

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

*Information for Primary Care Trusts*  
*Chapter 10*

Relocations that do not result in significant change to  
pharmaceutical services provision

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# Chapter 10: Relocations that do not result in significant change to pharmaceutical services provision

1. This chapter deals with *excepted applications* submitted by contractors who wish to relocate to different premises either within a PCT's area or to a new PCT's area and the relocation would not result in significant change to *pharmaceutical services* or *local pharmaceutical services*. For these purposes, *pharmaceutical services* does not include dispensing services provided by dispensing doctors.

## Introduction

2. Part 4 of the 2012 Regulations makes provision for *excepted applications*. The name arises because Section 129(2A) and (2B) do not apply to such applications and consequently they are “excepted” from the market entry test. They are therefore not required to meet a need, or to secure improvements or better access, to services.
3. Applications to relocate to different premises fall within this category of applications where the move would not result in significant change to the arrangements that are in place for the provision of *pharmaceutical services* or *local pharmaceutical services*. They therefore differ from *routine applications* to relocate that would result in significant change and are to meet an identified need (submitted under **regulation 12(b)(ii)**).
4. *Excepted applications* to relocate to new premises are required to meet certain criteria and these are listed in **regulation 24**. If an *excepted application* fails to meet any one of these criteria, it must be refused.
5. **Regulation 24** makes provision for the applications to relocate (that would not result in significant change) within a PCT's area (**Regulation 24(1)**) or to a neighbouring PCT (**Regulation 24(2)**) that are not combined with a change of ownership, and also includes circumstances when a PCT must refuse such an *excepted application* (**Regulation 24(3)**).

## Information to be included in all excepted applications to relocate to new premises

6. Part 1 of Schedule 2 sets out the information that is to be provided in the application to the PCT. Some of the requirements relate to all applications, whereas others are for specific types of application.

7. When submitting an *excepted* application to relocate, the following information must be included (**paragraph 1 of Schedule 2**):
- the name of the PCT to which the application is made (this is the PCT in whose area the proposed premises will be);
  - the type of application being made, for example, an application *to relocate* to new premises;
  - a statement of whether the application is an *excepted application*;
  - the name and address of the applicant i.e. the name and address of the sole trader/partnership<sup>1</sup>/body corporate;
  - if the applicant is a sole trader, their General Pharmaceutical Council (GPhC) registration number. A pharmacist does not have to provide their GPhC registration number if their business is as a dispensing appliance contractor (DAC) and not a pharmacy contractor;
  - if the applicant is a partnership, each partner's GPhC registration number<sup>2</sup>. A pharmacist does not have to provide their GPhC registration number if their partnership is as a DAC and not a pharmacy contractor;
  - if the applicant is a body corporate for the purposes of Medicines Act registration, the name and GPhC registration number of the superintendent pharmacist. If the applicant is a DAC, they are not required to have a superintendent pharmacist;
  - with regards to the premises where the applicant wishes to relocate to:
    - the address of those premises;
    - whether the applicant is currently in possession of the premises;
    - the proposed *core opening hours* for the premises; and
  - the total proposed opening hours for the premises (i.e. both *core opening* and *supplementary opening hours*);
  - where the application includes the provision of directed services which are provided at the current premises:
    - details of the directed services to be provided;
    - confirmation that the applicant is accredited to provide the services, where the PCT requires such accreditation;
    - confirmation that the premises are accredited in respect of the provision of the services, where the PCT requires such accreditation; and

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<sup>1</sup> If the applicant is a partnership then the address given in the application should be the one to which they wish all correspondence to be sent.

<sup>2</sup> The Medicines Act 1968 requires all partners to be pharmacists.

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- where relevant a floor plan showing the consultation area where the applicant proposes to offer the directed services, unless one cannot be provided for reasons that the PCT accepts as good cause, for example the premises are not in the applicant's possession.
8. As contractors may only change their *core opening hours* following a successful application to the PCT, the *core opening hours* will be the same as those at the existing premises. If the applicant wishes to change their *core opening hours*, they would need to complete the relocation (if approved) and then submit an application to change their *core opening hours*.
  9. Similarly, the *supplementary opening hours* listed in the application will be the same as for the existing premises. If the applicant wishes to vary their *supplementary opening hours*, they would need to complete the relocation (if approved) and then notify of a change to their *supplementary opening hours*.
  10. The applicant must confirm whether the application is an *excepted application* (**paragraph 1(3) of Schedule 2**). They cannot switch between the two types of application once the application has been made to the PCT. Should the application wish to change the type of application, they are required to withdraw the first application and submit a second application, along with the relevant fee.
  11. Where an applicant submits an *excepted application* for premises which are:
    - already *listed chemist premises*; or
    - are adjacent to or in close proximity to *listed chemist premises*.
- paragraph 6 of Schedule 2** requires the applicant to include in their application, details that explain why the application should not be refused pursuant to **regulation 31**.
12. For an *excepted application* to relocate, **paragraph 8 of Schedule 2** requires the applicant to include details that explain:
    - why they believe the application satisfies the criteria set out in **regulation 24(1)** or **(2)**; and
    - why the application should not be refused under **regulation 24(3)**(see the box below for further information on this).

### Example

A PCT receives an *excepted application* for a relocation to premises adjacent to another pharmacy. The applicant needs to explain to the PCT how the relocation satisfies the requirements of **regulation 24(1)** namely:

- that the pharmacy is not significantly less accessible to the patient groups that are accustomed to accessing *pharmaceutical services* at the current premises;
- why it will not cause a significant change to the arrangements for the provision of LPS or *pharmaceutical services* in any part of its area or in a *controlled locality* of a neighbouring PCT, where that *controlled locality* is within 1.6 km of the proposed premises;
- why it would not cause significant detriment to proper planning of *pharmaceutical services* in the PCT's area;
- confirm that the applicant undertakes to provide same services (whether or not, in the case of *enhanced services*, they will be commissioned – it may of course be a different PCT that might be doing the commissioning); and
- whether there is to be an interruption of service, and if there is the reasoning for this and why this reasoning amounts to good cause.

In addition, they must explain why the PCT should not refuse the application by virtue of **regulation 31** (refusal for same or adjacent premises).

Therefore, in this case, the applicant would need to explain why the existing pharmacy on that site should not be considered to be the same as the services that will be provided if the proposed relocation takes place.

If the pharmacy had previously relocated to the existing premises from other premises six months ago on the basis of another *excepted application*, under **regulation 24(3)(c)** they would have to satisfy that they had good cause for this further relocation (because the listing of the premises had been for less than 12 months).

13. In addition to the information required in **Paragraphs 1 to 6 and 8 of Schedule 2** applicants are required to provide the following undertakings:

- to notify the PCT within seven days of any material change to the information provided in the application (**paragraph 9(a) of Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
  - the application is withdrawn;
  - the application is finally determined, be that by the PCT, or on appeal the FHSAU or First-Tier Tribunal, or following an appeal through the Courts; or
  - if the application is granted, when the applicant commences the provision of *pharmaceutical services* to which the application relates.

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- to notify the PCT if they are included, or apply to be included, in any other *relevant list* (**paragraph 9(b) of Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
  - the application is withdrawn;
  - the application is finally determined, be that by the PCT, or on appeal the FHSAU or First-Tier Tribunal, or following an appeal through the Courts; or
  - if the application is granted, when the applicant commences the provision of *pharmaceutical services* to which the application relates.
- at the premises to which the application relates, to comply with all the obligations that are to be their terms of service under **regulation 11 (paragraph 9(c)(i) of Schedule 2)**.
- In particular, to provide all the services and perform all the activities at those proposed *pharmacy premises* that are required under the terms of service to be provided or performed as, or in connection with, *essential services* (**paragraph 9(c)(ii) of Schedule 2**).
- if the applicant currently providing *directed services*, an undertaking:
  - that they will provide the *directed services* if the PCT commissions them within three years of the date the premises are listed in relation to the applicant in the PCT's pharmaceutical list,
  - if the services are commissioned by the PCT, that they will provide them in accordance with an agreed service specification, and
  - the applicant will not unreasonably withhold agreement to a service specification (**paragraph 9(d) of Schedule 2**).

