NHS Resolution

GUIDANCE NOTE

Regulation 44 of the

NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

1. Regulation 44 as at 1 January 2017 reads as set out in Appendix 1.

2. This guidance note focuses on the prejudice test contained in Regulation 44 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations") and provides assistance to the Committee based on past decisions. As at the date of this note, there is no specific judicial guidance on the interpretation of Regulation 44 but the Committee should note comments made under paragraph 33 of this note.

3. Regulation 44 is discussed in Chapter 14 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*" (the "DH Guidance")[1]. Extracts from the DH Guidance are referred to in the paragraphs below.

What is the prejudice test?

4. If Regulation 44 applies, then an application must be refused if granting would, in the opinion of the Committee, prejudice the proper provision of relevant NHS services in the area of the relevant Health and Wellbeing Board ("HWB") or a neighbouring HWB of the relevant HWB[2].

5. The Committee should note that "*prejudice*" is not defined in the Regulations and will therefore carry its everyday meaning. "*Relevant NHS services*" is defined in the Regulations and means pharmaceutical services, local pharmaceutical services and primary medical services.

When does the prejudice test apply?

6. Regulation 44 will apply to a pharmacy application if:

   a. the application is a routine application where the applicant is seeking inclusion in the pharmaceutical list as an NHS pharmacist; or
   b. the application is a routine application from an NHS pharmacist already in the list who wishes to either relocate to a different pharmacy premises or open additional pharmacy premises in the same HWB.

7. If the proposed premises are in a controlled locality, then the Committee will have made a determination under Regulation 41 as to whether the premises are in a reserved location. The prejudice test will only be applied where no determination of a reserved location is made, or the determination is that the premises are not in a reserved location.

[1] Chapter 14 of the DH Guidance can be found at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255961/nhs_pharm_servs_market_entry_chpt_14.pdf

[2] Regulation 44(3) of the Regulations

What is the rationale behind the prejudice test?

8. If the Committee determines that premises proposed in a pharmacy application are in a reserved location and it grants that application, persons living within 1.6km of that pharmacy can have their NHS prescriptions dispensed at the pharmacy once it opens. If any of those persons are dispensing patients and previously were able to have their prescriptions dispensed by a dispensing doctor at a local GP practice, then they can choose whether to continue to have their prescriptions dispensed by the dispensing doctor or from the pharmacy instead.

9. If the Committee determines that premises proposed in a pharmacy application are not in a reserved location and it grants that application, then, on the opening of the pharmacy, Regulation 50 applies and a dispensing doctor must stop dispensing prescriptions[3] to persons living within 1.6km of the pharmacy who were previously able to have their prescriptions dispensed by the dispensing doctor.

10. It is these persons whose activity may be affected by the grant of the application and the issue is therefore at what point this effect becomes prejudicial to the provision of relevant NHS services.

11. The dispensing doctor can continue to dispense prescriptions to persons who were previously able to have their prescriptions dispensed by the dispensing doctor and who are resident at a distance of more than 1.6km from the pharmacy.

Which parties might allege prejudice?

12. In SHA/18249, a local GP practice claimed that granting the pharmacy application would have an adverse impact on the practice, including a loss of income to the practice and a reduction in the medical services provided.

13. Previous determinations have indicated that it is usually GP practices that allege prejudice. The Committee should, however, be mindful that it is not always GP practices that raise matters relating to prejudice.

14. In SHA/18026, two separate third party pharmacies to whom the appeal was circulated noted that a GP practice was located close to the proposed premises and that prejudice to the practice could occur.

15. An existing pharmacy may also allege prejudice to its provision of pharmaceutical services if a new pharmacy application was granted. In SHA/17939, an existing pharmacy suggested that granting the application would prejudice the proper provision of pharmaceutical services based on the viability of that pharmacy.

Guidance on the meaning of prejudice

16. The DH Guidance notes the lack of a definition of prejudice in the Regulations and offers its own interpretation in paragraph 94 of Chapter 14:

> "*it means that nothing must be done which would compromise the ability of people in any controlled locality to access pharmaceutical services, LPS, dispensing services or primary medical services*."

17. The Committee should note that the DH Guidance is non-statutory guidance. The DH Guidance itself states that it is "*…designed to assist NHS England in reaching decisions within the framework of the law. It is not an authoritative statement of the law.*" (Chapter 1, paragraph 5). However, the Committee should be aware that case law has held that non-statutory guidance may be binding where it is authoritative and expert.[4] With this in mind, the Committee would be free to apply a different interpretation to the term "*prejudice*" if it is reasonable to do so in the circumstances or it

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[3] Subject to any postponement of the discontinuation determined under Regulation 50

[4] *Ali v London Borough of Newham* [2012] EWHC 2970 (Admin)

considers applying the guidance rigidly would be contrary to the meaning of the legislation. The Committee should, however, always be able to articulate its reasons for departing from the guidance and applying a new test.

