

4 March 2021

REF: SHA/23387

**APPEAL AGAINST NHS COMMISSIONING BOARD
("NHS ENGLAND AND NHS IMPROVEMENT")
DECISION REGARDING A REMEDIAL NOTICE AT 33 –
35 MARKET STREET, HYDE, SK14 2AD**

Arena Point
Merrion Way
Leeds
LS2 8PA

Tel: 0203 928 2000
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1 Outcome

- 1.1 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations I substitute the decision to issue the Remedial Notice with a decision to issue a remedial notice as set out in paragraph 6.90 of this determination.

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1 The Remedial Notice

A remedial notice dated 7 August 2020 ("**Remedial Notice**") was sent to Boots UK Ltd (the "**Appellant**") in respect of 33 – 35 Market Street, Hyde, SK14 2AD.

- 1.1 **Name of contractor:** Boots UK Ltd
- 1.2 **Address of premises:** 33 – 35 Market Street, Hyde, SK14 2AD (FWP95)
- 1.3 **Date of inclusion in the pharmaceutical list for the area of Tameside Health and Wellbeing Board:** 1 April 2008
- 1.4 **This is a remedial notice issued under regulation 70 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended ("2013 Regulations").**
- 1.5 **Nature of the breach:**
- 1.6 Following an application to relocate from 19-21 Clarendon Street, Hyde SK14 2EL to 33 – 35 Market Street, Hyde, Boots UK Ltd ceased to provide any services at all as from the relocation date of 1 February 2020. It remains the case that Boots UK Ltd is not carrying on a retail pharmacy business (including any NHS pharmaceutical services) as at the date of this notice. Please see our letters of 06 February 2020 and 07 August 2020 for more details.
- 1.7 Having ceased all provision, Boots UK Ltd is in breach of all aspects of Schedule 4 of the 2013 Regulations (Terms of Service) in relation to service provision.
- 1.8 Grounds for removal from the Pharmaceutical List apply pursuant to regulation 74(1)(b) of the 2013 Regulations due to cessation of provision by Boots UK Ltd.
- 1.9 As you are aware from previous correspondence since February 2020, we consider that Boots UK Ltd is not providing any services at this address and that the former provider, The Hub Pharmacy Ltd, has continued to own and operate a pharmacy (including NHS pharmaceutical services) at this site, notwithstanding removal from the Pharmaceutical List and Boots' purported relocation.
- 1.10 As required by regulation 69 of the 2013 regulations, in the interim period NHSE&I has sought to engage with you to remedy this situation by demonstrating that Boots UK Ltd has genuinely taken on service provision at this site. NHSE&I is satisfied that it has made all reasonable efforts to communicate and co-operate with Boots UK Ltd directly so as to resolve this issue but has not been able to resolve it to date. The issue has

reached an impasse and it is not viable to allow this situation to continue, particularly as it constitutes grounds for removal.

- 1.11 **Steps Boots UK Ltd is required to take, to NHSE&I's satisfaction, in order to remedy the breach:**
- 1.12 Boots UK Ltd is required to demonstrate to NHSE&I's satisfaction that Boots UK Ltd has genuinely relocated its service provision to this site and that Boots UK Ltd is in fact providing the services here.
- 1.13 In doing so, NHSE&I requires Boots UK Ltd to confirm and provide evidence of:
- 1.13.1 change of GPhC premises registration into the name of Boots UK Ltd;
 - 1.13.2 SOPs utilised at this site being Boots UK Ltd-branded SOPs that have been reviewed, agreed and signed by the Superintendent Pharmacist of Boots UK Ltd;
 - 1.13.3 the same Boots UK Ltd processes and IT systems being utilised as prior to the relocation, as this is a no significant change relocation and not a change of ownership of the former 'The Hub Pharmacy Ltd' premises;
 - 1.13.4 clear communication to all NHS patients that this is a Boots UK Ltd pharmacy as opposed to the Hub Pharmacy Ltd pharmacy, delivering NHS services for Boots UK Ltd;
 - 1.13.5 cessation of any NHS service provision on by The Hub Pharmacy Ltd as a specific legal entity.
- 1.14 Taking the above steps will provide the necessary assurance that Boots UK Ltd is complying with its obligations under Schedule 4, that grounds for removal have been remedied and that there is no unauthorised provision of NHS services outside of the requirement for a provider to be on the Pharmaceutical List.
- 1.15 **The required steps must be completed:**
- 1.16 To be completed within 30 days of the date of this notice. If you believe that you will experience difficulty in completing the above steps within the required timeframe, please contact the Greater Manchester NHSE&I Pharmacy Team via england.gmtop@nhs.net
- 1.17 Boots UK Ltd has a right of appeal to the Secretary of State against the issuing of this remedial notice. Should Boots UK Ltd choose to appeal then you should send a concise and reasoned statement of the grounds for your appeal within 30 days of the date of this notice to appeals@resolution.nhs.uk or:
- 1.18 Primary Care Appeals
4th Floor
Arena Point
Merrion Way
Leeds LS2 8PA
- 1.19 Please note that should Boots UK Ltd fail to comply with the requirements of this remedial notice NHSE&I reserves the right to exercise our powers to take further action in relation to Boots UK Ltd's inclusion in the pharmaceutical list in respect of the above named premises. This may include removal of the premises from the pharmaceutical list under regulation 73 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, and/or further review of potential removal pursuant to regulation 74(1)(b).

2 The Appeal

In a letter dated 2 September 2020 and addressed to NHS Resolution, Boots UK Ltd, (“the Appellant”) appealed against NHSE&I’s decision. The grounds of appeal are:

- 2.1 Further to the Remedial Notice (the “Notice”) issued to the Appellant dated 7 August 2020, please find attached the Appellant’s appeal. Whilst this is the Appellant’s appeal, it has been submitted with the support of Hub Pharmacy Limited (“Hub”) which is directly interested in this appeal. Hub has sought advice from Rushport Advisory LLP and these grounds of appeal have been settled with the input of Leading Counsel, Samantha Broadfoot QC of Landmark Chambers, London. The Committee is asked to note that the significant delays caused by this process have caused considerable difficulty for both the Appellant and Hub. Whilst the Appellant understands that the Committee will process this appeal in accordance with the relevant Regulations, it would be grateful if a decision could be expedited as much as is possible.
- 2.2 References in this appeal to the “Regulations” means The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended).
- 2.3 The email to the Appellant dated 7 August 2020 sent by Mr Steve Riley of NHSE&I contained three separate documents:
 - 2.3.1 Cover Letter – this purports to set out the reasons why NHSE&I believes the Pharmacy can be removed from the pharmaceutical list under Regulation 74(1)(b) and then suggests that the breach is capable of remedy via a remedial notice which it refers to;
 - 2.3.2 Remedial Notice (see Attachment 1) – this Notice states that the view of NHSE&I that the Appellant has “ceased to provide any services at all” from the Pharmacy and lists five steps which NHSE&I says must be complied with to remedy the alleged breach; and
 - 2.3.3 Pharmacy Contract Issues Report (see Attachment 2) – this report appears to set out NHSE&I’s reasons for believing that “*the planned model of operation was not acceptable and the arrangement via management agreement was not support [sic] by the Regulations*” and that the Appellant “*has not delivered the NHS terms of service*”.
- 2.4 Despite the significant and detailed attempts by both the Appellant and Hub to assist NHSE&I, it is the Appellant’s view that the remedial steps in the Notice proposed by NHSE&I go beyond the requirements necessary to meet the Terms of Service set out in Schedule 4 of the Regulations.
- 2.5 The Appellant believes that the Pharmacy Appeals Committee should consider this appeal by deciding:
 - 2.5.1 Was there a breach of Regulation 74(1)(b) as alleged by NHSE&I?
 - 2.5.2 In the event that the answer to 1 above is no, then was there a breach of another regulation that the Committee should substitute for the breach of Regulation 74(1)(b)?
 - 2.5.3 If the Committee finds that there is no breach, then the Committee should allow the appeal.
 - 2.5.4 If the Committee finds that there was a breach, then it is required to consider if the breach is capable of being remedied and set out what steps can be taken to remedy the breach.

2.5.5 If the Committee agrees with NHSE&I's decision, then the Appellant must be notified.

2.6 **Background**

2.7 Whilst the Appellant appreciates that the Committee is tasked only with considering the lawfulness or otherwise of the Notice in the above way, it may be helpful to set out the background.

2.8 Hub operated a 100 hour NHS pharmacy on Market Street known as Market Street Pharmacy. The Appellant operated a "standard" hours NHS pharmacy a short distance away on Clarendon Street. With the Appellant's agreement, Hub wished to relocate the Appellant's NHS contract from Clarendon Street to the site of its 100 hour pharmacy and then apply for change of ownership thus enabling the Market Street Pharmacy to open for shorter opening hours under a "standard" hours NHS contract.

2.9 NHSE&I does not object in principle to the end result in which Hub would operate a "standard" hours contract at the Market Street Pharmacy having relocated and changed the ownership of the Appellant's "standard" hours contract. The issue appears to be the mechanics used to achieve that. As a result of Regulation 31, it was not possible for Hub to simply apply to change ownership and then relocate to the Appellant's pharmacy as previous Primary Care Appeals decisions have stated that, with both pharmacies in the same ownership, the application would be refused under Regulation 31.

2.10 In order to give effect to the same outcome, it was necessary to instead follow a process whereby the:

2.10.1 100 hour NHS contract owned by Hub submitted a closure notice;

2.10.2 Standard hour NHS contract owned by the Appellant applied to relocate to the site of the 100 hour pharmacy;

2.10.3 Hub 100 hour NHS contract ceased;

2.10.4 The Appellant's standard hour NHS contract relocated to the premises of the now ceased Hub 100 hour NHS contract location; and

2.10.5 Change of ownership application submitted to change the ownership of the NHS contract from the Appellant to Hub.

2.11 The above represents the process followed in this case and in many other cases across England. It should also be noted that a consolidation application under Regulation 26A could not be used as the site of the 100 hour NHS contract was to remain. While cumbersome for the two pharmacy contractors involved, the significant advantage of the process used is that it ensures continuity of NHS pharmaceutical services and patient care from the pharmacy premises that will remain open. The Appellant is unaware of any situation in which this arrangement has caused regulatory difficulties other than with this particular Area Team.

2.12 In May 2019, Hub (t/a Market Street Pharmacy – 100-hour NHS contractor) submitted a notice under Regulation 67 to cease provision of NHS pharmaceutical services. In June 2019, Boots at 21 Clarendon Street; applied to relocate to 33 – 35 Market Street under Regulation 24. The Appellant's relocation was approved by the NHS by letter dated 12 November 2019 (see Attachment 3) and no appeals were received against that decision.

2.13 NHSE&I agreed an amendment to the Hub closure date and Hub ceased provision of pharmaceutical services on 31 January 2020. The Appellant submitted a Notice of

Commencement to relocate to the Hub premises and this was accepted by NHSE&I. The relocation took place on 1 February 2020.

2.14 Hub then submitted a Change of Ownership application dated 3 February 2020 so that the Appellant's pharmaceutical list entry could be transferred to the name of Hub. Since the relocation of the Appellant's NHS contract, the Appellant has been providing pharmaceutical services at Market Street in accordance with the NHS Terms of Service. The provision of services by the Appellant has been supported by Hub by way of a Management Agreement, whereby Hub provides, amongst other things, members of staff. The Appellant does not anticipate that the precise arrangements under the Management Agreement are likely to be of direct concern to the Committee's decision in this appeal but, of course, we would be happy to provide further detail if the Committee considers this necessary.

2.15 **The Remedial Notice**

2.16 Turning to the Remedial Notice, it appears that NHSE&I's concern is that whilst it has accepted the closure of the 100 hour Hub NHS contract and approved the Appellant's NHS contract relocation to 33-35 Market Street, NHSE&I believes that:

2.16.1 *"...the planned model of operation was not acceptable and the arrangement via management agreement was not support [sic] by the Regulations"* (Issues Report - page 2).

2.17 The logic of NHSE&I's approach appears to be that because Boots is using a Management Agreement, that it is not in fact providing any pharmaceutical services. This is incorrect.

2.18 **Management Agreements**

2.19 Management Agreements have been used for many years by NHS pharmacy contractors and pre-date the current Regulations. Their use can be necessary in a range of circumstances: for example, because there are instances when an NHS pharmacy contractor wishes to sell their business on a certain date, but the NHS has not yet approved the Change of Ownership application or because an NHS contractor engages another legal entity to provide services such as staff. It is worth noting that whilst the NHSE&I refers to a "Change of Ownership" application, it is really a change of the entry on the pharmaceutical list, as the words of Regulation 26 make clear.

2.20 The Committee will be aware of many NHS pharmacy contracts being sold by various contractors over the years. Where such a sale has taken place prior to NHS Change of Ownership approval being finally provided, a management agreement (or equivalent) has operated. Each entity will have its own versions of these agreements although their basic principles remain the same, i.e. the new operator is engaged by the existing NHS pharmaceutical list entry holder to support delivery of NHS services on a short-term basis until the Change of Ownership application is processed.

2.21 Other very common examples of the use of management agreements in the sector include the many locums who provide their services via service companies, i.e. limited companies that are engaged by pharmacy contractors to support in provision of NHS pharmaceutical services and these operate in a similar manner to a management agreement, albeit in a less formal manner. Indeed, Boots does not employ staff itself. All Boots staff are employed by another entity and are engaged by Boots to support the provision of services.

2.22 Despite claiming that Management Agreements are not supported by the Regulations, Mr Riley of NHSE&I also stated in email correspondence on 3 February 2020 to the Appellant that:

2.22.1 *“As previously outlined the management agreement and planned model is not provided for in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended). It may be something you choose to do from a commercial perspective but it is not something which NHS England / Improvement recognise. Management agreements are utilised between pharmacy companies during a change of ownership process, however in those cases the incoming pharmacy company would operate the services at the premises of the existing contractor under an agreement and the pharmacy would be operated as if was the existing contractor. This includes the GPhC premises registration, SOPS and labelling being those of the existing contractor. However, in the model Boots UK Ltd is proposing to operate with the Hub Pharmacy Ltd, since the relocation on 01 February 2020 the premises at 33-35 Market Street will have never been registered with Boots UK Ltd with the GPhC, the SOPs will be the Hub Pharmacy Ltd and labels on prescriptions would show as Hub Pharmacy Ltd”.*

2.23 It would appear, therefore, that NHSE&I (correctly) accepts that management agreements may be used, but seeks to distinguish the present one by making claims about how management agreements can operate. A management agreement can take many forms and, in this situation, it is simply a commercial agreement between an NHS contractor and an entity that it engages to support in the provision of services by the NHS contractor. When some operators of multiple pharmacies sell individual branches, the “incoming pharmacy company” (to use NHSE&I’s words) do not, as far as we are aware, use the multiple’s SOPs or IT systems, for example. Instead, the incoming pharmacy company uses its own IT, SOPs etc. and places signage in the pharmacy to inform patients that NHS services continue to be provided by the previous incumbent until such time as the NHS Change of Ownership process is finalised.

2.24 **The Terms of Service**

2.25 Schedule 4 of the Regulations sets out the Terms of Service of NHS pharmacists. Paragraph 28 of the Terms of Service sets out the Clinical Governance requirements. It should be noted that the requirements on the NHS contractor include, for example, “appropriate standard operating procedures”, “a staffing and staff management programme” and “an information governance programme”. While the system of clinical governance must be delivered in a manner “reasonably required” by NHSE&I, it is not for NHSE&I to determine the specifics of how NHS contractors meet these requirements. For example, many NHS contractors use the template standard operating procedures supplied by the representative trade association. Also, in relation to information governance requirements, Boots currently operates three different patient medication record systems in its pharmacies while a new system is rolled out.

2.26 In relation to staff, paragraph 1 of the NHS Terms of Service states:

1.— Responsibilities of NHS pharmacists and pharmacy staff

(1) To the extent that this Schedule imposes a requirement on an NHS pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) if the NHS pharmacist is a registered pharmacist—

(i) that NHS pharmacist must comply with that requirement, or

(ii) if the NHS pharmacist employs or engages natural persons in connection with the provision of pharmaceutical services, the NHS pharmacist must either comply with that requirement or secure compliance with that requirement by—

(aa) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who

is not suspended), or 1 “NHS pharmacist” means a person included in a pharmaceutical list of the type referred to in Regulation 10(2)(a);

(bb) in other cases, by the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services; or

(b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—

(i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist **employs or engages in connection with the provision of pharmaceutical services**. [emphasis added]

- 2.27 It is quite clear that the Regulations foresee that a contractor may employ or engage natural persons in different ways, whether it be employment directly or engagement in a different manner, for example through a service company. As above, the Regulations do not stray into the details of those commercial relationships and nor should they.
- 2.28 **The General Pharmaceutical Council (“GPhC”) entry**
- 2.29 NHSE&I is also concerned that the GPhC entry for the 33-35 Market Street Pharmacy has remained as Hub Pharmacy Limited rather than Boots. There are two important points with regard to the GPhC entry that do not appear to have been considered by NHSE&I.
- 2.30 First, the GPhC is required to keep a register of persons who are “lawfully conducting a retail pharmacy business”, which may or may not also provide NHS services. This is a different register, operated by a different body.
- 2.31 Second, the Regulations require that NHS pharmaceutical services are provided from premises that are registered with the GPhC, but the Regulations do not require the GPhC registration to be in the name of the holder of the NHS pharmaceutical list entry holder, although it will often be so. In this case, the difference was intended to be temporary (as NHSE&I was aware), but, regrettably, the refusal of NHSE&I to process the Change of Ownership application has led to it subsisting for considerably longer than was envisaged by the Appellant or Hub.
- 2.32 The position with regards to the Market Street Pharmacy is as follows:
- 2.32.1 Hub was removed from the NHS pharmaceutical list for 33-35 Market Street, but not the GPhC register, from 31 January 2020.
- 2.32.2 From 1 February 2020 Hub has been operating as a retail pharmacy business in accordance with its GPhC entry and selling items such as P medicines and GSL lines, dispensing private prescriptions and supporting the Appellant in the Appellant’s provision of NHS pharmaceutical services.
- 2.32.3 NHS pharmaceutical services have at all times been provided from premises that are registered with the GPhC – as required by the Regulations.
- 2.32.4 The Appellant has continued to submit prescriptions to the NHS Business Services Authority for payment since 1 February 2020 and is being paid for all NHS pharmaceutical services it provides (see Attachments 4.1 – 4.5).

2.32.5 As is normal during Management Agreements, the Appellant has prominently displayed signage, including its practice leaflet, to inform patients that NHS services are provided by the Appellant.

2.32.6 The Appellant provided confirmation to NHSE&I from its Chief Pharmacist that the standard operating procedures being used at Market Street Pharmacy are appropriate for the delivery of NHS pharmaceutical services.

2.33 **Is there a breach of Regulation 74(1)(b)?**

2.34 Regulation 74 states:

“Removal of listings: cases relating to death, incapacity or cessation of service

74.—(1) Subject to paragraphs (2) and (4), if an NHS chemist (C)—

(a) dies;

(b) in the case of an NHS pharmacist, ceases to carry on a retail pharmacy business; or

(c) in the case of an NHS appliance contractor, ceases to carry on a business in the course of which C supplies appliances either by retail sale or in circumstances corresponding to retail sale, the NHSCB must remove C from the relevant pharmaceutical lists.”

2.35 This Regulation does not apply in these circumstances and, therefore, NHSE&I has wrongly issued a remedial notice in reliance on Regulation 74(1)(b).