**Directed services and relocations**

It is a requirement on the applicant that if they are providing *directed services* at their current premises that they will undertake to provide those same *directed services* at the new premises. However, there may be occasions where the PCT does not require the applicant to provide those same *directed services* at the new premises – because there is no need for them, for example.

If the applicant wishes to provide more *directed services* at the new premises then these would form a separate application under **regulation 23**.

Similarly, if the PCT would like the applicant to provide more or different *directed services*, this would be subject to separate discussions.

14. The applicant is also required by **regulation 24(1)(e)** (relocations within the PCT's area) and **regulation 24(2)(e)** (relocations to a neighbouring PCT) to undertake to provide the same services at the new premises as those they provide at the existing premises.



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15. The obligation on the applicant to provide information or documentation required by **paragraphs 1 to 6 and 8 to 9 of Schedule 2** is only discharged if the PCT is satisfied that no relevant information or documentation is missing (**paragraph 10 of Schedule 2**). The PCT must have good cause to believe that there is relevant information or documentation missing and must not use this provision simply to avoid determining, or to delay determining, an application.

**Additional information to be provided where the applicant is relocating to the area of another PCT and is not already included in that PCT's pharmaceutical list**

16. **Paragraph 2 of Schedule 2** requires the applicant to provide additional information where they are not already included in the PCT's pharmaceutical list in respect of other premises. These obligations will only apply if the relocation is from the area of another PCT and the applicant is not already included in the pharmaceutical list of that PCT.
17. Where the applicant is an individual they are required to provide their full name, sex, date of birth, private address and phone number, a declaration that they are a registered pharmacist (i.e. they are registered with the GPhC), and if they have other premises registered with the GPhC the registration number(s) for those premises.
18. If the applicant is a DAC, their premises are not required to be registered with the GPhC (there is no equivalent regulatory body for DACs) and they are not required to be a registered pharmacist.
19. Where the applicant is a partnership they are required to provide:
- each partner's full name, sex, date of birth, private address and telephone number and a declaration that each partner is a registered pharmacist (i.e. they are registered with the GPhC) and if they have other premises registered with the GPhC the registration number(s) for those premises; and
  - a declaration that the applicant is or will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968. DACs are not required to complete this declaration.
20. If the applicant is a DAC, their premises are not required to be registered with the GPhC (there is no equivalent regulatory body for DACs). Additionally the partnership is not required to consist only of registered pharmacists.
21. Where the applicant is a body corporate they are required to provide:
- the registered name and any other name under which the applicant trades;
  - the company's registration number (this is their Companies House registration number);

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- the registered office for the body corporate and any fixed line telephone number relating to that office;
  - the private address and date of birth of the superintendent pharmacist (not required from DACs);
  - the name, private address and date of birth of each director (excluding the superintendent pharmacist), and if any director is a registered pharmacist their GPhC registration number;
  - a declaration that the applicant is or will be lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968 (DACs are not required to complete this declaration); and
  - if the applicant has other premises registered with the GPhC, the registration number(s) for those premises.
22. If the applicant is a DAC, their premises are not required to be registered with the GPhC.
23. **Paragraph 3 of Schedule 2** requires them to provide certain fitness to practise information on:
- the individual making the application, or
  - where it is a partnership, each partner, or
  - where it is a body corporate, the director(s) and (unless it is a DAC) superintendent pharmacist.
24. **Paragraph 4 of Schedule 2** sets out further information that must be provided where the applicant is a body corporate and not already included in the PCT's pharmaceutical list for other premises.
25. Further information on these requirements can be found in separate guidance<sup>3</sup>. PCTs must ensure that none of the information provided under **paragraphs 3 and 4 of Schedule 2** – and no private addresses, private telephone numbers or dates of birth – are circulated with the application as part of the notification exercise. The PCT must also ensure that all fitness to practise checks are completed and a decision made on the applicant's suitability for inclusion in the pharmaceutical list before determining the *excepted application*.
26. Where the applicant is a body corporate with a registered office in England, **paragraph 5 of Schedule 2** makes provision for them to provide the information required by **paragraphs 3 and 4** to their *home PCT* instead. If they have already provided that information to their *home PCT* for another application, they need not provide that information again.

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<sup>3</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108206](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206)  
Gateway reference 4728

27. If the applicant wishes to use this flexibility, then it must:
- confirm to the PCT to whom it is making the application that their *home PCT* already has the information required under **paragraphs 3 and 4**; or
  - undertake to provide any missing information required under those paragraphs to its *home PCT* and confirm to the PCT to whom it is making the *excepted application* to relocate when that has taken place.
28. It is for the applicant to decide whether or not to use this flexibility, not the decision of the PCT to whom the *excepted application* is submitted or the *home PCT*. If the applicant does wish to use this flexibility, the PCT to which the *excepted application* is made must notify the *home PCT* of that *excepted application* and seek a recommendation from it as to whether or not the *excepted application* should be refused or deferred under **regulation 33 or 34** i.e. on fitness to practise grounds (**paragraph 13(1) of Schedule 2**).
29. The *home PCT* is required to consider whether the *excepted application* should be refused on fitness to practise grounds, and having done so must make a recommendation to the PCT that received the *excepted application* within 30 days of receiving the notification (**paragraph 13(2) of Schedule 2**).
30. The recommendation must set out all the relevant facts and be fully reasoned (**paragraph 13(2)(a) of Schedule 2**). If the recommendation is that the application be refused or deferred under **regulation 33 or 34** on fitness to practise grounds, the PCT that received the application must send a copy of the recommendation to the applicant and seek their views as to the accuracy of the facts set out by the *home PCT* (**paragraph 13(2)(b) of Schedule 2**). The PCT should note that this is only a recommendation by the *home PCT* and therefore the PCT could come to a different conclusion if it so wished based on the facts before it.

### Preliminary matters to consider following receipt of an application

31. On receipt of an *excepted application* to relocate, there are a number of preliminary matters which the PCT must consider before notifying the *excepted application* to interested parties. These matters are set out in **Part 2 of Schedule 2** and PCTs may wish to develop a checklist to ensure they consider all the matters prior to notifying the application.

### Missing relevant information or documents

32. Where the PCT considers that the application has not provided all the relevant information or documentation, it may request that missing information or documentation

and shall specify the timescale within which it is to be submitted (**paragraph 11(1) of Schedule 2**). The PCT should only request information or documentation that is required to determine the application i.e. information or documentation that is relevant to the application. The PCT should not request information that is not relevant to the application (see the example below).

33. The timescale must be reasonable and will depend on what information or documentation is required, for example, a timescale of one week may be reasonable to provide the GPhC registration number of the superintendent pharmacist required under **paragraph 1(6) of Schedule 2** but a longer period may be required to provide the fitness to practise information required under **paragraph 3 of Schedule 2** for all the partners in a partnership.
34. The PCT may make the request at any time between receiving and determining the *excepted application* to relocate, but it must consider whether or not it needs to request missing information or documentation prior to notifying the application as required by **paragraph 18 of Schedule 2 (paragraph 11(3) of Schedule 2)**. In the interests of fairness and transparency and to make sure those notified of the application have all the relevant information, the PCT may wish to ensure they have any missing information or documentation prior to notifying the application.
35. The applicant is required to provide the information or documentation within the specified timescale and where they are unable to meet the timescale, they must notify the PCT of the delay (**paragraph 11(1)(b)(i) and (ii) of Schedule 2**). Additionally, they must tell the PCT if they are unable to meet the original timescale and specify a date by which the information or documentation will be provided (**paragraph 11(1)(b)(ii) of Schedule 2**). The PCT must be satisfied that the delay and the length of the delay are for good cause (**paragraph 11(2)(a)(ii) of Schedule 2**).
36. If the applicant refuses to comply with a request for missing information or documentation within the timescale specified by the PCT, or by any subsequent date specified by the applicant and agreed with the PCT, the application is to be treated as withdrawn by the applicant (**paragraph 11(1)(b)(iii) of Schedule 2**).
37. If the applicant considers that the PCT's request is not reasonable, they may notify the PCT of that and seek a review by the PCT of the reasonableness of the request – see box below (**paragraph 11(1)(b)(iii) of Schedule 2**).
38. If the applicant seeks a review, the PCT is required to reconsider its request for missing information or documentation. The 2012 Regulations are silent as to the procedure for this review. PCTs may therefore wish to develop and agree a process with their LPC for this. In the interests of fairness and transparency, the review should be conducted by a different person/committee to that which determined the information or documentation is

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missing. PCTs may wish to consider whether the dispute resolution processes they have in place for other primary care contractors are suitable for this purpose.

