



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

Information for Primary Care Trusts
Chapter 13

Changes of ownership and relocations

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Chapter 13: Changes of ownership and relocations

1. It is sometimes the case that a relocation application is associated with a change of ownership application and vice versa, for example where a contractor wishes to sell their business and the new owner wishes to run that business from new premises. **Regulation 26(2)** allows applicants to submit, and for PCTs to consider these changes as, one *excepted application*.
2. This Chapter deals with such applications.

Introduction

3. 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.
4. Single applications for changes of ownership and relocations fall within this category of applications.
5. With regards to the change of ownership application, this must meet certain criteria listed in **regulation 26(2)(a) to (c) and (e)**.
6. With regards to the relocation element of the application this could be within a PCT’s area or to another PCT’s area. However, the relocation must not result in a significant change to the provision of *pharmaceutical services* i.e. it must meet the requirements of **regulation 26(2)(d)** and therefore **regulation 24(2)**.
7. If the application fails to meet any one of these criteria, it must be refused. It will be for the current owner and the prospective owner to decide whether to pursue separate applications or not. That is a matter for them to decide and the PCT should take no part in those discussions.

Information to be included in all excepted applications for a change of ownership and relocation

8. 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.

9. When submitting an *excepted* application for a change of ownership and relocation, 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 for a change of ownership and relocation;
 - 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/partnership¹/body corporate;
 - if the applicant is a sole trader, their GPhC registration number. A pharmacist does not have to provide their GPhC registration number if their business is as a DAC and not a pharmacy contractor;
 - if the applicant is a partnership, each partner's GPhC registration number². 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:
 - the address of the 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*); and
 - 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
 - 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.

¹ 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.

² The Medicines Act 1968 requires all partners to be pharmacists.

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. If the applicant fails to provide a precise location, this would be classed as missing relevant information for the purposes of **paragraph 11 of Schedule 2**.
12. Where an applicant submits an *excepted application* for premises which are:
 - already *listed premises*; or
 - are adjacent to or in close proximity to *listed chemist premises*,

paragraph 6 of Schedule 2 requires the applicant to include details that explain why the application should not be refused pursuant to **regulation 31** in their application.
13. Where the application is for an *excepted application*, **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 26(2)** and **regulation 24**; and
 - why the application should not be refused for the reasons set out in **regulation 24(3)** and **regulation 31**.

Example

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

- that the pharmacy is not significantly less accessible to the patients groups that access 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 same services will be provided; and
- whether there is to be an interruption of service, and if there is the reasoning for this.

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

In this case, therefore 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.

Additional information to be provided where the applicant is not already included in the PCT's pharmaceutical list

14. **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. Where the applicant is an individual, they are required to provide their full name, 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.
15. 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 pharmacist.
16. 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.
17. 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 pharmacists.

18. 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);
 - 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.
19. If the applicant is a DAC, their premises are not required to be registered with the GPhC.
20. **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 superintendent pharmacist.
21. **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.
22. Further information on these requirements can be found in separate guidance³. 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* for change of ownership and relocation.

³ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206 Gateway reference 4728

23. 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.
24. 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* for a change of ownership and relocation when that has taken place.
25. 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* for a change of ownership and relocation is submitted or the *home PCT*.

Undertakings to be provided by all applicants

26. 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;
 - until 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;
 - 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;
 - until 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)**;

- 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 is seeking to provide *directed services* as part of the application, an undertaking:
 - that they will provide the *directed services* if the PCT commissions them within three years of the date the premises are included 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**)

Example

The PCT receives an *excepted application* for a change of ownership and relocation. The current owner of the pharmacy provides advanced services, emergency hormonal contraception, chlamydia screening, smoking cessation and a minor ailments service. The applicant must therefore also offer to provide these services, and give an undertaking that if the PCT commissions those services within three years that they will provide them and will not unreasonably withhold agreement to the service specifications.

If the applicant has not seen the specification in advance of submitting their application, they may not have been able to give the undertakings required in **paragraph 9(d), Schedule 2**. Where this is the case the PCT should send the service specifications to the applicant and request that they give the required undertakings and only begin to process the application once these are received.

27. The obligation on the applicant to provide information or documentation required by **paragraphs 1 to 6 and 8 and 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 may not use this provision as a reason not to determine, or to delay determining, an application.

