage in face-to-face contact with patients or their representatives for essential services, whether within the premises or nearby”. Further, the Committee noted that the application form details the steps that would be taken if a member of the public approaches the premises requesting face-to-face provision of Essential Services. This was supported in the SOP titled ‘Communication’ that states:

5.20.1 “*If any staff members receives [sic] a request from a member of the public, patient, or their carers for face-to-face provision of Essential Services they must follow the established protocol:*

Informing the Individual

Clearly communicate to the person that face-to-face contact between the patient or their representative and any staff member is not permitted due to NHS Regulations.

Providing Information Leaflet

Issue the person with a copy of our patient information leaflet outlining the pharmacy’s [sic] services and the reasons for the restriction on face-to-face provision.

Referral to Responsible Pharmacist

Direct the person to the Responsible Pharmacist for further clarification if necessary.

Offering Alternative Providers

Confirm the person’s location and then utilise the NHS Choices website to locate suitable service providers near the patients.

Provide the person with contact details of these providers, emphasising that this action aligns with our commitment to proper patient care in accordance with GPhC standards.”

5.21 The Committee note the SOP titled ‘Communication’ states that:

5.21.1 “*Methods of communication available at our pharmacy:*

Telephone, email, video calling, letter.

Where necessary, live video calls for consultations can be held in a private are of the pharmacy i.e. the consultation room.”

5.22 The Committee was, however, concerned regarding the statement in the SOP entitled 'Accuracy Checking' under the heading 'Identification Check' which states that the Applicant would "make sure that the person receiving the prescription is the designated person". Further under the heading 'Controlled drugs' it states:

5.22.1 "*If the patient/carer does not immediately collect a schedule 2 or 3 CD, place the dispensed item in the CD cabinet with the prescription attached.*

Do not make an entry in the CD register until the patient/carer picks up the medicine".

5.23 The Committee further noted the statement in the SOP titled 'Assembling and labelling prescriptions' under the heading 'Controlled Drugs' that:

5.23.1 "*Whenever possible, assemble controlled drug prescriptions immediately to ensure availability for collection or delivery".*

5.24 Similarly, the Committee noted the statement on the checklist in SOP titled 'Accuracy Checking' that:

5.24.1 *"If there is any doubt as to the validity of the person collecting the prescription ask for identification".*

5.25 The Committee noted that there was a similar reference in the SOP titled 'Pharmaceutical Assessment' which listed a known risk to the Applicant that a "prescription collection by a representative rather than the patient" may occur. The Committee was concerned that the reference to 'collect' and 'pick up' indicated that patients, may be allowed to attend the pharmacy in order to collect their medication.

5.26 Within the context of a distance selling pharmacy where face to face contact for essential services is not permitted, the Committee considered that the wording creates sufficient ambiguity as to the Applicant's intentions regarding the non-face-to-face provision of services such that it could not be satisfied, in keeping with Regulation 64, that services would be provided other than with face to face contact..

5.27 The Committee was satisfied that the provision of services would be available to persons anywhere in England. The Committee was not satisfied that the provision of services would be without face to face contact or that services would be provided without interruption.

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

5.29 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:

5.29.1 Dispensing of drugs and appliances

5.29.2 Urgent supply without a prescription

5.29.3 Preliminary matters before providing ordered drugs or appliances

5.29.4 Providing ordered drugs or appliances

5.29.5 Refusal to provide drugs or appliances ordered

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

5.29.7 Disposal service in respect of unwanted drugs

5.29.8 Promotion of healthy lifestyles

5.29.9 Prescription linked intervention

5.29.10 Health campaigns

5.29.11 Signposting

5.29.12 Support for self-care

5.29.13 Discharge medicines service

5.29.14 Websites and health promotion zones

5.30 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 ordered drugs or appliances

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

5.32 The Committee noted that there was no reference in any of the supporting information provided by the Applicant either in the original application form or on appeal that dealt with the preliminary matters before providing ordered drugs or appliances.

5.33 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 7(3) of Schedule 4.

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

5.35 The Committee noted that there was no reference in any of the supporting information provided by the Applicant either in the original application form or on appeal that highlighted how patients would make payments for any charges incurred.

5.36 Given the lack of information, the Committee was not satisfied that it had been provided with information to show that there would be compliance with paragraph 7(5)(b) of Schedule 4.

Providing ordered drugs or appliances

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

5.38 The Committee noted the SOP titled 'Delivery of medication' states:

5.38.1 "*Method of delivery*

If the delivery is local to the pharmacy e.g. within 20 miles then the local delivery driver(s) can take these.

If not then a courier will be used.

Most deliveries national [sic] *can be made by Royal Mail. Where there is a CD or fridge item then the appropriate courier will need to be used. See below.*

All Royal Mail deliveries must be 'signed for' deliveries.

Point of delivery

At the point of delivery, the driver must ensure they confirm patient name & address.

Driver must also get the delivery log signed.

Driver must get the back of the prescription signed if appropriate.

Driver(s) must not enter the patient's house.

Driver needs to check address and patient name against the prescription bag.

…

Unsuccessful delivery

Post a 'missed delivery' card with date & time written on.

Return unsuccessful deliveries to the pharmacy.

Arrange with the patient for an appropriate time for re-delivery.

…

Deliveries must not be posted."

5.39 Further, it states:

5.39.1 "*Fridge medication delivery by courier*

For deliveries outside the local area where the pharmacy driver cannot deliver, a specialist courier will be used for delivery of fridge items. This is so that the cold-chain can be maintained.