39. If following the review, it is determined that any or all of the requested information or document must after all be provided, the applicant must be told of the timescale (which must be reasonable) within which it is to be provided. Should the applicant not comply with the request, the application is to be treated as withdrawn by the applicant (**paragraph 11(2)(b)(i) of Schedule 2**).
40. If following the review, it is determined that the information or documentation need not be provided, the original request made under **paragraph 11(1) of Schedule 2** is to be treated as withdrawn i.e. the applicant is not required to provide it (**paragraph 11(2)(b)(ii) of Schedule 2**).

### Example

A shared service agency receives an *excepted application* to relocate. On checking the application, it is noted that the applicant has stated the pharmacy will be in premises that are currently residential. The agency asks the applicant to provide evidence that they have applied for or been given approval by the local planning department for change of use.

The applicant considers this request unreasonable as it is not material to their application and asks for a review to be undertaken.

The PCT's pharmacy application panel considers the request for a review and agrees that as this information is outside the requirements of the 2012 Regulations, the request is unreasonable. The applicant is advised that the request for that information is withdrawn.

### Failure to provide undertakings

41. On receipt of an application, the PCT should check that the applicant has given all the undertakings required by **paragraph 9 of Schedule 2**. If the applicant has failed to do this, the PCT must, prior to notifying the application, request them to do so within a reasonable timescale (**paragraph 12(1) of Schedule 2**).
42. If the applicant fails to comply with this request within the PCT's timescale, the application is to be treated as withdrawn (**paragraph 12(2) of Schedule 2**).

### Excepted applications to relocate

43. There are two types of *excepted application* to relocate premises. The first is within the PCT's area and the second is to a neighbouring PCT.

## Relocations within a PCT area

44. The following table sets out five criteria for relocations within a PCT's area (**Regulation 24(1)**) along with an explanation of each. The first three criteria look at the impact of the relocation at different levels:

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Regulation 24(1) criteria	Explanation
<p><i>(a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;</i></p>	<p>The PCT should consider whether the new premises are significantly less accessible for those patient groups who use the current premises or not. The term “patient group” reflects the requirement for PCTs, when developing their PNAs, to have regard to the demography of their area and the different needs of people in their area who share a <i>protected characteristic</i>. These are the characteristics such as age, sex and disability that form the basis of the public sector equality duty under the Equality Act 2010.</p> <p>When deciding whether the new premises are significantly less accessible, the PCT will need to consider whether there are any physical barriers or other geographical, transport or communication factors which would affect the accessibility of the new premises.</p> <p>Relocations should result in improved access for those patient groups who use the current premises. However there may be occasions where this may not be the case. For example, the lease on the premises is due to expire and the pharmacy has to secure new premises at short notice. In this instance, the pharmacy may have to move into premises that do not offer the same level of access as at the current site and the PCT will need to exercise its judgement and decide whether this reduction in access is significant or not.</p>
<p><i>(b) in the opinion of the Primary Care Trust, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—</i></p>	<p>Having looked at any impact on patient groups, the PCT will need to consider whether the relocation would impact on the arrangements that are in place for the provision of local pharmaceutical services and <i>pharmaceutical services</i> in any part of their area.</p> <p>The PCT would need to be satisfied that any impact would not result in a significant change taking into account the particular circumstances.</p>



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<p>(i) <i>in any part of its area, or</i>  (ii) <i>in a controlled locality of a neighbouring Primary Care Trust, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;</i></p>	<p>The PCT should note that it is not required to consider the impact on the provision of <i>pharmaceutical services</i> by persons on the dispensing doctor list. Additionally the PCT must consider the impact on <i>pharmaceutical services</i>, provided in a <i>controlled locality</i> of a neighbouring PCT where that <i>controlled locality</i> is within 1.6 km of the proposed new premises. This provision therefore looks at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision.</p>
<p>(c) <i>the Primary Care Trust is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area;</i></p>	<p>Finally, the PCT is required to examine whether the relocation would affect its planning of <i>pharmaceutical services</i> in its area.</p> <p>Example - a particular pharmacy is unsuccessful in its attempts to relocate to a new one stop primary care centre – a number of applications from potential occupants for the pharmacy site at centre were considered and the particular pharmacy was one of the unsuccessful applicants. As an alternative, the particular pharmacy attempts to relocate to a site nearer to the centre – and if that application was granted, it would compromise the viability of the plans for <i>pharmaceutical services</i> at the centre that the PCT has put in place. In these circumstances, the PCT could refuse the application on the basis of detriment to proper planning.</p>



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<p><i>(d) the services the applicant undertakes to provide at the new premises are the same as the services the applicant has been providing at the existing premises (whether or not, in the case of enhanced services, the Primary Care Trust chooses to commission them); and</i></p>	<p>The applicant is obliged to undertake to provide the same services at the new premises. If the application is approved, the applicant would be required to provide <i>essential services</i>. They would also be required to continue to provide advanced services, and any <i>enhanced services</i> they were providing at the old premises if the PCT chose to commission them at the new premises. This gives the PCT the flexibility to commission only the <i>enhanced services</i> that are required.</p> <p>The applicant would also be required to be open for the same core and supplementary opening hours at the new premises. Once the relocation is complete, they could then apply to the PCT to change their <i>core opening hours</i>, or <i>notify</i> of a change in <i>supplementary opening hours</i>.</p> <p>The PCT cannot, however, require the contractor to provide additional <i>directed services</i> as a condition of granting the relocation application; they can only require the current <i>directed services</i> to be provided at the new premises.</p> <p>Example - a pharmacy that provides emergency hormonal contraception wishes to relocate to a site that is nearer to another pharmacy that provides this service. The pharmacy provides emergency hormonal contraception at its current premises and undertakes to do so at the new premises. Although the PCT is satisfied that the move does not result in significant change to the arrangements that it has in place for <i>pharmaceutical services</i>, it also considers that commissioning emergency hormonal contraception from both sites will become unnecessary and therefore the PCT decides not to commission that service from the relocated pharmacy once the relocation has taken place. The pharmacy has fulfilled its obligation under this regulation by undertaking to provide the service, but is not required to do so because the PCT does not wish to commission it.</p>
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<p><i>(e) the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow).</i></p>	<p>The PCT must be satisfied that the provision of <i>pharmaceutical services</i> will not be interrupted, except for such period as it may for “good cause” allow. What constitutes “good cause” is ultimately for the PCT to assess on the facts of the case.</p> <p>Example - there may be a temporary delay in handing over the premises to the new leaseholder. Alternatively, the applicant may request a short interruption to transfer stock and supplies from the old to the new premises and test computer systems etc before opening and the PCT may decide that this is good cause for service provision to be interrupted.</p>
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## Relocations to a neighbouring PCT

45. The following table sets out the criteria for relocations to a neighbouring PCT's area (**Regulation 24(2)**) along with an explanation of each. The first three criteria look at the impact of the relocation at different levels:
- the impact on patient groups (**Regulation 24(2)(b)**);
  - the impact on the provision of local pharmaceutical services and *pharmaceutical services* (but not on the provision of such services by persons on the dispensing doctor list) in PCT2's area or in a *controlled locality* of a neighbouring PCT (including the original PCT) that is within 1.6 km of the proposed premises (**Regulation 24(2)(c)**);
  - the impact on the PCT's planning for the provision of *pharmaceutical services* in its area (**Regulation 24(2)(d)**).
46. Throughout the explanations, PCT2 is the PCT into whose area the pharmacy wishes to relocate.