Preliminary matters to consider following receipt of an application

28. On receipt of an *excepted application* for a change of ownership and relocation, there are a number of preliminary matters which the PCT must consider before proceeding with it. 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

29. 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).
30. 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.
31. The PCT may make the request at any time between receiving and determining the *excepted application* for a change of ownership and relocation. It is suggested that requests are made as early as possible in order that the PCT does not delay the transfer of the business.
32. 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**).

33. 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**).
34. 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**).
35. 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 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.
36. 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, then the application is to be treated as withdrawn by the applicant (**paragraph 11(2)(b)(i) of Schedule 2**).
37. 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* for a change of ownership and relocation. 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

38. 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**).
39. 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 2B**).

Functions of a home PCT in relation to certain applications

40. Where the applicant is not already included in the PCT's pharmaceutical list and has a *home PCT* to whom they have provided the fitness to practise information required by **paragraphs 3 or 4 of Schedule 2**, then 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**).
41. 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**).
42. 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.

Refusal prior to notification of applications because of the language requirement for some NHS pharmacists

43. Where the PCT receives an *excepted application* for a change of ownership and relocation, if the applicant (sole traders and partnerships only) has qualified as a pharmacist in Switzerland or an European Economic Area State other than the UK, the PCT must be satisfied that the applicant has the necessary level of knowledge of

English which is necessary for the provision of services in the PCT's area (unless the applicant is already on the PCT's pharmaceutical list) (**Regulation 30**).

44. DH issued interim guidance⁴ regarding language knowledge for GPs. PCTs may find this useful when assessing the applicant's level of knowledge of English.
45. If the *excepted application* for a change of ownership and relocation is from a person who is not already included in the PCT's pharmaceutical list at other premises, it will need to determine before notification whether or not it must refuse the application under **regulation 30 (paragraph 15 of Schedule 2)**.

Example

An *excepted application* is received from a pharmacist who is not already included in the PCT's pharmaceutical list at other premises.

Prior to notification, it checks the fitness to practise information that is submitted with the application and it is noted that the pharmacist qualified in Switzerland.

The PCT requests evidence of the level of knowledge of English and meets with the pharmacist. After considering all the evidence, the PCT is not satisfied that the pharmacist has the level of knowledge of English which is necessary for the provision of pharmaceutical services in its area. It therefore refuses the *excepted application* under **regulation 30** and notifies the applicant of its decision and the reasons for it.

Refusal of applications on fitness to practise grounds prior to notification

46. Where the PCT receives an *excepted application* for a change of ownership and relocation from a person who is not already included in the PCT's pharmaceutical list at other premises, then 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**).

⁴ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_111901 Gateway reference 13564

Example

The PCT receives an *excepted application* from a pharmacist that is not already included in the PCT's pharmaceutical list. Prior to notifying the application to interested parties, it checks the fitness to practise information provided and it is noted that the pharmacist is the subject of a national disqualification. The PCT therefore refuses the application under **regulation 33(1)**.

Deferral of applications prior to notification

47. When the PCT receives an *excepted application* for a change of ownership and relocation from a person who is not already included in its pharmaceutical list at other premises, it must consider as soon as is practicable and in any case prior to notifying the application, whether or not to defer consideration of that application under **regulation 34** (on fitness to practise grounds) (**paragraph 14(1) of Schedule 2**).
48. If the PCT decides to defer consideration of the application before notification then as soon as it no longer has grounds to defer the application, it must proceed as soon as is practicable with the notification (**paragraph 14(2) of Schedule 2**). The only exception to this would be where the application has been withdrawn or the PCT is required to treat it as withdrawn.

Example

The PCT receives an *excepted application* for a change of ownership and relocation of DAC premises. The applicant is not already included in the PCT's pharmaceutical list and on checking the fitness to practise information it is noted that one of the directors is the subject of criminal proceedings in England.

Due to the nature of the allegations it is likely that:

- if the applicant was already included in the pharmaceutical list, and
- if the director was convicted

then the PCT would have removed the contractor from its pharmaceutical list. The PCT therefore defers the *excepted application* until such time as the outcome of the proceedings is known.

49. If the applicant has 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 if the *home PCT*'s recommendation led the PCT to defer the application under **regulation 34 (paragraph 14(3) of Schedule 2)**.