2.36 An “NHS chemist” includes an “NHS pharmacist” which is itself defined in Regulation 2 as “*a person included in a pharmaceutical list*” and it is uncontentious that this includes a corporate entity such as Boots UK Limited. Regulation 74(1)(b) is, therefore, directed at the question as to whether the Appellant has ceased “*to carry on a retail pharmacy business*”. Read in the natural and contextual sense, it is clear that this relates to the cessation of all pharmacy services provided by the entity and not just the services at one pharmacy. This fits with the natural reading of the provision, the remaining subparagraphs and the fact that it refers to “*pharmaceutical lists*” in the plural. Regulation 74(1)(b) is directed at an instance where a corporate entity was to, for example, enter bankruptcy or cease all operations for some other reason.

2.37 Further, and by contrast, where the regulation is specific to a particular pharmacy premises, it says so in terms: Regulation 74(3), which also deals with the failure to provide services, is specific to “*the particular premises*” and refers to removal from “*a particular pharmaceutical list*” in the singular.

2.38 The Appellant has carried on, and continues to carry on, a retail pharmacy business. The Appellant currently operates around 2,400 retail pharmacies in the UK, of which over 2,300 provide NHS pharmaceutical services. Regulation 74(1)(b) is simply inapposite in these circumstances.

2.39 In the Issues Report, NHSE&I’s response to this was:

2.39.1 *“Boots UK Ltd.’s position that the fact Boots UK Ltd have GPhC premises elsewhere means they can still be classed as carrying on a retail pharmacy business is not valid. This is because from NHS terms of service perspective each premises has a specific ODS code and holds a separate contractual relationship with NHSE&I; although one legal entity may own a number of premises. Therefore, each premises must have a valid and correct GPhC premises registration and appropriate ownership/lease arrangement in the name of the organisation listed on the Pharmaceutical List,”*

- 2.40 The Appellant accepts (and has never argued the contrary) that each premises has a separate code, but that simply fails to deal with the point being made, which is that Regulation 74(1)(b) relates to the contractor ceasing services in their entries across all entries in the pharmaceutical lists rather than at individual premises.
- 2.41 **In the event that there is no breach under Regulation 74(1)(b), then was there a breach of another regulation that the Committee should substitute for the breach of Regulation 74(1)(b)?**
- 2.42 Individual premises are dealt with at Regulation 74(3) which states:
- (3) If the NHSCB determines that C has not, during the preceding 6 months, provided pharmaceutical services at chemist premises (“the particular premises”) listed in a particular pharmaceutical list—*
- (a) if there are other chemist premises listed in that pharmaceutical list in relation to C, the NHSCB must remove the listing of the particular premises from that list; or*
- (b) if there are no other chemist premises listed in that pharmaceutical list in relation to C, the NHSCB must remove C from that list.*
- 2.43 The Committee will note that this differentiates between individual premises. For Regulation 74(3) to apply, it would require a contractor to have not provided pharmaceutical services during the preceding 6 months at a particular premises. In light of the fact that the Committee may substitute its own decision for that of NHSE&I, we address that point here. The Appellant has not ceased to provide pharmaceutical services. Boots has been providing, and been paid for, NHS services continuously since before the relocation to 33-35 Market Street and after the relocation.
- 2.44 In the Appellant’s submission, NHSE&I was wrong to issue the Notice, and the appeal should be allowed on this basis as the Appellant is not in breach of its Terms of Service.
- 2.45 Further, and in the alternative, it is submitted that it would be disproportionate and unfair to find a breach in circumstances where more than six months have now elapsed since the Regulation 26 change of ownership application was submitted to NHSE&I. The Appellant would therefore also kindly request that the Committee now directs NHSE&I to consider the Regulation 26 application as a matter of urgency so that this matter can be resolved.
- 2.46 The Appellant can conceive of no other regulation that might be relevant to the Committee’s consideration.
- 2.47 Finally, the Appellant and Hub Pharmacy are criticised by NHSE&I for a “complex situation of [their] own making” and it is asserted that if something is not specifically permitted then it is not permissible. The Appellant would like to highlight that this type of arrangement is commonplace when it is not possible to effect a simultaneous relocation and change of ownership. It was done in this way to maintain services to patients at the Market Street location as any other arrangement would have created gaps and caused disruption to patients. Further, it is not accepted that “if something is not specifically permitted then it is not permissible”. The regulatory framework lays down detailed requirements and if the arrangement is not expressly prohibited then permission cannot be refused for it. Further, what the Regulations require should always be considered in light of their objectives. Here the arrangement was a mechanism to end up in the perfectly lawful position of Hub with a “standard” hours NHS contract at Market Street having relocated and changed ownership from the Boots Clarendon Street location. This arrangement was structured to ensure continuity of care to patients in the meantime.

- 2.48 **If the Committee find that there was a breach, then it is required to consider if the breach is capable of being remedied and set out what steps can be taken to remedy the breach**
- 2.49 In the event that the Committee disagrees with the Appellant about the breach, then the Appellant considers the remedies proposed by NHSE&I below. The Appellant notes that there is no definition of a breach which is capable of remedy and each case will turn on its own facts.
- 2.50 The Appellant has listed the NHSE&I proposed remedies in turn below along with its response to each.
- 2.51 **change of GPhC premises registration into the name of Boots UK Ltd**
- 2.52 This point has been addressed above. It is not appropriate to make this change as to do so would be misleading. Hub continues to operate a retail pharmacy business from 33-35 Market Street. Hub has the lease for the premises in its name and provides staff. Hub sells medicines and other items, and dispenses private prescriptions. In the circumstances, it is right that Hub maintains its GPhC entry. It would be wholly wrong for the NHS to attempt to force a pharmacy operator to change its GPhC entry when the operator has a legal duty to inform the GPhC of who is “carrying on the retail pharmacy business” rather than the NHS pharmaceutical list entry. The requirement in the Regulations is only that NHS pharmaceutical services are provided from premises registered with the GPhC, which they are in this case.
- 2.53 **SOPs utilised at this site being Boots UK Ltd branded SOPs that have been reviewed, agreed and signed by the Superintendent Pharmacist of Boots UK Ltd**
- 2.54 As noted previously and advised to NHSE&I, the SOPs being used at 33-35 Market Street to deliver NHS pharmaceutical services in the Appellant’s name have been reviewed and approved by the Appellant’s superintendent pharmacist. It is inappropriate and beyond the requirement of the Regulations for NHSE&I to specify that a particular “brand” of SOPs should be used. This Committee will be well aware that different pharmacies use different SOPs and a number simply buy them ‘off the shelf’. NHSE&I has not expressed any concern about the appropriateness of SOPs being used at Market Street.
- 2.55 **the same Boots UK Ltd processes and IT systems being utilised as prior to the relocation, as this is a no significant change relocation and not a change of ownership of the former ‘The Hub Pharmacy Ltd’ premises**
- 2.56 Paragraph 10 of the Terms of Service requires contractors to “keep and maintain records”. The Regulations do not stipulate how such records should be kept and, as noted previously, the Appellant currently operates multiple patient medication record systems. This demand exceeds NHSE&I’s remit.
- 2.57 **clear communication to all NHS patients that this is a Boots UK Ltd pharmacy as opposed to the Hub Pharmacy Ltd pharmacy, delivering NHS services for Boots UK Ltd**
- 2.58 This already occurs with signage in the pharmacy to make this clear. Please find attached (Attachment 5) the text on the notices that are being displayed at the entry to the pharmacy and within it.
- 2.59 **cessation of any NHS service provision on by The Hub Pharmacy Ltd as a specific legal entity**
- 2.60 As explained above, the Appellant provides the pharmaceutical services at 33-35 Market Street. NHS prescriptions for payment pursuant to the Appellant’s NHS Pharmacy Contract are being submitted either electronically against the Appellant’s

ODS code, or on prescription forms stamped with the Appellant's name and being paid to the Appellant. Hub Pharmacy Limited is not providing the pharmaceutical services and therefore it cannot cease to do something that it is not in fact doing. Hub is only providing staff, premises, equipment etc. and has been engaged by the Appellant to support the Appellant's provision of NHS pharmaceutical services.

2.61 **Concluding Comments**

2.62 Finally, it is noted that in its Issues Report, NHSE&I asked the PSRC to consider whether it is "justifiable and proportionate to remove the Appellant at 33-35 Market Street (FWP95) from the Pharmaceutical List of the Tameside Health and Wellbeing Board". Insofar as this is a question to be answered by the Committee, it is respectfully submitted that the answer is no, it is neither proportionate nor justified in this case. If the NHSE&I simply proceeded to consider the Regulation 26 application in the normal way, the NHS pharmaceutical list entry would then transfer to Hub and the situation would immediately turn back into the most ordinary, straightforward set-up, and there could be no regulatory concerns.

2.63 The Appellant is also still waiting for a decision from NHSE&I in relation to the 'Change of Ownership' application submitted by Hub in relation to the Appellant's NHS pharmacy contract. This application was submitted in February 2020 and NHSE&I has refused to consider it whilst this appeal is ongoing (see NHS letter to Hub at Attachment 6). The Appellant would therefore be grateful if, as part of considering this appeal, the Committee could make it clear that there is no reason for NHSE&I to further delay the consideration of the Change of Ownership application and issue a direction to that effect.

2.64 The Committee will note that NHSE&I has raised various other points throughout this process and in correspondence. Without addressing every point here (as they are not directly relevant to the Committee's decision), the Appellant wishes to be clear that it does not accept that NHSE&I has acted lawfully in this case, nor does it accept the various other points that have been raised.

2.65 The Appellant would be happy to provide any more information that the Committee may request.

3 **Summary of Representations**

3.1 THE APPELLANT

3.1.1 With regards to submission of representations in relation to the appeal, the Appellant has already set out detailed representations in response to NHSE&I's Remedial Notice in its previous letter of 2 September 2020. The Appellant asks that the 2 September 2020 letter, along with the evidence attached to it, is considered by Primary Care Appeals.

3.1.2 With regards to the statement in the Remedial Notice that "Having ceased all provision, Boots UK Ltd is in breach of all aspects of Schedule 4 of the 2013 Regulations (Terms of Service) in relation to service provision", the Appellant would like to reiterate that it has not "ceased all provision" nor is it in breach of Schedule 4 for the reasons set out in that letter. However, and without prejudice to the detail contained in that letter, the Appellant emphasises that it:

3.1.2.1 is on the pharmaceutical list in relation to the premises at 33-35 Market Street;

3.1.2.2 continues to provide pharmaceutical services from 33-35 Market Street; and

3.1.2.3 is being paid for those services and has provided NHSBSA payment advice to demonstrate that Boots has been paid and continues to be paid for providing services.

3.2 NHS ENGLAND & NHS IMPROVEMENT (“NHSE&I”)

3.2.1 **Background**

3.2.2 NHSE&I wish to begin by providing some relevant background regarding the matter which has ultimately led to the remedial notice being issued.

3.2.3 The Appellant made an application to NHSE&I dated 6th June 2019 for a No Significant Change Relocation to move from its original premises trading as Boots, 21 Clarendon Street, Hyde, SK14 2EL; to premises at 33 – 35 Market Street, Hyde, SK14 2AD. At that time, 33-35 Market Street was occupied by The Hub Pharmacy Ltd trading as Market Street Pharmacy; a 100-hour contractor which had submitted a voluntary closure of premises in pursuant to Regulation 67(2)(b)(i) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (“the Regulations”); giving notice (dated 29th May 2019) to permanently close. Whereby The Hub Pharmacy Ltd would cease to provide NHS pharmaceutical services and their listing on the pharmaceutical list for the Tameside Health and Wellbeing Board area at 33-35 Market Street would be removed. As per the wording “voluntary closure of premises” in the Regulation listed above, it would be usual and expected for the premises to close altogether.

3.2.4 The No Significant Change Relocation application followed due regulatory process; and interested parties, pharmacies within 2km whose interest were likely to be affected by the PSRC decision were invited to make representation on the content of the Appellant’s application. Interested parties consulted raised no objection due to the relative short distance (74 metres) involved. The PSRC, in determining the application, took interested party views and supporting information provided by the contractor (prescription flow, patient journey and statement in respect of refusal by virtue of Regulation 31) into consideration and decided to grant the application based on the information provided and declarations made by the Appellant in its application. The Appellant’s No Significant Change Relocation application is included as Appendices A1 to A4. In determining the application, it was the reasonable understanding, of NHSE&I, that The Hub Pharmacy Ltd would cease all operations as a pharmacy and close the premises altogether prior to any relocation being enacted. It was also understood that in line with regulation 24 of the 2013 Regulations, and as stated expressly in the application, the Appellant would provide the same pharmaceutical services from the Market Street premises as it had been providing at Clarendon Street. This was an undertaking not only that the services would be the same, but that the Appellant would be the provider. It was also noted in the cover letter submitted by the Appellant (in support of their application – Appendix A2), that it planned to move the pharmacist from 21 Clarendon Street as part of the location. This too was consistent with the understanding that this was a relocation of the existing Boots pharmacy.

3.2.5 The application was granted on the basis that it met the necessary criteria for Boots UK Ltd to relocate one of its pharmacies.

3.2.6 **Initial discrepancies arising after approval of the relocation application**

3.2.7 Following the grant of this application, the Appellant duly submitted a Notice of Commencement (NOC); which originally stated that the pharmacy (once relocated) would trade as “Boots”. It subsequently became apparent that the Appellant intended to trade the premises as Market Street Pharmacy, following

the relocation. This differed from the NOC accepted as valid, which was dated 20th January 2020 and stated the trading name as Boots (Appendix B). The Appellant subsequently notified NHSE&I that it had made an administrative error and wished to submit an amended NOC, to enable it to change the trading name to "Market Street Pharmacy". An amended NOC was received on 3rd February 2020. NHSE&I informed the Appellant on 3rd February (as per Appendix C) that it was not possible to accept a revised NOC sent after the date of relocation, following a previously accepted NOC. The Appellant was informed that it must formally notify NHSE&I of a trading name change, within 30 days of the change. The Appellant subsequently notified NHSE&I of the change in trading name to Market Street Pharmacy in the required time period.

3.2.8 The NOC required the Appellant to state its "Premises registration number with the General Pharmaceutical Council" (GPhC), and this was stated as "1109406". NOCs must be deemed valid by NHSE&I on the basis of the information given if all required fields are populated; and it is expected that the incoming contractor will make appropriate arrangements with the GPhC to amend the premises registration entry to show itself (in this case, Boots UK Ltd) as the listed owner in due course. In fact, once a No Significant Change Relocation takes place, NHSE&I routinely checks the premises registration on the GPhC register to ensure that the listed owner's name matches the Pharmaceutical List entry; and it was noted in this case that the owner as listed with the GPhC remained (and still remains) as "The Hub Pharmacy Ltd", with a trading name of Market Street Pharmacy (the trading name the Appellant had advised it intended to use following the relocation). Furthermore, it has now been confirmed by the Appellant in its appeal that it had and has no intention of registering itself with the GPhC as the owner of the pharmacy operating from 33-35 Market Street, Hyde SK14 2AD under the GPhC premises registration number provided in the NOC. The NOC was accepted in good faith by NHSE&I. It only subsequently came to light that the premises remain registered as a retail pharmacy business operated by The Hub Pharmacy Ltd. NHSE&I's view is that this cannot be consistent with the purported relocation of a Boots pharmacy to these premises. NHSE&I has set out more details on this point under heading 5 below.

3.2.9 **Further issues and concerns about the purported relocation**

3.2.10 Concerns were first raised in respect of the Appellant's and The Hub Pharmacy Ltd.'s intentions following the granted No Significant Change Relocation from 21 Clarendon Street, Hyde SK14 2EL to 33-35 Market Street, Hyde SK14 2AD; when it was brought to NHSE&I's attention that the Appellant was displaying a notice stating that "This store is closing on Friday 31st January 2020" and that "Your nearest Boots store is 1A Market Place, Hyde, Cheshire, SK14 2LX Tel: 0161 368 2249". This was inconsistent with the purported relocation of the Clarendon Street pharmacy to the Market Street premises.

3.2.11 NHSE&I wrote to the Appellant on 22nd January 2020 (Appendix D) regarding this matter to advise that it considered this to be a misleading message to patients when the Clarendon Street branch was in fact relocating, not closing. In that letter, the Appellant was instructed to replace the message being displayed with one that was factually correct, to advise patients that the pharmacy would be relocating to 33 -35 Market Street. NHSE&I also set out concerns on related issues such as GDPR compliance.

3.2.12 Similarly, NHSE&I had been made aware that The Hub Pharmacy Ltd (the 100-hour contractor occupying 33-35 Market Street at that time) was displaying a notice stating that "Our Opening Hours Are Changing". This too was factually incorrect as The Hub Pharmacy Ltd had given notice to permanently close its pharmacy and should therefore not have been advertising itself as having new

opening hours from the date on which the Appellant was relocating into 33-35 Market Street.

- 3.2.13 Instead, if there really was a closure of The Hub Pharmacy Ltd and a relocation of the nearby Boots pharmacy, this should have been clearly communicated to their respective patients. NHSE&I's concern has always been that there has in fact been no closure and no relocation but instead a continuation of The Hub Pharmacy Ltd.'s business when they are no longer included on the NHS pharmaceutical list. This is not permitted under the regulatory framework and is not acceptable.
- 3.2.14 The actions of both parties placed the patients of both pharmacies at significant risk (as outlined in paragraph [3.2.44]) and because of this, the Appellant was reminded of its obligations in terms of the conditions of a No Significant Change Relocation. The Hub Pharmacy Ltd was also reminded of its obligations with regards to notifying commissioners, GP practices and patients of the voluntary closure.
- 3.2.15 This matter was particularly concerning as patients of Boots UK Ltd, 21 Clarendon Street should not have experienced any interruption or change in services other than that their NHS pharmaceutical needs would continue to be met from the Appellant's new location at 33-35 Market Street. This was a requirement under regulation 24.
- 3.2.16 Instead, the Appellant's patients were initially misled by being incorrectly informed that the Clarendon Street pharmacy was closing and that they would have to access pharmaceutical services from an alternative Boots UK Ltd pharmacy, should they wish to continue to receive services from Boots UK Ltd. It is important to note that the Appellant did not offer 33-35 Market Street as the site from which patients would continue to access services going forward; instead advising that the "next nearest branch of Boots is 1A Market Place." In addition to this being inconsistent with the purported relocation, NHSE&I wishes to highlight that in fact 33-35 Market Street is slightly closer to 21 Clarendon Street than 1A Market Place (in fact the rear entrance of 33-35 Market Street can clearly be seen from the rear of 21 Clarendon Street as the two sites are separated only by a small public car park). It is therefore unclear why the Appellant would choose to specifically direct patients to another of its branches rather than the site to which it was allegedly relocating.
- 3.2.17 This further demonstrates that Boots UK Ltd.'s intention was to operate as though The Hub Pharmacy Ltd remained at 33-35 Market Street and was appearing to offer "continuity of services" for The Hub Pharmacy Ltd.'s patients, rather than protecting the interests of its own patients by enacting the requirements of the No Significant Change Relocation. There are two key issues with this:
- 3.2.17.1 first, the question of whether there was any "relocation" as provided for under regulation 24; and
- 3.2.17.2 secondly, this course of action pre-empted the Change of Ownership process and assumed that it would be granted. This is wholly unacceptable. Unless and until such change of ownership is granted, the pharmacy should be clearly under the ownership and control of the Appellant and not The Hub Pharmacy Ltd.
- 3.2.18 The Appellant responded to NHSE&I's letter of 22nd January on 27th January 2020 via email from Ms S Mody, Walgreens Boots Alliance – Retail Pharmacy International. Subsequently there were further communications between both NHSE&I and Ms Mody dated 30th January 2020, 31st January 2020, 3rd February 2020, 4th February 2020, 6th February 2020, 7th February 2020, 10th

February 2020 and 11th February 2020, and this email trail is included as part of this appeal response as Appendix E. These emails set out extensively the issues as identified by NHSE&I, and the Appellant's response to the issues highlighted. NHSE&I also engaged in a number of telephone calls with Ms S Mody during this period. In summary, the emails set out NHSE&I's ongoing attempts to establish whether there was genuinely a relocation of the Appellant's pharmacy and whether and how the Appellant was in fact providing services at the Market Street premises. The email correspondence also demonstrates the local dispute resolution measures undertaken by NHSE&I with the Appellant.

