

GUIDANCE NOTE

Pharmaceutical Needs Assessment (PNA)

NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

NB – Excerpts from past decisions are included in this guidance note. The full version of a decision may not be available as NHS Resolution only retains past decisions for up to 6 years, in line with its file retention policy.

1. Introduction

- 1.1 This guidance note focuses on the determination of appeals where the Pharmacy Appeals Committee (“Committee”) has been required to consider which PNA should apply to its determination. Its purpose is to provide guidance based on past decisions. The referenced cases are based on particular circumstances and other determinations regarding PNAs may be relevant which are published at [PCA Decisions Archive - NHS Resolution](#). As at the date of this note, 21 May 2024, there is no judicial guidance on this subject matter.
- 1.2 Pharmacy applications and appeals are governed by the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (“the Regulations”). Regulation 22 is particularly relevant to this guidance and is referred to in a number of past decisions. As of 6 November 2023, Regulation 22 states:
 - "(1) If NHS England receives a routine application to which regulation 19(6) does not apply, NHS England must refuse it unless granting it, or granting it in respect of some only of the services specified in it, would—
 - (a) meet a current or future need for pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 2 of Schedule 1; or
 - (b) secure (including in the future) improvements, or better access, to pharmaceutical services, or pharmaceutical services of a specified type, in the area of the relevant HWB that have or has been included in the relevant pharmaceutical needs assessment in accordance with paragraph 4 of Schedule 1.
 - (2) For the purposes of paragraph (1), the relevant pharmaceutical needs assessment is—
 - (a) the pharmaceutical needs assessment of the relevant HWB that is current at the time that NHS England takes its decision to grant or refuse the application, unless in the opinion of NHS England (or on appeal the Secretary of State) the only way to determine the application justly is with regard to an earlier pharmaceutical needs

assessment, in which case the relevant pharmaceutical needs assessment is that earlier assessment; or

- (b) if the relevant HWB has not published a pharmaceutical needs assessment, the pharmaceutical needs assessment of a Primary Care Trust (as extended by regulation 7(1)) that relates to the locality in which the location or premises to which the application relates is or are situated."

1.3 This guidance note sets out:

- 1.3.1 different approaches taken by NHS Resolution when a new PNA has been issued after the application was determined by the Commissioner but before the appeal was determined by NHS Resolution; and
- 1.3.2 the approach adopted by the Committee where an application has been made on the basis of a draft new PNA that has been issued for comments and the final version of the PNA has been published by the time the Commissioner makes its decision.

2. **Approaches where a new PNA has been issued after the application was determined by the Commissioner but before the appeal was determined by the Committee**

SHA/18847 - Case background (application based on a current need)

- 2.1 In case SHA/18847 (dated 14 June 2018) the Committee noted that Regulation 22 states that the relevant PNA for the purpose of determining a pharmacy application is the PNA that was current at the time "NHSCB" (as of 6 November 2023, the Regulations were amended to refer to NHS England) makes the determination unless the only way to determine the application justly was with regard to an earlier PNA. As is common practice when determining appeals, the Committee considered that it was appropriate to consider that the reference to "NHSCB" in Regulation 22 should be read to be "NHS Resolution" for the purpose of an appeal. The Committee considered that Regulations 5 and 6 envisaged there would be a revised PNA published by each Health and Wellbeing Board by 1 April 2018. The Committee noted that the original decision of NHS England in this matter was taken in relation to an earlier PNA.
- 2.2 In this case, the Committee had received information from an objector about a revised PNA. It was noted that applications made pursuant to Regulation 13 are based on a PNA identifying a current need for pharmaceutical services. A revised PNA could contain wording that is significantly different from an earlier PNA and therefore an application made pursuant to Regulation 13 could be significantly affected by the existence of a revised PNA. In such circumstances, Regulation 22 may be relevant.