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Regulation 24(2) criteria	Explanation
<i>(a) the purpose of the application is to relocate to different premises;</i>	PCT2 must be satisfied that the application is for a relocation as opposed to a <i>routine application</i> to open new premises. The latter should be submitted as a <i>routine application</i> under one of the Regulations in Part 3.
<i>(b) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises (P1), the location of the new premises is not significantly less accessible;</i>	<p>PCT2 should consider whether the new premises (P2) are accessible for those patient groups who use the current premises (P1). The term “patient group” reflects the requirement for PCTs, when developing their PNAs, to have regard to the demography of their area and the different needs of people in their area who share a <i>protected characteristic</i>. These are the characteristics such as age, sex and disability that form the basis of the public sector equality duty under the Equality Act 2010.</p> <p>When deciding whether the new premises are significantly less accessible, PCT2 will need to consider whether there are any physical barriers or other geographical, transport or communication factors which would affect the accessibility of the new premises (P2).</p> <p>Relocations should result in improved access for those patient groups who use the current premises. However, there may be occasions where this may not be the case. For example, the lease on the premises is due to expire and the pharmacy has to secure new premises (P2) at short notice. In this instance, the pharmacy may have to move into premises that do not offer access that same level of access as at the current site and PCT2 will need to exercise its judgement and decide whether this reduction in access is significant or not.</p>

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	<p>Example – a pharmacy is located on one side of a road which is the boundary between two PCTs in a city. The pharmacist applies to relocate across the road to PCT2 and undertakes to provide the same services. There is a zebra crossing outside the new premises which are easy to access from the pavement. PCT2 is therefore satisfied that the location of the new premises is as accessible as the current premises and approves the application. Conversely, if the road is a major arterial route which can only be crossed with difficulty, PCT2 may not be so satisfied.</p>
<p><i>(c) in the opinion of the PCT2, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—</i></p> <p><i>(i) in any part of PCT2's area; or</i></p> <p><i>(ii) in a controlled locality of a neighbouring Primary Care Trust (including PCT1), where that controlled locality is within 1.6 kilometres of P2;</i></p>	<p>Having looked at any impact on patient groups, PCT2 will then need to consider whether the relocation would impact on the arrangements that are in place for the provision of local pharmaceutical services and <i>pharmaceutical services</i> in any part of their area.</p> <p>The PCT would need to be satisfied that any impact would not result in a significant change taking into account the particular circumstances.</p> <p>The PCT should note that they are not required to consider the impact on the provision of <i>pharmaceutical services</i> by persons on the dispensing doctor list.</p> <p>Additionally PCT2 must consider the impact on <i>pharmaceutical services</i>, provided in a <i>controlled locality</i> of a neighbouring PCT (which could include the PCT from where the applicant wishes to relocate) where that <i>controlled locality</i> is within 1.6 km of the proposed new premises.</p>

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	<p>This provision therefore looks at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision.</p> <p>Example – a pharmacy is located on one side of a road which is the boundary between two PCTs in a city. The pharmacist applies to relocate across the road to PCT2 and undertakes to provide the same services. There are no other pharmacies in the vicinity. As there would be no change to the arrangements in place for the provision of <i>pharmaceutical services</i>, PCT2 approves the application.</p>
<p><i>(d) PCT2 is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area;</i></p>	<p>Finally, PCT2 is required to examine whether the relocation would affect its planning of <i>pharmaceutical services</i> in its area.</p> <p>Example – the PCT received a <i>routine application</i> to meet an identified current need and decided under <b>regulation 14(1)</b> to defer that <i>routine application</i> and invite other applications to meet that same need for a new pharmacy offering a range of essential and directed services in that locality. The PCT received no other applications and approved the initial <i>routine application</i>. The PCT then received an <i>excepted application</i> from a pharmacy just over the border in a neighbouring PCT to relocate close to the premises for which it had just approved the <i>routine application</i>. The PCT decided to refuse the <i>excepted application</i> to relocate as it would cause significant detriment to its proper planning for <i>pharmaceutical services</i>.</p>

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<p><i>(e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, PCT2 chooses to commission them);</i></p>	<p>The applicant is obliged to undertake to provide the same services at the new premises. If the application is approved, the applicant would be required to provide <i>essential services</i>. They would also be required to continue to provide advanced services and any <i>enhanced services</i> they were providing at the old premises if PCT2 chose to commission them at the new premises. This gives PCT2 the flexibility to commission only the <i>enhanced services</i> that are required.</p> <p>The applicant would also be required to be open for the same core and supplementary hours at the new premises. Once the relocation is complete, they could then apply to the PCT to change their <i>core opening hours</i>, or <i>notify</i> of a change in <i>supplementary opening hours</i>.</p> <p>The PCT cannot however, require the contractor to provide additional <i>directed services</i> as a condition of granting the relocation application; they can only require the current <i>directed services</i> to be provided at the new premises.</p> <p>Example - a pharmacy wishes to relocate from PCT1 to PCT2. The pharmacy is commissioned to provide emergency hormonal contraception at its current premises by PCT1 and undertakes to do so at the new premises. However, PCT2 does not commission that service in the area to which the pharmacy wishes to relocate. The pharmacy has fulfilled its obligation under this regulation by undertaking to provide the service, but is not required to do so because PCT2 does not commission it.</p>
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<p><i>(f) the provision of pharmaceutical services will not be interrupted (except for such period as PCT2 may for good cause allow);</i></p>	<p>PCT2 must be satisfied that the provision of <i>pharmaceutical services</i> will not be interrupted, except for such period as it may for “good cause” allow.</p> <p>What constitutes “good cause” is ultimately for PCT2 to assess on the facts of the case. For example, there may be a temporary delay in handing over the premises to the new leaseholder. Alternatively, the applicant may request a short interruption to transfer stock and supplies from the old to the new premises and test computer systems etc before opening and the PCT may decide that this is good cause for service provision to be interrupted.</p>
<p><i>(g) the applicant consents to—</i>  <i>(i) where the applicant has only one set of listed chemist premises in PCT1’s pharmaceutical list, the removal of the applicant’s name from PCT1’s pharmaceutical list, or</i>  <i>(ii) where the applicant has more than one set of listed chemist premises in PCT1’s pharmaceutical list, the removal of P1 from being listed in relation to the applicant in PCT1’s pharmaceutical list,</i></p> <p><i>with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.</i></p>	<p>The final criterion for PCT2 to consider is the applicant’s consent to the removal of its existing premises (P1) from PCT1’s pharmaceutical list. Where this consent is withheld or not given by the applicant, then the application cannot be finally determined.</p> <p>Clarity is provided as to which set of premises are to be removed from PCT1’s pharmaceutical list where the applicant has multiple premises included in that list.</p> <p>The date the old premises (P1) are removed from PCT1’s list is the date that service provision commences at the new premises (P2). PCT1 and PCT2 will therefore need to liaise closely to ensure premises are removed at the appropriate time.</p>



## Refusal and deferral of applications on fitness to practise grounds prior to notification

47. Where the PCT2 receives an *excepted application* to relocate from a neighbouring PCT from a person who is not already included in its pharmaceutical list at other premises, prior to notification it must consider whether or not it must refuse that application under **regulation 33(1)** – mandatory refusal on fitness to practise grounds (**paragraph 16 of Schedule 2**).

### Example

A PCT receives an *excepted application* from a pharmacist that is not already included in its pharmaceutical list who is seeking to relocate the pharmacy from the area of a neighbouring PCT. The pharmacist does not have a *home PCT* and it emerges from the information supplied with the application that the pharmacist has recently been sentenced to a term of imprisonment of over six months, albeit that the sentence was suspended. This sentence had not been disclosed to the neighbouring PCT. The PCT therefore refuses the application under **regulation 33(1)**.

48. If the applicant is from a neighbouring PCT, they would be new to the PCT's pharmaceutical list, and have a *home PCT*, the PCT that received the application must wait for the *home PCT*'s recommendation before deciding whether to defer the application under **regulation 34** i.e. on fitness to practise grounds. In this instance, the PCT could only delay notification of the application to interested persons for fitness to practise reasons if the *home PCT*'s recommendation which led the PCT to defer the application under **regulation 34 (paragraph 14(3) of Schedule 2)** arrived during the course of delay in notifying that occurred for other reasons, for example, a delay in providing the necessary undertakings. The PCT must not use waiting for a *home PCT*'s recommendation as the reason for holding up a notification.
49. Where a PCT does decide to defer the *excepted application* under **regulation 34**, once the outcome of the cause of that deferral is known the PCT must notify the applicant that they must within a specified period of not less than 30 days update their application and notify the PCT whether or not they still wish to proceed with it (**paragraph 24(2)(f) of Schedule 2**).
50. If the applicant informs the PCT within the specified period that they do not wish to proceed with the application then the application is to be treated as withdrawn by the applicant (**paragraph 24(3) of Schedule 2**). If the applicant fails to respond in the required manner then the application is also to be treated as withdrawn.