- 3.2.19 On 6th March 2020, NHSE&I wrote to the Appellant to advise that the Change of Ownership application received from the Appellant and The Hub Pharmacy Ltd in respect of the pharmacy at 33-35 Market Street (which had been received on 4th February 2020) would not be processed until NHSE&I was satisfied that the outstanding issues relating to the Appellant at this site had been resolved. NHSE&I maintain that this was appropriate because at the time the Change of Ownership application was received, NHSE&I was not satisfied that this was genuinely a pharmacy that was owned and managed by Boots UK Ltd and that Boots was responsible for the provision of the relevant NHS pharmaceutical services. It is reasonable not to consider change of ownership until the current ownership position is established.
- 3.2.20 There was a pause on activities related to these matters between March and June 2020. This was owing to the COVID-19 pandemic. As a result of the pandemic there were a number of urgent priorities for NHSE&I that had to take priority, also a national decision was taken to pause Market Entry processes. Prior to March 2020, the matter with the Appellant and The Hub Pharmacy Ltd was reviewed within NHSE&I, whilst deemed an unacceptable situation from a clinical governance and regulatory perspective (as outlined in paragraph [3.2.44]), it was not deemed to be of such a patient concern to pursue a suspension of services. It was made clear to the Appellant that this pause in activity was by no means any signal that the matter was concluded or acceptable to NHSE&I.
- 3.2.21 **Has there been a relocation of the Boots pharmacy?**
- 3.2.22 NHSE&I's view is that when all of the information and evidence is taken together, it is impossible to establish to our reasonable satisfaction that there has been a genuine relocation of the Clarendon Street Boots pharmacy, resulting in the Appellant owning and providing NHS pharmaceutical services from the Market Street pharmacy. Despite many attempts to clarify the position over an extensive period (as explained above and detailed in the Appendices), NHSE&I has no assurance that the Appellant is responsible and accountable for the services at this pharmacy. From a regulatory perspective, this is unacceptable.
- 3.2.23 As a result, NHSE&I is also extremely concerned that the Appellant's actions have in fact led to The Hub Pharmacy Ltd continuing to run its pharmacy and deliver NHS pharmaceutical services after it voluntarily removed itself from the pharmaceutical list. This is equally unacceptable from a regulatory perspective.
- 3.2.24 Whilst the Appellant has made a number of submissions about management arrangements generally being something that is possible, they have failed to provide any assurance about the suitability of the arrangement in this particular case, or any explanation of exactly how this pharmacy is a Boots pharmacy for which they are fully responsible.
- 3.2.25 Based on the evidence available to NHSE&I, what NHSE&I have is the following:

3.2.25.1As regards the Appellant:

- 3.2.25.1.1 public notification that the “relocating” pharmacy was closing;
- 3.2.25.1.2 redirection of that pharmacy’s patients to another (further away) Boots branch and not the Market Street address;
- 3.2.25.1.3 no Boots branding at the Market Street premises (including, as indicated in the emails at Appendix E, no mention of Boots on the prescription labels or in the original complaints process);
- 3.2.25.1.4 no transfer of Boots IT systems on relocation;
- 3.2.25.1.5 no use of Boots UK Ltd.’s usual SOPs;
- 3.2.25.1.6 Boots UK Ltd not registered with the GPhC as conducting the retail pharmacy business at this site;
- 3.2.25.1.7 inclusion on the NHS pharmaceutical list.

3.2.25.2As regards The Hub Pharmacy Ltd:

- 3.2.25.2.1 no indication to patients that they were closing down;
- 3.2.25.2.2 notification to patients that The Hub Pharmacy Ltd was changing its opening hours (as opposed to Boots taking over and opening during those hours);
- 3.2.25.2.3 registration with the GPhC as conducting the retail pharmacy business at this site;
- 3.2.25.2.4 dispensing of NHS prescriptions with The Hub Pharmacy Ltd labelling;
- 3.2.25.2.5 use of The Hub Pharmacy Ltd SOPs;
- 3.2.25.2.6 use of The Hub Pharmacy Ltd IT systems;
- 3.2.25.2.7 no inclusion on the NHS pharmaceutical list.

3.2.26 The Appellant has sought to raise a number of arguments that focus on their freedom to make their own detailed commercial arrangements, for example choice of SOPs and choosing to use staff employed by others. NHSE&I is not seeking to impose particular commercial or operational arrangements on the Appellant as suggested. NHSE&I was trying to verify the arrangements at this pharmacy and so cannot consider these factors in isolation. The issue here is that taking all of these things together, they appear to indicate that the Appellant is not the provider. NHSE&I cannot find any satisfactory explanation that the Boots UK Ltd pharmacy has relocated or that The Hub Pharmacy Ltd pharmacy has closed. NHSE&I have commented further about SOPs and IT systems under [paragraph 3.2.53] below.

3.2.27 **Why is the current situation a problem?**

3.2.28 The Appellant has submitted that it has had to use this route as the 2013 Regulations do not permit a straightforward change from a 100 hours contract to a 40 hours contract, or a simultaneous relocation and change of ownership.

NHSE&I's view is that as these things are not provided for by the 2013 Regulations, then this was an intentional omission from the regulatory scheme, and it is not intended that it should be happening.

- 3.2.29 NHSE&I does not dispute the possibility of an end result whereby the Appellant relocates a pharmacy and subsequently transfers it to The Hub Pharmacy Ltd via a change of ownership. What NHSE&I does dispute is any ability to ignore or circumvent the 2013 Regulations by effectively acting as if the end result has already been approved and cutting out the middle step, required by the 2013 Regulations, of Boots UK Ltd genuinely relocating and providing services at the Market Street premises.
- 3.2.30 There is a clear regulatory framework in place governing NHS community pharmacy services. This exists to ensure appropriate standards and patient safety. As commissioner of NHS pharmaceutical services, NHSE&I's role includes contract monitoring and taking remedial action where necessary. NHSE&I has legitimate concerns that it cannot appropriately carry out its function of managing this particular contract when it appears that the named NHS contractor for the site does not have any meaningful link with or control over the services being provided at the site.
- 3.2.31 Likewise, NHSE&I has no relationship with The Hub Pharmacy Ltd that would allow NHSE&I to take any steps to address any issues with its provision of NHS pharmaceutical services. NHSE&I are not assured that there is any clear chain of responsibility that would ensure that it can enforce against the Appellant in the event of a problem and in turn this would be enforced against The Hub Pharmacy Ltd. Further, the 2013 Regulations do not provide for sub-contracting arrangements that would achieve this, nor do they provide for anyone not on an NHS pharmaceutical list to provide NHS pharmaceutical services.
- 3.2.32 It cannot be acceptable within the scheme of 2013 Regulations and NHS Act 2006 for anyone (in this case The Hub Pharmacy Ltd) to provide NHS pharmaceutical services without being on the NHS pharmaceutical list.
- 3.2.33 At the same time, NHSE&I has serious concerns about the attempt to separate GPhC registration of the premises from the listing on the NHS pharmaceutical list. NHSE&I does not consider that it is possible or feasible for different entities to be listed. By virtue of its listing with the GPhC, The Hub Pharmacy Ltd is responsible for conducting the retail pharmacy business at this site for the purposes of s69 Medicines Act 1968. This means that the keeping, preparing and dispensing of medicinal products other than medicinal products on a general sale list, is under the management of The Hub Pharmacy Ltd.'s superintendent (s71 Medicines Act 1968).
- 3.2.34 It also means that the responsible pharmacist at the site must either be The Hub Pharmacy Ltd.'s superintendent, or a pharmacist subject to the directions of The Hub Pharmacy Ltd.'s superintendent (s71 Medicines Act 1968).
- 3.2.35 In the Appellant's application, they have named their own superintendent pharmacist in relation to the Market Street pharmacy upon relocation. However, NHSE&I are not satisfied that their superintendent has any meaningful role in relation to this particular pharmacy, or any responsibility for its services. The legislation mentioned above does not provide for two different superintendents to simultaneously oversee services at the same site.
- 3.2.36 In the event of a serious breach or serious patient safety issue, there would be a pharmacist under the management of The Hub Pharmacy Ltd.'s superintendent and The Hub Pharmacy Ltd would be responsible for the dispensing at the site. NHSE&I has no direct relationship or recourse against

that entity. At the same time, it is not clear that the Appellant and its superintendent have any ability to control what The Hub Pharmacy Ltd is doing in conducting the retail pharmacy business at this site.

- 3.2.37 Without registration with the GPhC at this site, the Appellant is not lawfully conducting the retail pharmacy business there. They freely admit this is the case. Accordingly, the Appellant does not appear to have any responsibility or accountability for, or any control over, the services provided at this pharmacy. This leaves a serious gap in the accountability at this site and our ability to contract manage the NHS pharmaceutical services. Ultimately this undermines the regulatory framework governing these services.
- 3.2.38 In not registering the premises at 33-35 Market Street, along with their wider lack of involvement in the pharmacy, the Appellant has ceased to operate a retail pharmacy business at that site since relocation took effect. Contrary to the Appellant's submissions, it cannot be acceptable for an NHS community pharmacy contractor to be able to operate from any premises registered with another legal entity, just because they have GPhC premises registered elsewhere. This is not supported by the regulations.
- 3.2.39 NHSE&I also wishes NHS Resolution to have regard to the following published by the GPhC:
- 3.2.39.1 "Pharmacies must also be registered with the GPhC (or be a pharmacy department based in a hospital or health centre) to operate in Great Britain and to use the title 'pharmacy'". The Appellant's failure to register as the owner of the pharmacy premises at 33-35 Market Street therefore raises two significant issues:
- 3.2.39.2 The Appellant does not have permission to use the title "Pharmacy" at these specific premises and so should not be trading there as "Market Street Pharmacy".
- 3.2.40 The Appellant would not bear any responsibility for annual renewal of the premises registration, which involves completing a declaration stating that they meet all professional, fitness to practice and ethical standards. Registration is also important to ensure that information is reliable, up to date and accurate; and is a trusted source of information on which the public can rely. Whilst the Appellant may argue that it does submit fitness to practice information in relation to its registration, the point again is that it does not cover this pharmacy and so there is a clear gap in assurance.
- 3.2.41 Under s132(2) of the NHS Act 2006, it is not possible for NHSE&I to make any arrangements for the dispensing of NHS medicines with any person who is not a registered pharmacist or a person lawfully conducting a retail pharmacy business in accordance with s69 of the Medicines Act 1968. As detailed above, the definition under s69 includes, for a body corporate, medicines being under the control of their superintendent.
- 3.2.42 NHSE&I were able to commission services from the Appellant because it is a body corporate lawfully conducting a retail pharmacy business and therefore satisfies the requirement of s132. However, by its own admission its retail pharmacy business does not cover the Market Street location that it asked to move to. The Hub Pharmacy Ltd lawfully conducts that retail pharmacy business. In NHSE&I's view, it follows that any NHS pharmaceutical services being provided by The Hub Pharmacy Ltd at its registered premises must be commissioned directly from The Hub Pharmacy Ltd and not from the Appellant.
- 3.2.43 In NHSE&I's view, this further confirms that the Appellant is not providing any services at this site following the purported relocation, as well as further

highlighting the practical difficulties that arise if NHSE&I does not address this issue.

- 3.2.44 Clinical governance and patient safety are key concerns. As the GPhC registered pharmacy premises owner differs from the legal entity approved to deliver NHS pharmaceutical services, the clinical governance lines are extremely confused, and it is not clear which legal entity is responsible for delivery of NHS pharmaceutical services. If a patient medication error occurs would accountability lie with Hub Pharmacy Ltd and the Appellant? The Appellant's Superintendent Pharmacist has no direct or meaningful accountability for services delivered by Hub Pharmacy Ltd and has no authority to enact changes at the Hub Pharmacy Ltd following any issues /patient errors as the Hub Pharmacy Ltd are delivering all NHS pharmaceutical services; but are not commissioned to do so. It is not clear that patients would be properly indemnified if harm were to occur. NHSE&I have no contractual relationship with The Hub Pharmacy Ltd so cannot enforce remedial actions or assure adherence to the NHS terms of service. The security of patient data is compromised, as patients have consented to receive NHS pharmaceutical services from the Appellant. However, the Appellant has given all patient data to another legal entity. Patients have the right to expect that the provider they consented to hold their details is the provider delivering their services.
- 3.2.45 It is also important to highlight that if the arrangements in this case are deemed to be acceptable by Primary Care Appeals, it will set a precedent allowing others to enter into loose arrangements that allow for those not on the NHS pharmaceutical list to provide NHS services. This will have further repercussions on the ability of NHSE&I to appropriately manage those services.
- 3.2.46 It would also set a precedent allowing those involved in a change of ownership to pre-empt the outcome and effectively proceed without approval under the 2013 Regulations.
- 3.2.47 You can see from the supporting correspondence submitted that NHSE&I also has concerns as to GDPR compliance and change of EPS nominations without the necessary patient consent.
- 3.2.48 Finally, NHSE&I would submit that the responses and actions from the Appellant to date either demonstrate a lack of understanding of the seriousness of the issues, or a complete disregard for the correct procedures required under the regulations.
- 3.2.49 In order to comply with the 2013 Regulations, there needs to be two distinct steps to this process: (i) the Appellant relocates and is genuinely the provider until any change; and (ii) change of ownership subsequently allows The Hub Pharmacy Ltd to take over if approved.
- 3.2.50 **PSRC consideration and decision to issue a remedial notice**
- 3.2.51 The matter was considered by the NHSE&I's Greater Manchester Pharmaceutical Services Regulations Committee (PSRC) at its meeting on 23rd July 2020, and the issues report is enclosed as Appendix F which sets out the timeline of events and actions taken by NHSE&I to try to resolve the matter via local dispute resolution without further action having to be considered. Unfortunately the Appellant chose not to agree to the required remedial actions in this respect, which ultimately led to consideration of removal. The PSRC determined that the criteria to remove the Appellant's premises at 33-35 Market Street, pursuant to regulation 74. -(1)(b), was met. However, owing to the COVID -19 pandemic and in an effort to retain NHS pharmaceutical service provision, before moving to action the removal of Boots

UK Ltd from the Tameside HWB Pharmaceutical List, the PSRC determined to issue a remedial notice. This was to allow the Appellant a final opportunity to demonstrate that it had enacted the No Significant Change Relocation as granted (and so was fulfilling its Terms of Service) by virtue of undertaking the actions set out. This is set out in the letter dated 7th August 2020 from NHSE&I to the Appellant (Appendix G).

3.2.52 As Boots UK Ltd chose to appeal the issuing of this remedial notice, to date, NHSE&I understands that Boots UK Ltd awaits the outcome of this appeal before any action will be taken in this respect.

3.2.53 **Response to appeal submissions**

3.2.54 It is noted from the appeal submissions that there is heavy reliance on financial statements showing that the Appellant has been paid for the services provided from 33-35 Market Street since February 2020. NHSE&I would address this by advising that, as part of the required administrative process following a No Significant Change Relocation, the contractor and ODS code must transfer to the new site; and NHSE&I is responsible for administering this change.

3.2.55 Therefore all the financial statements evidence is that NHSE&I followed the required process to assign the contractor and ODS code formerly at 21 Clarendon Street to the new site at 33-35 Market Street, and this was undertaken in good faith by NHSE&I on the basis that the Appellant enacted the No Significant Change Relocation as per the declarations it had made in the application. It is apparent that all that has relocated to 33- 35 Market Street is the Appellant's ODS code, which appears to have enabled The Hub Pharmacy Ltd to continue provision of NHS pharmaceutical provision at the site. Even if the Appellant had wanted The Hub Pharmacy Ltd to be paid direct for the services it is currently providing under the "Management Agreement", the Appellant will be aware that NHSE&I would not have facilitated such a request, as The Hub Pharmacy Ltd no longer has an entry on the Pharmaceutical List at this address and as a result is not allowed to provide (nor receive payment for) any NHS pharmaceutical services. The fact that NHSE&I have continued to pay the Appellant for NHS pharmaceutical service provision in good faith, whilst this matter is resolved is not an indication that they are delivering NHS pharmaceutical service provision or conducting retail pharmacy business. The issue in this case is that NHSE&I believe that The Hub Pharmacy Ltd is wrongly using this ODS code when it is not entitled to do so and that the Appellant is permitting this, while not actually providing any services from this pharmacy itself. NHSE&I do not dispute that items have been dispensed and paid for. Should the removal of the Appellant at the above site be actioned, the recovery of monies paid since the purported relocation will be considered.

3.2.56 With respect to the SOPs being utilised at 33-35 Market Street, as this is a No Significant Change Relocation; it is expected and usual practice for the current SOPs to continue to be used and adapted as required for the new premises. In this particular matter it would have been the Appellant continuing to utilise the Appellant's SOPs. However, during the initial review with Ms S Mody, it was made clear that the Appellant would be using the Hub Pharmacy SOPs following the relocation. The reason cited was patient safety, as the Hub Pharmacy Ltd were to continue to deliver the NHS pharmaceutical services and it would not be possible for them to learn the Appellant's SOPs before relocation. Also, it was brought to the attention of NHSE&I that the Hub Pharmacy Ltd would continue the retail pharmacy business at the site and therefore should not be expected to follow different SOPs for provision of non-NHS and NHS services.

- 3.2.57 NHSE&I do not accept as appropriate a pharmacy contractor utilising the SOPs of another legal entity for the provision of NHS pharmaceutical services. Whilst NHSE&I does not consider the Hub Pharmacy Ltd SOPs to be inappropriate themselves, it is not appropriate for a contractor to utilise the SOPs of another legal entity. NHSE&I has previously challenged this with other contractors and they have been required to amend SOPs to demonstrate that they are those of the legal entity listed on the pharmaceutical list.
- 3.2.58 Whilst NHSE&I acknowledge that the Appellant's Superintendent Pharmacist has reviewed and agreed to the use of the Hub Pharmacy Ltd SOPs; this is not the same as "buying SOPs off the shelf"; as the Appellant has indicated in their appeal. In the circumstances whereby a pharmacy procures a template set of SOPs, these will be individually signed by the Superintendent Pharmacist and branded as the contractor's SOPs. NHSE&I are not aware of or seen evidence of the Appellant branding a version of The Hub Pharmacy Ltd's SOPs for use at 33-35 Market Street.
- 3.2.59 The fact that the Appellant is utilising another legal entity's SOPs and that they have not utilised the standard Boots UK Ltd SOPs following relocation gives further weight to concerns that The Hub Pharmacy Ltd is delivering NHS pharmaceutical services and not the Appellant. Also, the fact that the Appellant has had to utilise The Hub Pharmacy Ltd SOPs also supports the NHSE&I view that their "management arrangement" is not the same as simply engaging staff or a locum pharmacist.
- 3.2.60 In response to the Appellant's comments regarding IT systems, NHSE&I's main concern is that in the absence of relating the systems the Appellant used at 21 Clarendon Street to 33-35 Market Street, and in particular following the misleading information previously provided to patients by both Boots UK Ltd and The Hub Pharmacy Ltd, there have been no assurances that (a) the patient information for Boots UK Ltd, 21 Clarendon Street has been transferred onto this system as part of the No Significant Change Relocation process; and (b) that the Appellant is not accessing patient information which previously belonged to The Hub Pharmacy Ltd; as there is no facility which allows the bulk transfer of patients from one contractor to another without individual patients' explicit consent. The Appellant Ltd has highlighted perceived challenges in moving an IT system from one site to another; yet this is routine practice in respect of No Significant Change Relocations. NHSE&I has not been given any assurances that patients have been made aware by the Appellant that when accessing services from this site their data is being freely accessed and processed by a separate legal entity. It is also unclear as to whether patients have specifically given informed consent for this arrangement. If a patient accesses NHS pharmaceutical services from an organisation it is reasonable for them to expect only that entity to access and process their data.
- 3.2.61 It was also noted that in the responses given to NHSE&I by the Appellant regarding moving the IT system and utilising this at 33-35 Market, post relocation that this would be "prohibitive". This was most surprising to NHSE&I, as the usual and routine process for no significant change relocations would be for the contractor to move the pharmacy team, branding, procedures, stock and IT systems to the new premises. This was not a Change of Ownership and it is very unclear as to why it would be prohibitive for the Appellant to move and operate the existing IT system to the new premises; as reasonably expected to do so.
- 3.2.62 The fact that the Appellant is not utilising its own IT system or own SOPs, gives further evidence, when taken together with all the available information about this pharmacy, to demonstrate that they are not delivering NHS pharmaceutical services. Also, the fact the Appellant is using another legal entity's SOPs and

IT system support the NHSE&I view that they are not demonstrating an acceptable system of clinical governance.

