

## GUIDANCE NOTE

### Regulation 24(1) of the

### NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1. Regulation 24(1) as at 1 December 2015 reads as set out in Appendix 1.
2. This guidance note focuses on the tests contained in Regulation 24(1) and provides assistance to the Committee based on past decisions. As at the date of this note, there is no judicial guidance on the interpretation of Regulation 24.
3. Regulation 24(1) is discussed in Chapter 10 of the Department of Health's guidance to NHS England in *Regulations under the Health and Social Care Act 2012: Market entry by means of Pharmaceutical Needs Assessments* (November 2013). Extracts from the guidance are set out under the relevant paragraphs below.

#### **Regulation 24(1)(a)**

4. In relation to Regulation 24(1)(a), the Department of Health's guidance states:

*"NHS England should consider whether the new premises are significantly less accessible for those patient groups who use the current premises or not.*

*The term "patient group" reflects the requirement for HWBs, when developing their PNAs, to have regard to the demography of their area and the different needs of people in their area who share a protected characteristic, for example, a large travellers' site, a large sheltered housing complex. These are the characteristics such as age, sex and disability that form the basis of the public sector equality duty under the Equality Act 2010.*

*When deciding whether the new premises are significantly less accessible, NHS England will need to consider whether there are any physical barriers or other geographical, transport or communication factors which would affect the accessibility of the new premises.*

*Relocations should result in improved access for those patient groups who use the current premises. However there may be occasions where this may not be the case. For example, the lease on the premises is due to expire and the pharmacy has to secure new premises at short notice. In this instance, the pharmacy may have to move into premises that do not offer the same level of access as at the current site and NHS England will need to exercise its judgement and decide whether this reduction in access is significant or not."*

5. The Committee will need to consider the information before it with regard to the patient groups who are accustomed to accessing pharmaceutical services at the existing premises. The Committee must seek to identify the patient groups who would potentially be affected by the relocation based upon the information provided by the parties. This information is most commonly going to be provided by the applicant but others may also be able to contribute to the information on which the Committee will proceed. The applicant or other parties may not use the exact term 'patient group'. If the information indicates that a particular patient group exists, or if it can be inferred that a particular patient group exists, irrespective of size or location, the Committee will need to be satisfied that the information provided allows it to decide whether the location of the proposed premises is not significantly less accessible for that patient group.
6. The Committee should be alert to the fact that the number and type of patient groups will differ on a case by case basis and much will depend on the location of the existing and proposed premises. It is therefore not possible to provide an exhaustive list but, as a result of recent decisions, a clear approach to decision making has emerged. The approach is summarised in this note.

7. The wording of Regulation 24(1)(a) requires patient groups to be identified in order for the test to be met. If patient groups are not referenced in the information provided, the Committee cannot find that the test is met.

### ***Broad patient groups***

8. Applicants may identify a patient group in very broad terms. In case 17995 (18/08/15), the applicant referred to the main patient group as those accessing services at the existing premises (i.e. effectively grouping all of its current customers into one "group") and focused on the route a person would take on foot from the existing premises to the proposed premises. The Committee could only draw limited conclusions on the effect of the relocation on patient groups on the basis of the information provided.

### ***Specific patient groups***

9. Patient groups might be identified in relation to:
  - a. local GP practices;
  - b. methods of travel (on foot, by car, or public transport);
  - c. types of pharmaceutical services accessed (dispensing/collection and delivery);
  - d. the location of the patient group's geographic starting point of the journey to the pharmacy;
  - e. demography;
  - f. care homes; and/or
  - g. areas of deprivation.
10. Patient groups will likely overlap. This can be an issue where the applicant identifies patient groups in one way and parties providing representations identifying patient groups in other ways. In case 17976 (26/07/15), the applicant identified three patient groups based on patients' registration at three local GP practices. Additional comments from the applicant and other parties led the Committee to note 14 other potential patient groups.
11. As a principle of public law, the Committee must consider all comments made by parties with regard to patient groups regardless of how they are described. The Committee should not prefer one party's identification of patient groups over another if this ignores comments on access for patient groups from other parties.