## Notification

51. Once all the above preliminary checks are completed, the PCT in receipt of the application may then move on to give *notice* of the *excepted application* to relocate to new premises.
52. The PCT must give *notice* of the *excepted application* to relocate to:
- the LPC for its area, which may be an LPC that it shares with another PCT;
  - the LMC for its area which may be an LMC that it shares with another PCT;
  - any person in its pharmaceutical list whose interests the PCT believes might be significantly affected if the application was granted;
  - any person who is entitled to be included in its list because of the grant by the PCT or on appeal by the FHSAU, of a *routine* or *excepted application*, but who is not (yet) included, and whose interests the PCT believes might be significantly affected if the application was granted;
  - any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application was granted;
  - any local involvement network (LINK) for its area, and any other patient, consumer or community group in its area (for example Parish and Town Councils) which the PCT believes has a significant interest in the outcome of the application;
  - if the proposed premises within the application are in, or are within, 1.6 km of a *controlled locality* in its area, any provider of primary medical services or any other person on its dispensing doctor list if it has one (i.e. doctors on the list who are performers as opposed to providers) who the PCT believes has a significant interest in the outcome of the application; and
  - any other PCT or Local Health Board (LHB) any part of whose area is within 2 km of the proposed premises (**paragraph 19(1) of Schedule 2**).
53. Persons in the above list must receive notice of the application. The PCT is free to notify any other person who it believes has a significant interest in the outcome of the application for example MPs, councillors (**paragraph 19(2) of Schedule 2**).
54. It is recommended that the PCT records its reasoning for why it believes persons have a significant interest in the outcome of the application.
55. For *excepted applications* to relocate distance selling premises applications, it is sufficient to notify those persons listed above along with the nearest neighbouring PCT(s). There is no need to notify all PCTs of such applications.

56. Other than LPCs, LMCs and neighbouring PCTs or LHBs, the PCT should note the requirement to notify only those who it believes might be significantly affected if the application were granted, or those it believes have a significant interest in the outcome. PCTs will therefore need to identify those relevant persons rather than automatically notifying everyone on their pharmaceutical list, dispensing doctor list and all providers of primary medical services.

### Example

The PCT receives an *excepted application* to relocate and after completing its preliminary checks is ready to notify it as required by **paragraph 19 of Schedule 2**. The application is for premises on the outskirts of a town and is within 1 km of a *controlled locality*. 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 five 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 five dispensing patients in the area would not have a significant interest in the outcome of the application and does not notify them of the application. This decision is noted in the paperwork for the application.

57. Where a neighbouring PCT is notified under **paragraph 19(1)(g) of Schedule 2** it must, within 14 days of receiving the notification, give *notice* of the application to:
- the LPC for its area if this is different to the notifying PCT's LPC;
  - the LMC for its area if this is different to the notifying PCT's LMC;
  - any person in its pharmaceutical list whose interests the PCT believes might be significantly affected if the application were granted;
  - any person who is entitled to be included in its list because of the grant of a *routine* or *excepted application*, but who is not (yet) included, and whose interests the PCT believes might be significantly affected if the application were granted;
  - any LPS chemist with whom the PCT has a contract and whose interests the PCT believes might be significantly affected if the application were granted;
  - any LINK for its area, and any other patient, consumer or community group in its area which the PCT believes has a significant interest in the outcome of the application; and
  - if the proposed premises within the application are within 1.6 km, of a *controlled locality* in its area, any provider of primary medical services or any other person on its dispensing doctor list if it has one (i.e. doctors on the list who are performers as opposed to providers) who the PCT believes has a significant interest in the outcome of the application (**paragraph 19(3)(a) of Schedule 2**).

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58. Once it has notified the above listed persons, it is required to confirm this to the PCT that received the application (**paragraph 19(3)(b) of Schedule 2**). PCTs should note their duty to give *notice* of applications received from neighbouring PCTs. There is no appeal right against failure to do so, therefore the only recourse for a person who feels they have been adversely affected by such a failure is through the Courts.
59. Those persons who have been notified may make written representations about the application to the PCT to whom the application was made provided they do so:
- within 45 days of the date on which *notice* of the application was given to them; or
  - for persons notified under **paragraph 19(2) or (3)** within such longer period as the PCT that received the application may specify (**paragraph 19(4) of Schedule 2**)
60. Where a PCT has notified a neighbouring PCT or LHB about an application, it may wish to allow 59 days for responses. As the neighbouring PCT must circulate the notification within 14 days of receipt this will ensure those persons notified by the neighbouring PCT have at least 45 days within which to consider the application.
61. PCTs may like to contact their neighbouring PCTs to seek contact details for the person to whom the applications should be sent. This will ensure that applications are passed on in a timely manner.
62. The general expectation is that notified persons will have 45 days to respond from the date on which they receive the notification, and the PCT's power to extend should only really be needed and used in exceptional circumstances.

### Possible need for parallel notifications

63. There may be occasions where an *excepted application* to relocate will result in a pharmacy moving into an area that is or may be a *controlled locality*. PCTs should note that the two grounds for refusing applications in Part 7 of the 2012 Regulations – the “5 year rule” in **regulation 40** and the “prejudice test” in **regulation 44** – do not apply to determinations of *excepted applications*. Accordingly, PCTs are not required under **regulation 38(4)** to defer consideration of *excepted applications* to locate pharmacies in areas that are, or might become, *controlled localities*. If the area in question is the subject of a process for determining whether or not it is a *controlled locality*, it is advisable to keep the two notifications separate so as not to unintentionally misrepresent to those who are notified that the decisions are linked. See chapter 14 for further information on *controlled localities*.
64. Similarly, it is possible that a PCT may receive an *excepted application* for a relocation that, if the application were a *routine application*, would result in consideration of whether or not the proposed premises are within a *reserved location*. However, the

rules relating to *reserved locations* only apply in relation to new premises that are included in a pharmaceutical list as a consequence of a *routine application*. If a relocation application is granted under **regulation 25** and the new premises are within 1.6 km of *medical practice premises of a dispensing doctor*, the rules on “gradualisation” in **regulation 50(3)** will however apply. See chapter 14 for further information on *reserved locations*.

65. If the PCT wishes to consider two or more applications together and in relation to each other, for example, where it has deferred a *routine application* to consider it alongside an *excepted application* to relocate, it is required by **paragraph 22(3) of Schedule 2** to give *notice* of its intention to do so.

## Content of notifications

66. **Paragraph 21(1) of Schedule 2** sets out the information that must be contained within the *notification* letter. As well as sending a copy of the application, the PCT must inform those it is notifying:
- of their right to make representations under **paragraph 19(4)**;
  - of the circumstances in which notified persons would be permitted to make oral representations should the PCT subsequently decide to hold an oral hearing; and
  - where the PCT intends to consider the application at the same time as another application, notification of that intention (**paragraph 21(1)(a) of Schedule 2**)
67. When notifying of applications PCTs must ensure that they send sufficient information to enable those notified to make informed representations as to whether or not the application should be granted (**paragraph 21(1)(b) of Schedule 2**). PCTs are not, however, required to provide copies or excerpts of their PNA with the notification letter (**paragraph 21(2) of Schedule 2**).
68. PCTs must not send any private personal information or fitness to practise information provided by the applicant under **paragraphs 2 to 4** or by their *home PCT*, where relevant (**paragraph 21(3) of Schedule 2**). This includes any private addresses, private telephone numbers or dates of birth that may have been supplied.
69. If the applicant advises the PCT that they consider:
- any information to be confidential; and
  - that they do not consent to that information being disclosed as part of the *notification*

the PCT must withhold that information if it believes that the full disclosure principle does not require it to provide that information to those notified of the application (**paragraph 21(4) of Schedule 2**). If the PCT does withhold any information under

**paragraph 21(4) of Schedule 2**, it must inform those notified of the application of the nature of the information that is being withheld (**paragraph 21(6) of Schedule 2**).

70. The full disclosure principle means that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application. The only exception is where it is fair and proper for that information to be withheld (**paragraph 21(5) of Schedule 2**) from that individual. Where the PCT is in any doubt as to whether the full disclosure principle applies, it should seek legal advice.

