

GUIDANCE NOTE

Regulation 31 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1. Regulation 31 reads, as at the date of this guidance note (1 August 2024), as set out in the Appendix.
2. This guidance note is designed to provide assistance to parties on the application of Regulation 31, based on decisions of the Administrative Court, guidance produced by the Department of Health¹ and relevant decisions of NHS Resolution's Pharmacy Appeals Committee. Referenced decisions are embedded on page 9.
3. In this guidance note:
 - "applicant" is the pharmacy contractor that originally submitted the application to the Commissioner;
 - "commissioner" is the commissioning body that manages the arrangements with pharmacy contractors;
 - "Committee" is NHS Resolution's Pharmacy Appeals Committee which redetermines appeals of pharmacy applications; and
 - "Regulations" refer to the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulation 2013.

Regulation 31(1)

4. Regulation 31 must be considered in respect of any routine or excepted application, which means any application made under:
 - Regulation 13 (current needs);
 - Regulation 15 (future needs);
 - Regulation 17 (improvements or better access to current services);
 - Regulation 18 (unforeseen benefits);
 - Regulation 20 (future improvements or better access);
 - Regulation 23 (directed services);
 - Regulation 24 (no significant change relocations);
 - Regulation 25 (distance selling);
 - Regulation 26 (change of ownership);
 - Regulation 27 (temporary listing arising from suspension);
 - Regulation 28 (right of return to pharmaceutical list); and
 - Regulation 29 (temporary arrangements during emergencies).

¹ <https://www.gov.uk/government/publications/nhs-pharmaceutical-services-assessing-applications>

5. If the Committee is reconsidering an application but neither the applicant nor the commissioner have commented on Regulation 31, the Committee will nevertheless consider if the application needs to be refused under Regulation 31(1).
6. The Committee has noted in a number of determinations that the applicant did not provide information in the application form on Regulation 31. In these determinations, the Committee has noted that the wording of the application form appears to only require the applicant to include information in the relevant section if the proposed premises were adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. The Committee determined that the lack of information in the application form, when read with the wording of the application form, allows the Committee to be reasonably satisfied that the applicant considered that the proposed premises were not adjacent to, or in close proximity to, another pharmacy or dispensing appliance contractor premises. In such cases, the Committee will consider whether it agrees with this in light of the information provided to it.
7. If the Committee is satisfied that the information indicates that a refusal under Regulation 31 is not required, the Committee may simply note:

"The Committee was satisfied that Regulation 31 did not require the application to be refused and went on to consider the substance of the application against the criteria in Regulation [x]"

Regulation 31(2)(a)

8. Regulation 31(2)(a) has two limbs. Regulation 31(2)(a) will apply where either the first limb or the second limb is satisfied. Both limbs relate to a person on the pharmaceutical list (which may or may not be the applicant) who is providing or has undertaken to provide pharmaceutical services.
9. Before considering each limb in more detail, it should be noted that the Committee has considered the meaning of *"has undertaken to provide pharmaceutical services"*.
10. In SHA/24700 (July 2022), the applicant already had an extant grant for a pharmacy to relocate to the new Medical Centre which were the proposed premises for the application. The issue before the Committee was whether a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services.
11. The Committee considered the relevant parts of Regulation 31(2)(a). The first part refers to *"a person on the pharmaceutical list"*. There was no dispute that the applicant was on the pharmaceutical list. The Committee noted that if the person that held the extant grant was a new entrant and so was not already on the pharmaceutical list, then it was not clear how Regulation 31 was to be

interpreted. This was not, however, a point which the Committee needed to determine in SHA/24700.