Action following decisions to defer an excepted application

50. Where the PCT decides to defer consideration or determination of the *excepted application*, it must:
- notify the applicant of its decision and the reasons for it; and
 - where possible, notify the applicant of the length of time that the application is being deferred. If necessary, the PCT can refer to a future event as opposed to a period of time (**paragraph 24(1) of Schedule 2**)
51. The PCT may advise the applicant of this decision either before or after it has carried out the notification exercise. It is suggested that in most instances deferral will take place prior to notification.
52. Where the applicant is not already included in the PCT's pharmaceutical list and the PCT decides 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**).
53. 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, the application is also to be treated as withdrawn.

Notification

54. Once the PCT has considered the matters listed in **paragraphs 11 to 17 of Schedule 2** and has decided not to refuse the application under **paragraph 15, 16 or 17 of Schedule 2**, or to defer it, the PCT must give *notice* of the *excepted application* for a change of ownership and relocation to:
- the LPC for its area, which may be an LPC that it shares with another PCT;
 - the LMC for its area which may include 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 is in 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**)

55. 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**).
56. It is recommended that the PCT records its reasoning for why it believes persons have a significant interest in the outcome of the application.
57. For applications relating to distance selling premises, 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.
58. Other than LPCs, LMCs and neighbouring PCTs or LHBs, the PCT should note the requirement to only notify those who it believes might be significantly affected if the application was 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* for a change of ownership and relocation 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.

59. 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 was 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 was granted;
 - any LPS chemist with whom the PCT is in contract and whose interests the PCT believes might be significantly affected if the application was 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 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 (**paragraph 19(3)(a) of Schedule 3**)

60. 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 penalised is through the Courts.
61. 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**)
62. 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 45 days within which to consider the application.
63. 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.
64. 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.

Parallel notifications

65. There may be occasions where an *excepted application* for a change of ownership and relocation will result in premises opening in an area that is or may be a *controlled locality*. This will require the PCT to consider whether or not it needs to make or revise a determination as to whether or not an area is a *controlled locality*, or is part of a *controlled locality*. Where this is the case it must give *notice* of the *excepted application* at the same time as it gives *notice* of its intention to make such a determination under **regulation 38(1) (paragraph 20(1) of Schedule 2)**.
66. The PCT may also receive an *excepted application* for a change of ownership and relocation that requires it to consider whether or not the proposed premises are within a *reserved location*. Where this is the case it must consider giving *notice* of the *routine application* at the same time as it gives *notice* of its intention to make such a determination under **regulation 41(4) (paragraph 20(2) of Schedule 2)**.

67. See chapter 14 for further information on *controlled localities* and *reserved locations*.
68. If the PCT wishes to consider two or more applications together and in relation to each other, then it is required by **paragraph 22(3) of Schedule 2** to give *notice* of its intention to do so.

Content of notifications

69. **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**)
70. 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**).
71. PCTs must not send any 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.
72. 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 (**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**).

73. 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), Schedule 2**). 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

74. The PCT is able to determine an *excepted application* for a change of ownership and relocation 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).
75. 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.
76. 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, it may do so but it must give *notice* of this to the applicants concerned before determining the applications.

Oral hearings

77. 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.
78. If the PCT decides to hear oral representations prior to determining an *excepted application* 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**)

79. **Paragraph 25(2) of Schedule 2** defines a person as an *additional presenter* if:

- the application to which the hearing applies is an *excepted application* for a change of ownership and relocation;
- 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.

80. 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.

81. 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

82. **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

83. **Paragraph 27 of Schedule 2** requires PCTs to determine the *excepted application* as soon as it is practicable to do so and within 4 months of the date on which all the required information and documentation was received by the PCT (**paragraph 27(b)(i) of Schedule 2**).
84. The only exceptions to this timescale are where the PCT has deferred the application under the 2012 Regulations or where it has good cause for a delay. The table below summarises when the timescale starts and stops.

Scenario	Point at which four month time period starts
PCT receives a deficient <i>excepted application</i>	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, for example, not all the relevant information or documentation is received. It then restarts at the point all the relevant information or documentation is received.
PCT defers an application for inclusion in the pharmaceutical list by a person not already included in it on fitness to practise grounds (Regulation 34).	The four-month time period initially starts at the point the application is received. It then stops at the point the PCT decides to defer it on fitness to practise grounds set out in regulation 34 . It then restarts when the outcome of the cause for deferral is known.