- 3.2.63 As part of its appeal response, the Appellant has provided a copy of the signage it states is presently being displayed at 33-35 Market Street. The signage reads: *“All NHS Pharmaceutical Services from this pharmacy are being provided by Boots UK Limited via a Management Agreement with Hub Pharmacy Limited. This will continue until the Change of Ownership application is granted by the NHS. Please speak to the pharmacist with any queries.”* NHSE&I considers that the wording has been written in such a way as to lead patients to believe that the Appellant is providing services on behalf of The Hub Pharmacy Ltd, rather than the other way around. The reference to the Change of Ownership will mean little to patients and it is not clear why this has been referred to at all. Also, there is no automatic guarantee that the application to change the ownership would be granted. NHSE&I simply required Boots UK Ltd to make it clear to patients from whom they were receiving NHS pharmaceutical services, thus enabling patients to make an informed choice regarding where they access NHS pharmaceutical services from.
- 3.2.64 Disappointingly the Appellant openly admits in its appeal letter that what it wished to do in terms of its business agreement with The Hub Pharmacy Ltd was not permissible within the Regulations, and so it took the decision to circumvent the Regulations in order to achieve its desired outcome. The actions the Appellant has taken do not correspond with the declarations made in its No Significant Change Relocation application; and it is now clear from the appeal that it was never the Appellant’s intention to comply with the requirements of a No Significant Change Relocation application despite making declarations suggesting that it was. Effectively, the Appellant has not completed a no significant change relocation as per the grant. In reality it is merely the location of the ODS code, to facilitate a commercial arrangement for The Hub Pharmacy Ltd to divest itself of the requirement to operate for 100 hours a week or more. NHSE&I has already explained that it does not consider this approach to be permitted under the existing legislative framework and why it would be problematic to permit it.
- 3.2.65 The Appellant states that The Hub Pharmacy Ltd is the registered premises owner with the GPhC and “carrying on the retail pharmacy business” in its appeal. The Appellant also states that it is not in breach of Regulation 74.–(1)(b). However, it appears to have misunderstood the context of this regulation. NHSE&I has never stated that it is in breach of the regulation, as it cannot be breached as such. However, the criteria does apply in this case.
- 3.2.66 The Appellant is under the misapprehension that the fact it is a legal entity that has a number of GPhC registered pharmacy premises this would entitle it to hold a contract for NHS pharmaceutical service provision at GPhC pharmacy premises owned and operated by any other legal entity. It is clear that the Appellant is not carrying on a retail pharmacy business at 33-35 Market Street, emphasised by the statement in its own appeal. It ceased to conduct a retail pharmacy business at 21 Clarendon Street on 31st January 2020 and has not conducted a retail pharmacy business at 33-35 Market Street, despite their application for a relocation. The fact it has other GPhC listed premises is immaterial, the contractual relationship is at individual premises level via the ODS code. Therefore, the regulation applies and NHSE&I maintains that the Appellant would be liable for removal from the pharmaceutical list at the aforementioned premises. As outlined previously, the remedial notice was a final attempt to preserve NHS pharmaceutical service provision instead of seeking removal. It cannot be acceptable for the provider of NHS pharmaceutical services to differ from the GPhC registered premises owner and this poses a considerable clinical governance risk. NHSE&I has precedent for taking contractual action against contractors whereby the GPhC premises

is changed to a different legal entity, which has included consideration for removal.

- 3.2.67 It is noted that in the appeal the Appellant has made reference to email correspondence with Ms S Mody and stated that NHSE&I accepted management agreements occur. This has been taken and quoted out of context. The point was made that NHSE&I is aware management agreements are used during a Change of Ownership process. However, they are not sanctioned nor approved, and NHSE&I will not usually be aware that they are in place. If NHSE&I does become aware of such agreements it is made clear that the outgoing contractor is responsible for all NHS pharmaceutical service delivery until the application is approved and a valid NOC from the incoming contractor is accepted. The pharmacy must also appear and operate as the outgoing contractor until the process is complete. There is precedent whereby NHSE&I have taken contractual action against contractors who have rebranded pharmacy premises and changed GPhC premises registration during these periods and have been required to revert to the outgoing contractor. In this particular matter the Appellant is not using a management agreement in that context, but to operate the premises as a legal entity which is not listed on the pharmaceutical list. The fact that NHSE&I is aware that such arrangements may exist does not mean that they are agreed, accepted or condoned.
- 3.2.68 It is also noted that the Appellant is asserting that engaging The Hub Pharmacy Ltd to deliver NHS pharmaceutical services on its behalf is no different than employing a locum pharmacist or staff. NHSE&I considers this not to be the case, as it is not The Hub Pharmacy Ltd providing staff to operate a Boots UK Ltd; more that the Appellant have wholesale subcontracted all NHS pharmaceutical service provision (or even are just allowing another entity to use their ODS code). This type of arrangement is not permitted in the Regulations. The Appellant appears to be under the misapprehension that if something is not specifically prohibited in the Regulations, then it is permitted. However, NHSE&I would submit that the Regulations provide a very clear and specific legal framework for the provision of NHS pharmaceutical services. If something is not specifically permitted, then NHSE&I's understanding is that there is no intention for it to form part of that framework. NHSE&I consider that as a minimum any sub-contracting would only be permissible if in agreement with NHSE&I, if it is possible at all.
- 3.2.69 Based on all available information, NHSE&I maintains that the Appellant is in breach of the Terms of Service in their entirety. This is on the basis that it cannot be considered to be carrying out a retail pharmacy business or providing any NHS pharmaceutical services from the point it purported to relocate to 33 – 35 Market Street from Clarendon Street, when you consider all of the evidence and reasoning set out in NHSE&I's submissions. The Appellant itself has confirmed that The Hub Pharmacy Ltd is operating from that site, providing NHS services in place of the Appellant, which it is not entitled to do as The Hub Pharmacy Ltd is no longer included in the Tameside HWB Pharmaceutical List.
- 3.2.70 This appeal appears to concern the validity of the remedial notice issued. NHSE&I wishes to clarify that the remedial notice was served in relation to a breach of Schedule 4 Terms of Service, due to a complete failure to provide any services at all. It was not served, as alleged by the Appellant, in reliance on any "breach" of regulation 74(1)(b) (see Appendix G – remedial notice).
- 3.2.71 Whilst NHSE&I had initially considered a removal, it has explained why it felt it preferable to pursue a breach instead, in the hope of resolving the situation and maintaining services. Whilst NHSE&I considers that it was correct to

consider removal, this is not the issue under appeal as NHSE&I did not progress to any such removal.

- 3.2.72 The validity of the remedial notice is therefore determined by whether there has been a breach of Schedule 4 Terms of Service. In its submissions, the Appellant has selected a few specific provisions of the Terms of Service to comment on. NHSE&I's submission is that a complete failure by the Appellant to provide any services at all from the Market Street premises amounts to a fundamental breach of the Terms of Service generally. For example, the Appellant has not provided any dispensing, the Appellant has not opened for its contracted hours, the Appellant has not put in place an acceptable system of clinical governance.
- 3.2.73 NHSE&I remain fully satisfied that there is sufficient evidence that the Appellant ceased to provide services at the point of "relocation". Instead, it closed down its Clarendon Street pharmacy and has not provided any services at all from the Market Street premises. It has allowed The Hub Pharmacy Ltd to use its ODS code at those premises, despite change of ownership to The Hub Pharmacy Ltd not having taken place.
- 3.2.74 As regards the remedial steps set out, NHSE&I also considers those appropriate in the circumstances. NHSE&I has explained why the lack of GPhC registration on the part of the Appellant at this pharmacy is not feasible. As regards SOPs, IT and communications, NHSE&I considers these steps to be reasonable given the overall context of the Appellant appearing to have no real involvement or control at this site currently, and in the context of usual practice on relocation as explained above.
- 3.2.75 It is also appropriate to ask the Appellant to confirm that The Hub Pharmacy Ltd is no longer providing NHS pharmaceutical services, given that it is only the Appellant that is permitted to provide those services.
- 3.2.76 The Appellant has asked NHS Resolution to determine particular questions. However, those questions do not appear to correctly reflect the facts of the case or the issue of whether or not the remedial notice is valid:
- 3.2.76.1 Question 1 – is there a breach of regulation 74(1)(b)? NHSE&I has noted above that it does not consider this capable of breach and this was not alleged by NHSE&I;
- 3.2.76.2 Question 2 – NHSE&I does not follow this question given that regulation 74(1)(b) cannot be breached and NHSE&I has not relied on any such breach;
- 3.2.76.3 Question 3 – it does not follow that the appeal should be allowed where there is no breach of regulation 74(1)(b), for the same reasons;
- 3.2.76.4 Question 4 – similarly, NHSE&I does not follow this question, as the breach at issue is a breach of Schedule 4.
- 3.2.77 As a result, NHSE&I submits that the remedial notice should not be considered invalid on the basis of the particular questions put forward by the Appellant for determination.
- 3.2.78 NHSE&I therefore believes that the action taken in respect of issuing a remedial breach notice which clearly sets out the actions required in order to remedy the breach (a copy of which the Appellant provided as part of its appeal) is entirely justifiable and proportionate, and that it would not be appropriate to allow such a significant breach to continue. NHSE&I has set out why we consider there to be significant risks and gaps in regulation if this

arrangement is permitted. It is essential that NHSE&I is able to verify who is providing services and is able to take contractual action where needed, in line with the existing legislation. NHSE&I does not consider that this can be achieved if this arrangement is permitted. NHSE&I therefore respectfully request that Primary Care Appeals upholds the remedial notice in this case.

4 Observations

4.1 NHSE&I

4.1.1 **Remedial Notice**

4.1.2 NHSE&I wish to rebut the Appellant's assertions in the letter dated 22 September 2020 and would emphasise that in engaging another legal entity to deliver all NHS pharmaceutical service provision; Boots UK Ltd has ceased all NHS pharmaceutical service provision.

4.1.3 In cessation of all NHS pharmaceutical service position, the Appellant is in breach of all aspects of schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended).

4.1.4 The Hub Pharmacy Ltd has delivered all NHS pharmaceutical services since the Appellant relocated to 33 – 35 Market Street and remained the GPhC registered pharmacy premises owner.

4.1.5 **The Appellant is on the Pharmaceutical List at 33 – 35 Market Street**

4.1.6 Following the grant of the no significant relocation application, the Appellant submitted a Notice of Commencement (NOC); which was accepted as valid by NHSE&I. Therefore, the entry for Boots UK Ltd at 21 Clarendon Street, on the Pharmaceutical List for the Tameside Health and Wellbeing Board area was amended to 33 – 35 Market Street; with effect from 1 February 2020.

4.1.7 As detailed in NHSE&I's letter of 16 October 2020, NHSE&I attempted local dispute resolution efforts with the Appellant and followed due regulatory process to address the contractual concerns. This led to the consideration for removal of the premises at 33 – 35 Market Street from the Pharmaceutical List for the Tameside Health and Wellbeing Board area. Resulting in the PSRC making a determination to issue a remedial notice in final attempt to correct the contractual concerns; whilst preserving the NHS pharmaceutical service delivery.

4.1.8 Therefore, the fact that the Appellant at 33 – 35 Market Street has remained on the Pharmaceutical List for the Tameside Health and Wellbeing Board area is owing to NHSE&I having followed due process. It would not have been appropriate to simply remove the Appellant at 33 – 35 Market Street from the Pharmaceutical List for the Tameside Health and Wellbeing Board area. The fact that Boots, the Appellant, at 33 – 35 remains on the Pharmaceutical List is not evidence of continued NHS pharmaceutical service provision.

4.1.9 **The Appellant continues to provide pharmaceutical services from 33 – 35 Market Street**

4.1.10 As outlined above, set out in detail in our letter of 16 October 2020 and their own admission, Boots UK Ltd has engaged The Hub Pharmacy Ltd to provide all NHS pharmaceutical services. This includes the use of The Hub Pharmacy Ltd SOPs and IT system to delivery all NHS pharmaceutical services. Also, Boots UK Ltd does not have any pharmacy premises listing with the GPhC at 33 – 35 Market Street, so would not be able to deliver pharmacy services. It is The Hub Pharmacy Ltd which is the GPhC registered premises owners and

the legal entity carrying out a retail pharmacy business at 33 – 35 Market Street.

- 4.1.11 Boots UK Ltd has not provided any pharmaceutical services (NHS or private) since the relocation from 21 Clarendon Street to 33 – 35 Market Street on 1 February 2020.
- 4.1.12 **The Appellant is been paid (sic) for the delivery of NHS pharmaceutical services**
- 4.1.13 The Appellant has submitted that it has continued to be paid by NHSE&I for the provision of NHS pharmaceutical services since relocation to 33 – 35 Market Street. Providing copies of payment schedules from the NHSBSA as supporting evidence.
- 4.1.14 NHSE&I has paid the Appellant for NHS pharmaceutical service provision in good faith since the relocation to 33 – 35 Market Street; as claims were submitted by the Appellant via the allotted ODS code (FWP95). As previously outlined, NHSE&I followed a process of local dispute resolution and then a formal contractual process via the PSRC, which included consideration of removal of the premises from the pharmaceutical list. It was not considered proportionate during the due process to withhold payments at this stage. However, recovery of payments made in respect of provision of NHS pharmaceutical services at 33 -35 Market Street by the Appellant could be considered should further contractual action be required.
- 4.1.15 Therefore, the fact that the Appellant has been paid by NHSE&I in good faith is not in itself evidence of continued NHS pharmaceutical service provision.
- 4.1.16 **Additional evidence that The Hub Pharmacy Ltd is operating the site and providing NHS pharmaceutical services at 33 – 35 Market Street**
- 4.1.17 Additional evidence has come to the attention of NHSE&I in Greater Manchester that the pharmacy is operated by and NHS pharmaceutical services delivered by The Hub Pharmacy Ltd.
- 4.1.18 An email trail regarding waste medicines collections from the Appellant, since relocation to 33 – 35 Market Street; includes an email from the Boots UK Ltd premises specific NHSmail shared mailbox on 10 March 2020 and a further email from the Hub Pharmacy Ltd central team office on 26 March 2020.
- 4.1.19 The email of 10 March 2020 states that the pharmacy has moved address and is branded as the Hub Pharmacy. This is in contradiction to the Appellant's previous notification that the pharmacy is trading as Market Street Pharmacy; whereby it is expected to operate as a Boots UK Ltd pharmacy and branded as Market Street Pharmacy.
- 4.1.20 The email of 26 March 2020 has been by The Hub Pharmacy Ltd central office team and demonstrates that it is they operating the pharmacy and providing NHS pharmaceutical services as they are attempting to engage the NHSE&I team on matters pertaining to NHS pharmaceutical services.
- 4.1.21 NHSE&I would highlight that these two emails provide additional evidence that it is in fact The Hub Pharmacy Ltd is providing NHS pharmaceutical services and it is a Hub Pharmacy as opposed to a Boots UK Ltd pharmacy. This further supports NHSE&I's assertion that the Appellant has ceased NHS pharmaceutical service provision since the relocation to 33 -35 Market Street. The two emails have been copied below for information. Ms T Thewlis is a member of the Greater Manchester NHSE&I Pharmacy team and leads on

waste medication collection queries, and “Gmtop” - england.gmtop@nhs.net - is the generic email box for the team.

4.2 THE APPELLANT

4.2.1 References in this letter to the “Regulations” mean The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (as amended).

4.2.2 Nature of the appeal

4.2.3 The Appellant notes that Greater Manchester NHS (“NHSE”) has stated that the matter to be determined is not whether the Remedial Notice was valid, but whether the Appellant has in fact failed to provide any pharmaceutical services under the Terms of Service at 33-35 Market Street, Hyde, SK14 2AD and that NHSE now claims to have in fact issued its Remedial Notice “due to a complete failure to provide any services at all” rather than in relation to Regulation 74(1)(b).

4.2.4 With regards to this, Primary Care Appeals should note that:

4.2.4.1 the 6 February 2020 letter from NHSE specifically stated that the Appellant had “ceased to carry on a retail pharmacy business” i.e. it used the precise language found in Regulation 74(1)(b);

4.2.4.2 the cover letter sent by NHSE dated 7 August 2020 (the subject of this appeal) states:

“Consequently, the PSRC has considered removal pursuant to Part 10, regulation 74(1)(b) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, which provides for removal where an NHS pharmacist ceases to carry on a retail pharmacy business. This is on the basis that Boots UK Ltd ceased to carry on a retail pharmacy business when it relocated from 19-21 Clarendon Street, Hyde SK14 2EL to the above address.

The PSRC has concluded that Boots UK Ltd did cease to carry on a retail pharmacy business on the relocation date and since then has provided no services from the Market Street Pharmacy site.”

4.2.5 Now, however, at para [3.2.76.1] of NHSE’s reply to its appeal, it says that a breach of Regulation 74(1)(b) “was not alleged by NHSE&I”.

4.2.6 As NHSE is no longer alleging that that any breach of Regulation 74(1)(b) occurred or that Regulation 74(1)(b) applies in this case, the Appellant trusts that this will be acknowledged when the Committee considers this appeal. The Appellant does acknowledge that technically a contractor would not be “in breach” of Regulation 74(1)(b) and the question would be whether Regulation 74(1)(b) applied to any particular set of circumstances. For the avoidance of doubt, Regulation 74(1)(b) does not apply for the reasons already given in the Appellant’s letter of appeal.

4.2.7 The central question is “has Boots been providing NHS pharmaceutical services at the relevant premises since it relocated?”, to which the answer is clearly yes for the reasons set out in the Appellant’s letter of 2 September 2020.

4.2.8 The argument now put forward by NHSE appears largely to be centred around the optics of how the relocation was carried out rather than any legal basis for claiming any breach of the Terms of Service. It is necessary to respond briefly to the points made.

Overview

- 4.2.9 As explained in the Appellant's 2 September letter, the Appellant is providing pharmaceutical services in accordance with the Terms of Service and is, and remains, responsible under the legislation. The mechanism through which the Appellant is providing the services is by entering into a contract for services, known as a Management Agreement, with its agent Hub Pharmacy Limited. Hub Pharmacy Limited is responsible (amongst other things) for maintaining a properly registered premises with the General Pharmaceutical Council ("GPhC"). The requirement under the Regulations is for pharmaceutical services to be provided from premises that are registered with the GPhC. There is no provision, whether in the Regulations or elsewhere, which states in terms that the entity who holds the pharmaceutical list entry must be the person who holds GPhC entry. Whilst this will often be the case, the two are clearly separate, regulated under different legal frameworks and by different bodies.