## Determination and deferral of applications

### Flexibility with regard to determining or deferring applications

71. The PCT is able to determine an *excepted application* to relocate as it sees fit, unless the Regulations provide to the contrary (**paragraph 22(1) of Schedule 2**). An example of this is **paragraph 26 of Schedule 2** which sets out who cannot take part in the decision-making process.
72. The PCT may determine an *excepted application* without holding an oral hearing if it considers that oral representations are unnecessary (**paragraph 22(2) of Schedule 2**). Where a decision is taken not to hold an oral hearing, it is good practice to document that decision.
73. The PCT may consider two or more applications together and in relation to each other, but must give *notice* of this intention (**paragraph 22(3) of Schedule 2**). This should be done as part of the notification exercise. However, if the PCT decides after the notification exercise that it wishes to consider two or more applications together then it may do so but it must give *notice* of this to the applicants concerned before determining the applications.

## Oral hearings

74. Oral hearings are not required to be held for every application decision and PCTs should make a judgement on when it is necessary to do so. This is likely to be based on the complexity of the application, previous applications in the area and any appeals, particularly upheld appeals, to the FHSAU regarding those applications, and the number and type of representations made in respect of the application from those notified of it.



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75. If the PCT decides to hear oral representations prior to determining an *excepted application* to relocate then it must:
- give the applicant and any *additional presenters* not less than 14 days *notice* of the time and place for the oral hearing; and
  - advise the applicant who else has been invited to make representations at the hearing. This may include other applicants where the PCT has decided to determine two or more applications together (**paragraph 25(1) of Schedule 2**)
76. **Paragraph 25(2) of Schedule 2** defines a person as an *additional presenter* if:
- the application to which the hearing applies is a *notifiable application* (which *excepted applications to relocate* are);
  - they were given *notice* of the application and made representations in accordance with **paragraph 19(4)**. As part of the representations the person must have indicated that they would wish to make oral representations if an oral hearing took place, and they must have identified a matter about which the PCT considers it would be desirable to hear further evidence about from the person at the oral hearing; and
  - the PCT is satisfied that the person made a reasonable attempt to express their views on the application in their written representation.
77. Written representations must therefore take a view on whether the application should be refused or granted, and the reasoning for that view. It is for the PCT to then decide whether they wish to hear further evidence on those reasons at the oral hearing. PCTs should note that simply saying that you would wish to attend an oral hearing without giving a view on the application is not sufficient. If a person notified of an application does not state in their written representations that they would wish to make oral representations, the PCT is not required to invite them to an oral hearing if it decides to hold one.
78. If the PCT decides at or after the oral hearing that an application is to be deferred, it may hold a further oral hearing once the period of deferral has expired if it so wishes (**paragraph 25(3) of Schedule 2**). This is a matter for the PCT to make a decision on and it is not obliged to hold a further hearing.

**Persons barred from taking part in decision making on excepted applications**

79. **Paragraph 26 of Schedule 2** sets out a list of persons who may take no part in determining any *excepted application*. Further information on this can be found in Chapter 3.

## Timetable for determining applications

80. **Paragraph 27 of Schedule 2** requires PCTs to determine *excepted applications* which are *notifiable applications* as soon as it is practicable to do so within four months of the date on which all the required information and documentation was received by the PCT (**paragraph 27(b)(i) of Schedule 2**).
81. The only exceptions to this timescale are:
- where the application is deferred in accordance with a provision of the Regulations, for example fitness to practise reasons such as an ongoing investigation for fraud; or
  - there is good cause for the delay, for example where the application is deficient i.e. there is missing relevant information or documentation. In this case the four month time period initially starts at the point the application is received. It then stops at the point the PCT discovers it is deficient e.g. not all the relevant information or documentation is received. It then restarts at the point all the relevant information or documentation is received.
82. Good cause for delaying an application will very much depend on the facts of the case.

### Example

The PCT receives an *excepted application* from an existing pharmacy that wishes to relocate to part of a new health centre. The PCT duly notifies interested parties under **paragraph 19 of Schedule 2**.

The PNA has identified the need for a new pharmacy at that centre providing essential and advanced services and certain *enhanced services* that are not provided at the existing pharmacy that wishes to relocate. Halfway through the notification period for the *excepted application*, it receives a *routine application* for the same location which is offering to meet the identified needs in full. As the relocation application is not offering to provide all the specified *enhanced services*, the PCT decides it has good cause to defer the relocation application so as to consider it with the *routine application*.

If however the PCT decided that it did not have good cause to delay the relocation application, it would need to be satisfied before granting it that doing so would not cause significant detriment to proper planning of the provision of *pharmaceutical services* in its area (**Regulation 24(1)(c)**).



## Refusal, deferral and conditional inclusion in pharmaceutical lists of neighbouring PCTs on fitness to practise grounds

83. Where the applicant is proposing to relocate to a neighbouring PCT and they are not already included in that PCT's pharmaceutical list they will also have to have submitted information on their fitness to practise (**paragraphs 2 to 4 of Schedule 2**). The PCT may process this information either in advance of processing the *excepted application* to relocate, or alongside. Whichever course of action is taken, the PCT must come to a decision on the fitness to practise information in advance of the *excepted application*. It is not possible for PCTs to approve the *excepted application*, subject to the satisfactory approval of the fitness to practise information.
84. Part 6 of the 2012 Regulations sets out the grounds on which the neighbouring PCT:
- must or may refuse the *excepted application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 33**);
  - may defer consideration of the *excepted application* for inclusion in its pharmaceutical list on fitness to practise grounds (**Regulation 34**); and
  - may grant the *excepted application* for inclusion in the pharmaceutical list subject to efficiency conditions and conditions to combat fraud (**Regulation 35**).
85. Further information on these provisions can be found in guidance<sup>4</sup> issued by DH.
86. Where the *excepted application* to relocate has been made by someone who is not already included in the neighbouring PCT's pharmaceutical list, there are additional actions that the PCT must undertake prior to determining the *excepted application*. **Paragraph 23(1) of Schedule 2** requires the PCT to:
- where the applicant is an individual, check with the Business Services Authority Counter Fraud Service, now better known as NHS Protect<sup>5</sup> whether the applicant has any record of, or is under investigation for, fraud;
  - where the applicant is a body corporate, check with NHS Protect whether any director or the superintendent pharmacist has any record of, or is under investigation for, fraud;
  - where the applicant is an individual, check whether the Secretary of State (who has delegated this function to the NHSLA<sup>6</sup>) holds any information on the applicant that is relevant to the PCT's consideration of whether the application should be refused or deferred under **regulation 33 or 34** (i.e. on fitness to practise grounds) or whether

<sup>4</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4108206](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206)  
Gateway reference 4728

<sup>5</sup> <http://www.nhsbsa.nhs.uk/fraud>

<sup>6</sup> <http://www.fhsaa.tribunals.gov.uk/index.htm>

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conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information can be accessed by PCTs via a secure website;

- where the applicant is a body corporate, check whether the NHSLA holds any information on any director or the superintendent pharmacist that is relevant to its consideration of whether the application should be refused or deferred under **regulation 33** or **34** (i.e. on fitness to practise grounds) or whether conditions should be imposed under **regulation 35** (i.e. conditional inclusion). This information can be accessed by PCTs via a secure website; and
- take up references from the referees provided under **paragraph 3(8) of Schedule 2** and check those references.

87. Once the PCT has received and considered any information received as a result of these checks, it must consider whether:

- the *excepted application* should be refused or deferred under **regulations 33 or 34**; or
- conditions should be imposed on the applicant under **regulation 35**.

88. If the PCT is minded to impose conditions under **regulation 35** (conditional inclusion) then before it decides that it will impose conditions, it must *notify* the applicant of its intention. This must take place at least seven days before the determination that conditions will be imposed, and the applicant must be given the opportunity to make written or, potentially, oral representations before the PCT makes its decision (**paragraph 23(2) of Schedule 2**).

### Refusal: same or adjacent premises

89. Where the premises within *an excepted application to relocate* are:

- already included in the PCT's pharmaceutical list; or
- adjacent to or in close proximity to premises that are already included in the PCT's pharmaceutical list,

the applicant will have had to explain why their application should not be refused pursuant to **regulation 31**.