What is and what isn't prejudice?

18. The DH guidance states at Chapter 14, paragraph 95 that prejudice arises where the service that people can rightly expect to be provided by the NHS has in some respect to cease or otherwise be curtailed or withdrawn without proper substitution in the area. It is worth highlighting that prejudice is prejudice to services, not to providers of services.

19. If there is proper substitution in the area, the Committee is likely to find that there is no prejudice. As the new application will be for the provision of pharmaceutical services, it is likely that granting the application would not prejudice the proper provision of pharmaceutical services whether provided by a GP practice through its dispensing of prescriptions to eligible patients or an existing pharmacy, as the new pharmacy would be likely to substitute for the provision of any pharmaceutical services that ceased or were curtailed.

20. In SHA/17930, a GP practice alleged prejudice and the Committee concluded that pharmaceutical services by doctors (dispensing services) would be replaced by pharmaceutical services by those on the pharmaceutical list for those persons living within 1.6km of the pharmacy and therefore there was no prejudice to services.

21. In SHA/17939, an existing pharmacy suggested that granting the application would prejudice the proper provision of pharmaceutical services based on the viability of that pharmacy. The Committee was of the view that the existing pharmacy had not provided information to support its claims that the pharmaceutical services it provided would be curtailed or even lost (without replacement in the area) should the application be granted.

22. The DH Guidance clarifies the services that are relevant to considerations of prejudice:

> "*In considering questions of prejudice, it is important that decision-takers focus only on those services which have to be provided within the terms of service of NHS primary medical and pharmaceutical services provision."*

23. In SHA/18085 the Committee noted that the term "primary medical services" is defined in the NHS Act 2006 as relating to services provided under the GMS/PMS contract.

24. Where the evidence indicates there will be a reduction in the level of an applicable service, the DH Guidance indicates that may not necessarily constitute prejudice:

> "*A mere reduction in the total level of service provided by a particular pharmacy or GP practice is not of itself prejudice*."

> *"The fact that non-NHS services or NHS services provided above the standard level set by the terms of service may be curtailed should not be regarded as relevant*."

25. It will be for the Committee to determine whether the evidence indicates that services will fall below the standard level.

26. As stated above, the DH Guidance suggests that the concept of prejudice:

> "…*means that nothing must be done which would compromise the ability of people in any controlled locality to access* [primary medical services]".

27. The Committee should therefore not only consider whether prejudice will be caused to the proper provision of services generally, but also the provision of services to particular people/patients. For example, if granting the application would prevent elderly or disabled patients from accessing standard services, that may constitute prejudice. Where such arguments are raised by a party, the Committee should be mindful of its duties under the Equality Act 2010.

Evidencing prejudice

28. The Committee should note that the DH Guidance states at Chapter 14, paragraph 93:

> "*The onus is on the person/organisation alleging prejudice to provide evidence of this.*"

29. If no party alleges prejudice, the Committee will be likely to determine that it is not required to refuse the application on the basis of prejudice under Regulation 44 (see, for example, SHA/18211 and SHA/18161).

30. If no evidence is provided to substantiate an allegation that prejudice would occur, then the Committee is unlikely to attribute much weight to those allegations, particularly if those allegations are disputed by comments from other parties (see, for example, SHA/17545, SHA/18249 and SHA/18296). In support of this the Committee should also note the example given at Chapter 14, paragraph 96 of the DH Guidance. In this example, a GP practice alleges that it would close due to loss of income if the application was approved, however, due to no information being provided to substantiate that statement, no prejudice is found.

31. If evidence is provided, the Committee will need to attribute appropriate weight to that evidence based on its relevance, extent, cogency and the degree to which it supports the allegations of prejudice.

What evidence should be provided?

32. Parties often support allegations of evidence by indicating the financial impact of a drop in income caused by the opening of a new pharmacy. In SHA/18362, a third party pharmacy produced copies of the profit and loss account and projections of the likely impact of granting the application of a new pharmacy.

33. The DH Guidance extracts a paragraph from the 1996 case of R –v- North Yorkshire FHSA ex parte Dr. Wilson and Partners when Carnwath J said:

> "*It is not part of the scheme of those regulations or indeed of the statute that pharmaceutical services should be relied upon to provide financial underpinning for medical services which are intended to be financed in other ways*."