Management Agreements

- 4.2.10 NHSE's position appears to be that the use of a Management Agreement is "not recognised" under the Regulations and that, because of this, the Appellant cannot have been providing any pharmaceutical services. It is the Appellant's position that NHSE's recognition of arrangements made with a third party for the purposes of providing services is not the issue. The issue is whether such an arrangement is prohibited by the regulatory scheme and the Appellant's view is that it is not prohibited.
- 4.2.11 First, and as a matter of practice, the Committee will be aware that there are a range of circumstances under which pharmaceutical services are provided with the support of a third party.
- 4.2.12 Second, as previously noted in the Appellant's letter of appeal, this is expressly envisaged in Schedule 4 of the Regulations which deal with the Terms of Service. Paragraph 1(1)(b)(ii) of that Schedule provides that where the NHS pharmacist is not a natural person, it must secure compliance with those requirements which can only be carried out a natural person by those it "employs or engages in connection with the provision of pharmaceutical services". This is a very broad provision: the Regulations themselves (at Regulation 2) define "staff" as including "locums and other persons engaged on contracts **for** services" (the Appellant's emphasis), and "employment" as including "employment under a contract **for** services" (my emphasis). Schedule 4 Paragraph 1 of the Regulations is widely drafted and can clearly include an agreement between two parties that allows the body corporate, here Boots, to engage others via a contractual arrangement, here the Management Agreement.
- 4.2.13 Third, as Lord Justice Stuart Smith said in *Family Health Services Appeal Authority, ex parte Elmfield Drugs Ltd and others* - 46 BMLR 191 at paragraph 11:
- 4.2.13.1 *"It is a general principle of the law that, in the absence of any rule or express provision to the contrary, a natural person can act by his servants or agents. A corporate person can only act by its servants or agents. In Chitty on Contracts (27th edn, 1994) vol 2, para 31-001 it is stated: 'It is sometimes said that prima facie what a person can do himself he can do by an agent; but this is not always so.' In relation to statutory interpretation the footnote indicates 'Where the statute is silent, the normal implication is that, in the absence of other indications, the basic rule permitting acts by an agent applies.'"*

- 4.2.14 This quote continues to appear in the current (33rd edition) of Chitty on Contracts.
- 4.2.15 Far from the Regulations having any express rule or provision to the contrary, they envisage such arrangements being made with persons who may not be directly employed by the relevant pharmacy. Accordingly, the Appellant is fulfilling its obligations via its servants or agents – the terms between them being contained in the Management Agreement.
- 4.2.16 Whilst NHSE may not like certain commercial arrangements, it does appear to accept that third party organisations may provide pharmaceutical services on behalf of a pharmaceutical list holder: see page 45 of the NHSE response to the Appellant’s appeal, the email dated 11 February 2020 from NHSE to Boots in which Mr Riley of NHSE stated:
- 4.2.16.1 *“Also, in this instance as Boots UK is utilising a third party organisation to deliver all pharmaceutical services the flyer should make it clear that NHS pharmaceutical services are commissioned from Boots UK Ltd and how patients can complain to Boots UK Ltd, as per your practice leaflet.”*
- 4.2.17 As the Committee will note, there was a lengthy exchange of correspondence between NHSE and the Appellant to try to ensure that the exact wording / signage etc. was provided to satisfy NHSE that the correct process was followed.
- 4.2.18 The position adopted by NHSE on the issue of Management Agreements is, however, muddled. As can be seen from its reply to the appeal, it acknowledges the use of Management Agreements (as they are often used pending final approval of a Change of Ownership application) but say that it does not accept them. As to the comments made about “precedent” in other cases (para. [3.2.67]), this should be given no weight. Faced with a refusal to process change of ownership application or the withholding of some other vital permission by NHSE, it is the Appellant’s understanding that applicants may simply agree to take specific steps even if they believe that they are unwarranted on the basis that it is the quickest way to reach the desired end result.
- 4.2.19 Accordingly, the submission that the use of Management Agreements is unlawful or ‘not supported’ by the Regulations is simply wrong. The Court of Appeal decision puts an end to the claim made by NHSE that Boots cannot have been providing pharmaceutical services by engaging Hub Pharmacy via a Management Agreement as an agent.
- 4.2.20 Notwithstanding the above, there are a number of inaccuracies in NHSE’s response to the appeal that the Appellant feels obliged to address specifically in this reply.

Additional Responses

- 4.2.21 In relation to paragraph 1.2 of NHSE’s submission, The Hub Pharmacy Ltd gave notice under Regulation 67(2)(b)(i) of the Regulations. This is not a notice to “permanently close” as claimed by NHSE. The words “permanently close” are not found anywhere in the Regulations. Further, and notwithstanding the title of that Regulation, it is clear from the terms of Regulation 67(1) that a notice represents a wish to withdraw from a pharmaceutical list or for particular premises no longer to be listed. Such a notice would be necessary if the NHS premises was permanently closing but the reverse is not true.

- 4.2.22 Section 3 of NHSE's submission sets out various matters relating to the optics of the relocation. At all times, the Appellant has operated to try to avoid any confusion for patients. For example, patients would normally expect a Boots store to sell Boots own brand products and the Appellant provided a notice to let patients know where such a store would be located. The Appellant fully accepts that a more technical and legal position could have been set out in its notice, but there is already a difference of opinion (at paragraph [3.2.63] of NHSE's document) on whether the notice is clear – the Appellant considers the notice makes it absolutely clear to customers that Boots is providing NHS pharmaceutical services and a longer, more technical and legal, notice is likely to be ignored by customers.
- 4.2.23 The main substantive thread running through NHSE's submission essentially relates to its perceived inability to regulate this type of arrangement and the potential impact on patient safety (see paragraph [3.2.30]). As set out below, this is unfounded.
- 4.2.24 The Appellant's Superintendent Pharmacist is responsible for all actions in the Appellant's pharmacies and, as was explicitly confirmed to NHSE, has approved the operational procedures being used at the 33-35 Market Street pharmacy. See the Appellant's email to NHSE of 4 February 2020 at page 53 of NHSE's submission which states:
- 4.2.24.1 *"I can confirm that Boots has reviewed the Hub SOPs, confirmed any required changes, considers them appropriate and takes responsibility for their use"*
- 4.2.25 This was then followed up with a specific email from the Appellant's Superintendent Pharmacist on 6 February 2020 (noted in the email from Boots on page 50 of NHSE's document and annexed to this letter) which stated:
- 4.2.25.1 *"I am content that the Hub SOPs are appropriate, subject to amendments agreed, for use in delivering NHS pharmaceutical services by Boots UK Ltd at the Market Street Pharmacy in Hyde."*
- 4.2.26 The procedures are followed by the Appellant's agent, Hub Pharmacy Limited, in accordance with the Appellant's contract with them.
- 4.2.27 It is the Appellant that is on the pharmaceutical list and the Appellant which has an obligation to provide NHS pharmaceutical services to patients. The Appellant has responsibility and accountability to NHSE as it is the pharmacy contractor. The Appellant controls the actions of its agent in delivering NHS pharmaceutical services via the Management Agreement. This must not be confused with the GPhC requirements.
- 4.2.28 The Appellant is the contracting party with the NHS and delivers the contracted services via Hub Pharmacy who operate a GPhC registered pharmacy. Contrary to NHSE's submissions, there has been a closure (in the sense set out in Regulation 67) and a relocation of the Appellant's NHS contract to the Market Street site. The final part of the transaction, which has not yet happened because NHSE is refusing to consider it, relates to the change of ownership. As the Committee will be aware, subject to Regulation 31, the Regulations do not prohibit one NHS contract closing and another NHS contract relocating to the premises previously occupied by the closing pharmacy and subsequently applying for a change of ownership. That is what has happened in this case, albeit NHSE has yet to consider the Change of Ownership application.
- 4.2.29 The Appellant agrees with NHSE that there is a clear regulatory framework that exists to ensure appropriate standards and patient safety. However, the Appellant rejects entirely any suggestion that appropriate standards have not

been maintained or that patient safety has been in any way compromised. NHSE has not identified a single patient safety issue. Nor can NHSE identify any standard that has not been met. NHSE has both the right and the responsibility to ensure standards are met and safety is maintained, and there is a clear line of responsibility from NHSE to the Appellant as the Appellant is on the pharmaceutical list for the relevant premises. It is unclear what NHSE considers it cannot do as a result of the arrangement.

4.2.30 Similarly, whilst NHSE talks about its concerns in respect of the GPhC entry, it must be remembered that the GPhC is the regulator for all pharmacies in Great Britain. The GPhC issues and enforces its own standards. Paragraph [3.2.32] demonstrates a misunderstanding of the position in this case where it says:

4.2.30.1 *“It cannot be acceptable within the scheme of 2013 Regulations and NHS Act 2006 for anyone (in this case The Hub Pharmacy Ltd) to provide NHS pharmaceutical services without being on the NHS pharmaceutical list.”*

4.2.31 It is the Appellant that is on the pharmaceutical list at 33-35 Market Street, Hyde and, therefore, it is the Appellant that must provide the NHS pharmaceutical services and it is the Appellant that is responsible for meeting the Terms of Service. In this particular instance, the Appellant has done so by entering into a contract for services, known as a Management Agreement, with Hub Pharmacy Limited as an agent. Hub Pharmacy Limited is responsible (amongst other things) for maintaining a properly registered premises with the GPhC. The requirement under the Regulations is for NHS pharmaceutical services to be provided from premises that are registered with the GPhC. There is no express requirement that the GPhC entry should match the entry on the pharmaceutical list and there is no policy imperative that would require such a requirement to be implied. Section 132(2) of the NHS Act 2006 does not mandate a different view. NHSE has failed to quote the opening words of that section, which provide: “Except as may be provided for by or under regulations...” and it is therefore the Regulations that must be examined to determine if the relationship is lawful or not. The requirement under the Regulations is for NHS pharmaceutical services to be provided from premises that are registered with the GPhC which they are. Section 132 is clearly intended to ensure that all medicines are dispensed at registered pharmacy premises, by or under the supervision of a registered pharmacist – which they are and always have been in this case.

4.2.32 The Committee will note that an almost identical provision exists in s132(1) of the NHS Act 2006 which prohibits any arrangements being made with a medical practitioner (or dental practitioner) to provide pharmaceutical services. However, as the Committee will be aware, the relevant Regulations do then provide a mechanism for exactly such arrangements to be made with Schedule 6 of the Regulations setting out the ‘Terms of service of dispensing doctors’.

4.2.33 The comments in paragraphs [3.2.33 and 3.2.34] are further examples of NHSE failing to appreciate the law relating to a body corporate acting through its servants and agents.

4.2.34 At [3.2.35], NHSE states;

4.2.34.1 *“In the Boots UK Ltd application, they have named their own superintendent pharmacist in relation to the Market Street pharmacy upon relocation. However, we are not satisfied that their superintendent has any meaningful role in relation to this particular pharmacy, or any responsibility for its services.”*

- 4.2.35 The Appellant's superintendent pharmacist has responsibility for the operation of over 2,300 NHS pharmacies. As noted in [paragraphs 4.2.24 and 4.2.25], NHSE sought and received specific confirmation that the Appellant's superintendent pharmacist had reviewed and approved the operating procedures to be used to deliver NHS pharmaceutical services specifically at 33-35 Market Street, Hyde. It is unclear why NHSE remains unsatisfied despite this very specific confirmation. Any concern the NHS has with regards to the operation of any NHS pharmacy contract held by the Appellant should be raised with the Appellant.
- 4.2.36 At paragraphs [3.2.37 to 3.2.40] of NHSE's submission, it again confuses the GPhC entry with the pharmaceutical list entry. The GPhC carried out an unannounced inspection of the 33-35 Market Street premises on 31 January 2020, the last day of the operation of Hub Pharmacy's 100 hour contract. The GPhC found that all standards were met and its report is available on its website at:
- <https://inspections.pharmacyregulation.org/pharmacy/detail/market-street-pharmacy-1109406>.
- 4.2.37 Paragraph [3.2.38] of NHSE's submission again attempts to introduce the breach (or application) of Regulation 74(1)(b) by claiming that the Appellant has ceased to operate a retail pharmacy business, even though it is equally clear in its response that NHSE is not alleging that this has occurred.
- 4.2.38 Paragraphs [3.2.41 to 3.2.43] are, in effect, identical to the argument used in relation to NHSE original, and now withdrawn, claim that the Appellant is not "a person conducting a retail pharmacy business" when the Appellant clearly is such a person.
- 4.2.39 The remainder of section 5 of NHSE's submission deals with the issues of patient consent and GDPR. Throughout this process NHSE has demanded that every single patient was contacted to provide written consent for any change in their pharmacy nomination. NHSE's view now appears to be that no patient data should be accessed by Hub Pharmacy Ltd even though Hub Pharmacy Limited is acting as the Appellant's agent. In such circumstances, it is the Appellant's understanding that other grounds for processing data under Article 6 and Article 9 of GDPR apply and such consent is not required.
- 4.2.40 The Appellant does not believe that a line by line response to section 6 or section 7 of the NHSE's submission is required as most of it has been addressed already either here or in the Appellant's letter of 2 September, save to emphasise the following:
- 4.2.40.1 The Appellant rejects and denies NHSE's allegation that it sought to or "admits" to taking a "decision to circumvent the Regulations". On the contrary, the Appellant has operated and behaved lawfully at all times and at each stage of the process, and there has not been any pre-emption of the outcome (paragraph [3.2.46]);
- 4.2.40.2 it is denied that services which have been paid for have not been properly delivered and it is denied that monies paid are recoverable. The arrangement has gone on this long because of the delays by NHSE – the Change of Ownership application should have been processed by the NHS within a matter of weeks given the requirements of Regulation 26 have been met and there is no scope for discretion over those requirements by NHSE; and

4.2.40.3 regarding the complaints about IT systems and SOPs: as NHSE is aware, Boots already operate three different IT systems and there is no obligation to use any particular SOPs.

4.2.41 In summary, the Appellant is responsible for the delivery of NHS pharmaceutical services and has provided and continues to provide them in a proper and lawful manner.

5 Additional comments

- 5.1 NHS Resolution wrote to the parties on 11 January 2020 requesting additional information. The letter stated:
- 5.2 “We have been considering the parties’ submissions in respect of this appeal and any relevant provisions of the Regulations. The subject of this appeal is NHS England’s decision to issue a remedial notice, requiring Boots to take steps set out in the Remedial Notice, to satisfy NHS England that it is Boots that is providing NHS pharmaceutical services at the relevant premises and not the third party (Hub) appointed by Boots under the management agreement to support Boot’s delivery of the NHS pharmaceutical services.
- 5.3 We note the parties’ comments and the opposing views in relation to whether the provision of NHS pharmaceutical services can be undertaken by a person other than the person listed on the pharmaceutical list.
- 5.4 In order to assist us with a just and expedient consideration of this appeal, we are providing the parties to this appeal with an opportunity to provide further comments, explanation, evidence and or other details on the actual arrangements between Boots and Hub. The management agreement is referenced in the parties’ comments received to date and there is reference made by Boots to Hub acting as their agent. There is however little information provided on the extent of interaction between Boots and Hub in respect of the provision of NHS pharmaceutical services. We are providing the opportunity to provide explanation and comments on this point and similarly on the issue of the extent to which Boots has control over Hub in respect of the provision of NHS pharmaceutical services. We appreciate that NHS England may not know the details of the arrangements between Boots and Hub in detail. NHS England may make any comments it deems relevant and both parties will be given the chance to respond to the other party’s comments.”

Further representations

THE APPELLANT

- 5.5 On 15 January 2020 the Appellant provided the schedules to the management agreement, stating:
- 5.6 The Appellant notes that NHS Resolution is requesting representations from both the Appellant and NHSE&I on the Management Agreement referenced by the parties in this appeal. The Appellant also notes NHS Resolution’s comment that “NHS England may not know the details of the arrangements between Boots and Hub in detail” which is correct.
- 5.7 The Appellant believes it would be fairer for it to provide a copy of the Schedules to the Management Agreement (which are enclosed) so that these Schedules can be provided to NHSE&I. Then both the Appellant and NHSE&I can provide comments on this rather than NHSE&I waiting to first see the Appellant’s comments and then respond to them. The Appellant believes this would be fairer as it would then allow both parties to provide final comments in a more balanced way.

- 5.8 On 20 January 2020, the Appellant provided its further representations in respect of the request for additional comments.

Preliminary Points

- 5.9 As noted in the previous correspondence, the Schedules of the Management Agreement were extracted from a more substantive document agreed between the Appellant and Hub for the transfer of the NHS pharmacy contract. The main contract requires Hub to provide management services to the Appellant in accordance with the Schedules from the date of relocation of the Appellant's NHS pharmacy contract until the change of ownership is approved by NHSE&I.
- 5.10 As noted in the Appellant's correspondence dated 1 November 2020, provisions such as those contained in the Management Agreement are commonly utilised by NHS pharmacy contractors whilst waiting for a change of ownership to be processed by NHSE&I.
- 5.11 In NHS Resolution's letter of 11 January 2021, it states:

We note the parties' comments and the opposing views in relation to whether the provision of NHS pharmaceutical services can be undertaken by a person other than the person listed on the pharmaceutical list.

- 5.12 The Appellant wishes to reiterate that it has always been the Appellant that has provided the NHS pharmaceutical services, via a Management Agreement with Hub, rather than the NHS pharmaceutical services being "*undertaken by a person other than the person listed on the pharmaceutical list*". While the Appellant notes locums are included as "staff" under the NHS Pharmacy Regulations, the structure is not dissimilar, with a locum providing services to an NHS pharmacy contractor under agreed terms.

The Management Agreement

- 5.13 The Appellant provided a copy of the Schedules to the Management Agreement on 15 January 2021. As explained with regards to the suggested process of obtaining initial comments from both the Appellant and NHSE&I, the Appellant now makes the following comments regarding the Management Agreement.
- 5.14 The Management Agreement is in place to cover the period from the relocation of our NHS pharmacy contract until change of ownership is approved by NHS England. By its very nature, therefore, the Appellant determines how the pharmacy is managed under Schedule 1, the professional responsibilities under Schedule 2, and the pharmacist's obligations under Schedule 3. It is clear that the Appellant is the provider of the NHS pharmaceutical services, is responsible for them, and has control over the actions of Hub acting as its agent. The Appellant is responsible and accountable for the NHS pharmaceutical services provided at Market Street.
- 5.15 Whilst all parts of the agreement are relevant, the Committee should note that:

- 5.15.1 Across the Schedules to the Management Agreement, it is repeated that the NHS pharmacy contract is the Appellant's pharmacy contract and not that of Hub. See, for example:

5.15.1.1 "Interim Business" definition: refers to "Boots' NHS Pharmacy Contract"

5.15.1.2 "NHS Income" definition: refers to "amounts payable to Boots by NHS England ... in respect of services provided under Boots' NHS Pharmacy Contract"

5.15.1.3“Pharmaceutical Stock” definition: refers to “stocks of pharmaceutical products ... for dispensing pursuant to Boots’ NHS Pharmacy Contract”

5.15.1.4“Services” definition: refers to services provided by Hub “pursuant to Boots’ NHS Pharmacy Contract”

5.16 These defined terms are used throughout the Schedules.

5.16.1 Schedule 1 Clause 2.1: Hub is appointed as a manager and agent to the Appellant, not a provider in its own right.

5.16.2 Schedule 1 Clause 2.2: the provision of services must be in accordance with “the terms of Boots’ NHS Pharmacy Contract”.

5.16.3 Schedule 1 Clause 2.4: requires the placing of a notice that confirms that the NHS contract is the Appellant’s NHS Pharmacy Contract. Multiple notices were put in place and remain in place.