90. The PCT must refuse *an excepted application to relocate* where:

- a person on the pharmaceutical list (which does not have to be the applicant) is providing (or has undertaken to provide) *pharmaceutical services* from the premises mentioned in the application or from adjacent premises; and
- the PCT is satisfied that it is reasonable to treat the applicant's proposed services as part of those services that are already being provided, and so the premises listed in

the application and the existing premises should be treated as the same site (**Regulation 31(2)**).

91. The purpose of this regulation is to prevent a contractor from applying for multiple inclusions in the PCT's pharmaceutical list at the same address with no benefit to patients.

### Refusal of excepted applications to relocate

92. **Regulation 24(3)** provides for three specific situations where a PCT must refuse to approve an *excepted application* to relocate.
93. The first of these is pharmacies that successfully applied under **regulation 13(1)(a)** of the 2005 Regulations and were included in the PCT's pharmaceutical list on the basis of that exemption, namely pharmacies in approved retail areas that fell within **regulation 15** of those Regulations. **Regulation 24(3)(a)** requires PCTs to refuse *excepted applications* from such pharmacies wishing to relocate outside of the approved retail area.
94. The second situation relates to exempt applications successfully made under **regulation 13(1)(c)** of the 2005 Regulations, namely premises which are in a new one stop primary care centre (within the definition of **regulation 16** of those Regulations). **Regulation 24(3)(b)** requires PCTs to refuse *excepted applications* from such pharmacies wishing to relocate unless the following criteria are met:
- i. the provider or providers of primary medical services at the one stop primary care centre are relocating with the applicant to a new discrete site or building,
  - ii. at that new discrete site or building primary medical services are or will be provided by one or more providers of primary medical services with a patient list of, or patients lists with a combined total of, 18,000 patients, and
  - iii. at that site or building the services of a broad range of health care professionals are or will be regularly and frequently provided (together with other health and social services where appropriate).
95. **Regulation 24(3)(b)** therefore ensures that pharmacies that had previously been included in a PCT's list under **regulation 13(1)(c)** of the 2005 Regulations remain under the same conditions as at the point they were included in the pharmaceutical list.
96. Once an *excepted application* to relocate has been granted under the 2012 Regulations, **regulation 24(3)(c)** requires the applicant to trade for a minimum period of 12 months from the new premises before any further *excepted application* for a relocation can be made unless the PCT for good cause allows the applicant do so before the end of that

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period, for example on grounds of health and safety, or because the pharmacy temporarily relocated to premises while the original premises were being upgraded and the return to those premises was part of the planned refurbishment.

97. It should be noted that the onus is on the applicant to demonstrate good cause within their application (**Regulation 24(3)(c)(iii)**).
98. The minimum period of 12 months in **regulation 24(3)(c)** also applies to pharmacies who may have relocated under the minor relocation provisions in either **regulation 6** or **7** of the 2005 Regulations. PCTs will therefore need to consider how they maintain records of applications in order to comply with this regulation particularly in the first year of the 2012 Regulations.

### Conditions relating to directed services

99. Where the *excepted application* for a relocation is made under the 2012 Regulations and as part of the application, the applicant undertook:
  - to provide the *directed services* it has been providing at the old premises, if the PCT commissioned them within three years the date the premises are included in the pharmaceutical list;
  - if the *directed services* were commissioned by the PCT, to provide them in accordance with an agreed service specification; and
  - not to unreasonably withhold agreement to the service specification,

**regulation 66(4)** states that their inclusion in the PCT's pharmaceutical list is subject to the condition set out in **regulation 66(5)**.
100. This condition is that at those premises the applicant must:
  - provide the *directed services* (and this condition applies to any future owners of the listed premises); and
  - not unreasonably withhold agreement to the service specification.
101. However, the PCT is required to commission the services within three years of the date on which the new premises are included in the pharmaceutical list.
102. PCTs may, under **regulation 66(6)(a)** specify a date on which service provision is to commence, or alternatively the PCT and contractor can agree a mutually convenient commencement date for the *directed services* (**Regulation 66(6)(b)**), whichever is the sooner.

103. PCTs may not vary or remove the condition imposed by virtue of **Regulations 66(3) to (5)**.

#### Example

The PCT receives an *excepted application* to relocate to new premises. As part of the application the applicant is required to offer to provide:

- emergency hormonal contraception;
- smoking cessation;
- witnessed methadone consumption and needle exchange.

These services are currently provided by the applicant. In addition, the applicant wishes to offer to provide:

- minor ailments; and
- NHS health checks

at the new premises as there is an identified current need for these in the locality and the new premises are larger which means the pharmacy can offer more enhanced services.

Where there is a need for emergency hormonal contraception, smoking cessation and witnessed methadone consumption and needle exchange, the PCT may commission those and provision becomes a condition on the applicant's inclusion in the pharmaceutical list in respect of the new premises. If there is no need, the PCT may choose not to commission them from the applicant.

With regards to minor ailments and NHS health checks, the applicant should either apply to provide these via the PCT's normal processes for commissioning *enhanced services*. Where an application to provide these services is made on the basis of an *excepted application* under **regulation 23**, the PCT can make provision of these two enhanced services a condition of the applicant's inclusion in the pharmaceutical list.

### Postponement of the discontinuation of provision of pharmaceutical services by doctors

104. If the PCT grants the *excepted application*, it must also decide what if any action is to be taken under **regulation 50(4) or (5)** (postponement of the discontinuation of arrangements for the provision of *pharmaceutical services* by doctors). See Chapter 15 for further information on this.

## Notification, taking effect of decisions and rights of appeal

105. Once the PCT has made a decision on the *excepted application*, it must as soon as practicable notify certain persons of its decision (**paragraph 28(3)(b) of Schedule 2**).
106. The 2012 Regulations make provision for certain persons to have a right of appeal against the PCT's decisions. Where an appeal right is provided in accordance with the Regulations 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<sup>7</sup>. If there is a right of appeal on a matter related to fitness to practise (i.e some relocation applications to a neighbouring PCT), the appeal is to the First-Tier Tribunal and its contact details must instead be provided by the PCT.
107. 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.

## Notification of decisions

108. Once the PCT has made a decision on the *excepted application* to relocate, it must, as soon as is practicable, notify certain persons of its decision (**paragraph 28(3) of Schedule 2**). Those persons are:
- the applicant;
  - any LPC for its area which may be an LPC that it shares with another PCT;
  - any LMC for its area which may be an LMC that it shares with another PCT; and
  - any person notified under paragraph 19 (including by a neighbouring PCT) who made representations under **paragraph 19(4) of Schedule 2**.
109. The requirement is to notify the decision as soon as is practicable. The PCT should aim to notify decisions within a week unless they have good cause not to do so. The notification of the decision must include a statement from the PCT of the reasons for that decision (**paragraph 28(6) of Schedule 2**).

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<sup>7</sup> <http://www.nhsla.com/ContactUs/>

110. If the PCT decided to consider two or more applications together pursuant to **paragraph 22(3) of Schedule 2**, it must give *notice* to each applicant of the decision taken with regard the other application(s) considered with their application (**paragraph 28(5) of Schedule 2**).

### Template notice of commencement to be included with a notice of decision

111. If the PCT grants the *excepted application* it must send, with its decision letter, a *notice of commencement* for the applicant to complete and send when it is ready to start service provision. The *notice of commencement* must contain the following information:
- the address of the premises to which the application relates;
  - the services that are to be provided from those premises i.e. in the case of pharmacy premises essential and any directed services;
  - the date of the grant of the application;
  - a declaration with regard to when the applicant intends to commence the provision of those services at those premises;
  - the GPhC registration number of those premises; and
  - a signature on behalf of the applicant and the date of notice (**paragraph 29 of Schedule 2**).
112. The PCT may wish to pre-populate the form where it holds the information.

### Appeals to the Secretary of State by the applicant

113. **Paragraph 36(1) of Schedule 2** gives the applicant rights of appeal against certain PCT decisions. The right of appeal against decisions that are not fitness to practise related is to the Secretary of State who has delegated this function to the FHSAU. The applicant may appeal to the FHSAU against a decision by the PCT:
- to refuse the application on grounds set out in **regulation 24**;
  - to refuse the application on grounds set out **regulation 31** (refusal same or adjacent premises) of the 2012 Regulations;
  - to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**; or
114. The *notice* of appeal is only valid if it includes a concise and reasoned statement of the grounds of the appeal (**paragraph 36(2) of Schedule 2**).



