Regulations under the Health Act 2009: Market entry by means of Pharmaceutical Needs Assessments

Information for Primary Care Trusts
Chapter 14

Provision of pharmaceutical services in controlled localities

August 2012

DH INFORMATION READER BOX

Policy	Estates
HR / Workforce	Commissioning
Management	IM & T
Planning / Performance	Finance
Clinical	Social Care / Partnership Working

Document Purpose	Best Practice Guidance
Gateway Reference	17930
Title	Market entry by PNAs - Information for PCTs - Chapter 14
Author	Dept of Health - Medicines and Pharmacy
Publication Date	August 2012
Target Audience	PCT CEs, SHA CEs, Directors of PH, Pharmacy organisations, Primary Care Trust Commissioning, Patient groups
Circulation List	
Description	Guidance on the NHS (Pharmaceutical Services) Regulations 2012 - controlled localities
Cross Ref	The NHS (Pharmaceutical Services) Regulations 2012 and accompanying documents
Superseded Docs	The NHS (Pharmaceutical Services) Regulations 2005 Accompanying directions and guidance
Action Required	n/a
Timing	**n/a**
Contact Details	Gillian Farnfield MPI - Community Pharmacy Policy 4th Floor, Skipton House 80 London Road SE1 8LH 0207 972 2700
For Recipient's Use	

Contents

Chapter 14: Provision of pharmaceutical services in controlled localities

1. This chapter discusses the establishment of *controlled localities*, *reserved locations* and *routine applications* for pharmacies within these areas. Part 7 of the 2012 Regulations. **Regulations 36 to 45** deal with these.

2. PCTs should note that where they receive an application from a dispensing appliance contractor (DAC), the provisions contained within Part 7 of the 2012 Regulations do not apply. In such cases, the PCT is not required to consider the issue of rurality or apply the test of "prejudice". Such applications fall to be dealt with under Part 3 of the 2012 Regulations and will either have been submitted to meet an identified need within the PNA or as an unforeseen benefit.

3. This chapter will need to be read with the chapter that is relevant to the type of *routine application*. The box below shows how this chapter links with chapters 5 to 9.

Outline process for routine applications for pharmacies in areas that are or may be controlled localities

- *Routine applications* for *pharmacy premises* that are, or may be, in a *controlled locality* are subject to further considerations than those set out in the Chapters 5 to 9.

- On receipt of such a *routine application,* the first action required is to undertake a GP registered patient count of the area within 1.6 km of the proposed premises. This must take place on the day the application is received, before anything else is done, even if at this stage it has not been determined that the proposed premises are in a *controlled locality*.

- If the area has not previously been the subject of a determination as to whether or not it is a *controlled locality* but the area is or may be considered rural in character, the PCT should defer the *routine application* and make that determination. Also, if the area has been the subject of a determination, the PCT will need to consider whether that determination needs to be revised. However, if the relevant decision was made in the previous five years, it may only redetermine the matter if there has been a substantial change in circumstances in relation to the area.

- If there is to be a determination, once the determination has been made, if the area is not a *controlled locality,* return to the chapter that is relevant for the type of *routine application* that has been received (there may also be other action that needs to be taken if there are patients of dispensing doctors that live in the area). If it is determined to be a *controlled locality,* there are further matters that the PCT will need to consider before moving on to consider the *routine* application.

- Once the PCT knows that the proposed premises are in a *controlled locality*, they will need to check that all the relevant information and documentation has been submitted and request any that is missing. Follow the procedure that is set out in the relevant chapter for the type of *routine application* that has been received.

- Additional matters that the PCT will need to consider where *a routine application* is for premises in a *controlled locality* include whether the application is time-barred under the "five year rule" and whether proposed premises are in a *reserved location.* If neither of these considerations apply, then the PCT will need to consider the test of prejudice.

- If the application is not time-barred under the "five year rule", the PCT will need to *notify* interested parties of the *routine application* as per the chapter which relates to the type of *routine application* that has been received. When the PCT notifies the *routine application,* if it is considering making a determination that the area is a *reserved location*, it will have to notify the same people as it notifies of the *routine application* that it is considering making a *reserved location* determination as well, so it is good practice to seeks views on the proposed *reserved location* determination at the same time (i.e. combine the two notifications).

- If the proposed pharmacy premises might not be in a reserved location, as part of the notification of the *routine application,* the PCT should nevertheless seek views as to whether it would prejudice the provision of *relevant NHS services.* It is advisable to do this even if, in due course, the representations might not be relevant – but this possibility should also be explained to those notified. If the area is definitely not a *reserved location* views on whether the new pharmacy would prejudice the provision of *relevant NHS services* should always be sought.

- Once interested parties have responded to the *notification* of the application, the PCT will need to determine the *routine application*. The PCT will first need to decide if the proposed premises are in a *reserved location*. If they are, the PCT is not required to consider the test of prejudice but is required to consider the other matters that are relevant to that type of application and which are set out in the relevant chapter. If it grants the application and dispensing patients of the dispensing doctor elect to receive *pharmaceutical services* from the pharmacy premises rather than the dispensing doctor, the PCT will need to consider any necessary postponement of the arrangements it has with the dispensing doctor to provide *pharmaceutical services* to those patients.

- If the PCT decides that the proposed premises are not within a *reserved location* , it must consider the test of prejudice. If the PCT is satisfied that approving the application would lead to prejudice of the proper provision of *relevant NHS services* in its area, or the area of a neighbouring PCT, it must refuse the *routine application*.

- If there is no prejudice and the PCT goes on to approve the application (having considered other the matters relevant to that type of application that are set out in the relevant chapter) then it will need to consider whether to postpone the termination of the arrangements it has with doctors who provide *pharmaceutical services* to patients who live within 1.6 km of the proposed premises.

Introduction

4. Pharmacies will not always be viable in every part of the country, especially in more rural areas. Patients need to receive their NHS-prescribed medicines promptly, efficiently, conveniently and to high quality. That is where the services of dispensing doctors can, and do, play a vital role; ensuring patients receive their medicines from the surgery's dispensary without having a possibly very lengthy journey to their nearest pharmacy.

5. The overall objective of defining rural areas as *controlled localities* is to ensure that people living in rural areas have access to *pharmaceutical services* which are no less adequate than would be the case in non-controlled localities.