### ***Patient groups relating to GP practices***

12. Applicants often identify patient groups with reference to GP practices. Identifying patient groups in relation to which GP practice the patients are registered is not, on its own, helpful in assessing the effect of relocation on those patient groups.
13. References to GP practices may be relevant where patients attend the GP practice prior to, or after, accessing pharmaceutical services (e.g. to have prescribed drugs dispensed). This may be very relevant where the existing or proposed pharmacy premises are located at or adjacent to the GP practice.
14. Where a patient group is identified that accesses pharmaceutical services in conjunction with a visit to the GP practice and subject to any evidence to the contrary, it is likely to be reasonable to infer that there will be patients registered with the practice who access pharmaceutical services otherwise than in conjunction with a visit to the GP practice. This may be where such patients are in possession of a repeat prescription or require essential services other than the dispensing of a prescription. In such cases, much will depend on how this patient group (or sub-group within it) accesses the existing premises and how the patient group will access the proposed premises (e.g. methods of travel and from where the patient group starts its journey).

15. A patient group may be identified that consists of patients registered with a number of GP practices rather than one specific GP practice. In case 17774 (22/01/15) the Committee identified as a patient group:

*"Patients registered with the Medical Centre, patients registered with practices in the wider locality and patients in the whole locality but not attending for a GP appointment at the time of accessing pharmaceutical services [starting point, for example, from home]"*.

16. The applicant may make a statement that it currently provides services to a wide number of patients registered with a number of GP practices. To satisfy Regulation 24(1)(a), the Committee would need to be satisfied that the information demonstrates that the proposed premises do not make services significantly less accessible. Examples are provided below where the proposed premises may be significantly less accessible:
- a. there are shopping facilities in the immediate vicinity for a number of walk-ins and as such any relocation outside this area may mean an extra journey for this patient group and thus make it significantly less accessible;
  - b. the pharmacy provides specific services such as drug dependency and as such any relocation takes the service physically and/or socially 'away' from this group and thus makes it significantly less accessible;
  - c. there are businesses/offices in the immediate area and any relocation will take services away from where the patient group of employees find themselves on a daily basis and thus make it significantly less accessible; and/or
  - d. there are tourists that frequent a particular area or areas and any relocation outside this area may mean an extra journey for this patient group and/or will take services away from where tourists find themselves and thus make it significantly less accessible.

#### ***Journey between the existing and proposed premises***

17. Applicants often provide information on the journey between the existing premises and the proposed premises. This is likely to assist the Committee in considering the effect of the relocation on a patient group that is accustomed to accessing pharmaceutical services at the existing premises from a point close to the existing premises.
18. In case 17885 (19/6/2015), the applicant suggested that if the journey between the existing and proposed premises itself does not make the proposed location significantly less accessible compared to the existing location, then the test in Regulation 24(1)(1) is met.
19. The Committee was of the view that in extremely limited circumstances, it could be presumed that the proposed location is not significantly less accessible to any patient groups without any need to identify the patient groups. An example might be where the proposed premises are next door to the existing premises. It is highly likely that no patient group would find the proposed premises in this example significantly less accessible.
20. The Committee was mindful that this can only be a presumption and could be rebutted by evidence to the contrary, e.g. if the pharmacy next door was up a flight of stairs or otherwise less accessible. The Committee was also of the view that the presumption becomes less appropriate the further removed the circumstances are from that example.
21. The Committee was of the view that the presumption would only be appropriate in extremely limited circumstances, i.e. it has a very high threshold. Once the distance is more than merely negligible, the identification of patient groups and analysis of the impact of the proposed relocation on the accessibility of the proposed premises is necessary to determine whether Regulation 24(1)(a) is met.
22. The Committee did not agree with the Applicant's further contention that if a patient, for whom the journey to the new location makes up 100% of their required travel, does not find the new location significantly less accessible, then no other patient or patient group can either. The Committee considered that this argument must fail as a matter of fact and law. Other than in very limited circumstances, a patient group may have a longer or qualitatively different journey to the proposed premises in absolute terms than a person who started from the existing premises.