- 2.3 Paragraph 9 of Schedule 3 of the Regulations enabled the Committee to quash NHS England's decision on an application and remit the matter back to NHS England for re-determination where the Committee considered that there should be a (further) notification under paragraph 19 of Schedule 2.
- 2.4 It was possible for the Committee to have made a decision to remit this matter to NHS England on the basis that:
 - 2.4.1 the parties had not had the opportunity to comment on the application of Regulation 22 and NHS England had not made a determination on this point;
 - 2.4.2 the application and appeal may be determined on the basis of the revised PNA;
 - 2.4.3 parties that were originally notified of the application (pursuant to paragraph 19 of Schedule 2 of the Regulations) have not commented on the revised PNA; and
 - 2.4.4 notification under paragraph 19 included parties that have not been notified of this appeal. Such parties would not be able to comment on a fundamental part of this application if the matter was not remitted to NHS England and was determined by the Committee on the basis of the revised PNA.
- 2.5 The Committee acknowledged that remitting to NHS England may cause a delay in the determination of this matter and this was taken into account in any decision about whether to remit.
- 2.6 In the interests of transparency and fairness, NHS Resolution invited comments on this issue.

The outcome

- 2.7 The Committee considered that this appeal was an appeal of a refusal of a routine application and that the appeal was therefore made under paragraph 36(1)(a) of Schedule 2 of the Regulations. The Committee therefore considered that, in determining the appeal, it had the options under paragraphs 9(1)(a)(i) to (iii) of Schedule 3. These are confirmation of NHS England's decision, quashing NHS England's decision and re-determining the application or quashing NHS England's decision and remitting the matter back to NHS England for it to re-determine with such direction as the Committee considers appropriate.
- 2.8 The Committee considered that an application made under Regulation 13 relied heavily on the wording of the relevant PNA as the application related to a current need which Regulation 13(1)(b) requires "has been included in the relevant pharmaceutical needs assessment".
- 2.9 It was the Committee's view that the question as to which PNA was relevant was a major factor in this application. That issue had to be

determined before the application could be considered any further. The determination as to which PNA was to be applied to the application was likely to have a significant impact on whether the application was granted or refused.

- 2.10 NHS England had not considered the application of Regulation 22 and the issue of which PNA to apply at the time it made its original decision because a revised PNA had not been published at that time. During the appeal process, the deadline in the Regulations for publishing a revised PNA had passed. The Committee considered it had to take account of the fact that it was aware that a new PNA had been published.
- 2.11 The Committee therefore considered that it had to quash NHS England's decision on the grounds that this new factor, which had to be taken into account in order to determine the appeal, had not been taken into account in the original decision. The Committee considered, therefore, that its options for determining the appeal were to re-determine it itself or remit the matter to NHS England for it to re-determine.
- 2.12 Paragraph 9(1)(a)(iii) of Schedule 3 indicates that the matter may be remitted to NHS England where it is considered that there should be a (further) notification under paragraph 19 of Schedule 2.
- 2.13 The Committee considered whether there should be further notification under paragraph 19. The Committee noted that paragraph 19 requires an application to be notified to a number of persons including the local pharmaceutical committee, the local medical committee, certain persons on the pharmaceutical list, certain LPS chemists, potentially the local Healthwatch organisation and potentially a Local Health Board. NHS England may also notify any other person who, in its opinion, has a significant interest in the outcome of the application.
- 2.14 The Committee noted from NHS England's papers that NHS England had notified parties of the application which were not parties to the appeal.
- 2.15 The Committee considered that, depending on how Regulation 22 was applied and therefore which PNA was applied to the application, the outcome of the application could be significantly affected. The Committee considered that if it re-determined the application, the parties who were notified by NHS England but were not parties to the appeal, would not be able to make comments on this issue.
- 2.16 The Committee considered that it could be argued that such organisations are unlikely to provide any comments, even if the matter was remitted to NHS England, if they did not provide comments to NHS England when it originally considered the application. The Committee considered, however, that it had no information or comments on which to assume this. When coupled with the fact that a significant issue relating to the application needed to be determined, the Committee considered it reasonable to give such organisations the opportunity to

make representations if they so wished.