6. From 2005, the over-riding principle has been to improve access to, and the quality of, *pharmaceutical services* for people in rural areas by encouraging new services, whilst retaining the existing need of some people to access medicines from their GP.

7. A *controlled locality* is an area which has been determined, either by a PCT/a predecessor organisation or on appeal by the FHSAU, to be "rural in character" (**Regulation 36(2)**).

8. A *reserved location* is an area within a *controlled locality* where the GP registered population within 1.6 km of the proposed location of a pharmacy is less than 2,750 at the date the application is received by the PCT (**Regulation 41(3)**).

9. Areas that have not been formally determined as rural in character and therefore *controlled localities*, are not *controlled localities* unless and until the PCT determines them to be. Such areas may be considered as rural because they consist open fields with few houses but they are not a *controlled locality* until they have been subject to a formal determination.

10. Similarly, any area that is determined not to be rural in character nature cannot be a *controlled locality*, even if it has a some features of a rural area, for example low population density. Where a PCT determines that an area which was once determined to be rural in character no longer is such, it shall cease to be a *controlled locality*.

Creation of controlled localities and determinations that areas are rural in character under previous regulations

11. Prior to 1 April 1983, the term *controlled locality* did not exist in regulation; it was introduced by the NHS (General Medical and Pharmaceutical Services) Amendment Regulations 1983[1] (Regulation 30D).

12. Prior to 1 April 1983, Family Practitioner Committees (FPCs) were required to form an opinion by virtue of the extant regulations as to whether an area was rural in character.

13. From 1 April 1983, such determinations became known as *controlled localities* and FPCs and successor organisations were required to delineate the boundaries of any *controlled localities* that they subsequently determined on a map. Later regulations required these maps to be published.

14. Any areas that had been determined as rural in character prior to 1 April 1983 automatically became termed *controlled localities* with effect from that date. However, there was no requirement to delineate such areas on a map, although some FPCs may have chosen to do so.

15. PCTs may therefore find themselves in the position whereby they have:

- maps of controlled localities that were determined from 1 April 1983;
- lists of villages that were determined to be rural in character prior to 1 April 1983;
- descriptions of areas that were determined to be rural in character prior to 1 April 1983;
- a mixture of the above; or
- none of the above.

16. It is strongly recommended that PCTs ensure they address this issue in order that they comply with their duties set out in 2012 Regulations. Otherwise, it will be difficult for patients and the public to understand on what basis they may be eligible (or ineligible) to receive *pharmaceutical services* from their doctor.

17. PCTs are advised to work with their LPCs, LMCs and dispensing doctors who may have records or maps showing determinations of *controlled localities*.

[1] Statutory Instrument 1983/313

Maps of controlled localities

18. PCTs are required to publish maps with areas which have been determined as rural in character clearly delineated on them (**Regulation 39(2)(a)**).This carries forward the same requirement in previous regulations. If there has been no substantial change of circumstances, such maps will show which areas have been determined as rural and therefore *controlled localities*. It is important that the boundaries of such areas should be clearly marked, using appropriate geographical markers, for example rivers, not simply the squared off grid markings overprinted on Ordnance Survey maps. They should also be at a sufficient level of detail to enable any enquirer to tell whether any particular location falls within a *controlled locality* or not. Other areas are, by definition, not rural areas for the purposes of the 2012 Regulations until they have been determined as such.

19. The PCT may either publish its *controlled locality* maps alongside its PNA map or it may decide to include the boundaries in its PNA map (**Regulation 39(2)(a)(ii)**). In both cases, the PCT must ensure that the map is capable of being reproduced without breach of copyright.

Determination that an area is a controlled locality

20. Changes can occur to the appropriate designation of an area, particularly where an urban area is expanding into the surrounding countryside, or where there has been a substantial development permitted in what has hitherto been a *controlled locality*. The reverse is much rarer but can happen, for example, where an industrial area in the country (for example mining) ceases. When determining questions of rurality, **it is essential** that PCTs undertake site visits.

21. If there are no maps showing defined *controlled localities* available or there is doubt that an area is rural, the PCT should assure itself that where patients receive *pharmaceutical services* from their doctor, they reside in properly determined *controlled localities*. Where a PCT identifies such areas that have not been so determined, or where they have no evidence that they have been determined, they should work with their LPC and LMC and follow the procedures set out below. Additionally, the PCT should not take any further action on any application it may have received until it, or the FHSAU on appeal, has determined whether the application is in a *controlled locality* or not.

22. The PCT may at any time consider and determine whether or not any part of its area is a *controlled locality*, or is part of a *controlled locality* (**Regulation 36(2)**). The only exception to this is where the PCT has considered whether or not an area is a *controlled locality*, or is part of a *controlled locality*, within the last five years.

The five year period begins with the date of the determination by the PCT, or if that determination was appealed, the date of the decision of that appeal (**Regulation 36(3)(a)**).

23. However, if the PCT is satisfied that within that five year period there has been a substantial change in circumstances in relation to that area then it may reconsider the matter afresh (**Regulation 36(3)(b)**). An example of this could be where a housing development has been built or is in the process of being built and the population of a village has increased or will increase as a consequence with increases in shopping, leisure and other facilities usually found in non-rural areas. It is, however, for the PCT to be satisfied that there has been a substantial change.

24. It is therefore important that PCTs maintain accurate records of when determinations are made in order to ensure they meet the requirements of **regulation 36(3)(a)**.

What makes an area "rural in character"?

25. A *controlled locality* must be rural in character (**Regulation 36(2)**). There is, however, no prescribed way to define what is rural in character. Each case must be judged on individual circumstances and will depend on a variety of factors.

26. A rural area is normally characterised by a limited range of local services. There are a range of factors (as they pertain at the time of the determination) that might be considered by PCTs in determining whether an area is rural and these have been clarified over the years. They include, for example:

- environmental – the balance between different types of land use;
- employment patterns (bearing in mind that those who live in rural areas may not work there);
- the size of the community and distance between settlements;
- the overall population density;
- transportation – the availability or otherwise of public transport and the frequency of such provision including access to services such as shopping facilities; and
- the provision of other facilities, such as recreational and entertainment facilities.

27. In 2004, following a review in 2002 of the urban and rural area definitions used by government, the Department for Environment, Food and Rural Affairs (DEFRA) Rural Strategy described a definition of rurality[2]. The definition is available to download from the Office for National Statistics website[3] and PCTs may find this useful to consider alongside their knowledge of the area in question.