85. Good cause for delaying an application will very much depend on the facts of the case.

Refusal, deferral and conditional inclusion in pharmaceutical lists of chemists on fitness to practise grounds

86. Where the applicant is not already included in the 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 for distance-selling premises*, 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.

87. 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**).
88. Further information on these provisions can be found in guidance⁵ issued by DH.
89. Where the *excepted application* 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 NHS Business Services Authority Counter Fraud Service, better known as NHS Protect⁶ 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 NHSLA⁷) 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 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.

⁵ http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108206 Gateway reference 4728

⁶ <http://www.nhsbsa.nhs.uk/CounterFraud.aspx>

⁷ <http://www.fhsaa.tribunals.gov.uk/index.htm>

90. 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**.
91. 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

92. Where the premises within an *excepted application* for a change of ownership and relocation 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**.
93. The PCT must refuse an *excepted application* for a change of ownership and relocation where:
- a person on the pharmaceutical list (which doesn't 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)**).
94. 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.

Changes of ownership and relocation applications

95. **Regulation 26(2)(a) to (e)** sets out the criteria that such *excepted applications* must meet. Where any criterion is not met then the application must be refused.
96. The following table lists the criteria:

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Criteria set out in Regulation 26(2)	Explanation
<p>(a) <i>the applicant (X) is undertaking to provide the pharmaceutical services that another person (Y)-</i></p> <p><i>(i) is providing at listed chemist premises (“Y’s premises”), or</i></p> <p><i>(ii) has provided at Y’s premises but Y is no longer able to provide pharmaceutical services at those premises for reasons that the Primary Care Trust accepts are good cause;</i></p>	<p>The applicant must undertake to provide the <i>pharmaceutical services</i> that the current owner is providing at the <i>listed chemist premises</i>, or was providing but has ceased to do so for reasons that the PCT accepts as good cause for example current contractor has gone into administration and the premises have closed.</p> <p>It is for the PCT to determine whether there is good cause for provision to stop.</p> <p>This requirement relates to the change of ownership element of the application.</p>
<p>(b) <i>X is proposing to carry on, in place of Y, the business in the course of which Y is providing, or has provided, pharmaceutical services at Y’s premises;</i></p>	<p>The applicant must be proposing to carry on the current owner’s business in the course of which the current owner is either providing or has provided <i>pharmaceutical services</i> at the <i>listed chemist premises</i>.</p> <p>This requirement relates to the change of ownership element of the application.</p>
<p>(c) <i>X is undertaking to provide the same pharmaceutical services as Y is providing or has provided at Y’s premises, but at different premises (“X’s premises”);</i></p>	<p>The applicant must undertake to provide the same <i>pharmaceutical services</i> as the current owner, but at different premises.</p> <p>This requirement relates to the relocation element of the application.</p>
<p>(d) <i>if Y had applied to move to X’s premises, that application would have been granted under regulation 24; and</i></p>	<p>If the current owner had applied to move to the applicant’s premises, the application would have been granted under regulation 24 i.e. it meets the requirements for an excepted relocation application.</p> <p>This requirement relates to the relocation element of the application.</p>

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<p>(e) if pharmaceutical services-</p> <p>(i) are being provided at Y's premises, the provision of pharmaceutical services will not be interrupted (except for such period as the Primary Care Trust may for good cause allow) by the move of the business from Y's premises to X's premises, or</p> <p>(ii) are not being provided at Y's premises, the provision of pharmaceutical services will commence at X's premises within the period that the Primary Care Trust considers is an acceptable period for the interruption of the provision of pharmaceutical services by the business that X is taking over.</p>	<p>If the current owner is providing services at the <i>listed chemist premises</i>, then the provision of <i>pharmaceutical services</i> is not be interrupted by the move to the applicant's premises unless the PCT allows this for good cause.</p> <p>If the current owner is not providing services at the <i>listed chemist premises</i>, then the applicant is required to start providing services at their premises within a period of time that the PCT considers is an acceptable period for an interruption in service provision. The aim of this is to ensure that any disruption to patients is kept to a minimum.</p> <p>This requirement relates to both elements of the application.</p>
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Criteria for the relocation element where the relocation is within the PCT's area

97. The following table sets out five criteria where the relocation is within the 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:
- the impact on patient groups (**Regulation 24(1)(a)**);
 - 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 the PCT's area or in a *controlled locality* of a neighbouring PCT that is within 1.6 km of the proposed premises (**Regulation 24(1)(b)**); and
 - the impact on the PCT's planning for the provision of pharmaceutical services in its area (**Regulation 24(1)(c)**).