23. The Committee may have to accept that some users of the pharmacy may have further to travel to the new location whereas others may have less distance to travel. It will be necessary for the Committee to factor this in to its overall assessment but to remind itself that the test to be met is whether, for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible.

### ***Collection and delivery services***

24. It is common for applicants to identify a patient group to whom collection and delivery services are provided. It is often claimed that such a patient group falls outside the scope of Regulation 24(1)(a) or are unaffected by a relocation because this patient group is not accustomed to accessing pharmaceutical services at the existing premises. The Committee should consider and note any such assertions and any comments from other parties. It may be that the patient group accesses dispensing services that way but routinely attend the premises for other essential services and the Committee will need to be satisfied that they are not significantly less accessible.

### ***Protected characteristics***

25. The Committee must consider accessibility, in particular, for those with a 'protected characteristic' (i.e. age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex and sexual orientation).
26. It is likely that age, disability and pregnancy and maternity will be the protected characteristics which are most relevant to a proposed relocation in light of potential related mobility issues.
27. The Committee is required by the public sector equality duty imposed by the Equality Act 2010 to consider, among other matters, the elimination of discrimination and enhancement of equality between the patient groups that comprise persons who share protected characteristics and those without such characteristics. The Committee should therefore carefully consider the potential effect of the relocation on accessibility for those with protected characteristics and ensure such consideration has been noted.

### ***Considering patient groups together***

28. The overlap in the membership of patient groups means that consideration of each patient group individually may result in a large amount of duplication. Previous determinations have sought to reduce this duplication while ensuring that all comments relating to patient groups are taken into account.
29. In case 17976 (28/07/15), three broad patient groups were identified (of patients registered with three different GP practices). A further 14 patient groups (relating to methods of transport, protected characteristics etc) were identified from comments from other parties. The determination was structured in such a way as to focus on the three GP practice patient groups but within each one was consideration of the relevant patient groups identified by other parties. This approach preserved the applicant's categorisation of patient groups but allowed the Committee to refer to all comments. The overlap of patient groups was highlighted and where a specific patient group (e.g. the elderly) was considered within a broader patient group, the specific patient group was referred to as a "sub-group". It was made clear, however, that such sub-groups were considered patient groups in their own right for the purposes of Regulation 24(1)(a).
30. The most appropriate approach to consideration of patient groups will usually depend on the patient groups identified and whether comments are made on those patient groups.

### ***Supporting data and limited information***

31. The applicant or other parties may support identification of patient groups by reference to dispensing or other data. Where supporting data is provided, it should be considered alongside other data available to the Committee and any comments on the data by other parties. The Committee should place whatever evidential weight it deems appropriate on information that is provided without supporting data and on any supporting data that is produced.

32. The Committee may consider that the information available to it references the existence of patient groups about which limited information is provided. This could lead the Committee to draw limited conclusions regarding access for these identified patient groups.
33. The Committee should bear in mind that it has to be satisfied that the proposed premises are not significantly less accessible for those patient groups who are accustomed to accessing pharmaceutical services at the existing premises.
34. The Committee should ensure determinations include relevant wording where:
  - a. it is reasonable to infer that a patient group exists from the information provided regardless of whether any information has been provided on that specific patient group; and/or
  - b. parties other than the applicant assert the existence of patient groups and those patient groups are not subsequently addressed by the applicant.
35. The Committee should note the existence of or absence of supporting information where comments are made on accessibility. This may include information relating to:
  - a. journeys on foot and any barriers that may present accessibility problems for those with mobility issues;
  - b. private transportation such as parking facilities located at or near premises; and/or
  - c. public transportation such as bus or tram routes, bus or tram stops, train stations and features that may affect accessibility such as one way systems, pedestrian precincts or no vehicle zones.
36. The lack of evidence supporting contentions made in relation to accessibility for patient groups can often result in the Committee not being satisfied that Regulation 24(1)(a) is met.