5.16.4 Schedule 1 Clause 3.1.8: places a requirement (which has been met) on Hub to be clear about its capacity as the agent of the Appellant in its dealings with others.

5.16.5 Schedule 1 Clause 3.1.13: allows the Appellant to request any information possessed by Hub in relation to the operation of the NHS contract. The Appellant currently receives monthly information updates from Hub. In addition, there is a wider provision in the main body of the Management Agreement giving the Appellant right of access to the Hub premises and to information.

5.16.6 Schedule 1 Clauses 3.1.15 and 3.1.16: places an obligation on Hub, as our agent, to keep the Appellant informed of any complaints or written notice or demand received. Other than these proceedings, no such complaint, notice or demand has been received.

5.16.7 Schedule 1 Clause 3.1.19: places an obligation on Hub, as the Appellant’s agent, to maintain and preserve records in respect of its NHS Pharmacy Contract during the Management Agreement and for a period of six years after.

5.16.8 Schedule 1 Clause 3.1.21: places a restriction on Hub, despite its appointment as the Appellant’s agent, that prohibits its ability to enter into contracts on behalf of the Appellant.

5.16.9 Schedule 1 Clause 3.1.22: requires Hub to have written permission from the Appellant for any capital expenditure or commitment.

5.16.10 Schedule 1 Clause 3.2: places significant responsibilities and liability on Hub for any failure or negligence in the conduct or operation of the Appellant’s NHS Pharmacy Contract. This strongly reinforces the position that this is the Appellant’s NHS pharmacy contract and not that of Hub.

5.16.11 Schedule 2: sets out the professional responsibilities of any pharmacist that works at the Market Street pharmacy and reiterates that services are provided “under Boots’ NHS Pharmacy Contract”, and requires adherence to “professional and regulatory requirements and standard operating procedures”, with the SOPs having been approved for use by the Appellant’s Chief Pharmacist.

5.16.12 Schedule 3: sets out further obligations on Hub, as the Appellant’s agent, including that it ensures the pharmacist: “conform[s] to and compl[ies] with the proper and reasonable directions of Boots in all material respects in relation to

Boots' NHS Pharmacy Contract". This provision makes it clear that it is the Appellant, and the Appellant alone, who can decide how the pharmacy operates "in all material respects" with regards to the NHS pharmacy contract.

- 5.17 NHS Resolution's letter also asks about "*the extent of interaction between Boots and Hub in respect of the provision of NHS pharmaceutical services*".
- 5.18 As has been demonstrated by the extensive correspondence and emails provided as part of this appeal, the Appellant has gone to great lengths to ensure that the provision of NHS pharmaceutical services at Market Street is in accordance with the legal, regulatory and professional requirements on it as the provider of NHS pharmaceutical services.
- 5.19 The purpose of entering into a Management Agreement is to ensure the Appellant has in place robust procedures for the delivery of NHS pharmaceutical service by Hub, acting as its agent. The Appellant is in regular contact with the Hub team and, in addition, there are obligations on Hub to notify the Appellant as soon as is "reasonably practicable" of any issues.

NHSE&I

- 5.20 NHS England and Improvement (NHSE&I) does not have specific details of the business agreement in place between the Appellant and The Hub Pharmacy Ltd. The Appellant has never offered to share the detailed content of any management agreement; nor has NHSE&I ever requested it. As previously stated in NHSE&I's representations, there is no provision within the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, (from this point forward referred to as "the Regulations") to permit the use of a management agreement to enable one contractor to subcontract NHS service provision to another legal entity. Therefore, the detailed content of any such business agreement would still not permit the current arrangement between The Hub Pharmacy Ltd and the Appellant.
- 5.21 NHSE&I wishes to take the opportunity however to provide the following further representations which are relevant to consideration of this appeal by NHS Resolution.
- 5.22 NHSE&I has, in its previous representations, set out in detail the nature of the breach and specifically why it believes that the Appellant has not operated NHS pharmaceutical services from 33-35 Market Street, Hyde SK14 2AD since the date of the relocation, nor does the Appellant hold pharmacy premises at this address. NHSE&I acknowledges that there is a limited number of prescribed circumstances that would enable a pharmacy contractor to operate services in lieu of another (i.e. Regulation 27: Applications for temporary listings arising out of suspensions, and Regulation 74: Removal of listings: cases relating to death, incapacity or cessation of service). However, the current arrangement between Boots UK Ltd and The Hub Pharmacy Ltd does not meet the requirements of the aforementioned Regulations.
- 5.23 In Schedule 4, Part 1, Responsibilities of NHS pharmacists and pharmacy staff it states:
- 1.—(1) To the extent that this Schedule imposes a requirement on an NHS pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—*
- (b)if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—*
- (i)where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or*

(ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.

5.24 During local dispute resolution processes, the Appellant has intimated that the arrangement they have in place with The Hub Pharmacy Ltd is the same as engaging suitable staff to meet the requirements stated above. However the use of a management agreement to wholesale subcontract all NHS pharmaceutical service provision to another legal entity is not the same as engaging or employing staff. The wording in the Regulations uses the terminology “employs or engages” to cover the direct employment of individuals in a business and engagement of locum pharmacists. This is not to enable a pharmacy contractor to engage another legal entity in its entirety. NHSE&I does not prescribe the exact arrangements by which a pharmacy contractor engages and employs individual staff, however the pharmacy should operate as one owned by the legal entity (listed pharmacy contractor). In this case, the pharmacy should appear and operate as a Boots UK Ltd regardless of any business agreement in place.

5.25 NHSE&I also considers that it is important to raise the following, additional points.

5.25.1 The Appellant’s website does not acknowledge the above pharmacy as being a Boots UK Ltd pharmacy as it is not returned as a result when a search is undertaken on postcode SK14 2AD using the Boots website store locator function. Screenshot provided below shows the results from the search:

5.25.2 [screen shot]

5.25.3 The pharmacy is listed by The Hub Pharmacy Ltd on its website as one of its own pharmacies. Furthermore the site contains a message to patients regarding the arrangements in place which are factually incorrect. This matter was in fact previously raised with both the Appellant and The Hub Pharmacy Ltd prior to the date on which the Appellant’s no significant change relocation was due to take effect. NHSE&I was given assurances by both the Appellant and The Hub Pharmacy Ltd that the messages being displayed would be amended to accurately convey to patients that The Hub Pharmacy Ltd was permanently closing, and that the Appellant’s pharmacy at 19-21 Clarendon Street was relocating onto the Hub pharmacy’s former site at 33-35 Market Street. However, the incorrect message remains live on The Hub Pharmacy Ltd website and can be seen in the second screenshot, highlighted yellow. The message indicates that the Appellant is providing services via a management agreement with The Hub Pharmacy Ltd until such time as a change of ownership is granted; rather than the opposite, which would be the case if the Appellant was in fact the contractor operating the pharmacy at this site. This message implies that The Hub Pharmacy Ltd is the contractor with the Appellant providing services on its behalf, which directly contradicts the Appellant’s description of the arrangement that is reportedly in place:

5.25.4 [screen shot]

5.25.5 This is also supported by the fact that the outward appearance of the pharmacy remains identical to that of The Hub Pharmacy Ltd, which permanently closed as an NHS pharmacy and was accordingly removed from the Tameside HWB Pharmaceutical List. There is nothing to indicate to patients that this is in fact the Appellant’s pharmacy which relocated from 19-21 Clarendon Street. Furthermore, The Hub Pharmacy Ltd poster displayed in the window of 33-35 Market Street is offering the NHS flu jab which is an advanced service. Screenshot below:

5.25.6 [screen shot]

5.25.7 The Appellant has never registered the pharmacy premises as a Boots UK Ltd pharmacy with the General Pharmaceutical Council (GPhC), and the premises registration continues to show the pharmacy owner as The Hub Pharmacy Ltd – screenshot below:

5.25.8 [screen shot]

5.26 The Appellant's pharmacy profile on the NHS Site has also not been updated, and continues to show the former address of 19-21 Clarendon Street.

5.27 Based on all available evidence it remains clear that the Appellant never intended to relocate its pharmacy from 19-21 Clarendon Street onto the site at 33-35 Market Street, and therefore did not enact the granted relocation. It is instead clear that to all intents and purposes The Hub Pharmacy Ltd has never in fact closed, and has been allowed by the Appellant to continue to operate as a Hub pharmacy under the Appellant's relocated ODS code as part of their management agreement (which NHSE&I once again reiterates it does not acknowledge as the Regulations do not recognise nor make provision for such an arrangement). Effectively, The Hub Pharmacy Ltd has continued to operate as a NHS pharmacy contractor by proxy at 33-35 Market Street.

5.28 From a patient perspective, it appears as though The Hub Pharmacy Ltd has remained open at 33-35 Market Street and simply reduced its operating hours. Furthermore, it is concerning to NHSE&I that there appears to have been an attempt to protect the patient base for The Hub Pharmacy Ltd in preparation for a future change of ownership while not affording patients of the relocating Appellant's pharmacy the same level of care and reassurance, in terms of ensuring correct information is published informing the Appellant's patients of the impact of the relocation and assuring that nothing would change for patients who wishes to remain with the Appellant.

Observations on request for comments

THE APPELLANT

5.29 The Appellant notes that, instead of responding to NHS Resolution's letter of 11 January 2021 requesting comments on the Management Agreement, NHSE&I has instead used it as an opportunity to provide new evidence. Whilst this does not further the case being made by NHSE&I, it should not be permitted to continue to raise new matters in this way. The Appellant feels obliged to correct the comments made and these are noted below.

5.30 In addition, the Appellant notes the comment from NHSE&I that the Appellant has not offered to share the detailed content of the Management Agreement nor has NHSE&I ever requested it. Until 15 January 2021, the Appellant had not shared the detail of the Management Agreement as it is the Appellant on the NHS pharmaceutical list and the Appellant responsible for providing NHS pharmaceutical services. It would not be routine for the Appellant to share details of arrangements with third parties that support it in its provision of services. The Appellant did, however, explain the structure of the Management Agreement during its exchanges with NHSE&I in January/February 2020.

5.31 As noted above, there are a number of points in NHSE&I's letter that need to be addressed:

5.31.1 In the Appellant's letter of 1 November 2020, it raised some key issues in this case which NHSE&I has not responded to, namely;

5.31.1.1 The judgment of Lord Justice Stuart Smith in Family Health Services Appeal Authority, ex parte Elmfield Drugs Ltd and others - 46 BMLR 191

5.31.1.1 permitting a body corporate to act through its servants or agents; and

5.31.1.1.2 stating that 'Where the statute is silent, the normal implication is that, in the absence of other indications, the basic rule permitting acts by an agent applies' therefore there is no requirement for the Regulations to "permit" Management Agreements.

5.31.1.2 that Management Agreements are often used by NHS pharmacy contractors during the Change of Ownership process and that NHSE&I acknowledges their use whilst, at the same time, attempting to argue that they are not lawful.

5.31.2 NHSE&I's interpretation of the terms relating to employment of staff does not appear consistent with the Regulations. "Employment" is specifically defined in the Regulations and includes "unpaid employment and employment under a contract for services". A Management Agreement is a contract for services.

5.31.3 NHSE&I states that "NHSE&I does not prescribe the exact arrangements by which a pharmacy contractor engages and employs individual staff", but then it seeks to do exactly that and comment on how a pharmacy should "appear".

5.31.4 The Market Street Pharmacy entry was removed from the Appellant's website and it is seeking to correct this error. An error on the Appellant's website does not obviate the remainder of the evidence.

5.31.5 Hub's website is correct. It very clearly states that the Appellant is providing the NHS pharmaceutical services and is doing so by way of a Management Agreement with Hub.

5.31.6 NHSE&I has no jurisdiction over the appearance of a pharmacy and there is no need to identify the previous location of a relocated NHS pharmacy. The signage on the door, in the pharmacy and on practice leaflets clearly states that it is the Appellant providing the NHS pharmaceutical services.

5.31.7 The Appellant did relocate its contract from 19-21 Clarendon Street to Market Street. The Appellant served the required Notice of Commencement and NHSE&I amended its NHS pharmaceutical list entry accordingly. The 'Consideration of Removal' notice issued by NHSE&I on 6 February 2020 was issued to the Appellant in respect of its NHS pharmacy contract held at Market Street.

5.31.8 If NHSE&I has any concerns about the "level of care" being provided to patients, then it should advise the Appellant directly and immediately. The Appellant has not received any complaints about the provision of NHS pharmaceutical services.

5.32 As requested in the Appellant's previous correspondence, for procedural fairness, it had hoped the parties would both be able to provide comments on the Management Agreement and then respond to any issues raised. The Appellant is now in a position of NHSE&I being able to make further comments again without any right of reply, clarification or explanation from the Appellant. The Appellant trusts that the matter will be dealt with fairly by NHS Resolution.

NHSE&I

5.33 NHS England and Improvement (NHSE&I), having now had sight of the management agreement provided by the Appellant, wishes to make the following observations.

- 5.34 Paragraph 1, Schedule 4 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, sets out responsibilities on “NHS pharmacists”. This term is defined in regulation 2 as “a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a)” and therefore in this case is the Appellant. Paragraph 1(1), Schedule 4 states that where schedule 4 imposes a requirement on the Appellant in respect of an activity which could only be carried out, or would normally, be undertaken by a natural person the Appellant “must secure compliance with that requirement by –
- 5.34.1 where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or
 - 5.34.2 in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.
- 5.35 Paragraph 1(2) states that where reference in Schedule 4 is made to an NHS pharmacist:
- 5.35.1 being the subject of any activity, and it is an activity to which a natural person could only, or would normally, be subject; or
 - 5.35.2 forming a view,
- that reference is to be construed as a referring, as appropriate, to the NHS pharmacist (if a natural person) or to the NHS pharmacist’s staff. As the Appellant is not a natural person this paragraph is referring to their staff which is defined within regulation 2 as including locums and other persons engaged on contracts for services who act as staff.
- 5.36 It is therefore clear that the Appellant can employ or engage registered pharmacists and natural persons in order to fulfil its terms of service as set out in Schedule 4 of the 2013 regulations. It does not, however, allow the Appellant to engage a body corporate to fulfil its terms of service as that is not a natural person.
- 5.37 Paragraph 8, Schedule 1 of the management agreement makes it clear that nothing in the agreement shall in any way be construed as constituting or creating a partnership or joint venture between the two bodies corporate or a relationship of employer and employee. As the Appellant can only engage natural persons, which The Hub Pharmacy Ltd is not, the management agreement does not fall within the provisions of paragraph 1, Schedule 4 of the 2013 regulations.
- 5.38 In its letter of 20th January 2021, the Appellant states that it notes locums are included in the definition of “staff” and that the structure that is in place with The Hub Pharmacy Ltd is not dissimilar, with a locum providing services to an NHS pharmacy contractor under agreed terms. For the reasons set out above the 2013 regulations do not permit the Appellant to employ or engage a body corporate. In addition, NHSE&I does not believe it would be normal practice for a locum to provide everything that is required of The Hub Pharmacy Ltd under the management agreement – premises, staff, equipment, stock etc.
- 5.39 In providing the schedules to the management agreement there is no indication of which provision within the 2013 regulations the Appellant is relying upon for the basis of its management agreement. Throughout the agreement there is reference to “the NHS Pharmacy Contract” however there is no contract in place with NHSE&I and the Appellant in relation to the provision of services at 33-35 Market Street, Hyde, Cheshire SK14 2AD. Instead, the Appellant and the premises are included in the pharmaceutical list for the area of Tameside Health and Wellbeing Board and permitted to provide NHS pharmaceutical services in line with Schedule 4 of the 2013 regulations. Whilst other primary care contracts include provision for a contractor to subcontract the provision of

clinical services where certain conditions are met, there are no such provisions within the 2013 regulations.

- 5.40 In previous correspondence NHSE&I has outlined specific circumstances and provisions in the 2013 regulations, which would allow for a pharmacy contractor to operate services in lieu of another. In those circumstances the pharmacy contractor would have been granted a temporary listing for the specified premises on the relevant pharmaceutical list and would operate as the listed pharmacy contractor. NHSE&I would be able to undertake necessary fitness checks and would have a contractual relationship with the temporarily listed contractor. In the current model employed by the Appellant, none of the regulatory criteria have been met to allow The Hub Pharmacy Ltd to operate on behalf of the Appellant, and no applications for a temporary listing have been made nor granted. NHSE&I is not wishing to imply that The Hub Pharmacy Ltd is not a suitable entity to deliver NHS pharmaceutical services. However, it is not listed on the pharmaceutical list for the area of Tameside Health and Wellbeing Board, and since voluntarily withdrawing from said pharmaceutical list on 31st January 2020, is not permitted to deliver NHS pharmaceutical services. NHSE&I has no contractual relationship with The Hub Pharmacy Ltd.
- 5.41 NHSE&I would like to highlight that within the detail of the provided schedules of the management agreement, the Appellant requires The Hub Pharmacy Ltd to manage all complaints on behalf of the Appellant. The Hub Pharmacy Ltd is required to indemnify the Appellant against related costs, claims or liabilities. This would appear to be an attempt by the Appellant to divest itself of any responsibility or liability in the delivery of NHS pharmaceutical services. However, the Appellant previously has informed NHSE&I that it would have the same degree of professional oversight and responsibility via its Superintendent Pharmacist at 33 – 35 Market Street, Hyde, SK14 2AD as with any other pharmacy premises listed on a pharmaceutical list. It appears, however, from the management agreement that the Appellant has no operational or professional input into the management of complaints or concerns. This further supports the NHSE&I position that it is The Hub Pharmacy Ltd delivering NHS pharmaceutical services and not the Appellant from this site.
- 5.42 NHSE&I issued the remedial notice which the Appellant is appealing, for ceasing to provide any services at all from 33-35 Market Street, Hyde, SK14 2AD, following its relocation from 19-21 Clarendon Street on 1st February 2020. Based on the detail contained within the management agreement, and for the reasons set out above, it is clear that the Appellant is not carrying on a retail pharmacy business (including any NHS pharmaceutical services) at 33-35 Market Street, Hyde, SK14 2AD. In ceasing all provision, the Appellant was (and remains) in breach of all aspects of Schedule 4 of the 2013 Regulations (Terms of Service) in relation to service provision. The issuing of the remedial notice was therefore justifiable and proportionate and was issued as a final attempt to allow the Appellant to rectify matters in lieu of taking steps to remove the premises from the relevant pharmaceutical list. NHSE&I would further highlight that every attempt had been made to resolve this matter via local dispute resolution before the decision to issue a remedial notice was reached.

Unsolicited comments

THE APPELLANT

- 5.43 Thank you for NHS Resolution's letter of 11 February 2021 enclosing comments from NHSE&I submitted by letter dated 4 February 2021. Whilst the Appellant notes that NHS Resolution has not sought further comments from it, the Appellant feels it necessary to address the comments made by NHSE&I for the purposes of clarity.

Natural Person

- 5.44 The reference in Paragraph 1 Schedule 4 of the Regulations to a "natural person" seems to be misunderstood by NHSE&I. It is there to explain that where there are

obligations on an “NHS pharmacist” (i.e. the Appellant in this situation), then where that NHS pharmacist is not a natural person (as the Appellant is not, it is a body corporate so is a ‘legal person’), then the Appellant has to secure compliance with our obligations by employing or engaging registered pharmacists.

- 5.45 Activities listed in Schedule 4 that have to be done by a natural person include, for example, providing a time estimate under Paragraph 7; considering if a prescription might be stolen or forged under Paragraph 9, or engaging in discussions with a hospital under Paragraph 22C, etc.
- 5.46 The Appellant can confirm that at the Market Street Pharmacy, it fulfils its obligations under Schedule 4 of the Regulations and that, where activity set out in Schedule 4 can only be undertaken by a natural person, the Appellant engages registered pharmacists to undertake that activity.

