

**GUIDANCE NOTE**  
**Regulation 17 of the**  
**NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013**

1. Regulation 17 as at 18 January 2020 reads as set out in Appendix 1.
2. This guidance note focuses on matters that have arisen in the past in relation to appeals of applications made pursuant to Regulation 17 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the “Regulations”). It provides assistance to the Committee, appointed by NHS Resolution, as to how to determine similar matters based on the approach taken in past decisions.

**Regulation 17(1)(b) - whether the improvements or better access have/has been included in the PNA in accordance with paragraph 4(a) of Schedule 1**

3. Where a Regulation 17 application is appealed, the Committee must, pursuant to Regulation 17(1)(b), determine whether the improvements or better access that would be secured if the application was granted have or has been included in the relevant pharmaceutical needs assessment (“PNA”) in accordance with paragraph 4(a) of Schedule 1 of the Regulations.
4. The headings below identify issues that have arisen in one or more previous Regulation 17 appeals that relate to whether the improvements or better access have or has been included in the PNA in accordance with paragraph 4(a) of Schedule 1. Under each heading is an explanation of the approach of the Committee.

Two step test

5. A PNA often indicates gaps in the provision of pharmaceutical services in certain areas within the relevant Health and Wellbeing Board’s (HWB) area and/or at certain days/times of the week. The Committee is concerned with whether the PNA goes one step further than this. The Committee will determine if the PNA, in accordance with paragraph 4(a) of Schedule 1, not only identifies pharmaceutical services that are not provided but also indicates that the HWB is satisfied that those pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.

6. In SHA/18740 (11 September 2017) the Committee noted that:

*“the above paragraphs are statements of fact, that there is no pharmacy open on a Sunday in the North West locality. The Committee noted that the PNA had not taken this a step further and indicated that provision on a Sunday in Barne Barton would secure improvements or better access to pharmaceutical services pursuant to paragraph 4(a) of Schedule 1.”*

PNA wording - “potential improvements”

7. A PNA may not use the exact words found in paragraph 4(a) of Schedule 1. The Committee will consider the wording used and determine whether it is satisfied that the wording used in the PNA complies with paragraph 4(a) of Schedule 1.
8. The Committee has previously determined that use of the phrase “potential improvements or better access” suggests a lack of certainty on the part of the HWB

as to whether pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.

9. In SHA/21045 (28 May 2019), the Committee stated:

*“The Committee was of the view that the use of the word ‘potential’ indicated that this is something which is a possibility for the future, it does not state that there is an explicit gap in access to essential services during evenings for those living in Binfield with Warfield Ward.”*

10. Where there is reference to “potential improvements or better access”, the Committee will often consider whether there are any other references to the improvements or better access in the PNA that makes clearer the intent of the HWB.

11. In SHA/22122 (8 August 2019) the Committee stated:

*“In relation to the last column on page 5, the Committee noted that it was headed “Potential Improvement 2018 – 2021”. The Committee queried the reference to “potential” here. The use of the word “potential” suggests a lack of certainty. The Committee noted the comments on appeal from Lloyds and Boots to this effect. The Committee went on to consider the wording of the bullet points under this heading.”*

#### PNA wording - “potential gaps”

12. A similar issue arises where the PNA uses the term “potential gaps”. The Committee will consider this term alongside other references in the PNA and consider if the PNA goes on to indicate that the HWB is satisfied that those pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.

13. In SHA/18412 (25 October 2016) the Committee considered that:

*“the reference to “potential gaps” left the Committee in some difficulty. The reference to “potential gaps” is used frequently throughout the PNA and is not always accompanied by clear wording indicating that the gap is conditional on the occurrence of a specified event. The Committee noted that in paragraph 5.1 above, the Applicant reiterates that the PNA identifies potential gaps that need to be filled. However the Committee noted that the PNA does not expressly state at any point that any potential gaps it identified needed to be filled. The Committee considered that, where the PNA contained references to potential gaps, the Committee was required to determine whether, in reference to the potential gap, the HWB was satisfied that if the relevant services were provided during those gaps, this would secure improvements or better access. The Committee recognised that the PNA may not use these actual words.”*

#### PNA wording - “small areas” of a locality

14. A PNA may not be expressly clear in relation to the geographical area to which the improvements or better access relate. For example, a PNA may state that longer opening hours in “small areas” of a certain part of the HWB’s area would secure improvements or better access. The PNA may not identify to a granular level which areas of the part of the HWB’s area are considered those small areas.