#### ***Regulation 24(1)(a) - conclusion***

37. When considering the application of Regulation 24(1)(a), the Committee should:
  - a. ensure that all comments on patient groups (whether or not the term patient group is used) and any comments on accessibility are considered and given appropriate weight;
  - b. be satisfied that the information before it is sufficient to enable the Committee to assess and be satisfied as to the effects of relocation on different patient groups; and
  - c. set out clear reasoning why the Committee is or is not satisfied that for a particular patient group the test in Regulation 24(1)(a) is met.
38. The Committee is required to give reasons for its decision. The determination must therefore explain whether the Committee is satisfied, acting reasonably and on the basis of the information provided by all parties, that the test in Regulation 24(1)(a) is met.

#### **Regulation 24(1)(b)**

39. In relation to Regulation 24(1)(b), the Department of Health's guidance states:

*"...NHS England will need to consider whether the relocation would impact on the arrangements that are in place for the provision of local pharmaceutical services and pharmaceutical services in any part of the area of the relevant HWB.*

*NHS England would need to be satisfied that any impact would not result in a significant change taking into account the particular circumstances.*

*It should be noted that it is not required to consider the impact on the provision of pharmaceutical services by persons on the dispensing doctor list. Additionally NHS England must consider the impact on pharmaceutical services, provided in a controlled locality of a neighbouring HWB where that controlled locality is within 1.6 km of the proposed new premises. This provision therefore looks*

*at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision."*

40. Every relocation of a pharmacy on a pharmaceutical list will constitute a change to the arrangements for the provision of pharmaceutical services but where the Committee considers that such a change is not significant, Regulation 24(1)(b) will be satisfied.
41. This is illustrated by the approach of the Committee in SHA/17885. Certain parties referred to the undesirability of the "clustering" of pharmacies in the vicinity of the proposed location should the application be granted. The Committee considered that the relocation would be a change to the provision of pharmaceutical services as it would result in one less pharmacy in the existing location and one more pharmacy in the proposed location. The Committee considered that the change to the arrangements in place for the provision of pharmaceutical services was not significant because the relocation, if granted, would not lead to a significant change in the general availability of pharmaceutical services in the areas of the existing or proposed premises.
42. In SHA/17956, the Committee considered that Regulation 24(1)(b) was not met because, by the applicant's own admission, the proposed relocation would result in a significant change to the arrangements in place for the provision of pharmaceutical services by the removal of a generally accessible town centre general pharmacy and its relocation elsewhere away from the retailing area and within the same building as a newly combined medical practice.
43. The test in Regulation 24(1)(b) only relates to the consequences of the application being granted. In SHA/17885, the Committee noted that the applicant feared for the viability of the pharmacy at the existing location if the application was not granted. The Committee considered that this was not a relevant factor as the wording of Regulation 24(1)(b) only required consideration of whether there would be a significant change to the arrangements in place as a result of granting the application.
44. In SHA/17883, the appellant argued that its viability was threatened if the application was granted. The Committee noted that the appellant had not expanded upon this but was mindful of the possibility that granting the application may affect the number of prescriptions dispensed by the appellant. The Committee was, however, of the opinion that on the information provided to it the granting of the application would not result in the closure of the appellant's pharmacy. The Committee considered that relocation would amount to some change in the arrangements for the provision of pharmaceutical services but in the circumstances the Committee was of the opinion that the granting of the application would not result in a significant change to the arrangements in place for the provision of local pharmaceutical services or of pharmaceutical services.
45. The Committee will be greatly assisted in reaching its conclusions in connection with this test where the parties refer it to any relevant comments contained within the applicable Pharmaceutical Needs Assessment in relation to the whether a relocation might have an impact on the arrangements that are in place for the provision of pharmaceutical services and/or the provision of specific information and evidence in relation to possible consequences. Any appellant objecting on the basis of this limb of Regulation 24 ought properly to particularise the detrimental effect, to be dealt with appropriately by the applicant in seeking to satisfy the Committee that the test is met.