12. The next part that needed to be satisfied was that the person “*is providing or has undertaken to provide pharmaceutical services (the “existing services”) from the premises to which the application relates...*”. The Committee considered that “*is providing*” was clearly a reference to there being existing service provision at the proposed location. It was not in dispute that the applicant was not providing existing services from the proposed location.
13. The Committee went on to consider the “*or has undertaken to provide*” wording. The Committee considered that the additional wording “*or has undertaken to provide*” was a reference to an alternative contrasting situation than “*is providing*”. If this was to have the same meaning, there would have been no reason to include such wording. The Committee considered whether it was reasonable to take the view that “*or has undertaken to provide*” refers to an extant grant.
14. The Committee noted the parties’ comments in this regard. The Committee was faced with differing uses of “*undertake to provide*”, or “*has undertaken to provide*”, services within the Regulations with examples of it being used when a person is on the pharmaceutical list in relation to premises and when a person is not yet on a pharmaceutical list in relation to specific premises.
15. The Committee considered it was reasonable to look to the intent of Regulation 31. The Committee noted the reference by the applicant to the Department of Health guidance. The Committee noted that the applicant’s reference was to a section that indicated that where premises were listed, the applicant would have to explain why the application should not be refused pursuant to Regulation 31. The Committee did not consider that this reference adequately explained why the phrase “*has undertaken to provide*” services is used within Regulation 31.
16. The Committee noted that the Department of Health guidance clearly indicated the intent of Regulation 31:

“The purpose of this regulation is to prevent a contractor from applying for multiple inclusions in a pharmaceutical list at the same address with no benefit to patients.”
17. The Committee considered that it was reasonable to consider that if the applicant’s two applications to relocate to the same premises were both granted, then the consequence that Regulation 31 was intended to prevent would have occurred, i.e. a contractor would have succeeded in applying for multiple inclusions in a list at the same address.
18. Having considered the finely balanced arguments of the parties and the use of “*has undertaken to provide*” in the Regulations and having considered the intent of Regulation 31, the Committee determined that it was necessary to

interpret “*has undertaken to provide*” in Regulation 31 as referring to extant grants. To do otherwise would not achieve the clearly stated purpose of the Regulation.

19. The Committee therefore determined that it was required to refuse the application under the provisions of Regulation 31.
20. Looking in more detail at the two limbs under Regulation 31(2)(a), the first limb is concerned with the situation where a person on the pharmaceutical list who is providing or has undertaken to provide pharmaceutical services does so in relation to the premises to which the application relates.
21. The second limb is concerned with the situation where this is in relation to adjacent premises.
22. The Committee therefore considers whether the applicant's premises would be part of the existing premises or would be adjacent to them.
23. The Committee has previously determined that the applicant's premises are to be treated as:
 - part of the existing premises - if the applicant's premises share any part of their 'footprint' or (though predominantly detached from the existing premises) the applicant's premises are in some other way physically connected to the existing premises; and
 - adjacent premises - if the two sets of premises share a boundary whether to the front, side or rear via which access between the two sets of premises could be achieved (whether or not such access currently exists).
24. For the purposes of Regulation 31, the Committee has determined that existing premises which are “*in the vicinity*” of the applicant's premises are disregarded. In SHA/17479 (March 2014), two units of a centre housing multiple businesses were held not to be the same or adjacent premises as the two units were not the same unit and were not adjacent to each other.
25. In SHA/18005 (August 2015), the Committee explored in detail the existence of property boundaries and any barriers between the premises. The applicant presented arguments about the two sets of premises being owned by different people but the Committee determined that ownership of the land was not a relevant consideration. Instead the issue was whether the properties were adjacent, based on the address of the pharmacy premises. The Committee considered that there may be certain circumstances where a part of premises should reasonably be considered to be separate to another part of those premises for the purpose of Regulation 31 (e.g. two separate units in a shopping centre that had different “unit” addresses and were separated by other units). In SHA/18005, the Committee determined that, with reference to the address of the existing premises listed on the pharmaceutical list, it was

reasonable to consider the existing "pharmacy premises" to be adjacent to the address to which the application related.