15. The Committee needs to determine whether it is satisfied that the improvements or better access that an application is looking to secure relate to the “small areas”

referred to in the PNA. To do this, the Committee needs to identify the location of those “small areas”. This arose in SHA/18754 (30 October 2017) and the Committee adopted the following process:

*“The Committee considered the opening hours of the Applicant and the opening hours of nearby pharmacists. The Committee noted that the extended hours identified in the PNA as securing improvements and better access related to weekday evenings and weekends. The Committee considered therefore that, provided the proposed best estimate of the Applicant's pharmacy was in or reasonably accessible from an area that it could reasonably be said didn't have sufficient access to services on weekday evenings and weekends, then it could be reasonably concluded that the proposed best estimate of the Applicant's pharmacy was in or reasonably accessible from one of the small areas of Mayday referred to in the PNA. It would then be appropriate to have regard to the matters in Regulation 17(2) to determine if the application secured the improvements or better access.”*

#### PNA wording - “opportunity to improve”

16. A PNA may use the term “opportunity to improve”. The Committee will consider if this complies with paragraph 4(a) of Schedule 1.
17. The Committee will consider this term alongside other references in the PNA and consider if the PNA goes on to indicate that the HWB is satisfied that those pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.
18. In SHA/21044 (8 May 2019), it was stated:  
  
*“The Committee noted the wording “there is opportunity to improve access to essential services for residents living in Mapledurham, Thames, Whitley and Peppard wards”. It considered that this wording appeared to suggest that access could be improved...”*

#### PNA wording - “improvements could be made”

19. A PNA may state that improvements or better access “could be made” by taking some action, such as increasing opening hours. As with the wording above, the Committee will consider if this complies with paragraph 4(a) of Schedule 1.
20. The word “could” has different meanings in different contexts. The Committee will consider this wording alongside other references in the PNA and consider if the PNA indicates that the HWB is satisfied that those pharmaceutical services that are not provided would, if they were provided, secure improvements or better access to pharmaceutical services.
21. In SHA/21044 (8 May 2019) was stated:  
  
*“Paragraph 4(a) of Schedule 1 requires the HWB to identify pharmaceutical services that are not provided but that the HWB is satisfied would if they were provided secure improvements or better access (my emphasis). The use of the word “would” led the Committee to consider that the statement in the PNA needed to reflect a high level of certainty that provision of the relevant services would secure improvements or better access rather than it merely being possible that it would or a suggestion that it would do or that it would potentially do so.*

*The Committee considered that the use of the word “could” in the third paragraph on page 38 indicated that the evening and Sunday longer opening hours might improve access but that this was not certain. The use of the word “could” meant that it was a suggestion. The Committee considered that this wording did not reasonably convince it that the HWB was satisfied that the provision of longer opening hours in the evenings or Sundays would secure improvements or better access.”*

#### Opening hours are not services

22. A PNA may indicate that improvements or better access would be secured by longer opening hours or existing pharmacies or by existing pharmacies opening at certain times on specific days of the week.
23. In previous appeals, it has been argued that references in the PNA to improvements or better access being secured by pharmacies being open for longer hours or at certain times/days during the week cannot be considered to be a statement pursuant to paragraph 4(a) of Schedule 1 on the basis that “hours are not services”.
24. The Committee has previously determined that references in the PNA to improvements or better access in the form of longer or additional hours are references to improvements or better access to pharmaceutical services unless expressly indicated otherwise.
25. In SHA/21044 (8 May 2019) the Committee stated:

*“The Committee considered that pharmaceutical services are services which are provided (such as dispensing services or the other services listed in bullet points in the column heading “Services” on page 5 of the PNA) within the opening hours. The Committee considered that, while an hour, as a unit of time, cannot be considered to be a service, wording related to opening hours of a pharmacy clearly relate to the usual pharmaceutical services, including essential services, that a pharmacy provides during its opening hours. Where a statement refers to a need for pharmacies to be open at specific days/times, the clear, common sense, and, the Committee considers, the only meaning of this, is that it is a statement of the need for the provision of pharmaceutical services, including essential services, on/at those specific days/times.”*

#### No need for a new pharmacy

26. A PNA may expressly state that a new pharmacy (sometimes the term “a new contract” is also used) is not required to secure identified improvements or better access and instead the improvements or better access (usually indicated to be in the form of longer or additional opening hours) can be secured by existing pharmacies amending their opening hours. This is often quoted by parties to an appeal who oppose the application to open a new pharmacy to secure the identified improvements or better access.
27. The Committee has previously determined that, for the purpose of Regulation 17(1)(b), if a PNA contains a statement pursuant to paragraph 4(a) of Schedule 1, then a reference in the PNA to not needing a new pharmacy does not automatically mean the decision-maker has to refuse the application.
28. In SHA/22122 (8 August 2019) it was stated:

*“The Committee noted in particular NHS England’s reference to “an additional*

*contract". The Committee understood this to refer to the grant of a new application. The Committee noted that the requirements on the HWB set out in paragraph 4(a) of Schedule 1 do not include a requirement for the HWB to specify how any identified improvements or better access should be secured, e.g. through an extension to an existing pharmacy's opening hours or by the grant of a new application.*