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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” mirrors the requirement for PCTs to look at the needs of patients groups when developing the PNA. Regulation 9(1)(b) sets out the attributes that may be shared by members of these groups, for example age, disability, race, religion or belief.</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. In this instance, the PCT will need to exercise its judgement and decide whether this reduction in access is significant or not.</p>

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<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><i>(i) in any part of its area, or</i></p> <p><i>(ii) 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>Having looked at any impact on patient groups, the PCT 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 pharmaceutical services 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 it is not required to consider the impact on the provision of pharmaceutical services by persons on the dispensing doctor list.</p> <p>Additionally the PCT must consider the impact on pharmaceutical services, 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.</p> <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><i>(c) 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 pharmaceutical services in its area.</p> <p>For example, a pharmacy wishes to relocate from an area where it is meeting a need for pharmaceutical services to an area where there is no identified need for services. In this case if the PCT was satisfied that the move would be significantly detrimental to its planning of pharmaceutical services provision because it would worsen access in an area where there is already little provision, it could refuse the application.</p>

Market entry by means of pharmaceutical needs assessments

<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 then 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 only commission the <i>enhanced services</i> that are required.</p> <p>The applicant would also be required to be open for the same <i>core</i> and <i>supplementary opening hours</i> 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 notify 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> under regulation 66; they can only require the current <i>directed services</i> to be provided at the new premises.</p>
<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 pharmaceutical services 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>For example, 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>

Criteria for the relocation element where the relocation is to another PCT's area

98. The following table sets out the criteria where the relocation is 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)**); and
 - the impact on the PCT's planning for the provision of pharmaceutical services in its area (**Regulation 24(2)(d)**).
99. Throughout the explanations, PCT2 is the PCT into whose area the pharmacy wishes to relocate.

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 pharmaceutical services 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 pharmaceutical services by persons on the dispensing doctor list.</p> <p>Additionally PCT2 must consider the impact on pharmaceutical services, 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> <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>

Market entry by means of pharmaceutical needs assessments

	<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 pharmaceutical services, 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 pharmaceutical services in its area.</p> <p>Example – the PCT received a <i>routine application</i> to meet an identified current need and decided under regulation 14(1) to defer that <i>routine application</i> and invite other applications to meet that same need for a new pharmacy offering a range of <i>essential</i> and <i>directed services</i> 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 pharmaceutical services.</p>
<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>

Market entry by means of pharmaceutical needs assessments

	<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 notify 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>
<p>(f) <i>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 pharmaceutical services 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>

Market entry by means of pharmaceutical needs assessments

<p><i>(g) the applicant consents to—</i></p> <p><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></p> <p><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>
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Conditions relating to directed services

100. Where as part of an *excepted application* the applicant undertook:

- to provide the *directed services* provided by the current owner, if the PCT commissioned them within 3 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)**.

101. This condition is that at those premises the applicant must:

- provide the *directed services* mentioned in the application (and this condition applies to any future owners of the listed premises); and
- not unreasonably withhold agreement to the service specification.

102. However, the PCT is required to commission the services within 3 years of the date on which the premises are included in the pharmaceutical list.

103. 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.

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

Example

An *excepted application* for a change of ownership and relocation is received by the PCT. As part of the application the applicant is required to provide the same *directed services* as the previous owner and it is a condition on their inclusion in the PCT's pharmaceutical list that they do so.

The PCT already has agreed service specifications for the *enhanced services* which were being provided by the previous owner and other pharmacies within its area. Following discussions with the PCT the applicant advises that they are not willing to provide one of the *directed services* as it is felt that the requirements are too onerous.

In this instance as other contractors, including the current owner find the service specification to be acceptable then it would be unreasonable for the applicant to withhold agreement of the specification. The applicant fails to provide the undertaking to provide the service as required by **paragraph 9(d) of Schedule 2** and therefore the application is treated as withdrawn by virtue of **paragraph 12(2), Schedule 2**.