- 2.17 Further, the Committee noted that on the basis of the information in front of it, only one party had made comments on the actual content of the revised PNA. This was likely to be a relevant factor in consideration of Regulation 22 as well as being directly relevant to the application if, pursuant to Regulation 22, a decision was made to apply the revised PNA.
- 2.18 The Committee therefore considered a further round of inviting comments would be required to obtain comments on the content of the new PNA. As above, the Committee's view was that it was appropriate to enable all organisations who were required to be notified of the application to provide comments on this.
- 2.19 On the basis of the above consideration, the Committee went on to consider whether it was appropriate to re-determine the application itself or remit to NHS England. If the Committee re-determined the application itself, it would be considering a fundamental issue, the application of Regulation 22 and therefore which PNA to apply, effectively for the first time. It would also be considering the matter without having first received representations from all the parties. The Applicant's or other parties' only remedy if it disagreed with the Committee's decision on the re-determination of the application would be via the issue of judicial review proceedings. The Committee considered that if the Committee remitted the matter back to NHS England for re-determination and representations were sought from the relevant parties, it would be likely that the Applicant and certain other parties would have appeal rights against NHS England's decision.
- 2.20 As such, the Committee considered that it was fair and reasonable to ensure the applicant and other parties were able to comment on the matter and, where applicable, challenge the outcome of the re-determination to NHS Resolution rather than incur the costs and time associated with issuing judicial review proceedings.
- 2.21 The Committee noted that there may be a time delay in the outcome of NHS England's re-determination and that this favoured not remitting to NHS England. The Committee considered, however, that no parties had argued they would be prejudiced by any such delay and, given the comments above on the potential seriousness of the outcome of the application of Regulation 22, it was reasonable to remit the matter to NHS England.
- 2.22 For the reasons given above, the Committee, pursuant to paragraph 9(1)(a)(iii) of Schedule 3, quashed the decision and remitted the matter to NHS England for it to re-determine the application.
- 2.23 The Committee noted that paragraph 9(1)(a)(iii) enabled the Committee to make such directions as to the re-determination by NHS England as it considers appropriate.

- 2.24 The Committee therefore directed NHS England to:
- 2.24.1 re-determine the application in accordance with paragraph 19;
 - 2.24.2 ensure it is clear in communications with parties notified of the application why the matter was being re-determined and including in such communications a copy of this determination;
 - 2.24.3 ensure the parties notified of the application were given an explanation of Regulation 22 and the opportunity to comment on Regulation 22 and the contents of the revised PNA;
 - 2.24.4 after circulating comments for observations in the usual way, determine the application ensuring that such determination included its determination of the application of Regulation 22;
 - 2.24.5 provide to the parties that NHS England is required to notify about the outcome of the application and full reasons for that outcome.

SHA/19871 - Case background (application based on a current need)

- 2.25 In case SHA/19871 (dated 18 June 2018) the Committee again referred to Regulation 22.
- 2.26 The Committee noted that the application was made in November 2017 and a decision was taken by NHS England in February 2018. NHS England's decision was taken in relation to the earlier PNA.
- 2.27 There was a significant difference in this case when compared with SHA/18847 (referred to earlier in this guidance note). In SHA/19871, NHS Resolution noted that both appellants made specific reference to the revised PNA in their appeals (dated 7 March 2018) and that the applicant, in its representations, provided a substantial amount of detail on the impact of the contents of the revised PNA on the application. NHS Resolution also noted the applicant's comments on the low likelihood for additional parties to comment as well as the potential for significant detriment if a decision was delayed.
- 2.28 NHS Resolution therefore decided that it was appropriate not to remit the application back to NHS England and proceeded to continue the appeal in the usual way. When the representations on the appeal were circulated for observations, NHS Resolution also sought representations on Regulation 22.

The outcome

- 2.29 The Committee considered that this was an appeal of a grant of a routine application (based on Regulation 13) and that the appeal was therefore made under paragraph 30 of Schedule 2. The Committee therefore considered that, in determining the appeal, it had the options under paragraph 9(1)(a)(i) to (iii).