*The Committee therefore considered that the Regulations do not require a PNA to include reference to a need or improvements or better access to be met by the grant of a new application in order for the PNA to be in accordance with the provisions of Schedule 1.*

*In this regard, the Committee agreed with the Appellant who stated on appeal: "If contractors do not fill the gap themselves and/or NHS England does not take the lead in directing pharmacies to open to fill the gap, then the only other way for improvements or better access to services to be secured for residents is through the grant of a new pharmacy application."*

*Paragraph 4 of Schedule 1 states that a PNA must identify services, which, if they were provided, would secure improvement or better access. Paragraph 4 does not require such improvements or better access to be secured by the granting of an application. It is silent on the method as to how services are provided."*

**Reg 17(2)(d) - changes since the PNA means refusing is essential to prevent significant detriment**

29. Where a party claims that refusing the application is essential to prevent significant detriment, the Committee has previously considered a number of factors including but not limited to:

29.1 Whether the claimed detriment is actually detriment to the provision of pharmaceutical services – who suffers the detriment and what form does it take;

29.2 Whether the claimed detriment is significant; and

29.3 Whether the change that is relevant to the significant detriment actually occurred after the PNA was published.

30. In SHA/18769 (7 December 2017), the Committee stated:

*"[The Appellant] in its appeal states that it has extended its morning opening hours to 8am which is a change in the profile of pharmaceutical services. [The Appellant] goes on to say that if this application be granted, the commercial pressures on [the Appellant] will be significant such that it will no longer be able to open at 8am (or on bank holidays) and that this amounts to significant detriment to the provision of pharmaceutical services in the area. [The Appellant] indicates that this is particularly relevant given the opening of the Croydon Hub in April this year which opens at 8am seven days a week.*

*The Committee noted that NHS England, in its representations, state that [the Appellant's] change to an 8am opening was done before the PNA was published as the PNA indicates its current opening hours and that therefore this is not a change in the profile of pharmaceutical services. The Committee noted that Schedule G of the PNA indicated that [the Appellant's] pharmacy opened at 8am."*

**Reg 17(2)(e) - securing the improvements or better access in part and remainder unlikely to be secured**

31. A party may claim that the application must be refused because the application only secures the improvements or better access in part and the remainder is unlikely to be secured. The Committee has previously considered various matters in relation to this issue.
32. The Committee has noted previously that it is not always obvious whether the application secures the improvements or better access in full or in part because the PNA does not set out clearly the extent of the improvements or better access. For example, in SHA/18777 (8 December 2017), the Committee noted:

*“...the wording of the PNA does not state the extent of the opening hours that are required to secure the improvements or better access in East Croydon.”*
33. In such cases, the Committee has compared the improvements or better access offered in the application and those identified in the PNA. In SHA/18777 (8 December 2017), the applicant was proposing opening hours that were longer on a Sunday than the opening hours of other nearby pharmacies. The Committee stated:

*“As the Applicant was not proposing hours over or above what is currently being provided on a weekday evenings or on a Saturday and the wording of the PNA referred to extended opening hours on weekday evenings and at weekends (i.e. Saturdays and Sundays) then the Committee determined that the Applicant’s application would secure the improvements or better access in part.”*
34. Once it has determined that the application would secure the improvements or better access in part, the Committee will consider the second part of Regulation 17(2)(e), whether the remainder of the improvements or better access are unlikely to be secured.
35. In SHA/18769 (7 December 2017), the Committee considered how the remainder of the improvements or better access could be secured:

*“The Committee considered that there were various ways in which the remainder of the improvements or better access could be secured – given the hours proposed by the Applicant, it was possible that an application that included provision of services in the remaining hours could be made, existing pharmacies could agree with NHS England to change their core hours to cover the relevant days and times or NHS England could direct a pharmacy to open at the relevant days or times.”*
36. The Committee will need to assess how likely it is for the remainder to be secured which will likely be based on the characteristics of the area, the improvements or better access in the PNA and the application, the local provision of pharmaceutical services and any other relevant factor.

**Reg 17(2)(f) - since the PNA, the improvements or better access have/has been secured**

37. A PNA may identify improvements or better access in terms of longer or additional opening hours. A party may claim that an application looking to secure those improvements or better access must be refused pursuant to Regulation 17(2)(f) on the basis that a nearby pharmacy has agreed to extend its opening hours.

38. In previous determinations, the Committee has indicated that it will be satisfied that the improvements or better access have/has been secured in this situation if the nearby pharmacy's additional opening hours are core hours and not supplementary hours. A pharmacy may change supplementary hours on three months' notice.