Regulation 31(2)(b)

26. If Regulation 31(2)(a) is satisfied, then refusal under Regulation 31 can only occur when Regulation 31(2)(b) is also satisfied.
27. Regulation 31(2)(b) relates to whether it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services.
28. A judicial review judgment has considered this point albeit in relation to the NHS (Pharmaceutical Services) Regulations 2005 which contained a provision written in substantively the same terms. In **R (Pharmacy Care Plus) v FHSU [2013] EWHC 824 (Admin)**, the Administrative Court (*dealing with Regulation 17A of the NHS (Pharmaceutical Services) Regulation 2005*) provided the following guidance on deciding whether it would be reasonable to treat services provided by an applicant as part of the same service as an existing provider:
 - "34. *It is clear ... that it will almost always be an extremely relevant consideration to know whether or not there is any connection in terms of ownership and control between the entities who carry on the existing business and who propose to carry on the proposed new business. So, for example, if an existing business was owned by Company A and the proposed new business was owned by Company B, and there was absolutely no connection at all in terms of ownership and control between the two of them, it would be difficult to see how they could be regarded as providing the same service, even if the services which they were going to provide were complementary to each other. In contrast, if they were both to be provided by exactly the same company, then that would also be an extremely relevant consideration going the other way.*
 35. *But also I can well accept that there may be intermediate positions; so, for example, there may be a commonality of ownership but the owners may not be exactly the same, and it may very well be that in such cases one would have to consider things such as the nature of the respective businesses; whether or not they are going to be physically separate or separate from a business point of view; whether or not the employees would be working in both businesses, and any other relevant matters ..."*
29. In light of that Judgment, the Committee has previously considered the following factors:
 - whether the same company would be operating both sets of premises;
 - whether the two providers are separate legal entities;

- whether there is any shared ownership or control and, if so, what its impact might be;
 - whether any employees would work for both enterprises; and
 - any other matters which appear to the Committee to be relevant.
30. In SHA/18622 (July 2017), the intention of this application and the application in case SHA/18623 was effectively to "swap" premises such that each pharmacy relocated to the existing site of the other pharmacy. In this case, NHS Resolution had requested further comments on the application of Regulation 31 on the basis that a director and the superintendent pharmacist of the applicant shared a surname with the applicant in case SHA/18623. Further comments on this issue on behalf of the applicant indicated that the superintendent pharmacist of the Applicant and the applicant in case SHA/18623 were brothers.
31. The Committee considered that this family link in the ownership of the two pharmacies meant that there was a closer relationship between the two pharmacies than if they were owned by two separate legal entities with no connection at all. The Committee considered that the relationship between the pharmacies therefore fell into an "*intermediate position*" as set out in the judgement above. As per the judgment, the Committee went on to consider the nature of the respective businesses; whether or not they were going to be physically separate or separate from a business point of view; whether or not the employees would be working in both businesses, and any other relevant matters. The Applicant's representative indicated that neither brother had business interests in the other business, there were different superintendent pharmacists in each pharmacy and each pharmacy had separate SOPs. The Committee therefore considered that, notwithstanding that there was a family connection between the owners of the pharmacies, it was reasonable to consider that the pharmacies were running separate businesses, providing separate services from their respective premises and therefore that Regulation 31(2)(b) was not satisfied.
32. In SHA/23276 (February 2020), the Committee considered a combined change of ownership and relocation application. The applicant had stated that he was a sole trader and had no connection to Accrington Late Night Pharmacy (the existing pharmacy), either as a director or shareholder. The applicant further stated it was completely separate from Accrington Late Night Pharmacy from a physical, business and tax view. The Committee noted that NHS England, in its decision, had stated that there was no connection between the applicant and Accrington Late Night Pharmacy after it had completed its checks. However NHS England concluded that "*the pharmaceutical services offered by the Applicant to be part of the same services as the existing services already provided from that premise. As such Committee members refused the application in line with Regulation 31(2)(a)(i) and (b).*" As part of its redetermination of the application, the Committee determined that, due to the applicant being a sole trader and having no connection to Accrington Late Night Pharmacy, Regulation 31(2)(b) was not

satisfied, and therefore the Committee was not required to refuse the application.