- 2.30 The Committee noted that the application was based upon fulfilling a current need in the 2015 – 2018 PNA and noted that that NHS England had considered the application against the 2015 – 2018 PNA. The Committee was mindful that the 2018 – 2021 PNA has been published in place of the 2015 – 2018 PNA by the time the appeals were submitted.
- 2.31 The Committee was mindful of Regulation 22 which defines the relevant PNA (for the purposes of Regulation 22(1)) as the PNA that is current at the time. The Committee was of the view that in line with the Regulations it should consider the application against the current PNA unless the provisions of Regulation 22(1) apply.
- 2.32 The Committee noted that all parties had been invited to comment upon the new PNA and all parties were given the opportunity to make observations on all the parties' representations regarding Regulation 22.
- 2.33 The Committee noted the applicant referred to both the 2015 – 2018 PNA and the 2018 – 2021 PNA in its representations. The Applicant also stated, in relation to Regulation 22, that "if [NHS Resolution] decide to determine on the basis of the revised PNA then in the Applicant's opinion the application made by the Applicant pursuant to Regulation 13 is not significantly affected by the revised PNA. The wording has changed however the gap has still been identified, as confirmed by the HWB."
- 2.34 The Committee also noted that one of the Appellants stated: "the 2018 PNA is the 'relevant' document for the purpose of considering this application" and further that "the 2018 PNA provides a far more relevant picture of pharmaceutical services provision within the city at this moment in time than the 2015 PNA referred to by the Applicant. There is no reasonable argument why NHS England should, on this occasion, decide the application by reference to the previous document."
- 2.35 In late observations, a party stated "the application should be determined based on the latest City of York Health and Wellbeing Board Pharmaceutical Needs Assessment (PNA). This is the PNA that was published on 1 April 2018."
- 2.36 The Committee considered that it had been appropriate for NHS Resolution to enable the parties to make additional representations on Regulation 22 in light of the knowledge that a revised PNA had been published.
- 2.37 The Committee was of the view that the starting point as set out in Regulation 22 was that the relevant PNA was the PNA of the relevant HWB that is current at the time that the decision is taken. There is no dispute that the 2018 – 2021 PNA is the current PNA.
- 2.38 The Committee was mindful that Regulation 22 also indicates that if, in the opinion of the decision maker, the only way to determine the application justly is with regard to an earlier PNA, then the relevant PNA is the earlier PNA. The Committee was of the view that no party had

sought to argue that the only way to determine the application justly was with regard to an earlier PNA. Most parties agreed that the current PNA should be the PNA to be considered, and although the applicant had not expressly stated this, the applicant was of the view that the application was not significantly affected by the revised PNA.

- 2.39 The Committee therefore considered the 2018-21 PNA, given it was the current PNA as at the date the Committee determined the appeal and because no argument had been made that consideration of an earlier PNA, was the only just way to consider the application.
- 2.40 The Committee concluded that there was no finding in the 2018 – 2021 PNA which identified a need in accordance with paragraph 2(a) of Schedule 1.
- 2.41 As the Committee's consideration of the PNA had resulted in a different conclusion to that reached by NHS England (as NHS England had considered the application against the –earlier PNA, the Committee also considered the application against the earlier PNA, as it was noted that this was the most up to date PNA at the time the application had been submitted to NHS England and upon which NHS England's decision was made.
- 2.42 The Committee concluded that there was no finding in the earlier PNA which identified a need in accordance with paragraph 2(a) of Schedule 1.
- 2.43 The Committee determined that neither PNA included the need in question.
- 2.44 The Committee was aware that in a letter dated 24 April 2018 to parties, requesting representations on the subject of the PNA, NHS Resolution had advised the parties that it was an option open to the Committee to refer the matter back to NHS England on the basis of the application of Regulation 22.
- 2.45 The Committee noted that NHS Resolution had given all parties the opportunity to comment upon Regulation 22. Further, given the Committee's findings that whichever PNA it had regard to it would not materially affect its decision, the Committee was of the view that it would not be helpful to remit the application back to NHS England for a further consultation.
- 2.46 The Committee noted that representations on Regulation 13 had already been made by parties to NHS England, and these had been circulated and seen by all parties as part of the processing of the application by NHS England. The Committee further noted that when the appeal was circulated representations had been sought from parties on Regulation 13.
- 2.47 In this case, the provisions of Regulation 13(1) were not met and the

Committee therefore did not proceed to consider the application having regard to those matters set out in Regulation 13(2).