[2] http://www.defra.gov.uk/rural/documents/policy/strategy/rural_strategy_2004.pdf
[3] www.statistics.gov.uk/geography/nrudp.asp

28. None of the above will automatically determine the matter. For example, the expansion of housing provision may also be an indication that the status of the area should be reconsidered, but of itself will not necessarily change that status. That will remain a question of judgement.

29. Therefore, rurality is not something which can be subject to rules such as density or distribution of population or the number of trees. However, experience has shown that photographs and documents are an unreliable basis for determining rural questions. Judgement will need to depend on local knowledge of the area. A rural area need not have a high level of agricultural employment - many residents may commute to jobs in local towns.

30. A visit to the area is essential.

31. PCTs should be aware of misconceptions about rurality. The fact that an area is not classified as controlled or that a decision is taken to remove such a classification, does not necessarily mean that it is urban.

Process for determining a controlled locality – preliminary matters

32. In addition to the ability for PCTs to review an area, the LMC or LPC may apply in writing to the PCT for it to determine whether or not an area is to be a *controlled locality*, or is to be part of a *controlled locality* (**Regulation 37(1)**).

33. The five year bar (**Regulation 36(2)**) applies to applications by LMCs and LPCs and the PCT should first check that the question has not been considered within the previous five years (**Regulation 37(2)**).

34. If the PCT decides that it cannot consider the LMC or LPC's application for a determination because of the five year bar, then **regulation 37(3)** requires the PCT to:

- take no further action in relation to the application; and
- inform the committee of that decision and its right of appeal under **regulation 45(1)(b)**.

Process for determining controlled localities – local notification and deferment of routine applications

35. **Regulation 38** sets out the process for *notifying* relevant persons of the PCT's intention to determine whether an area is or is not to be a *controlled locality*, or is or is not to be part of a *controlled locality*. This intention could be in response to:

- a *routine application* to open a pharmacy;
- a request for a determination from the LMC or LPC; or
- at the PCT's own instigation.

Is an area a controlled locality or part of a controlled locality?

Whether a PCT determines an area to be a *controlled locality*, or whether it is determining that it is part of a *controlled locality* will depend on the situation.

For example, a PCT has previously determined that part of its area is a *controlled locality*. Within that area, there are three villages, one of which has expanded considerably as a result of a housing development with associated retail and office accommodation. A *routine application* is submitted to open a pharmacy within the retail area as an unforeseen benefit as no need for a pharmacy was foreseen at the time of the publication of the PCT's PNA.

The PCT decides to determine whether the village is still rural in character and should remain part of the larger *controlled locality* and defers the *routine application* whilst it makes this determination.

Taking into account the relevant factors, the PCT could decide that the village is no longer part of the *controlled locality* but that the surrounding area is. The map of the *controlled locality* would therefore be revised to exclude the village.

36. **Regulation 38(1)** requires the PCT to give *notice* in writing of its intention to the following organisations and people:

- any LPC for its area, which may include an LPC that it shares with other PCTs;
- any LMC for its area, which may include an LMC that it shares with other PCTs;
- any person on its pharmaceutical list who, in the opinion of the PCT, may be affected by the determination;
- any person on its dispensing doctor list who, in the opinion of the PCT, may be affected by the determination;
- any LPS chemist who, in the opinion of the PCT, may be affected by the determination;

- any provider of primary medical services who, in the opinion of the PCT, may be affected by the determination; and
- where it is considering making a determination as a consequence of a *routine application*, the person making that application.

37. PCTs should note that they are not required to notify all persons on their lists; only those that they believe may be affected by the determination.

Example

The PCT has previously determined that part of its area is a *controlled locality*. Within that area, there are three villages, one of which has expanded considerably as a result of a housing development with associated retail and office accommodation. A *routine application* is submitted to open a pharmacy within the retail area as an unforeseen benefit as no need for a pharmacy was foreseen at the time of the publication of the PCT's PNA.

The PCT decides to determine whether the village is still part of the larger *controlled locality* and defers the *routine application* whilst it makes this determination.

Using the Exeter system the PCT identifies all the dispensing patients living within the *controlled locality* and within 1.6 km of the proposed premises. It identifies that three GP practices have dispensing patients within this area. One practice has no dispensing patients, one has 300 dispensing patients and the other has 500 dispensing patients within this area. The PCT decides that the practice with only no dispensing patients in the area would not be affected by the determination, either as a dispensing practice or simply as a provider of primary medical services – in the latter case, because it draws its patients from a village that is a significant distance by road from the village with the new development because of the limited number of river crossings. Therefore, it does not *notify* them of its intention to determine whether the area is part of the larger *controlled locality*. This decision is noted in the paperwork for the application.

38. **Regulation 38(2)** gives the PCT the discretion to *notify* such other persons as it considers appropriate to do so. It is good practice for PCTs to notify local patient representative organisations as well as local councils (district, rural or parish) about the review of the rurality of an area and to seek their views. Whilst this is not a regulatory requirement, this will often help prevent complaints that PCTs are ignoring the views of local residents and potentially avoid heated and damaging public and media campaigns. PCTs should note that such groups do not have rights of appeal against the subsequent determination.

39. The *notice* must inform the person that they may make representations in writing within 30 days beginning on the day on which the notification was sent to them (**Regulation 38(3)(a)**). Additionally, the PCT is required within the *notice* to inform the person of the date by which the PCT expects to make a decision. This must not be later than six months after the day on which the PCT first gives *notice* of its intention (**Regulation 38(3)(b)**).

40. Where the decision to determine an area resulted from an application from an LMC or LPC under **regulation 37(1)**, then this notification process gives them the opportunity to make further representations to support their application.

Example

A PCT receives an application from their LMC to determine whether an area is a *controlled locality* or not on 1 September. The PCT notifies the required list of organisations and persons of the application on 15 September. The PCT is therefore required to make a determination as to whether the area is or is not a *controlled locality*, or is or is not part of a *controlled locality*, by 15 March of the following year.

As part of their response to the *notification*, the LMC who made the application is able to supply further information to support its application that it may have discovered since submitting its original application.

41. Once the PCT has issued notice under **regulation 38(1)** it must defer consideration of any *routine application* where:

- the applicant is seeking the listing of *pharmacy premises*, and
- the outcome of the *routine application* could be affected by the PCT's decision as to whether the area is or is not a *controlled locality*, or is or is not part of a *controlled locality* (**Regulation 38(4)**).