Management Agreement

- 5.47 NHSE&I comments that the Appellant has not indicated which provision within the Regulations it is relying on for use of a Management Agreement. As explained previously, this is not necessary. The case of Family Health Services Appeal Authority, ex parte Elmfield Drugs Ltd and others confirms that a body corporate can act by its servants or agents and that ‘Where the statute is silent, the normal implication is that, in the absence of other indications, the basic rule permitting acts by an agent applies.’ NHSE&I has not addressed this point in any of its correspondence, nor has it explained how the position with regards to locums operating through their own limited company differs, whatever the extent of services provided by the locum.
- 5.48 In addition, there are three points noted by NHSE&I which must be read in their legal and contractual context, not simply under the NHS Regulations.

Relationship Between the Parties

- 5.49 The clause in the Management Agreement stating that no partnership or joint venture is created between the Appellant and Hub is a standard clause found in contracts for services. Creation of such a relationship could have employment and tax consequences. This is entirely unrelated to the Appellant’s provision of NHS pharmaceutical services under the Regulations.
- 5.50 The Appellant is entitled to ‘employ or engage’ staff in connection with the provision of pharmaceutical services¹. The Regulations define “staff” to include “other persons engaged on contracts for services” and also defines “employment” (and “employs”) as employed “under a contract for services”.
- 5.51 NHSE&I is aware, from exchanges [with the Appellant] in January-February 2020, that the Appellant does not employ the staff that work in its stores. The Appellant’s staff are employed by Boots Management Services Limited and engaged by the Appellant under a contract for services. This structure is reflected in the arrangement with Hub.

‘Boots’ NHS Pharmacy Contract’ definition

- 5.52 This definition is self-explanatory and hence not included in the Appellant’s previous submissions, however, for completeness, it is defined in the main body of the Management Agreement as follows and refers to the Appellant’s entry in the NHS pharmaceutical list:
- 5.53 “Boots’ NHS Pharmacy Contract means the right of Boots to be included in the Pharmaceutical List for the provision of pharmacy services from [19-21 Clarendon Street] (and, if applicable, from the Relocation Date and pending the [change of ownership date] from [33-35 Market Street] pursuant to the NHS Regulations”

- 5.54 NHS Resolution will note that it is not “the NHS Pharmacy Contract” as noted by NHSE&I but it is referred to throughout the Management Agreement as “Boots’ NHS Pharmacy Contract” ([the Appellant’s] emphasis).

Indemnity arrangements

- 5.55 NHSE&I will be aware that it is the General Pharmaceutical Council that requires registrants to have professional indemnity arrangements in place, the nature of which is left to the individual. The Appellant requires this indemnity from Hub in the same way that it requires it from locums that work at the Appellant’s. The requirement for appropriate indemnity applies regardless of whether services are provided under the NHS or otherwise.
- 5.56 The requirement under the Management Agreement to handle complaints is not, as asserted by NHSE&I, “an attempt by Boots UK Ltd to divest itself of any responsibility or liability in the delivery of NHS pharmaceutical services.”. On the contrary, the Appellant maintains all responsibility and liability for the delivery of NHS pharmaceutical services as it is the contractor listed on the pharmaceutical list and, in order to fulfil that obligation, Hub provides support to the Appellant.

NHSE&I

- 5.57 Noting the date of the Appellant’s further representations (15th February 2021 - attached) which falls outside the deadline for submission of representations set by NHS Resolution (Primary Care Appeals) in [NHS Resolution’s] letter of 29th January 2021 (which allowed 7 days from that date for representations to be received before the appeal was to be determined). In the first instance, it is not for the Appellant to seek to ‘clarify’ any points made by NHS England and Improvement (NHSE&I) in its representations, without NHSE&I being afforded the same opportunity to respond. NHSE&I believes it would be unfair for NHS Resolution (Primary Care Appeals) to take into account representations received after the deadline lapsed, and is seeking assurances that any representations received “out of time”, specifically the attached, will not be taken into consideration when determining this appeal.

6 Consideration

- 6.1 Under regulation 70(1) “Breaches of terms of service: remedial notices” of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”), a remedial notice may be issued:

“Where an NHS Chemist (C) breaches a term of service and the breach is capable of remedy, the NHSCB may by notice (“a remedial notice”) require C to remedy the breach.”

- 6.2 The Regulations state that an NHS Chemist means “an NHS appliance contractor or an NHS pharmacist”. An NHS pharmacist is defined as “a person included in a pharmaceutical list of the type referred to in regulation 10(2)(a);”. Regulation 10(2)(a) states:

10(2) “Those lists (which are pharmaceutical lists) are

(a) a list of persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs;”

- 6.3 I note that the Appellant is included on the pharmaceutical list in relation to the pharmacy located at 33-35 Market Street (referred to as the “Pharmacy” in this determination) and that there is no dispute between the parties with regard to this.
- 6.4 I shall first consider the nature of the alleged breach. As above, a remedial notice may be issued where a contractor has failed to comply with a term of service and that breach

is capable of remedy. I note that the Regulations do not contain a definition of what constitutes a breach capable of remedy.

- 6.5 I note that the nature of the breach is described as the Appellant failing to provide pharmaceutical services as of 1 February 2020 and therefore being in breach of “*all aspects of schedule 4*” of the Regulations. This is a very broad description of the nature of the breach; Schedule 4 contains a significant number of provisions with which a contractor must comply in its provision of NHS pharmaceutical services. A breach of some terms of service may be capable of remedy for which a remedial notice would be appropriate and a breach of other terms of service may not be capable of remedy and so a breach notice would be more appropriate. However, it seems to me that it would be mistaken to treat an allegation of not providing pharmaceutical services at all (at least in the circumstances of this case) as if it was an allegation of being in breach of every requirement of Schedule 4. Clearly, if I were to find that services had not been provided for a period it is impossible for the Appellant retrospectively to provide those services, but that does not render the breach incapable of remedy. The question is can the breach (including any relevant present and future consequences of past actions) be fully cured for the future such that the contractor is in full compliance with its present and future obligations after cure. It seems to me that on the facts of this case it can and so this is a case of an alleged breach which is capable of remedy.
- 6.6 The Remedial Notice was issued on the basis that the Appellant is not providing pharmaceutical services. In the present matter, pharmaceutical services are being provided and there is no dispute as to that. The issue at the root of this appeal is which entity is providing those pharmaceutical services.
- 6.7 The Appellant states in its representations that it provides NHS pharmaceutical services at the Pharmacy. NHSE&I, in its representations, states that the Appellant cannot be considered to be providing any NHS pharmaceutical services at the Pharmacy.
- 6.8 Before considering the position of the parties, I set out my understanding of the matters which led to the issue of the Remedial Notice.
- 6.9 I note that Hub's notification of voluntary closure in respect of the Pharmacy and the Appellant's application to relocate its nearby pharmacy to the Pharmacy occurred as a result of an agreement between them which the Appellant explains at paragraph 2.8 above. The objective of the agreement, the Appellant states, was to enable the Pharmacy to be open for shorter opening hours under a “standard” hours NHS contract.
- 6.10 I also note that following the coming into effect of the removal of Hub from the pharmaceutical list in respect of the Pharmacy, and the inclusion of the Appellant in the pharmaceutical list in respect of the Pharmacy (as a result of the relocation), the Appellant submitted an application for a change of ownership of the Pharmacy to Hub.
- 6.11 I note that regulation 26, which governs change of ownership applications, is worded in such a way that there would always need to be a period (however short) when the pharmaceutical listing in respect of the Pharmacy premises was in the Appellant's name and during that period it is the Appellant who must be providing the NHS pharmaceutical services until such time as the application for the change of ownership is approved.
- 6.12 As at the date of this determination, I understand that NHSE&I has not considered the change of ownership application because it considers that, from the date the changes to the pharmaceutical list in respect of the Pharmacy came into force (1 February 2020), the Appellant has not been providing NHS pharmaceutical services at the Pharmacy and that Hub has continued to provide NHS pharmaceutical services at the Pharmacy despite the removal of Hub from the pharmaceutical list in respect of the Pharmacy.

- 6.13 I would add here that while this determination is not an appeal of any decision of NHSE&I linked to the change of ownership application, it seems to me that if the objective of NHSE&I was to ensure that there was no ambiguity as to the entity on the pharmaceutical list providing pharmaceutical services at the Pharmacy, then had NHSE&I considered the change of ownership application and had that been granted, that objective would have been met a long time ago. This is against a backdrop of a global pandemic which has required an urgent and extensive response by healthcare professionals including pharmacists.
- 6.14 I have not been pointed by the parties to any previous determinations of NHS Resolution on the issue at hand. The Appellant, in its representations, has provided an extract from a judicial case which refers to a corporate person acting via an agent and which I consider in more detail later in this determination. Beyond this, the parties have not provided any other guidance, judicial or otherwise, on this issue.
- 6.15 I would like to comment on four preliminary matters.
- 6.16 Firstly, I note the Appellant sets out five questions it believes NHS Resolution should consider. These are set out at paragraph 2.5 above. A number of these questions refer to a breach of regulation 74(1)(b). I note the Remedial Notice expressly states there is breach of all the terms of service. The Remedial Notice does refer to regulation 74 applying but in the context of an appeal of the decision to issue a remedial notice, I do not consider that the Remedial Notice purports to claim a breach of regulation 74. I therefore agree with NHSE&I's view that these five questions are not the appropriate way to determine this matter. I would add that this determination does not seek to make any determination on the issue of whether regulation 74 applies.
- 6.17 Secondly, NHSE&I states that following a voluntary closure notification, it would be usual and expected for the premises to close altogether. NHSE&I also refers to the Hub's notice of voluntary closure as being to permanently close the pharmacy. The Appellant points out that the words "permanently close" do not appear in regulation 67. I agree with the Appellant. Regulation 67 concerns itself with an entity being removed from the pharmaceutical list in relation to specific premises. It is not about the physical premises permanently closing or closing altogether.
- 6.18 Thirdly, I note that the parties make reference to management agreements being used in a range of circumstances with comments as to what this means or implies and whether they are sanctioned or not by NHSE&I. I make no finding in relation to the use of management agreements in other scenarios.
- 6.19 Fourthly, both parties have provided unsolicited comments. I have attributed little weight to these comments as they have been submitted after the relevant deadline for submission of additional comments.
- 6.20 In my opinion and in light of comments by the parties on this point, it is reasonable to consider the extent to which the Regulations refer (or not) to arrangements that a body corporate on a pharmaceutical list may have with a separate body corporate in respect of the provision of services.
- 6.21 I note that there is no express reference in the Regulations to an entity on the pharmaceutical list, where that entity is a body corporate, sub-contracting or otherwise delegating the provision of services to another body corporate.
- 6.22 NHSE&I is of the view that the Appellant has "*wholesale subcontracted*" all NHS pharmaceutical service provision and that such sub-contracting is not permitted by the Regulations. NHSE&I holds the view that if something is not specifically permitted, then there is no intention for it to form part of that regulatory framework.

- 6.23 The Appellant refers to its arrangement with Hub as an agency arrangement. The Appellant holds the view that if the arrangement is not expressly prohibited by the Regulations then permission cannot be refused for it.
- 6.24 In my view both propositions are over stated. The Regulations are not an empowering instrument, such that unless a power can be found in the regulations it must be assumed to be absent; still less NHSE&I's position that there must be an express power. Equally I consider the Appellant goes too far in saying everything must be permitted that is not expressly forbidden. The correct view, in my mind, is to approach the Regulations neutrally without a presumption either that they are of their nature prescriptive or permissive, and construe them in light of their ordinary meaning, in context, and with regard to their purpose.
- 6.25 On the Appellant's reference to the arrangement being one of agency, I note that there is a separate body of law in respect of commercial agency. The nature of the agency relationship specified in the current matter is not referred to as a commercial agency arrangement. I therefore assume that when the Appellant refers to Hub acting as its "agent" it does not mean that Hub is its commercial agent within the meaning of the law on commercial agency, but rather the Appellant has engaged Hub to act as its agent (in a looser meaning of the word, appointing Hub to do something on behalf of the Appellant) in the provision of pharmaceutical services.
- 6.26 The Appellant references the case of Family Health Services Appeal Authority, ex parte Elmfield Drugs Ltd and others [46 BMLR 191] and that, as the Hub acts as the Appellant's agent, this case puts an end to NHSE&I's position that the Appellant is not providing pharmaceutical services.
- 6.27 The extract from the case provided by the Appellant states that a corporate person can act only by its servants or agents. There is no further explanation as to the meaning of "servants" nor "agents" in this extract. I agree that as a general principle a corporate body cannot physically carry out an activity. It is also, in my opinion, why paragraph 1(1)(b) of Schedule 4 (referred to in more detail below) has been included in the Regulations.
- 6.28 The extract goes on to refer to a statement in Chitty on Contracts. The statement reads "*Where the statute is silent, the normal implication is that, in the absence of other indications, the basic rule permitting acts by an agent applies.*"
- 6.29 Although the Regulations do not contain a specific express reference to a corporate body on a pharmaceutical list subcontracting or delegating service provision to a separate body corporate, the Appellant states that the Regulations envisage arrangements being made by an entity on a pharmaceutical list with persons who may not be directly employed by that entity. The Appellant considers there are a range of circumstances under which pharmaceutical services are provided with the support of a third party and that this is expressly envisaged by paragraph 1(1)(b)(ii) of Schedule 4 of the Regulations.
- 6.30 This provision states:

"1. - Responsibilities of NHS pharmacists and pharmacy staff

(1) To the extent that this Schedule imposes a requirement on an NHS pharmacist in respect of an activity which could only, or would normally, be undertaken by a natural person—

(a) ...

(b) if the NHS pharmacist is not a natural person, that NHS pharmacist must secure compliance with that requirement by—

(i) where conformity with the standards generally accepted in the pharmaceutical profession so requires, a registered pharmacist (who is not suspended), or

(ii) in other cases, the natural persons (including registered pharmacists) whom the NHS pharmacist employs or engages in connection with the provision of pharmaceutical services.”

- 6.31 The Appellant states that this provision can clearly include an agreement between two parties that allows the Appellant to engage others via a contractual arrangement, which in the current case is the management agreement.
- 6.32 I consider that paragraph 1(1)(b) of Schedule 4 covers a situation where the entity on a pharmaceutical list is a body corporate but an activity required of the Regulations could only or would normally be done by a natural person (i.e. a human). In this situation, the body corporate must ensure compliance with that requirement by a registered pharmacist or another natural person whom the corporate body employs or engages to provide pharmaceutical services (my emphasis).
- 6.33 In my view this provision recognises that a body corporate cannot physically carry out certain activities and so sets out who must carry out such physical activities on behalf of that corporate body. It is limited in its application to activities that can only be undertaken by a natural person and paragraph 1(1)(b) expressly requires that an NHS pharmacist that is a body corporate must ensure compliance of that “human-only” activity by either a registered pharmacist (paragraph 1(1)(b)(i)) if the activity requires it, or in other cases a natural person that the NHS pharmacist employs or engages (paragraph 1(1)(b)(ii)). In my view this provision does not greatly assist me to determine the central issue in this dispute, save to put beyond doubt that a corporate body may act through a human appointee where required.
- 6.34 The Appellant compares the arrangement with Hub to one where an NHS pharmacist uses a locum agency to supply it with staff. The Appellant explains that its own staff are not employed by Boots UK Ltd but by another company in its group. I note that the Regulations define “staff” as including “locums and other persons engaged on contracts for services who act as staff”.
- 6.35 As I have set out above, my view of paragraph 1(1)(b) is that it assumes a body corporate may employ or engage a natural person, i.e. a human. The reference to “engage” as well as “employ” clearly indicates that a non-employee can carry out the relevant activity. A natural person engaged via a contract for services would suffice, for example, a locum.
- 6.36 In my view, direct engagement of a locum would require the locum to follow the processes, procedures and policies that the pharmacy has in place for the provision of pharmaceutical services. I would not expect the locum to have meaningful control over and be involved to any significant extent in setting the processes, procedures and policies of the pharmacy to which that locum is sent. Provided that arrangements with a locum agency (or indeed arrangements with another body corporate from whom staff are provided) to send a locum to the pharmacy followed this same approach, I do not consider this to be materially different to a direct engagement of a locum.
- 6.37 I consider that in relation to staff generally, the Regulations envisage the engagement by a corporate body on the pharmaceutical list of third parties (i.e. staff, locums, etc.) to carry out the relevant activity. It is clear, however, that the management agreement in place between the Appellant and Hub is not simply an agreement for the provision of staff.
- 6.38 I have had regard to the terms of service set out in Schedule 4 of the Regulations. I note the provision of pharmaceutical services includes activities such as, provision of drugs and appliances (paragraph 4), provision of unwanted drug disposal service

(paragraph 13) and provisions in relation to clinical governance, which include carrying out clinical audits, maintaining equipment and keeping premises clean (paragraph 28).

- 6.39 I do not consider that the entity on the pharmaceutical list must carry out each and every single element of activity that makes up the provision of pharmaceutical services with no involvement at all, whether directly or indirectly, from third party persons. I note the Appellant's comment that there are a range of circumstances under which pharmaceutical services are provided with the support of a third party.
- 6.40 I do, however, consider that if an entity on the pharmaceutical list engages a third party to assist it with the provision of pharmaceutical services, the Regulations envisage that the entity on the pharmaceutical list exerts a certain level of control over the third party and that the third party acts on the direction of the entity.
- 6.41 This is supported by my reading of regulation 10 which refers to NHSE&I preparing, maintaining and publishing the pharmaceutical lists and they are expressly stated to be lists of persons who "*undertake to provide pharmaceutical services from premises*". The fact that the wording states that the person on the pharmaceutical list will provide the services (as opposed to ensuring or arranging service provision) is, in my view, an indication that the identity of the person who provides pharmaceutical services and who is responsible for the provision of services is important in the framework of pharmaceutical services provision that the Regulations put in place.
- 6.42 I also consider that regulation 33 supports this view. Regulation 33 relates to the refusal of applications for inclusion in a pharmaceutical list on fitness grounds and includes a requirement or an ability to refuse the applicant (depending on which provision it falls under) where the applicant is a body corporate and:
- 6.42.1 if any of the directors or superintendent of the body corporate have been convicted of murder or been convicted of a criminal offence and sentenced to more than 6 months imprisonment;
- 6.42.2 if a director, superintendent or the body corporate itself is subject to a national disqualification; and
- 6.42.3 if having checked with the NHS BSA for any past or current fraud investigations into the directors, superintendents or the body corporate itself and having considered any such investigations, it considers the outcome justifies refusal.
- 6.43 The requirement to meet the fitness criteria is to ensure that certain checks are carried out on the suitability of those being included on a pharmaceutical list and as such those undertaking to provide pharmaceutical services. I appreciate that Hub were previously on the pharmaceutical list in relation to the Pharmacy and there is no suggestion that they would be refused pursuant to regulation 33 if they applied to be included on a pharmaceutical list. My point is that this is a further example indicating that the Regulations envisage that a body corporate included on the pharmaceutical list will have meaningful control/involvement in the provision of services as otherwise the fitness or otherwise of its directors, etc. would be irrelevant.
- 6.44 Paragraph 9(1)(c) of Schedule 2 requires an applicant seeking to be included on a pharmaceutical list to undertake "*in particular, in relation to any proposed pharmacy premises, to provide all the services and perform all the activities at those premises that are required under the terms of service to be provided or performed as or in connection with essential services*".
- 6.45 The fact that the wording of paragraph 9(1)(c) states that the person on the pharmaceutical list undertakes "in particular" to provide the services and perform all activities at the premises (and not, say, to "provide or secure the provision of" services or activities at the premises) is, in my view, a further indication that the Regulations

envisage that the person listed on the pharmaceutical list will have meaningful control/involvement in the provision of services.