2.48 In those circumstances, the Committee determined that the decision of NHS England must be quashed.

2.49 The Committee concluded that the application must be refused.

3. Approach where the application was based on a draft new PNA

SHA/19940 - Case background (application to secure identified improvements or better access)

3.1 In case SHA/19940 (dated 20 September 2018) the Committee considered that it had been appropriate for NHS Resolution to enable the parties to the appeal to make representations on Regulation 22 because:

3.1.1 the application was made on the basis of the draft Redcar and Cleveland PNA 2018 to 2021;

3.1.2 the Applicant submitted the application prior to the publication of the Redcar and Cleveland PNA 2018 to 2021 (the "2018 PNA");

3.1.3 in considering the application, NHS England had regard to the 2018 PNA which was the current PNA at the time NHS England made its decision;

3.1.4 NHS England had decided the application on the basis of the final published 2018 PNA that, according to various references in the NHS England decision report, contained wording that was different to the wording in the draft 2018 PNA;

3.1.5 NHS England appeared not to have considered the application of Regulation 22(2)(a) as there was no reference to Regulation 22 in its decision letter; and

3.1.6 Regulation 22 specifically provided the power to consider if the only way to determine the application justly is with regard to an earlier PNA.

The outcome

3.2 The Committee was concerned that the applicant had based their application on a draft PNA. The Committee considered that it would not be just or fair to allow an applicant to make an application on the basis of a draft PNA that had only been made public for the purposes of consultation. The Committee considered that such an applicant is attempting to "jump the queue" by making an application before the revised PNA is finalised whilst other potential applicants may be waiting until a final version has been made public before submitting applications.

3.3 The Committee considered that draft PNAs, by their very nature, are

subject to amendment. This was supported by the fact that in this specific case NHS England, in determining the application, identified different or additional wording that had been included in the final PNA but not in the draft PNA.

- 3.4 The Committee also noted that the applicant had indicated in its appeal letter that as the revised PNA had been published by the time of the appeal, there were certain different page numbers that it considered were relevant to its application and which it relied on in its appeal. The Committee noted that while the applicant's original application referred to pages 9, 127, 131 and 143 of the draft PNA, in its appeal it was relying on pages 9, 128, 132 and 144.
- 3.5 The Committee considered that if numerous parties made applications on the basis of a draft PNA which was later amended on appeal, as had clearly happened in this case, this would lead to a large amount of wasted public resources in assessing applications that are not well made.
- 3.6 The Committee considered that judging the application against the 2018 PNA and allowing the Applicant, for the purpose of a redetermination of the application on appeal, to rely on different and additional provisions of the published 2018 PNA, could allow the Applicant to have a "head start" against other applicants. This could give the Applicant an unfair advantage as it would allow its application to be considered before others, potentially leading to the Applicant's application being granted either by NHS England or, if refused by NHS England, by the Committee on appeal, instead of other applicants who had submitted an application on the basis of the final published PNA.
- 3.7 The Committee therefore determined that, in its opinion, the only way to determine the application justly was with regard to the 2015 PNA.
- 3.8 The Committee therefore directed NHS England to:
 - 3.8.1 carry out a further notification under paragraph 19 of Schedule 2 of the Regulations to enable parties to make comments on the application in light of the determination of the Committee that the application is to be assessed against the 2015 PNA and provide this determination to those parties; and
 - 3.8.2 re-determine the application against the 2015 PNA.

Document Control - Change Record

Date	Author	Version	Reason for Change
14 June 2024	Technical Case Manager, Primary Care Appeals	2	Amended to reflect recent changes to commissioning arrangements. Updated Regulation 22 wording to reflect Regulations in force as at 6 November 2023