42. If the *routine* application is deferred, **paragraph 24(3)(g) of Schedule 2** requires the PCT to proceed with the determination of whether the area is or is not to be part of a *controlled locality* as soon as practicable.

43. The *routine application* is deferred until:

- the PCT has determined whether the area in question is or is not a *controlled locality*, or is or is not part of a *controlled locality*, and
- the proceedings relating to that determination have reached their final outcome (i.e. any appeals have been heard)(**Regulation 38(4)**).

44. Once the proceedings have reached their final outcome, the PCT may no longer defer the *routine application*. It may be that once the determination has been made that the applicant wishes to withdraw their application. In the absence of any communication to this effect from the applicant, the PCT should continue to deal with the *routine application*.

Example

A PCT receives a *routine application* to open new premises in a village that falls within an area that has not been determined to be a *controlled locality* but could be described as rural in character. On checking its records, it sees that no determination has been made on that area within the last five years. It decides to defer the *routine application* under **regulation 38(4)** in order to determine whether the village is part of a *controlled locality* or not, and notifies the applicant of this decision, the reasons for it and advises that the application is being deferred until such time as the determination on whether the proposed premises are in a *controlled locality* or not (**paragraph 24(1) of Schedule 2**).

The PCT subsequently notifies the persons listed in **regulation 38(1)** (including the applicant) and goes on to determine that the area is a *controlled locality*. No appeals are made against its decision, and after the 30 day appeal period it begins the process of determining the original *routine application* (**paragraph 14(2) of Schedule 2**).

Process for determining a controlled locality – making the determination

45. When the PCT is deciding whether or not an area is or is part of a *controlled locality*, it must have regard to whether the provision of certain services is likely to be adversely affected by the consequences of its determination (**Regulation 39(1)**). These services are:

- primary medical services by a provider of primary medical services, unless the provider is the PCT,
- *pharmaceutical services* by a person on its pharmaceutical list, or
- LPS by a provider of such services.

46. Where the PCT decides that the provision of one or more of these types of service will be adversely affected, no immediate action is required to be taken other than factoring those adverse effects into its decision, but that decision must be noted.

Determination of controlled locality status – adverse effects

When determining whether or not an area is, or is part of, a *controlled locality* the PCT is required to have regard to whether its determination will adversely affect the provision of certain services. These are:

- primary medical service by GP practices, but not PCTMS practices,
- *pharmaceutical services* by a person on a pharmaceutical list,
- *local pharmaceutical services* by a provider of such services.

In effect, this allows the PCT to consider the impact of the determination on the communities affected by it, alongside the indicators of what does or does not make an area rural in character. This is not a decision that needs to be taken in isolation from its consequences for the availability of relevant NHS services.

The weight to be attached to these consequences will depend very much on the facts, but PCTs should also have regard the fact that it will, potentially, have options for mitigating the adverse affects that are identified (subject to the processes it will need to go through in order to exercise those options), once the determination is made.

The most common situations whereby controlled locality decisions may impact upon later decisions that need to take account of adverse effects on the provision of services are:

- The PCT determines that an area is a *controlled locality* or is part of a *controlled locality* – pharmacies will continue to be able to provide services to patients living in the area. However, if a GP practice subsequently submits an application for *outline consent* and *premises approval* to provide *pharmaceutical services* to that area, or the determination was made as a result of receiving such an application, when determining that application the PCT will need to consider whether there should be a gradual introduction of the GP practice's *premises approval* in order for any pharmacy to adjust to the loss of those patients – **Regulation 57** (see Chapter 15 for more information on this).

- The PCT determines that an area is no longer, or is no longer part of, a *controlled locality* – any GP providing *pharmaceutical services* to patients living in that area will no longer be able to do so. However, under **regulation 50,** the PCT may postpone the termination of those arrangements for such period as the PCT considers necessary in order to give the GP reasonable notice of the discontinuation (see Chapter 15 for more information on this).

47. After considering any responses received from the *notification* exercise and the evidence before it, the PCT will come to a decision as to whether or not an area is a *controlled locality*, or is part of a *controlled locality*, or is to cease to be part of a *controlled locality*. If it determines that it is a *controlled locality*, or is part of a *controlled locality*, or is to cease to be part of a *controlled locality*, then the PCT must:

- delineate precisely the boundary of the resulting *controlled locality* on a map using appropriate natural or geographical points such as rivers (**Regulation 39(2)(a)(i)**); and
- either publish that map alongside its PNA map, or include that boundary on its PNA map (**Regulation 39(2)(a)(ii)**).

48. Additionally the PCT must give *notice* of the determination to:

- where the LPC or LMC applied for the determination, that committee;
- the person whose *routine application* triggered the determination; and
- the persons notified in accordance with **regulation 38(1)** and **(2).**

49. The *notice* must include the determination and the PCT's reasons for that determination (**Regulation 39(2)(b)(i)**). Appeal rights against the PCT's determination should be given to whose who were originally notified of the PCT's intention to make the determination namely:

- the LPC;
- the LMC;
- providers of primary medical services;
- any LPS chemists; and
- a person on the PCT's pharmaceutical or dispensing doctors lists (**Regulation 39(2)(b)(ii)**).

50. The right of appeal rights against these types of determination are set out in **regulation 45(1)(a)**. It is for this reason that PCTs should **carefully consider who they believe may be affected by the determination** when they *notify* their intention to consider whether or not an area is a *controlled locality*, or is part of a *controlled locality*, to ensure that appeal rights are only given to contractors who the PCT is of the opinion may be affected by the determination.

Applications for new pharmacies in controlled localities

51. There are four separate issues for PCTs to consider when they receive a *routine application* in an area that may be rural in character. The first is whether the proposed premises are within a *controlled locality* which has been covered in the

paragraphs above. The second relates to whether or not the application needs to be refused on the basis of the "five year rule" as a preliminary matter. The third to whether or not the application relates to a reserved location, and the fourth relates to special provisions for applying to open premises within a *controlled locality* – the "prejudice" test.

Applications for new pharmacies in controlled localities – refusals due to preliminary matters

52. **Regulation 40** sets out two situations which the PCT must initially consider when it receives *routine applications* for new pharmacies in *controlled localities* to establish whether they are relevant to the application or not.