34. This is often quoted by parties to support their argument that prejudice cannot arise if it is caused by a drop in income which is caused by the loss of a GP practice's dispensing income.

35. In SHA/18085, the Committee concluded that Carnwath J's comment remains valid but should be treated with some circumspection since it concerned an application under regulation 4 of the NHS (Pharmaceutical Services) Regulations 1992 and that regulation made no reference to prejudice and was not in respect of a controlled location (regulation 12 of the 1992 Regulations dealt with controlled location and prejudice in similar terms to the 2013 Regulations). The Committee did not take the extract to mean that any impact the pharmacy application may have on NHS medical services is to be ignored.

36. Where financial information is provided that is relied on to support an allegation of prejudice, the Committee will need to consider that information carefully to determine whether it is reasonable to consider that it supports an allegation of prejudice.

Oral hearing

37. If an oral hearing is convened for an application that requires consideration of prejudice, the Committee may clarify and probe the financial information provided and elicit comments from and enable discussion between the parties present on the relevance, extent and cogency of the evidence and the degree to which it supports the allegations of prejudice. This should enable the Committee to reach a more reasoned position on the extent to which the information provided supports an allegation of prejudice.

38. However, the Committee should be mindful that the DH Guidance is clear that the burden of proof lies with the party alleging prejudice and that the example provided in the DH Guidance suggests

that if no evidence is provided to substantiate allegations of prejudice, it would be reasonable to conclude that it would not occur. As such, if limited information has been provided by the parties and the Committee is not satisfied that prejudice would occur, it is not for the Committee to embark on an information gathering exercise.

39. In SHA/18085 (for which an oral hearing was convened), the Committee had reservations about the information provided. A number of GP practices were alleging prejudice and provided information indicating estimated losses of income through the loss of dispensing rights. The practices asserted that closure or reduction in service at the branch surgery was the only way to meet the losses. The Committee found it difficult to determine that prejudice would occur on the basis that the GP practices had not provided fuller information on losses, had not provided information relating to what had been considered to mitigate estimated losses and had not provided information on what had been done to look at other models of service delivery.

Is indicating a risk of prejudice enough?

40. Regulation 44 states that an application must be refused if granting would, in the opinion of the Committee, prejudice the proper provision of relevant NHS services.

41. The Committee will therefore need to consider whether the evidence provides this level of certainty. If the evidence indicates that there is a risk of prejudice occurring, this may not be enough to satisfy the Committee.

42. In SHA/18362, the Committee considered that although there was a risk that prejudice might occur to the proper provision of pharmaceutical services, on the evidence provided, on the balance of probabilities, the risk would not materialise.

43. In SHA/18085, the Committee stated:

> "*the test is whether it is satisfied on the balance of the probabilities that there would be prejudice to NHS services or, as set out in the NHS guidance that prejudice will occur. It is not sufficient that there could be prejudice or that it may occur.*"

44. The DH guidance indicates that the existence of prejudice involves, to a greater or lesser extent, making a judgment about events that will occur in the future and that, therefore, it can often be extremely difficult to judge whether or not there will be prejudice.

45. Application of the balance of probabilities test to the question of prejudice means that the Committee will need to be satisfied on the evidence that the occurrence of prejudice is more likely than not.

10 May 2017

Appendix 1

Regulation 44 - Prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location – as at 1 January 2017

(1) This paragraph applies to all routine applications—

- (a) for inclusion in a pharmaceutical list as an NHS pharmacist; or
- (b) from an NHS pharmacist included in such a list—
  - (i) to relocate to different pharmacy premises in the area of the relevant HWB, or
  - (ii) to open, within the area of the relevant HWB, additional pharmacy premises from which to provide pharmaceutical services.

(2) As regards any application to which paragraph (1) applies, the NHSCB must have regard to whether or not the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not a reserved location.

(3) If the applicant is seeking the listing of pharmacy premises which are in a part of a controlled locality that is not in a reserved location, the NHSCB must refuse the application if granting it would, in the opinion of the NHSCB, prejudice the proper provision of relevant NHS services in the area of—

- (a) the relevant HWB; or
- (b) a neighbouring HWB of the relevant HWB.

(4) For the purposes of paragraphs (2) and (3), if no particular premises are proposed for listing in the application, the applicant is to be treated as seeking the listing of pharmacy premises which are in a controlled locality if the best estimate that the NHSCB is able to make of where the proposed pharmacy premises would be is at a location which is in a controlled locality, having regard to the best estimate given by the applicant under paragraph 1(7)(a)(ii) of Schedule 2.