## Third party rights of appeal to the Secretary of State where an application is granted

115. **Paragraph 30(1) of Schedule 2** gives third party rights of appeal against certain PCT decisions. The 2012 Regulations refer to these as third party rights of appeal as they are persons other than those who are party to the application and decision i.e. persons other than the applicant and the PCT. The right of appeal is to the Secretary of State who has delegated this function to the NHSLA's FHSAU.
116. If the PCT considers that a person notified under **paragraph 28 of Schedule 2** is a person with third party rights of appeal then it is required to notify them of that fact in their decision letter (**paragraph 30(4) of Schedule 2**).
117. **Paragraph 30(2)** confirms that for the purposes of **schedule 2** a person has third party rights of appeal if they were entitled to receive notification of the decision to grant the application by virtue of **paragraph 28(5) of Schedule 2** – i.e. they were notified because their application was considered together and in relation to the application to which the decision letter relates.
118. Other persons with third party rights of appeal are those who were:
- required to be notified of the application because they are on the PCT's pharmaceutical list or are entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believed might be significantly affected by the decision. This could be the PCT that granted the application, or a PCT any part of whose area is within 2 km of the proposed premises and was given notice of the application;
  - they made written representations about the application under **paragraph 19(4) of Schedule 2**; and
  - the PCT that made the decision is satisfied that within their written or oral representations they made a reasonable attempt to express their grounds for opposing the application. Their grounds for opposing the application must not amount to a challenge to the legality or reasonableness of the PCT's PNA or to the fairness of the process by which the PCT undertook that assessment and must not be vexatious or frivolous (**paragraph 30(3) of Schedule 2**)
119. The PCT should not give third party rights of appeal to all persons included in the pharmaceutical list or entitled to be included on that list who made representations. The PCT must carefully consider to whom it gives third party appeal rights and should not give them to persons who did not make a reasonable attempt to express their grounds for opposing the application.



120. Third party rights of appeal may not be given to LPCs, LMCs, LPS chemists, GPs, LINKs or other patient, consumer or community groups.

**Example**

Following notification of an *excepted application* to relocate the PCT received a number of responses. Several responses did not indicate whether or not they supported the application. Such persons were not given third party rights of appeal as they had not attempted to express their grounds for opposing the application, and indeed had not indicated whether they opposed or supported the application.

121. When a person with third party rights of appeal appeals to the FHSAU, their *notice* of appeal must contain a concise and reasoned statement of their grounds of appeal and must be sent within 30 days of the date on which they were notified of the PCT's decision (**paragraph 30(5) of Schedule 2**).
122. If a person believes that they should have been given third party rights of appeal by the PCT that made the decision but were not, they may appeal to the FHSAU against the PCT's determination not to give them rights. They must notify the FHSAU within 30 days of the date on which they were notified of the PCT's decision on the application but not given third party rights of appeal. Within that notification, they must give concise and reasoned statements as to their grounds of appeal against the decision not to give them third party rights of appeal and also against the PCT's decision on the application (**paragraph 30(6) of Schedule 2**). If their appeal on the procedural point is successful then they will gain third party rights of appeal in relation to the decision to grant the application.

Action to be taken by the PCT following notification of an appeal decision

123. 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**).
124. 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**).

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125. If the FHSAU has granted or confirmed the grant of the *excepted application*:
- the PCT must send the applicant a template *notice of commencement*, and
  - the six months within which to open take effect from the date the FHSAU makes its determination (**paragraph 10(2) of Schedule 3**).
126. If the FHSAU grants or confirms the grant of an *excepted application*, the PCT must proceed as soon as is practicable to take such action under **regulation 50(4) or (5)** (postponement or the discontinuation of arrangements for the provision of *pharmaceutical services* by doctors) as it thinks fit, subject to any directions of the FHSAU given under **paragraph 9(2)(b) of Schedule 3**. (See Chapter 15 for further information on this).

**Taking effect of listing decisions: general**

127. If the *excepted application* is granted, the applicant is required to submit a valid *notice of commencement* informing the PCT that they will commence the provision of services in the next 14 days (**paragraph 34(2) of Schedule 2**). The PCT then includes the applicant in their pharmaceutical list with effect from the date on the *notice of commencement*. If the date that the applicant intends to commence service provision is a public or bank holiday, the PCT may include the applicant and the premises in its pharmaceutical list as the applicant is not obliged to open on such a day.
128. In order to be in the correct form, the *notice of commencement* must:
- include the information required under **paragraph 29 of Schedule 2**; and
  - be in the same format as the version sent to the applicant by the PCT with its decision letter (**paragraph 34(3) of Schedule 2**)
129. Where the applicant undertakes to commence the provision of services within a period of less than six months and that undertaking was not withdrawn, the *notice of commencement* must be sent within that period otherwise it will be invalid (**paragraph 34(4)(a) of Schedule 2**). If the applicant fails to submit their *notice of commencement* within this shorter timescale, the grant of the application lapses.

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130. For all other applications the *notice of commencement* must be sent within six months of the dates shown in the following table (**paragraph 33(4)(b) of Schedule 2**).

<b>Scenario</b>	<b>Date on which the six month period starts</b>
Application granted by the PCT	Date on which the applicant is sent notice of the PCT's decision to approve under <b>paragraph 28 of Schedule 2</b> , unless the grant is appealed by a person with third party appeal rights, in which case the period starts on the date of determination of an unsuccessful appeal.
Refusal of the application was successfully appealed by the applicant	Date on which the FHSAU determines the appeal.
If in the course of granting an application to move to a neighbouring PCT, a decision was taken to impose a condition in accordance with <b>Regulation 35</b> (conditional inclusion on fitness to practise grounds) and that condition is appealed by the applicant to the First-Tier Tribunal	The applicant can temporarily accept the condition and open within the normal timeframes, but if it prefers, it can await the outcome of the decision of the First-Tier Tribunal. If the First-Tier Tribunal confirms the PCT's decision or imposes a different condition, the applicant must within 30 days of being notified of the First-Tier Tribunal's decision, <i>notify</i> the PCT as to whether or not it wishes to withdraw the application. If the applicant notifies that they do not wish to withdraw the application the six months starts at the date of the First-Tier Tribunal's decision.

131. If the applicant fails to submit their *notice of commencement* within the correct timescale, the grant of that application lapses (**paragraph 34(4) of Schedule 2**).
132. During the six month period following grant of the *excepted application*, the PCT may approve a longer period not exceeding a further three months (**paragraph 34(4)(c)(i) of Schedule 2**). Should the applicant fail to submit their *notice of commencement* within that extended period, then the grant of that application lapses (**paragraph 34(4) of Schedule 2**).

133. Under **paragraph 34(4)(c)(ii) of Schedule 2** the FHSAU may allow a longer period of time if:
- the grant is appealed by a person with third party appeal rights;
  - the applicant successfully appeals against the PCT's decision not to allow a longer period under **paragraph 34(4)(c)(i) of Schedule 2**.
134. Should the applicant fail to submit their *notice of commencement* within that extended period, then the grant of that *excepted application* lapses (**paragraph 34(4) of Schedule 2**).
135. Where the PCT approves an application and issues a *notice of commencement* and the FHSAU subsequently receives a valid notice of appeal from a person with third party appeal rights relating to the grant of that application, the *notice of commencement* shall cease to have effect (**paragraph 34(5)(a) of Schedule 2**).
136. If, on appeal, the FHSAU grants or confirms the grant of the *excepted application* for an extension of the time period within which to open, the PCT is required to send to the applicant another template of the *notice of commencement* (**paragraph 10(2)(a) of Schedule 3**).

#### Example

The PCT approves an *excepted application* to relocate. It issues its decision and template *notice of commencement* to the applicant. It issues its decision to interested parties as required by **paragraph 28 of Schedule 2**.

An appeal against the PCT's decision is subsequently made to the FHSAU by a person with third party appeal rights. The template *notice of commencement* sent by the PCT ceases to have effect.

The FHSAU considers the appeal and dismisses it and the PCT sends a second template *notice of commencement* giving the applicant six months from the date of the FHSAU's determination within which to open.