53. On receipt of such a *routine application,* the PCT must refuse it where one of the situations listed in **regulation 40(2)** is applicable. The PCT is not required to *notify* the *routine application* to interested parties prior to coming to the decision to refuse under this regulation.

54. Subject to the proviso mentioned in the next paragraph, the PCT must refuse the *routine application* where the location of the proposed premises is:

- in an area in relation to which outline consent has been granted[4] (either under the 2012 Regulations or the 2005 Regulations) within the last five years. The five year period starts on the date on which proceedings relating to the *outline consent* application reached their final outcome and ends on the date on which this application is made (**Regulation 40(2)(a)**); or
- within 1.6 km of the location of the proposed *pharmacy premises* specified in another application which was refused within the previous five years (**Regulation 40(2)(b)**). This other application could have been a *routine application* for new or additional premises under the 2012 Regulations or an application to which the 'necessary or expedient test' applied under the 2005 Regulations. The five year period starts on the date on which the proceedings relating to the refusal of the application for new or additional pharmacy premises reached their final outcome and ends on the date on which this application is made.

55. The only exception to this is where the PCT is satisfied that since the date on which the five year period started, there has been a substantial and relevant change of circumstances affecting the *controlled locality* (**Regulation 40(2)**).

[4] Outline consent applications must describe the area to which the doctor wishes to provide pharmaceutical services. The PCT will therefore need to check the proposed location against the information included in its dispensing doctor list – see Chapter 15 for more information.

Example

A village within a *controlled locality* contains a pharmacy. The PCT receives a *routine application* to open another pharmacy which it refuses as there is no identified need within its PNA. The pharmacy in the village closes 12 months later, and a *routine application* is immediately submitted as an unforeseen benefit. The PCT could approve the application as the closure of the pharmacy could be deemed to be a substantial and relevant change of circumstances affecting the *controlled locality*.

56. For the purposes of this regulation, **regulation 40(3)** states that if the application does not contain the precise address of the proposed premises, it is for the PCT to make its *best estimate* as to where the proposed premises would be having regard to the *best estimate* that the applicant gave in their application as required by **paragraph 1(7)(a)(ii) of Schedule 2**.

Reserved locations

57. It is important that when a PCT receives a *routine application* to open new or additional *pharmacy premises* in a location that is, or could be, within a *controlled locality* that it **immediately ascertains the total GP registered population** for the area within 1.6 km of the proposed premises. This is so that the PCT can determine at a later stage whether or not the application is in a *reserved location* on the basis of the circumstances that pertained on the day the *routine application* was received (**Regulation 41(2)**). PCTs should note that they are not required to determine *reserved locations* for applications received from DACs.

58. A *reserved location* is an area within 1.6 km of the proposed premises (applicants should specify the location as precisely as possible within their application) where the GP registered population is less than 2,750 **at the date of receipt of the application** (**Regulation 41(3)(a)**) and the PCT is not satisfied that the use of a pharmacy at the proposed location would be similar to or greater than what would be expected of a larger population. The total number of patients in issue is the total number of patients on all the lists of GP practices that cover that area. It does not matter whether all the area within 1.6 km of the proposed premises is a *controlled locality* or not. Temporary residents, such as students, are not included for these purposes.

59. If the *routine application* does not contain the precise address of the proposed premises, the applicant will have given their *best estimate* of where the premises will be located (**paragraph 1(7)(a)(ii) of Schedule 2**). The location of the proposed premises will be the location that the PCT estimates based on the *best estimate* provided by the applicant (**Regulation 41(2)(b)**).

Example

A PCT receives a *routine application* to open a pharmacy on the High Street in a village in response to an identified need within the PNA. The applicant has given their *best* estimate of where the premises will be.

The High Street is long and houses and retail units are scattered along its length. The PCT decides it is not satisfied with the *best estimate* and asks the applicant to provide further information on a more precise location. The applicant then submits a map which shows that they intend to open within one of the retail units in the village centre. The PCT is satisfied with this description of the applicant's *best estimate* and proceeds with the registered patient count of the area within 1.6 km of this location.

60. Calculation of the relevant population should be done by postcode using the last three digits. The PCT may find it helpful to work from large scale Ordnance Survey maps with the radius distance clearly marked. All postcodes linked to streets or roads within the circle would then count.

61. Whilst this may not yield 100% accuracy, this should usually provide adequate information on which to base a calculation.

62. A manual count may then be necessary where the population is on the borderline of 2,750 in which case the PCT should ascertain the streets/locations on the edge of the circle. The PCT may wish to adopt the same procedures here that it has for notifying patients when they can no longer use the services of their dispensing doctor after a new pharmacy opens.

63. The reason the figure of 2,750 has been chosen is that this is the figure below which pharmacy viability becomes questionable. There is, however, a proviso that requires the PCT in specified circumstances to determine that an area is not a *reserved location* even if the population is below 2,750. This will occur where the PCT is satisfied that if *pharmaceutical services* were provided at the location, the use of those services would be similar to or greater than the use that might be expected if the number of GP registered patients was greater than 2,750 (**Regulation 41(3)(b)**). For example, the GP registered population totals 2,500. However within that population there are a considerable number of older residents living in care homes or sheltered accommodation that would generate the level of need for *pharmaceutical services* that would be expected from 3,200 people.

64. It is important that the PCT determines whether or not the premises listed in the application are in a *reserved location* or not. If the PCT determines that the premises are in a *reserved location*, if the pharmacy subsequently opens, people living within 1.6 km of it are able to exercise a choice as to whether they continue to receive *pharmaceutical services* from their dispensing doctor or from a pharmacy, or both. The pharmacy would not therefore have the usual 1.6 km protection of patients living within that area ceasing to receive *pharmaceutical services* from their GP practice, and instead use the services of a pharmacy (subject to gradualisation). If no determination of a *reserved location* is made, or it is determined that the proposed premises are not in a *reserved location*, the PCT will need to consider the test of prejudice.

65. Before making any determination, the PCT must notify certain persons listed in **paragraph 19(1) of Schedule 2** that it will be making such a determination and invite them within a specified period of not less than 30 days to make representations on the matter (**Regulation 41(4)**).

66. When deciding how long to give those persons notified of the PCT's intention to make a determination of *reserved location* status, it is suggested that the PCT bear in mind the frequency with which some interested parties meet.