33. In SHA/18750 (November 2017), the Committee considered a combined change of ownership and relocation application. In the covering letter to the application, the applicant stated *"I have also enclosed with the application a copy of the notice for closure of our 100 hours Pharmacy (FWC93) that I ... have sent to NHSE that is alongside this application under Regulation 25(2)"*. The Committee considered that the use of the words *"our 100 hours Pharmacy"*, implied that there was a close link between the applicant and the individual whose name was on the pharmaceutical list in relation to the 100 hours pharmacy. The Committee considered that the implication was that the person who signed the application (director of the applicant company), was involved in the business of the existing 100 hours pharmacy.
34. The Committee also noted that the notice of closure signed by the person giving notice of withdrawal from the pharmaceutical list of the 100 hour pharmacy at 2 Market Square, Bicester. The notice contained a number of references, which implied that the person had an interest in the business of the applicant. These references were:
- the notice was sent on the applicant company's headed notepaper, which implied that the person giving notice of withdrawal had access to the applicant's stationery and this would not normally be the case if the entities were separate;
 - the notice stated:

"I have also submitted an application for combined relocation/change of ownership in relation to the Lloyds Pharmacy premises at 34 Sheep Street Bicester OX26 6LG for permission to relocate to 2 Market Square, Bicester".

which the Committee considered was evidence that the relationship between the entities was so close that the person signing the withdrawal notice referred to himself when in actual fact he was referring to the applicant company;
 - the terms *"we"*, *"our"* and *"us"* were used throughout the letter when referring to both the intended closure of the 100 hour pharmacy and the application to relocate/change ownership. The Committee considered that this implied that the applicant and the person on the pharmaceutical list for the existing 100 hours pharmacy were acting together as one business;

The Committee noted NHS England's comments that:

- the applicant and the person on the pharmaceutical list for the 100 hours pharmacy shared an email address and NHS England had received emails from them both using this address;
 - the GPhC premises register showed the applicant company as the registered owner of the existing pharmacy premises at 2 Market Square, Bicester;
 - the website for the existing pharmacy at 2 Market Square on NHS Choices shared a name with the applicant company. The website listed three branches, one of which was in Bicester and the phone number was that of the pharmacy at 2 Market Square, Bicester. The website indicated that the existing pharmacy was owned by the applicant company; and
 - in an email sent from an email address that included the name of the applicant company, the person signing the notice of closure of the existing pharmacy confirmed that he was at the registered office of the applicant company when he wrote the letter notice of closure which accompanied the application.
35. The Committee was therefore satisfied that this closeness made it reasonable for the Committee to consider that the services that the applicant proposed to provide were part of the same services as the existing services (and so the premises to which the application related and the existing listed chemist premises should be treated as the same site).
36. In addition, the Committee did not consider that the issuing of a notice of closure was enough to displace a finding that Regulation 31(2)(b) is satisfied where it is clear that there is a close connection between the two entities.
37. In SHA/19993 (January 2019), the Committee refused a relocation application under Regulation 31(2)(b) on the following basis:
- both entities shared a director;
 - the director of the applicant and the directors of the existing pharmacy at the proposed site were all directors of a third company;
 - all three companies shared the same registered office address;
 - there were further links between the directors in respect of other companies; and
 - the applicant company was owned by the company listed on the pharmaceutical list for the existing pharmacy at the same premises to which the application related.