- 6.46 I consider that arrangements in which a body corporate A arranges with a separate body corporate B for B to provide certain activities connected with pharmaceutical services on behalf of A are permitted by the Regulations, provided that the arrangements between A and B are such that A retains meaningful control/involvement in, and is responsible for, all of the matters regulated by or relevant to any consideration under the Regulations. To borrow a concept from administrative law, I see no reason why A may not delegate to B, but A may only delegate routine administrative matters, and must itself exercise meaningful control and decision making authority over the services (subject of course to provisions such as paragraph 1(1)(b)(ii) above).
- 6.47 To permit looser control of B by A cannot be compatible with the Regulations because it is clear that the actual identity of the individual or body on the pharmaceutical list is an essential element in the framework of control created by the Regulations. It cannot be right that that framework of control could be weakened by the substitution of a third party for the listed entity.
- 6.48 Equally, I see nothing in the Regulations or in context that would require a listed entity itself directly to undertake absolutely every activity connected with the delivery of pharmaceutical services. That goes beyond what the Regulations seek to control.
- 6.49 Provided that A has meaningful control (which is actually exercised) over B then for the purposes of the Regulations, I consider that A can be said to be providing the services itself. Control must extend to any matter relevant to the decision to list or not list.
- 6.50 I shall therefore consider the extent of which the Appellant exercises meaningful control over Hub.
- 6.51 I have had regard to the comments of the parties set out in this determination and the schedules of the management agreement provided by the Appellant.
- 6.52 I note that I have not been provided with the entire copy of the management agreement but the Appellant confirms that the main body of the management agreement requires Hub to provide management services to the Appellant in accordance with the schedules from the date of relocation until the change of ownership is approved by NHSE&I.
- 6.53 The Appellant states that the management agreement by its very nature determines how the Pharmacy is managed under Schedule 1, the professional responsibilities under Schedule 2 and the pharmacist's obligations under Schedule 3.
- 6.54 I note that Schedule 1 of the management agreement contains the terms upon which Hub is appointed "as its manager and agent", these include, among others:
- 6.54.1 permission for the Pharmacist to operate and manage the provision of pharmaceutical services in accordance with the terms of the Appellant's NHS Pharmacy Contract;
 - 6.54.2 display a notice stating that Hub is operating and managing the Appellant's NHS Pharmacy Contract; and
 - 6.54.3 appoint Hub as its agent to submit NHS prescriptions for payment.
- 6.55 I note that "Pharmacist" is defined as "the pharmacist nominated by The Hub to Boots to be pharmacist-in-charge".
- 6.56 I note that paragraph 3 of Schedule 1 of the management agreement contains obligations on Hub. These are numerous and include obligations to, among others:

- 6.56.1 conduct the Appellant's NHS contract in a legal, professional and efficient manner;
 - 6.56.2 provide pharmaceutical stock required to satisfy NHS prescriptions;
 - 6.56.3 submit NHS prescriptions for payment;
 - 6.56.4 maintain full records of dispensing;
 - 6.56.5 not to do anything that would constitute a breach of the "Legal Requirements";
 - 6.56.6 as appropriate inform patients of its capacity as the agent of Boots in the conduct of Boots NHS Pharmacy Contract;
 - 6.56.7 maintain insurance;
 - 6.56.8 assume responsibility for all debts and liabilities in connection with Boots' NHS Pharmacy Contract; and
 - 6.56.9 at the request of the Appellant (acting reasonably) provide the Appellant with information to demonstrate it has complied with the obligations in the management agreement.
- 6.57 Schedule 1 also contains an obligation to carry out the Services at the Pharmacy. "Services" is defined as the "Pharmacist's services to be provided pursuant to Boots' NHS Pharmacy Contract". I note there is a warranty from Hub to the Appellant in relation to the Pharmacist's (as defined in the management agreement in this case) compliance with its obligations and professional responsibilities. There is also a section on the obligations of Boots which includes:
- 6.57.1 do what is necessary to enable Hub to exercise rights and perform the obligations in Schedule 1; and
 - 6.57.2 provide Hub with copies of statements provided by NHS England in respect of income.
- 6.58 There are also sections on payments and termination.
- 6.59 Schedules 2 and 3 of the management agreement states the obligations that Hub must procure that the Pharmacist will do. Schedule 2 lists professional responsibilities and Schedule 3 lists other obligations.
- 6.60 I consider that the existence of the management agreement is evidence that the Appellant:
- 6.60.1 has considered the activities that Hub are to undertake;
 - 6.60.2 has recorded these in writing; and
 - 6.60.3 as they are contained within what I assume is a legally binding agreement, has the ability to ultimately issue breach of contract proceedings if Hub does not carry out those activities.
- 6.61 In my mind, the existence of the management agreement should therefore provide some comfort that there is an ability for the Appellant to require Hub to take action to ensure Hub provides services in accordance with the Terms of Service. Indeed paragraph 1 of Schedule 3 indicates that the Hub must procure that the Pharmacist conforms to and complies with the proper and reasonable directions of the Appellant in respect of the Appellant's "NHS Pharmacy Contract".

- 6.62 I do, however, consider that the arrangement between the Appellant and Hub does not evidence the level of control, accountability and involvement that the Regulations envisage that the person on the pharmaceutical list would impose on a third party it engages to support its provision of pharmaceutical services.
- 6.63 In particular, I note that the Appellant permits the Pharmacist (i.e. a person nominated by Hub, not the Appellant) to operate and manage the provision of pharmacy services. There are no obligations on Hub to liaise with the Appellant on an ongoing basis in this regard and there are no provisions which indicate that the Appellant will be involved to any degree in the provision of pharmacy services.
- 6.64 While there are provisions relating to the Appellant being able to require provision of information or for the Appellant to have access to Hub's records, there are no provisions that envisage that information will be routinely provided to the Appellant and that Boots will be involved in decision-making about the provision of services.
- 6.65 There is the ability for the Appellant to direct the Pharmacist in respect of the "NHS Pharmacy Contract" but there is no indication of when or if that might happen in practice. As I have referred to earlier in this determination, the Regulations set out a framework of control that the entity on the pharmaceutical list should be applying to the provision of pharmaceutical services. There may be the mechanism to exert control in the management agreement but that does not provide any assurance that the Appellant is actually exerting the expected level of control.
- 6.66 Hub is required to "carry out the Services" at the Pharmacy. There are no express provisions that indicate how those services are to be provided beyond ensuring they comply with professional, regulatory and other requirements. This indicates to me that the Appellant is providing a high degree of autonomy to Hub and its Pharmacist in respect of the provision of pharmaceutical services. This adds to the perception that the Appellant is not involved in a meaningful way in the provision of services. An example is the management of complaints which is stated to be the responsibility of Hub. While there is a requirement on Hub to keep the Appellant informed, this does not indicate or suggest that the Appellant will take any more than a passive role in respect of the complaints procedure.
- 6.67 There is no indication in the management agreement that the Appellant is involved to any significant extent in setting the processes, procedures and policies of the Pharmacy. The lack of any such reference suggests that it is for Hub to determine the processes, procedures and policies of the Pharmacy. In my mind, the person that sets or decides the processes, procedures and policies of a pharmacy has, by virtue of a requirement on a third party to comply with those processes, procedures and policies, meaningful control over that third party. But if, as here, there is no such requirement, then it suggests a weaker level of control.
- 6.68 In terms of enforcing compliance with the terms of services, there are provisions that require adherence to the terms of service but there is no indication of what happens if the terms of service are breached. Although the existence of the agreement provides a mechanism for the Appellant to take legal action if the obligations of Hub are not met, this does not, in my view, provide enough assurance that any breach notified by NHSE&I to Hub will be actioned. There are no contract management provisions that make clear that Hub must do what the Appellant requires of it in respect of remedying a breach. Similarly, there is no indication that the Appellant could "step-in" to the provision of services if Hub were not acting in accordance with the terms of service.
- 6.69 In my opinion, the management agreement requires Hub to provide the pharmaceutical services. When Schedules 1 to 3 are considered in the round, it is clear that Hub are afforded considerable discretion and autonomy in the provision of pharmaceutical services. While there is the ability for the Appellant to exert control, there is little indication that the Appellant actually is exerting the level of control or is providing the

level of involvement in the provision of pharmaceutical services that the Regulations envisage from the entity on the pharmaceutical list.

- 6.70 It may be the case that in reality the Appellant is exerting the envisaged level of meaningful control but the comments of the Appellant and the information presented to me does not enable me to be satisfied that this is the case.
- 6.71 As I have indicated earlier in this determination, if it is not evident that the Appellant has meaningful control over Hub, then I cannot consider that the Appellant is providing pharmaceutical services. In other words, I consider that it is reasonable for me to consider that Hub, and not the Appellant, is providing pharmaceutical services.
- 6.72 It follows that the Appellant is in breach of the terms of service as the Appellant has not carried out the actions that the Regulations require the person on the pharmaceutical list to carry out.
- 6.73 I therefore consider that it is right to issue a remedial notice to the Appellant.
- 6.74 I now need to consider the actions required to remedy the breach and whether the actions set out in the Remedial Notice are appropriate or should be replaced/amended.
- 6.75 I note that pharmaceutical services have been provided to patients and, putting to one side for a moment that I have determined that those services have been provided by Hub and not the Appellant, no information has been provided to me to suggest that the services have not been provided in accordance with the terms of service. This is important as the breach has not led to the standard of services being provided dropping below the level required by the Regulations. Rather than requiring the provision of services to be brought up to the standard required by the Regulations as is usually the case with a remedial notice, the remedial actions in this matter must focus on providing assurance that there is meaningful control by the Appellant in the provision of the services as envisaged by the Regulations.
- 6.76 NHSE&I refers in a number of places to the issues caused by the arrangements between Hub and the Appellant which include NHSE&I not being able to take steps to address issues with the provision of pharmaceutical services. NHSE&I are not assured that there is any chain of responsibility of the Appellant and this leaves a gap in accountability and NHSE&I's ability to contract manage the provision of pharmaceutical services.
- 6.77 In my opinion, there are therefore two related and interlinked objectives to the remedial actions. In order to remedy the breach, the remedial actions must firstly provide assurance that there is meaningful control by the Appellant over Hub in the provision of services and secondly that where an issue arises with the provision of services, NHSE&I is assured that its interaction with the Appellant will result in the relevant actions with regards the provision of services being taken.
- 6.78 The remedial actions also need to be objectively evidenced so it is clear to the parties what must be achieved within the remedial action timescale. In my opinion, NHSE&I's remedial actions, as set out in the Remedial Notice, are attempting to provide a level of assurance to NHSE&I that the Appellant does have the necessary level of meaningful control of Hub but there is a risk that they intrude into a pharmacy contractor's right to determine its own method of working, e.g. its choice of IT systems. In my mind, there is a balance here that must be struck and I set out comments on NHSE&I's remedial actions below along with my determination as to the remedial actions required to be achieved by the Appellant in the remedial action timescale.
- 6.79 The identity of the person operating a retail pharmacy business at specific pharmacy premises as set out in the GPhC register will, I have no doubt, be a factor that feeds into consideration of whether the entity on the pharmaceutical list exerts meaningful control over the provision of services. If the entity on the pharmaceutical list is not the

entity on the GPhC register, this creates a presumption that the entity on the pharmaceutical list does not have the required level of control over the provision of pharmaceutical services. I do, however, consider that this is a rebuttable presumption. There may be a range of other factors indicating the required level of control. It may be that in certain cases the collective weight given to those other factors is enough to rebut the presumption.

6.80 I therefore do not consider that in every situation the entity on the pharmaceutical list must be the entity on the GPhC registration. I note the Appellant's comments that the Regulations do not expressly require the entity on the pharmaceutical list to be the entity listed on the GPhC register. I also consider that it is not appropriate to require in a remedial notice issued by NHSE&I that a pharmacy must change the entity listed on the GPhC register. The determination of which entity is listed in the register is a regulatory matter that comes under the jurisdiction of GPhC not NHSE&I. Any pharmacy must act in accordance with the relevant regulatory framework in this respect. In my view, it is not for NHSE&I in its role of commissioner of pharmaceutical services to specify an action that is governed by a separate regulatory framework. I determine that there should not be a remedial action in respect of the GPhC register. I do consider that the Appellant and the Hub, after considering the remedial actions that I determine below, will need to consider the appropriate regulatory requirements and ensure the appropriate entity is listed on the GPhC register.

6.81 I do not consider that branding the SOPs used at the Pharmacy with the Appellant's name is appropriate. It will simply be a name on documents. I note that NHSE&I first required the Appellant's Superintendent Pharmacist to review, agree and sign the SOPs in place at the Pharmacy. The Appellant states that the SOPs have been reviewed and approved by that person which NHSE&I acknowledges. Bearing in mind my comments above as to the expectation that the entity on the pharmaceutical list will decide the processes, procedures and policies that the pharmacy (which will, to any extent, be contained within the SOPs), I determine that the appropriate remedial action in relation to the SOPs is that:

6.81.1 The Appellant's Superintendent Pharmacist is to indicate in writing to NHSE&I that it has reviewed and approved the SOPs being used at the Pharmacy and it considers that those SOPs enable the provision of pharmaceutical services to be in accordance with the requirements of the Regulations; and

6.81.2 The Appellant is to commit in writing to NHSE&I that it will be involved in any discussions and decision-making as to any amendments required to the SOPs and that it will promptly provide to NHSE&I on request evidence of its involvement (e.g. relevant meeting minutes).

6.82 I do not consider that the same Boots UK Ltd IT systems must be utilised at the Pharmacy as were used by the Appellant at its premises prior to the relocation. It is for a pharmacy contractor to determine what IT systems are used not NHSE&I. I do consider, however, that it is for the Appellant to make clear to NHSE&I that it has considered the IT systems that are used at the Pharmacy and that it is satisfied that they are appropriate. Bearing in mind my comments above as to the expectation that the entity on the pharmaceutical list will decide the processes used at the pharmacy, I determine that the appropriate remedial action in relation to the IT systems is that:

6.82.1 The Appellant is to indicate in writing to NHSE&I that it has reviewed and approved the IT systems being used at the Pharmacy and it considers that the IT systems are appropriate to enable the provision of pharmaceutical services to be in accordance with the requirements of the Regulations; and

6.82.2 The Appellant is to commit in writing to NHSE&I that it will be involved in any discussions and decision-making as to any changes to the IT systems and that it will promptly provide to NHSE&I on request evidence of its involvement (e.g. relevant meeting minutes).

- 6.83 In respect of communication to all NHS patients that the Pharmacy is a Boots UK Ltd pharmacy as opposed to the Hub Pharmacy Ltd pharmacy, I note the wording of the sign and the comments of the parties on this. In light of my comments above in respect of the GPhC register entry, I consider that the wording is appropriate albeit there should not be any reference to the change of ownership application. I determine that the appropriate remedial action in relation to the sign to patients is that:
- 6.83.1 A sign is prominently displayed at the Pharmacy with the following wording:
“All NHS Pharmaceutical Services from this pharmacy are being provided by Boots UK Limited via a Management Agreement with Hub Pharmacy Limited. Please speak to the pharmacist with any queries.”
- 6.84 In respect of the cessation of any NHS service provision by Hub, I have indicated that there can be assistance provided by another entity to the person on the pharmaceutical list but it is subject to the requirements of control and involvement that I have referred to in this determination. I therefore determine that there need not be any remedial action that requires cessation of activity by Hub but instead I determine that the appropriate remedial actions in this respect are:
- 6.84.1 That the Appellant indicates to NHSE&I in writing that it has agreed with Hub that Hub will provide the Appellant with monthly management information about activity undertaken at the Pharmacy. The Appellant must indicate to NHSE&I the management information that the Hub must provide which must include numbers of prescriptions dispensed, any issues that have arisen in respect of dispensing, any failure to provide services during opening hours, any failures to provide appropriate levels of staffing and activities undertaken by the Hub in the last month in respect of the matters set out in paragraphs 16 to 22A of Schedule 4 of the Regulations. The Appellant is to commit in writing to NHSE&I that it will be involved in any discussions and decision-making as to any of these matters and that it will promptly provide to NHSE&I on request evidence of its involvement (e.g. relevant meeting minutes).
- 6.84.2 That the Appellant provides to NHSE&I in writing a process for management of complaints that makes clear that the Appellant will be involved to the same extent that Hub is involved in considering a complaint and determining the outcome. The Appellant must make clear that any lessons learned in respect of complaints must be determined by the Appellant and that the Appellant will require the Hub to put such lessons learned into operation. The Appellant is to commit in writing to NHSE&I that it will promptly provide to NHSE&I on request evidence of its involvement as set out above in complaints management (e.g. relevant meeting minutes).
- 6.84.3 That the Appellant provides to NHSE&I in writing a process for how the Appellant will manage a situation in which it is issued with a breach or remedial notice. Such process is to indicate timescales for liaising with Hub, making clear that the Appellant will determine the necessary actions after consulting with Hub and that the Appellant will require Hub to carry out the necessary actions.
- 6.85 I determine that the timescale for these actions is 30 days from the date of this determination.
- 6.86 Where a remedial action is for the Appellant to commit to promptly providing evidence of a matter, the action to commit in writing to NHSE&I must be done within 30 days of the date of this determination but there is also an ongoing requirement to provide the information when requested to do so. It is not appropriate to include a timescale for this but I consider that if there was failure to provide such information, then this could be grounds for NHSE&I to consider that the Appellant is not exercising the required level of control over Hub such that a further breach or remedial notice may be appropriate.

- 6.87 I have found it difficult to specify exactly what an entity must do to evidence that it has meaningful control over the provision of the pharmaceutical services at the Pharmacy. The matters above reflect the particular concerns of NHSE&I in this regard and I consider that if the same issue was to arise in respect of arrangements at a different pharmacy, then the areas of concern could be different which would then generate a different set of remedial actions.
- 6.88 I am of the view that under NHS Resolution's powers, as set out in paragraph 9(5) of Schedule 3 of the Regulations, I may either confirm the decision of NHSE&I or substitute for that decision any decision that NHS England could have taken when it took that decision.
- 6.89 I have not confirmed the same Remedial Notice that NHSE&I issued to the Appellant and so instead I substitute the decision to issue with the Remedial Notice with another decision.
- 6.90 I substitute the decision to issue the Remedial Notice with a decision to issue a remedial notice which states that the Appellant has not provided pharmaceutical services at the Pharmacy as envisaged by the Regulations. The Appellant is therefore in breach of the terms of services. That breach is capable of remedy. To remedy the breach, the Appellant must carry out the actions sets out in paragraphs 6.81.1, 6.81.2, 6.82.1, 6.82.2, 6.83.1 and 6.84.1 to 6.84.3. Subject to paragraph 6.86, the timescale for the remedial action is as set out in paragraph 6.85.
- 6.91 I also consider it appropriate that, provided the remedial actions required to be done within 30 days of this determination have been undertaken, NHSE&I should consider the Appellant's change of ownership application relating to the Pharmacy.
- 6.92 As a final comment, I would like to state that had the Regulations included reference to the permissibility (or not) of sub-contracting/delegation of terms of service or, if relevant, the conditions for sub-contracting/delegating, then, bearing in mind the reality of running a pharmacy business and the involvement of third parties, it would have been clearer to the parties what actions would be required to be in compliance with the Regulations.

7 Decision

- 7.1 Pursuant to paragraph 9(5)(a) of Schedule 3 to the Regulations I substitute the decision to issue the Remedial Notice with a decision to issue a remedial notice as set out in paragraph 6.90 of this determination.

Head of Operations, Primary Care Appeals

A copy of this decision is being sent to:

Boots UK Ltd
NHS England & NHS Improvement