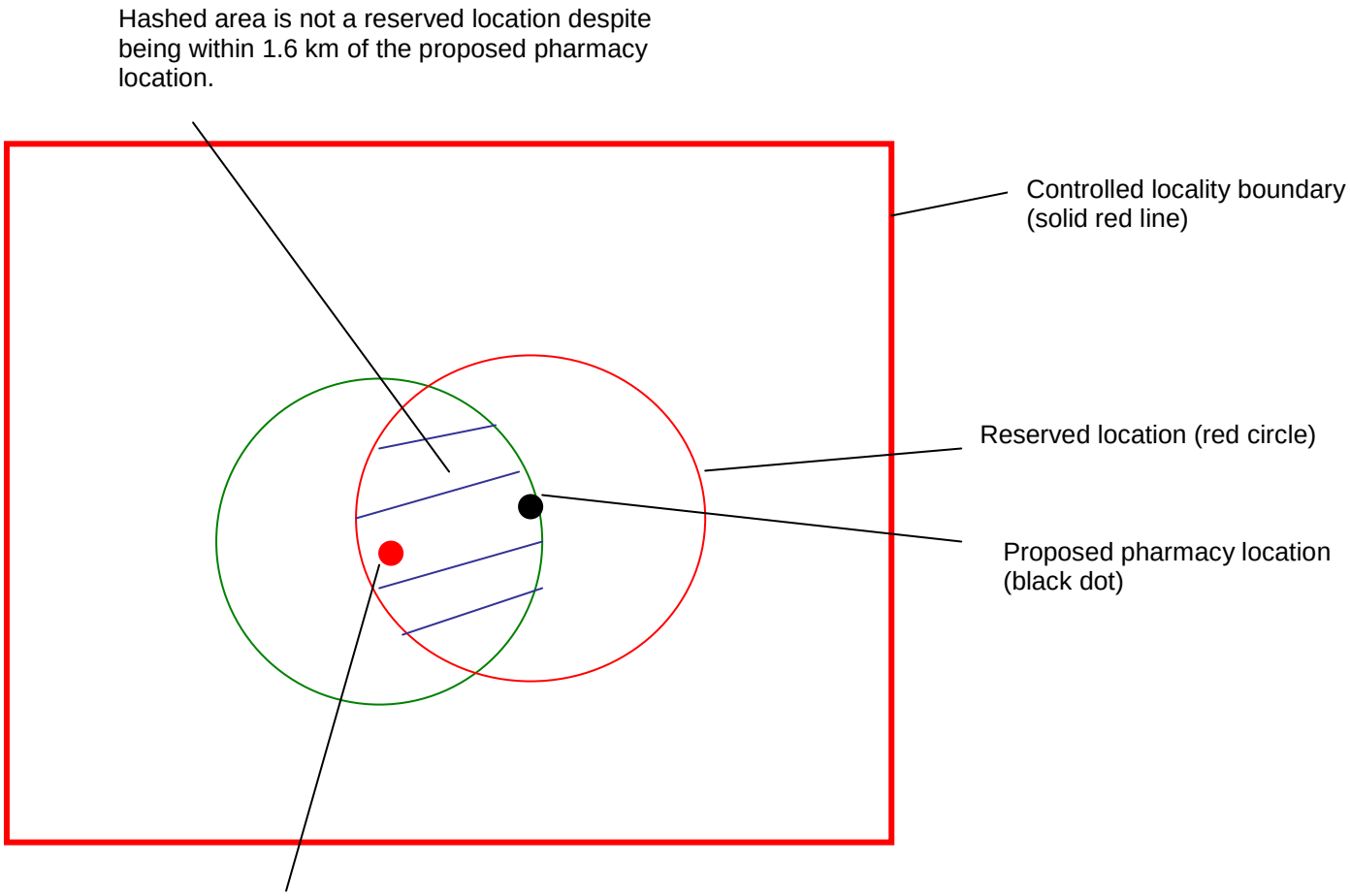
67. It is suggested that the PCT seeks views on this matter at the same time as they seek views on the test of prejudice.

68. Where the PCT is satisfied, having taken into account any representations it has received, that the number of GP registered patients residing within a 1.6 km radius of the proposed premises is less than 2,750, if it is not satisfied that the proviso relating to the level of expected use applies, then subject to any carve-out as explained below, it shall determine the area to be a *reserved location*.

69. There may be occasion where not all of the area within 1.6 km of the proposed premises will be a *reserved location* (**Regulation 43(2)**). This would occur where part of the area of what would otherwise be determined a *reserved location*:

- is within 1.6 km of another existing pharmacy, and
- no determination of a *reserved location* was made at the point the application for that pharmacy was determined.

70. In this instance, that part of the area is not to be treated as part of the *reserved location* for the *routine application*, even though the population in that area were relevant to the patient calculation that preceded the *reserved location* classification. See the diagram below.



71. As a consequence, patients living within the red circle but outside of the hashed area would, if the application was approved, be able to choose to receive *pharmaceutical services* either from their doctor or from a pharmacy. Patients living within the green circle would continue to be ineligible to receive *pharmaceutical services* from their doctor unless they could prove serious difficulty (see Chapter 15 for further information on this).

72. Once the PCT has determined whether or not an area is a *reserved location* **regulation 43(1)(a)** requires it to give *notice* of the determination to the person whose *routine application* triggered the determination and to the persons notified in accordance with **regulation 41(4).** The *notice* must include:

- the PCT's determination and the reasons for it; and
- in the case of the LMC, LPC, provider of primary medical services, an LPS chemist or a person on the pharmaceutical or dispensing doctor list who was notified of the application, their right of appeal under **regulation 45(1)(c)** .

73. The right of appeal against these types of determination is set out in **regulation 45(1)(c)**. It is for this reason that PCTs should **carefully consider which contractors they believe may be significantly affected by the routine application** when they *notify* their intention to consider whether or not an area is a *reserved location*, to ensure that appeal rights are only given to contractors who the PCT is of the opinion would indeed be significantly affected.

74. It should be noted that a *reserved location* only takes effect once the pharmacy premises are included in the PCT's pharmaceutical list i.e. if the application is approved and the applicant submits their notice of commencement (**Regulation 43(3)**). If the *routine application* is refused or the pharmacy fails to open, the determination ceases to exist and the PCT will need to consider the matter afresh for any subsequent *routine applications*.