39. In SHA/18777 (8 December 2017) it was stated:

*"The Committee agreed with the Applicant that, in determining whether improvements or better access had been secured by another person, it needed to be satisfied that the improvements or better access would be provided on a long term basis. The ability of a pharmacy to withdraw the improvements or better access on the provision of a short period of notice did not satisfy the Committee in this regard."*

**Reg 17(2)(g) – whether improvements or better access are for services other than essential services and granting leads to an undesirable increase in essential services**

40. In previous appeals, the "opening hours are not services" argument set out above in this note has also been used to argue that the application should be refused pursuant to Regulation 17(2)(g). The argument used is that hours are not essential services so the improvements or better access does/do not relate to essential service. As such, Regulation 17(2)(g) applies and granting the application would lead to an undesirable increase in availability of essential services and the application must be refused.

41. As indicated above under the heading "Opening hours are not services", the Committee considers that references in the PNA to improvements or better access in the form of longer or additional hours are references to improvements or better access to pharmaceutical services including essential services unless expressly stated otherwise.

42. In SHA/18777 (8 December 2017) the Committee considered that:

*"an indication in the PNA that services were not being provided at certain times in certain areas related to the non-provision of services, including essential services (unless otherwise stated). The improvements or better access therefore related to the provision of services including essential services."*

*The Committee considered that, to argue that a need in the PNA for additional hours for the provision of pharmaceutical services (without this being restricted to a particular type of services) was not in respect of essential services, was odd. It appeared clear to the Committee that the intent behind Regulation 17(2)(g)(i) was if the PNA specifically referred to a service other than essential services (i.e. advanced or enhanced services).*

*The Committee agreed with the Applicant that it is impossible to separate an identified need for opening hours on a Sunday (where there is no indication that the need refers only to a certain type of pharmaceutical services) from the requirement to provide pharmaceutical services, including essential services) during those opening hours.*

*The Committee noted that as Regulation 17(2)(g)(i) did not apply, it was not required to consider the undesirable increase in the availability of essential services as set out in Regulation 17(2)(g)(ii)."*

## Appendix 1

### Regulation 17 (Improvements or better access to the current service: additional matters to which the NHSCB must have regard)

(1) If —

(a) the NHSCB receives a routine application and is required to determine whether granting it, or granting it in respect of some only of the services specified in it, would secure improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB; and

(b) the improvements or better access that would be secured have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4(a) of Schedule 1,

in determining whether it is satisfied as mentioned in section 129(2A) of the 2006 Act (regulations as to pharmaceutical services), the NHSCB must have regard to the matters set out in paragraph (2).

(2) Those matters are —

(a) whether it is satisfied that it would be desirable to consider, at the same time as the applicant's application, applications from other persons offering to secure the improvements or better access mentioned in paragraph (1) that the applicant is offering to secure;

(b) whether it is satisfied that another application offering to secure the improvements or better access mentioned in paragraph (1) has been submitted to it, and it would be desirable to consider, at the same time as the applicant's application, that other application;

(c) whether it is satisfied that an appeal relating to another application offering to secure the improvements or better access mentioned in paragraph (1) is pending, and it would be desirable to await the outcome of that appeal before considering the applicant's application;

(d) whether it is satisfied that, since the publication of the relevant pharmaceutical needs assessment, there have been changes to the profile of pharmaceutical services in the area of the relevant HWB that are such that refusing the application is essential in order to prevent significant detriment to the provision of pharmaceutical services in that area;

(e) whether it is satisfied that —

(i) granting the application would only secure the improvements or better access mentioned in paragraph (1) in part, and

(ii) if the application were granted, it would be unlikely, in the reasonably foreseeable future, that the remainder of those improvements or that better access would be secured;

(f) whether it is satisfied that, since the publication of the relevant

pharmaceutical needs assessment, the improvements or better access mentioned in paragraph (1) have or has been secured by another person who is providing, or is due to be secured by another person who has undertaken to provide, either in the area of the relevant HWB or in the area of another HWB, NHS services;

(g) whether it is satisfied that —

(i) the improvements or better access mentioned in paragraph (1) were or was in respect of services other than essential services, and

(ii) granting the application would result in an undesirable increase in the availability of essential services in the area of the relevant HWB;

(h) whether the application needs to be deferred or refused by virtue of any provision of Part 5 to 7.

(3) For the purposes of paragraph (2)(f), the improvements or better access is to be treated as due to be secured by another person who has undertaken to provide services if—

(a) the person (P) undertaking to secure the improvements or better access is entitled to give the NHSCB a notice of commencement, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet given that notice;

(b) P has entered into an LPS scheme with the NHSCB, as a consequence of which P will be able to commence the provision of services to secure the improvements or better access, but P has not yet commenced the provision of those services.

#### Document Control - Change Record

Date	Author	Version	Reason for Change
18 January 2020	Head of Operations, Primary Care Appeals	1	New document