#### **Regulation 24(1)(c)**

46. In relation to Regulation 24(1)(c), the Department of Health's guidance states:

*"... NHS England is required to examine whether the relocation would affect its planning of pharmaceutical services in its area.*

*Example – NHS England decides to amalgamate a number of GP practices in a non-controlled locality at a new large health centre, decides to include a pharmacy in the centre and invites applications. A number of applications from potential occupants for the pharmacy site at the centre are considered and the particular pharmacy was one of the unsuccessful applicants. As an alternative, the particular pharmacy attempts to relocate to a site nearer to the centre – and if that application was granted, it would compromise the viability of the plans for pharmaceutical services at the centre that NHS England has put in place. In these circumstances, NHS England could refuse the application on the basis of detriment to proper planning."*

47. It is unlikely that parties other than NHS England will be in a position to identify planning issues as NHS England holds the plans relating to the provision of pharmaceutical services. The Committee should, however, be alert to any matters raised by other parties relating to any specific circumstances relating to planning and consider them appropriately.
48. The Committee should consider any reasons provided by NHS England in relation to this test. In SHA/17976, the Committee noted that NHS England had stated that, if the application was granted, it would cause significant detriment to proper planning of pharmaceutical services in the area because the relocation was 550 metres away and patients and residents unable to drive or walk could be aggrieved by the loss of local access to a pharmacy. The Committee was of the view that distance, of itself, does not automatically result in a detriment to proper planning in respect of the provision of pharmaceutical services and, in the circumstances of the particular case, there was no evidence that this would be significant.
49. Parties may provide comments under Regulation 24(1)(c) that appear to relate to arrangements for the provision of pharmaceutical services under Regulation 24(1)(b), such as the viability of existing pharmacies. In such circumstances, the Committee should consider which part of Regulation 24(1) the comments and information provided properly relates to and provide reasons for considering comments under a different part of the test to that which they were originally made.
50. The Committee will be greatly assisted by clear explanations provided by the other parties seeking to suggest detriment to proper planning and clear reasoning and copies of relevant planning documents from NHS England in connection with the position reached by it on this point.

#### **Regulation 24(1)(d)**

51. In relation to Regulation 24(1)(d), the Department of Health's guidance states:

*"The applicant is obliged to undertake to provide the same services at the new premises. If the application is approved, the applicant would be required to provide essential services. They would also be required to continue to provide advanced services, and any enhanced services they were providing at the old premises if NHS England chooses to commission them at the new premises. This gives NHS England the flexibility to commission only the enhanced services that are required.*

*The applicant would also be required to be open for the same core and supplementary opening hours at the new premises. Once the relocation is complete, they could then apply to NHS England to change their core opening hours, or notify of a change in supplementary opening hours.*

*NHS England cannot, however, require the contractor to provide additional directed services as a condition of granting the relocation application; they can only require the current directed services to be provided at the new premises.*

*Example - a pharmacy that provides a needle exchange service wishes to relocate to a site that is nearer to another pharmacy that provides this service. The pharmacy provides a needle exchange service at its current premises and undertakes to do so at the new premises. Although NHS England is satisfied that the move does not result in significant change to the arrangements that it has in place for pharmaceutical services, it also considers that commissioning a needle exchange service from both sites will become unnecessary and therefore NHS England decides not to commission that service from the relocated pharmacy once the relocation has taken place. The pharmacy has fulfilled its obligation under this regulation by undertaking to provide the service, but is not required to do so because NHS England does not wish to commission it."*

52. This test requires an undertaking that the services provided will be the same. The Committee should note any comments provided that suggest the applicant could not provide the same services. In SHA/18010, the Committee noted that the applicant had stated that the same pharmaceutical services would be available without any reduction in service. The appellant argued that space in the proposed premises meant that delivery of certain pharmaceutical services was unsuitable. The Committee noted that there was no floorplan to illustrate the layout of the pharmacy. The Committee, however, was not persuaded by the information provided that the applicant did not intend to provide the same pharmaceutical services without any reduction in service.