75. There is a backstop provision which prevents PCTs making reserved location determinations in respect of proposed pharmacy premises that are at a location where a pharmacy premises application has been turned down within the previous five years on prejudice grounds. Generally, it will not be possible to make a further pharmacy application in respect of those pharmacy premises within the previous five years anyway, but that bar is subject to the proviso that the PCT can revisit the matter if there has been a 'substantial and relevant change of circumstances affecting the controlled locality'. If there has, and so a new pharmacy application can be made, the same test will need to apply to the question of whether a reserved location determination can be made. In practice, the change that led to the first decision is also likely to lead to a second being made along similar lines, but historically it has been recognised that these are in fact two separate decisions, and this continues under the 2012 Regulations.

Reserved locations – maps

76. Once a *reserved location* takes effect, (i.e. the pharmacy is included in the PCT's pharmaceutical list) the PCT that determined it must delineate precisely the boundary of the *reserved location* on the map that shows the *controlled locality* within which the *reserved location* is located (**Regulation 43(4)**).

Subsequent determinations of reserved location status

77. Once a *reserved location* has been determined, the pharmacy contractor whose *routine application* triggered this determination may ask the PCT to re-determine the matter (**Regulation 42(1)**) potentially with a view to lifting the determination. Where the original person has subsequently sold the pharmacy, the new owner may also request the PCT to make a re-determination. Determinations of *reserved locations* made under the 2005 Regulations can also be re-considered by the PCT, on request.

78. This request could be made for one of two reasons. These are where the applicant:

- made their *best estimate* in their *routine application* of where the premises would be, and they have now identified the precise location for the premises; or
- believes the premises, or the *best estimate* of the proposed premises, is no longer within a *reserved location* (**Regulation 42(1)**)

79. On receipt of the request, the PCT must immediately identify the number of GP registered patients living within 1.6 km of the premises.

80. Before making a new determination the PCT must:

- notify the persons listed at **paragraph 19(1) of Schedule 2** that it is required to make a determination (if the determination is not linked to an application for listing, the PCT must notify the persons it would notify, if it were linked to an application for listing); and
- invite them within a specified period of at least 30 days but no more than three months to make representations to the PCT (**Regulation 42(2)**)

81. The PCT must only decide that the area or any part of the area, encircling the premises is no longer a *reserved location* if it is satisfied that the change in classification will not prejudice the proper provision of *relevant NHS services* in its area or in the area of a neighbouring PCT (**Regulation 42(3)**). It is possible that not all of the area may be a reserved location (**Regulation 43(2)**).

82. Once the PCT has determined whether or not an area is still a *reserved location* **regulation 43(1)(a)** requires it to give *notice* of the determination to the person whose application triggered the determination and to the persons *notified* in accordance with **regulation 42(2)**. The *notice* must include:

- the PCT's determination and the reasons for it; and

- in the case of the LMC, LPC, provider of primary medical services, an LPS chemist or a person on the pharmaceutical or dispensing doctor list who was notified of the application, their right of appeal under **regulation 45(1)(d)**.

83. The right of appeal against these types of determination is set out in **regulation 45(1)(d)**. It is for this reason that PCTs should carefully consider who they believe may be significantly affected by the determination when they *notify* their intention to consider whether or not an area is still a *reserved location*, to ensure that appeal rights are only given to contractors who the PCT is of the opinion would be significantly affected by the determination.

84. Once the new determination has been made the original one will lapse (**Regulation 42(4)(a)**). If the PCT is satisfied that a provider of primary medical services or a dispensing doctor is likely to be adversely affected by this new determination, it may postpone the variation or termination of the arrangements it has with the provider or dispensing doctor for such period as it thinks fit (**Regulation 50(1)(f), (4) and (5)**). This is known as "gradualisation" (see below).

85. Where a *reserved location* status is removed and there is deemed to be no prejudice to the proper provision of primary medical services, subject to any "gradualisation" arrangements, the dispensing practice will lose the right to dispense to patients living within 1.6 km of the pharmacy. However, they can continue to dispense to patients that live in the *controlled locality* at a greater distance from the pharmacy.

86. It is unusual, but not unknown, for a PCT to determine *reserved location* status when there are no dispensing GP premises within the area under consideration - for example, patients receive dispensing services from a surgery some miles distant. PCTs should bear in mind that the provision for *reserved locations* was not introduced primarily to protect dispensing rights in such circumstances, but to protect the rights where there was an existing dispensing service with premises in the area under consideration.

87. If the PCT determines that the area is still a reserved location, or still part of a reserved location, the contractor may make a request for a further determination at a later date (**Regulation 42(5)**).

88. If the pharmacy has opened, the PCT should remember to amend the *controlled locality* map showing the boundary of the *reserved location* in line with any determination made under **regulation 42** (**Regulation 43(4)**). If the pharmacy has yet to open, the map will not show the *reserved location* but as and when it does the PCT will need to remember to show the correct *reserved location* if one has been determined.

The prejudice test

89. Where a *routine application* to open new or additional pharmacy premises is received for a *controlled locality* and the PCT determines that it is not in a *reserved location*, the test of "prejudice" must be applied.

90. If the PCT is satisfied that granting the *routine application* would, in its opinion, prejudice the proper provision of *relevant NHS services*, either in its area or in the area of a neighbouring PCT, then it must refuse the application (**Regulation 44(3)**).

91. If the applicant gave their *best estimate* of where the proposed premises will be in the *routine application*, it is for the PCT to make its best estimate of where the location may be (**Regulation 44(4)**).

92. The PCT should note the requirement to consider prejudice with respect to *relevant NHS services* in the area of a neighbouring PCT. **Paragraph 19(1)(g) of Schedule 2** requires the PCT to *notify* any other PCT any part of whose area is within 2 km of the proposed premises of the *routine application*. The neighbouring PCT is required by **paragraph 19(3) of Schedule 2** to then notify certain persons of that *routine application*. Those persons may then make representations to the original PCT on that *routine application*.

93. PCTs should note that the onus is on the person/organisation alleging prejudice to provide evidence of this. The PCT that is determining the *routine application* will therefore have to take into account all representations it receives with regards to the issue of prejudice.

94. The Regulations do not provide any definition of the concept of prejudice. In general, 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. In the 1996 case R –v- North Yorkshire FHSA ex parte Dr. Wilson and Partners Justice Carnwath 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".