If there is a failed delivery of a fridge item by a courier then they will ensure the maintenance of the cold-chain until re-delivery as soon as possible. If there is another failed delivery then the item will be returned to the pharmacy and stored in the pharmacy fridge until further arrangements can be made."

5.40 The Committee was of the opinion that simply stating that "*a specialist courier*" would be used provided very little information as to how the Applicant, if the application was granted, would ensure that the cold-chain would be maintained and monitored, up to and including the point of delivery. Further there was no information to explain what the Applicant would do if the cold-chain isn't maintained during transit.

5.41 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(1) of Schedule 4.

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

5.43 The Committee noted it had no detailed information to indicate the type of containers to be used, their robustness and security when used in the transit of medicines by post or courier delivery.

5.44 Based on the information before it, the Committee was not satisfied that the Applicant had provided sufficient information to show that there would be compliance with paragraph 8(15) of Schedule 4.

Refusal to provide drugs or appliances

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

5.46 The Committee noted that there was no reference in any of the supporting information provided by the Applicant either in the original application form or on appeal that dealt with this aspect.

5.47 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraph 9(4) of Schedule 4.

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

5.48 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.

5.49 The Committee considered that whilst the Applicant has a SOP titled ‘Repeat Dispensing’, it had not described how patients will be identified and advised about the benefits of the service to promote its use other than a reference at “*Pharmacy staff identifies suitable patients*” and “*Patients identified as suitable for the service or those interested…*”. The Committee was of the view that this was not sufficient information to demonstrate how the Applicant would promote the benefits of this service or how they would identify patients who might benefit from this service who were not already in receipt of repeat dispensing.

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

Prescription linked intervention

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

5.52 The Committee noted that the SOP titled ‘Interventions and problem solving’ states:

5.52.1 “*Purpose:*

To ensure that interventions are dealt with appropriately and promptly and that the patients confident in the prescriber is maintained.

Scope:

This procedure covers interventions and problem solving for all NHS and private prescriptions.

…

Consult with the patient

Patients may be able to resolve the problem themselves by talking it through with them.

If the prescription will take longer than usual, reassure the patient that everything possible is done to reduce the delay and give an accurate estimated time of arrival."

5.53 The Committee was of the view that this SOP addressed what interventions would be implemented in the event of a problem that arises with dispensing medication rather than prescription linked intervention as envisaged by paragraph 17 of Schedule 4.

5.54 The Committee further noted that the SOP titled 'Supplying oral methotrexate' detailed under the heading 'Interventions and problem solving' that the Applicant would "*Monitor the patient for any signs of toxicity, check the BNF. If the patient is showing signs of toxicity you may need to contact the prescriber for a possible dose reduction*". The Committee was of the view that this limited information was not sufficient to demonstrate how the Applicant would assess whether patients require prescription linked intervention on the general scale and in fact focused solely on if any intervention would be needed for patients specifically prescribed oral Methotrexate.

5.55 The Committee was therefore not satisfied that it had been provided with sufficient information to show that there would be compliance with paragraph 17 of Schedule 4.

Health campaigns

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

5.57 The Committee noted the fleeting reference to health campaigns in the SOP titled 'Promoting healthy lifestyles (public health)' that stated that the scope of the SOP was to "*cover[s] offering healthy lifestyle guidance to patients and providing advice based on local or national campaigns endorsed by NHS authorities*". The Committee further noted that the same SOP details that the Applicant would "*direct patients to pharmacy services and provide written information like leaflets or referrals to healthcare professionals*".

5.58 The Committee was of the view that this limited information did not effectively demonstrate how the Applicant would safely and effectively participate in health campaigns if requested to do so by the Commissioner. Therefore, the Committee was not satisfied that it had been provided with sufficient information to show that there would be compliance with paragraph 18 of Schedule 4.

Signposting

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

5.60 The Committee noted that in the original application, the Applicant details how it will signpost users of the pharmacy who attend for Advanced and Enhanced Services, and those mistakenly wishing to access Essential Services face to face, to NHS Choices "*to find suitable service providers near to the patient and offer them their details to contact them*".

5.61 The Committee was of the view that, whilst this addressed how the Applicant would signpost patients that visited the premises, there was no information provided in either the application or further documents provided at appeal that addressed how the Applicant would signpost pharmacy users in a non-face-to-face capacity.

5.62 Based on the lack of information provided to it, the Committee was not satisfied that there would be compliance with paragraphs 19 – 20 of Schedule 4.

Support for self-care

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

5.64 The Committee noted that there was no reference in any of the supporting information provided by the Applicant in either the original application form or on appeal that addressed how it would provide advice and support for self-care.

5.65 Given the lack of information the Committee was not satisfied that it had been provided with information sufficient to show that there would be compliance with paragraphs 22 – 21 of Schedule 4.

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

Summary

5.67 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).

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

5.68.1 confirm the Commissioner's decision;

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

5.68.3 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.

5.69 The Committee noted that whilst it had reached the same overall decision as the Commissioner, it had done so for different reasons. The Committee therefore determined that the decision of the Commissioner must be quashed.

5.70 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.

5.71 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.

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

6 Decision

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

6.2 Accordingly, the Committee:

6.2.1 quashes the decision of the Commissioner; and

6.2.2 redetermines the application as follows -

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

6.2.2.2 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,

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

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

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

6.2.2.6 the Committee was not satisfied that all essential services were likely to be secured without face to face contact;

6.2.3 The application is refused.

Case Manager
Primary Care Appeals