### **Regulation 24(1)(e)**

53. In relation to Regulation 24(1)(e), the Department of Health's guidance states:

*"NHS England must be satisfied that the provision of pharmaceutical services will not be interrupted, except for such period as it may for "good cause" allow. What constitutes "good cause" is ultimately for NHS England to assess on the facts of the case.*

*Example - there may be a temporary delay in handing over the premises to the new leaseholder. Alternatively, the applicant may request a short interruption to transfer stock and supplies from the old to the new premises and test computer systems etc before opening and NHS England may decide that this is good cause for service provision to be interrupted."*

54. The Committee should note that the standard application form for relocations asks for a yes/no answer to this test. Further information is only required on the application form if the applicant indicates that there will be an interruption. In SHA/17995, the Committee noted that the applicant had ticked "No" to the question "Will there be any interruption to service provision" in the application form and that no other party had provided comments on this test. On the basis of the information before it, the Committee determined that the test was satisfied.
55. The Committee should consider whether a tick in the right box allows it to be satisfied that the test is met in the absence of indication to the contrary or whether, in the circumstances of the particular case, some explanation of business continuity planning in relation to continued provision of services during relocation is required in order for the Committee to be satisfied that there will be no interruption (except for such period as the Committee may for good cause allow).

### **Regulation 24(1)(b) to (e) - conclusion**

56. In a similar way to assessing the application of Regulation 24(1)(a), the Committee should, when considering the application of Regulation 24(1)(b) to (e):
- a. ensure that all comments relating to the subject matter of the tests are considered, even where the comments made are general or are directed primarily at another limb of the test;
  - b. be satisfied that the information before it is sufficient to enable the Committee to determine whether the tests are satisfied; and
  - c. set out clear reasoning why the Committee is or is not satisfied that the tests in Regulation 24(1)(b) to (e) are/are not met.
57. The Committee is required to give reasons for its decision. The determination must therefore explain whether the Committee is satisfied, acting reasonably and on the basis of the information provided by all parties, that the tests in Regulation 24(1)(b) to (e) are met.

### **Conclusion in relation to Regulation 24**

58. An application made under Regulation 24 is an excepted application. The Committee ought properly to give appropriate weight to its status as an excepted application in its deliberations.
59. In essence, Regulation 24 will be met where the Committee can be positively satisfied that the limbs of the test are met, with the result that the applicant will effectively continue to meet the same need or provide the same benefit in connection with which it was originally granted inclusion on a pharmaceutical list notwithstanding a move in premises such that it does not need to go, instead, through the routine application route to set up a pharmacy in a different location.
60. The onus in demonstrating that this is the case will be on the applicant, in light of comments made by other parties including (particularly) NHS England.

**9 December 2015**

## Appendix 1

24—(1) Section 129(2A) of the 2006 Act (regulations as to pharmaceutical services) does not apply to an application from a person already included in a pharmaceutical list to relocate to different premises in the area of the relevant HWB (HWB1) if—

- (a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;
- (b) in the opinion of the NHSCB, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—
  - (i) in any part of the area of HWB1, or
  - (ii) in a controlled locality in the area of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;
- (c) the NHSCB is not of the opinion that granting the application would cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of HWB1;
- (d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, the NHSCB chooses to commission them); and
- (e) the provision of pharmaceutical services will not be interrupted (except for such period as the NHSCB may for good cause allow).