38. In SHA/21102 (July 2019), a relocation application, the Committee noted that the applicant was already included in the pharmaceutical list at the proposed site. The applicant stated that it had submitted a closure notice to close the services that were operated from the proposed premises. The applicant's representative stated that the applicant had no intention of rescinding its notice of closure but if, in a hypothetical situation, a closure notice was rescinded then NHS England would be able to issue a breach notice in relation to the service provider's failure to provide 100 hours services and the listing to the 100 hour provision could be removed because of the breach of its terms of service. The Committee was of the view that, whilst this scenario may provide a solution to "*get around*" a situation that may occur should a closure notice be rescinded, it was the intention of Regulation 31 to prevent such an occurrence from happening in the first place. The Committee therefore determined that it was reasonable to consider that the intention to close one pharmacy before relocating the other pharmacy to the premises was not enough to displace a finding that where there was a close connection between the relevant entities; i.e. only one company was involved in this application, Regulation 31(2)(b) would be satisfied, resulting in the application needing to be refused.
39. In SHA/26141 (July 2024), the Committee noted that the application, signed on behalf of the Applicant by Mr Asif did not reveal any connection between the Applicant and JMA Pharma Ltd, which owned the proposed premises for the relocation. The question of a link between the Applicant and JMA Pharma Ltd was first raised by the Appellant
40. The Committee noted that although the Applicant referred to it being possible for family members to have business interests independent of each other there was no acknowledgement of a familial or any other link between the directors of Mohammadi Healthcare Limited and JMA Pharma Ltd. The Applicant was required to explain why Regulation 31 had been met. The Committee considered that the Applicant must always have been aware that there was a familial relationship between the two businesses and that he was frequently working at JMA Pharma Ltd. This was not disclosed or admitted by the Applicant until it was queried by the Appellant as part of the appeal.
41. During the oral hearing of the appeal, the Committee considered a range of factors and found the following:
- the fact that Mr Asif advised his brothers not to purchase the pharmacy led the Committee to consider that Mr Asif had been involved in the decision, at the very least his views had been sought;
 - it was not persuaded that experienced businessman such as the directors of JMA Pharma Ltd, who had previously been involved as directors in their family companies and who had paid what was described as a significant sum for their new pharmacy, would decide within a matter of weeks that they would walk away from their new

pharmacy business without financial recompense, so that a company with a distinct identity could relocate to those premises;

- that Mr Asif had been working on a regular basis in the pharmacy until immediately prior to the hearing was suggested that there could be a degree of involvement and control in the business;
- this application was distinct from SHA/18622 and SHA/18623, in that there was indeed other information and evidence that warranted consideration. It was not the case that there was only a familial relationship between the Applicant and JMA Pharma Ltd, as was accepted by both parties.

42. Consequently, when balancing the fact that there was not an overlap in Companies House information of the legal entities, against the factors which indicated that there was a tangible connection, the Committee was not satisfied that the Applicant had a sufficiently distinct identity and would be providing a distinct service. The contributing factors that the Committee considered was the familial relationship, the fact that Mr Asif worked at JMA Pharma Ltd, the involvement in the purchase by Mr Asif, the length of time between the purchase and the request for relocation, and the lack of financial compensation for the transfer of the lease. Consequently, it determined that the evidence indicated that it was reasonable to treat the services that the Applicant proposes to provide as part of the same service as the existing services based on the test provided in the Judgment.

See below, copies of decision letters referred to above.



1 August 2024

APPENDIX

REGULATION 31

- (1) *A routine or excepted application, other than a consolidation application, must be refused where paragraph (2) applies.*
- (2) *This paragraph applies where—*
- (a) *a person on the pharmaceutical list (which may or may not be the applicant) is providing or has undertaken to provide pharmaceutical services (“the existing services”) from—*
 - (i) *the premises to which the application relates, or*
 - (ii) *adjacent premises; and*
 - (b) *NHS England is satisfied that it is reasonable to treat the services that the applicant proposes to provide as part of the same service as the existing services (and so the premises to which the application relates and the existing listed chemist premises should be treated as the same site).*

SCHEDULE 2

Applications seeking the listing of premises that are already, or are in close proximity to, listed chemist premises

6. *If, as regards a routine or excepted application—*

(a)

(b)

the premises which the applicant (A) is seeking to be listed in relation to A are already listed chemist premises or are adjacent to or in close proximity to such premises, A must include with the application details that explain why A believes the application should not be refused pursuant to regulation 31.