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(1) 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 website⁸. 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*, 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;

⁸ <http://www.nhsla.com/ContactUs/>

- any person who is included in the PCT's pharmaceutical list, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believes might be significantly affected by the decision;
- any LPS chemist with whom the PCT is in contract and whose interests the PCT believes might be significantly affected by the decision;
- any LINK, other patient, consumer or community group in the PCT's area which the PCT believes has a significant interest in the decision; and
- any other PCT or LHB any part of whose area is within 2 km of the proposed pharmacy premises to which the decision relates.

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**).
110. The PCT should note the requirement to only notify those pharmacy contractors and DACs who it believes might be significantly affected if the application was granted, or those it believes have a significant interest in the outcome. Careful decisions at this stage should be made as there are later implications when it comes to third party rights of appeal. PCTs will therefore need to identify those relevant persons rather than automatically notifying everyone on their pharmaceutical list, or entitled to be included in that list.

Example

The PCT receives and approves an *excepted application* for a change of ownership and relocation of a DAC. It notifies the LPC, LMC and LINK. There are no LPS chemists in the PCT's area and no other DACs on the PCT's pharmaceutical list.

The DAC provides specialist appliances which the PCT knows are not provided by any of the pharmacies in the area. It therefore decides that none of the pharmacies would be significantly affected by its decision and does not therefore notify any of the pharmacies in its area.

111. Any PCT notified under **paragraph 28(3)** is required by **paragraph 28(4), Schedule 2** to notify certain persons of the decision as soon as is practicable. Those persons are:
- the LPC for the PCT's area if this is different to the LPC for the PCT that made the decision;
 - the LMC for the PCT's area if this is different to the LMC for the PCT that made the decision;

Market entry by means of pharmaceutical needs assessments

- any person who is included in the PCT's pharmaceutical list, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests the PCT believes might be significantly affected by the decision;
 - any LPS chemist with whom the PCT is in contract and whose interests the PCT believes might be significantly affected by the decision; and
 - any LINK, other patient, consumer or community group in the PCT's area which the PCT believes has a significant interest in the decision.
112. 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. Each notification of the decision must include a statement from the PCT that made the decision of the reasons for that decision (**paragraph 28(6) of Schedule 2**).
113. Once the PCT has done this, it must notify the PCT who made the decision on the application that it has notified the interested parties listed above (**paragraph 28(4)(a) of Schedule 2**).
114. 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

115. 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**).
116. The PCT may wish to pre-populate the form where it holds the information.

Appeals to the Secretary of State by the applicant

117. **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
118. Applicants may appeal against decisions to refuse under the following regulations in Part 5:
- Regulation 30 (refusal: language requirements); and
 - Regulation 31 (refusal: same or adjacent premises).
119. 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

120. **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 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.
121. 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**).
122. **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.

123. 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**)
124. 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.
125. 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* for change of ownership and relocation 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.

126. 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**).
127. 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

128. 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**).
129. 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**).
130. 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**).

Taking effect of listing decisions: general

131. 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.
132. 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**)
133. Where the applicant undertook 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.

134. 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**).

Scenario	Date on which the six month period starts
Application granted by the PCT	Date on which the applicant is sent notice of the PCT's decision to approve under paragraph 28, Schedule 2 .
Refusal of the application was successfully appealed by the applicant	Date on which the FHSAU determines the appeal.
In the course of granting the application a decision was taken to impose a condition in accordance with regulation 35 (conditional inclusion) and that condition is successfully appealed by the applicant, unless regulation 35(7) applies.	Date on which the First-Tier Tribunal determines the appeal. If at that time, the applicant is not included in the pharmaceutical list and the First-Tier Tribunal confirms the PCT's decision or imposes a different condition, then the applicant must within 30 days of being notified of the First-Tier Tribunal's decision, notify 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 6 months starts at that point.
In the course of granting the application a decision was taken to impose a condition in accordance with regulation 35 (conditional inclusion) and that condition is unsuccessfully appealed by the applicant, unless regulation 35(7) applies.	Date on which the PCT made its decision to impose conditions on the applicant's inclusion in the pharmaceutical list.

135. 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**).

136. During the six month period following grant of the *excepted application*, the PCT may approve a longer period not exceeding a further three months where it has good cause (**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**).
137. 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; or
 - the applicant successfully appeals against the PCT's decision not to allow a longer period under **paragraph 34(4)(c)(i) of Schedule 2**.
138. 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**).
139. 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**).
140. 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* for change of ownership and relocation. 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.