95. A mere reduction in the total level of service provided by a particular pharmacy or GP practice is not of itself prejudice. 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. In practice, the existence of prejudice involves, to a greater or lesser extent, making a judgment about events that will occur in the future. Inevitably, therefore, it can often be extremely difficult to judge whether or not there will be prejudice.

96. The burden of proof is on the party alleging that prejudice will occur. Each case will, therefore, turn very much on its own particular facts. 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. 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.

Example

A *routine application* is submitted to open a pharmacy within a village which is situated in a *controlled locality*. There is a GP practice within the same village that provides *pharmaceutical services* to its patients living within the *controlled locality* more than 1.6 km from a pharmacy.

The PCT does a GP registered patient count on the day it receives the application and after checking that all the relevant information and documentation has been received it notifies the application to interested parties.

The GP practice responds to the *notification* saying that if the application was approved then the practice would have to close as the loss of income for those dispensing patients living within 1.6 km of the proposed premises. No further information is provided to substantiate this statement.

When it comes to determine the application the PCT notes the practice's statement but in the absence of any evidence from either the practice or any other interested party, it concludes that there would be no prejudice to the proper provision of *pharmaceutical services*.

Adverse effects/gradualisation

97. In some situations, the PCT will need to consider whether to impose conditions with the aim of reducing adverse consequences arising from a decision taken by the PCT. This means in effect that the PCT may decide to postpone, for such period as it thinks fit, the

making or termination of arrangements for the provision by a doctor of *pharmaceutical services* to his patients. The situations in which the need to consider such action (which has become known as "gradualisation") are:

- in the case of decisions that would otherwise lead to discontinuation of arrangements with doctors, the decisions listed in **regulation 50,** which include where an area ceases to be a *controlled locality* or a *reserved location* (**Regulation 50(1)(b) and (f)**); and
- where *premises approval* is granted to a doctor and the PCT is satisfied that a *provider of primary medical services* is likely to be adversely affected (**Regulation 57**)**.**

98. In all these cases, reasonable notice of the basic decision must be given. Normally this might be three months. However, in some cases, the PCT's have a discretion to give a longer period of gradualisation, that is for such period as the PCT thinks fit. This is permissible where the discontinuation arises because *reserved location* status has been removed.

99. Perhaps most significantly, it is also permissible where the discontinuation arises because of the grant of a *routine* or *excepted application* for new pharmacy premises which will be in a *controlled locality* or within 1.6 km of a *controlled locality*, and granting the application, in the opinion of the PCT, results in "significant change" to the arrangements that are in place for the provision of *pharmaceutical services* in any part of the *controlled locality* (*pharmaceutical services* for these purposes including *pharmaceutical services* provided by dispensing doctors). In these cases, the gradualisation is for the period that the PCT "thinks fit", in recognition of the fact that where a dispensing doctor faces new competition from a pharmacy, the arrangements for gradualisation may need to be for a longer period than simply reasonable notice of the actual decision. What the PCT might "think fit" is for the PCT to determine and it is good practice to specify the reasons behind any decision on gradualisation.

100. PCTs may wish to note that the purpose of gradualisation is to allow the affected dispensing practice time to make whatever alterations to their working practices may be necessary, such as reducing stock holdings and altering staff duties.

Appeals against decisions under Part 7

101. **Regulation 45** sets out the rights of appeal against decisions made by the PCT under Part 7. The right of appeal is to the Secretary of State who has delegated this function to the NHSLA's FHSAU.

102. Where an appeal right is provided in accordance with **regulation 45,** a person who is entitled to appeal must be provided with the following:

- *notification* of their right to make an appeal;
- confirmation of their entitlement to make an appeal within 30 days from the date of the PCT's letter;
- information on the FHSAU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website[5].

103. It should be noted that rights of appeal should still be given to those persons who are entitled to be given rights even in the event of the decision being in favour of them. There may potentially be a part of the decision which they do not agree with and are therefore entitled to appeal this part of the decision. The table below summarises which decisions may be appealed and by whom.

Decision	**Person with appeal rights**
Determination of whether an area is or is part of a *controlled locality*.	• the person who made the *routine application* which triggered the determination; • the LPC and LMC; and • any *provider of primary medical services*, LPS chemist, or persons on the PCT's pharmaceutical or dispensing doctor lists who were notified of the intention to make a determination because the PCT was of the opinion that they would be likely to be adversely affected by it. (**Regulation 45(1)(a)**)
Refusal to consider an application from the LMC or LPC to determine whether or not an area is or is part of a *controlled locality* by virtue of **regulation 36(3).**	• the committee that made the application. (**Regulation 45(1)(b)**)
Initial determination of whether proposed premises within a *routine application* are within a *reserved location* or not.	• the person who made the routine application which triggered the determination; • the LPC and LMC; and • any provider or primary medical services, LPS chemist, or persons on the PCT's pharmaceutical or dispensing doctor lists who were notified of the intention to make a determination because the PCT was of the opinion that they would be significantly affected by it. (**Regulation 45(1)(c)**)

[5] http://www.nhsla.com/ContactUs/

Second and subsequent determinations of whether actual or proposed premises are within a *reserved location* or not.	• the person who made the application for the redetermination; • the LPC and LMC; and • any provider or primary medical services, LPS chemist, or persons on the PCT's pharmaceutical or dispensing doctor lists who were notified of the intention to make a determination because the PCT was of the opinion that they would by significantly affected by it. **(Regulation 45(1)(d))**

104. The *notice* of appeal is only valid if it includes a concise and reasoned statement of the grounds of the appeal (**Regulation 45(2)**).

Possible FHSAU decisions

105. Once the FHSAU has determined any appeal, the PCT will be notified of the decision. This *notification* will also include a statement of the reasons for the decision and the findings of fact (**paragraph 10(1) of Schedule 3**).

106. For the purposes of the 2012 Regulations, the FHSAU's decision becomes the PCT's decision on the matter unless the FHSAU's decision is overruled by a court (**paragraph 11 of Schedule 3**).

107. On determining the appeal the FHSAU may:

- confirm the decision or determination of the PCT;
- substitute for that decision or determination any decision or determination that the PCT could have taken when it took that decision or made that determination; or
- quash the decision or determination of the PCT and remit the matter to it for it to redetermine the decision or determination, subject to any directions the FHSAU considers appropriate (**paragraph 9(3) of Schedule 3)**