



Department  
of Health

# Regulations under the Health and Social Care Act 2012: Market entry by means of Pharmaceutical Needs Assessments

Information for NHS England

Chapter 12 – changes of ownership

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## Chapter 12 – Changes of ownership

1. This chapter deals with applications for changes of ownership. The purpose of this type of application is to ensure that only fit and proper persons are included in a pharmaceutical list in order to provide *pharmaceutical services*.

### Introduction

2. Part 4 of the 2013 Regulations makes provision for *excepted applications*. The name arises because Section 129(2A) does not apply to such applications and consequently they are “excepted” from the market entry test. They are therefore not required to meet a need, or to secure improvements or better access, to services.
3. Applications for changes of ownership fall within this category of applications.
4. NHS England will wish to note that in situations where Company A has taken over Company B by buying its shares and Company B continues to trade this is **not** a change of ownership. All that has happened is that the issued share capital is in new hands. However, if the directors of Company B have also changed, then this information needs to be sent to NHS England together with information about the directors’ and superintendent pharmacist’s fitness to practise. The key test is whether the legal identity of the contractor has changed.
5. Change of ownership applications are however required to meet certain criteria, listed in **regulation 26**, and must be refused if they fail to meet any one of them.

### Changes of ownership

6. Change of ownership applications will occur where a person applies to provide services at premises from which services are, at the time of the application, provided by another person who is on a pharmaceutical list (**Regulation 26(1)(a)**).
7. Such applications are made where the person currently providing *pharmaceutical services* and who is on a pharmaceutical list wishes to sell or otherwise transfer ownership of the pharmacy to another. The new owner submits the application, thereby proposing to carry on the business at the *listed chemist premises* (**Regulation 26(1)(b)**).
8. NHS England must be satisfied that the same *pharmaceutical services* will be provided by the applicant as are provided by the person currently included in a pharmaceutical list (**Regulation 26(1)(c)**).

9. If NHS England considers there has been a change of circumstances and either wants to discontinue certain services, or commission new ones, these should be the subject of separate negotiations once the change of ownership has completed. If the applicant wished to provide more *directed services* then they would need to submit a separate *excepted application* under **regulation 23**.
10. In addition, the applicant must show that the provision of *pharmaceutical services* will not be interrupted, except for such period as NHS England may for “good cause” allow (**Regulation 26(1)(d)**). It is for NHS England to determine what is and what is not good cause.

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

11. **Part 1 of Schedule 2** sets out the information that is to be provided in the application to NHS England. Some of the requirements relate to all applications, whereas others are for specific types of application.
12. When submitting an *excepted application* for a change of ownership, the following information must be included (**paragraph 1 of Schedule 2**):
  - the name of the relevant Health and Wellbeing Board (HWB) for the area where the application is made;
  - the type of application being made, for example, an application for a change of ownership;
  - a statement that the application is an *excepted application*;
  - the name and address of the applicant i.e. the name and address of the sole trader/partnership<sup>1</sup>/body corporate;
  - if the applicant is a pharmacist 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 number<sup>2</sup>. A pharmacist does not have to provide their GPhC registration number if their partnership is as a DAC and not a pharmacy contractor;

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

<sup>2</sup> The Medicines Act 1968 requires all partners to be pharmacists. Partners in limited liability partnerships should be dealt with as bodies corporate.

- if the applicant is a body corporate for the purposes of the Medicines Act registration rules, 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*).
- 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 NHS England requires such accreditation;
  - confirmation that the premises are accredited in respect of the provision of the services, where NHS England 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 NHS England accepts as good cause, for example the premises are not in the applicant's possession.

The applicant must confirm whether the application is a *routine* or 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 NHS England (**paragraph 1(9) of Schedule 2**). 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.

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**.

#### Example

NHS England receives an *excepted* application for a change of ownership.

The applicant confirms within the application that:

- they undertake to provide *pharmaceutical services* at High Street Pharmacy, 16-18 High Street, Anytown;

- they are proposing to carry on at those premises the business of Smith and Jones and provide *pharmaceutical services*;
- they undertake to provide *essential services*, *advanced services*, minor ailment schemes and witnessed methadone which are currently provided by Smith and Jones.

The provision of those services will however be interrupted for a period of one week in order that the premises can be completely refurbished. The applicant plans to undertake this work the week after a bank holiday and therefore the pharmacy will only be closed for a maximum of four working days (Tuesday to Friday inclusive).

## Additional information to be provided where the applicant is not already included in a pharmaceutical list

14. **Paragraph 2 of Schedule 2** requires the applicant to provide additional information where they are not already included in a 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 is entitled to 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 name and date of birth of the superintendent pharmacist (not required from DACs);
  - the name 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 is entitled to 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 the 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 a pharmaceutical list for other premises.
22. Further information on these requirements can be found in separate guidance. NHS England 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. NHS England must also ensure that all fitness to practise checks are completed and a decision made on the applicant's suitability for inclusion in a pharmaceutical list before determining the *excepted application* for change of ownership.
23. Where the applicant is a body corporate with a registered office in England, **paragraph 5 of Schedule 2** makes provision for them, where they have already provided information under **paragraphs 3 and 4 of Schedule 2** to NHS England on a previous occasion, of not providing that information again to NHS England in relation to the current application (**paragraph 5(1) of Schedule 2**).

24. If the applicant wishes to use this flexibility, they must:
- confirm NHS England already has the information required under **paragraphs 3 and 4 of Schedule 2**; or
  - if there is any missing information required under those paragraphs, confirm to NHS England what information NHS England already has, and provide the missing information (**paragraph 5(2) of Schedule 2**).

## Undertakings to be provided by all applicants

25. 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 NHS England 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 NHS England, or on appeal the FHSAU or First-Tier Tribunal (FTT), 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 NHS England 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 NHS England, or on appeal the FHSAU or FTT, 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 NHS England commissions them within three years of the date the premises are included in pharmaceutical list;



- if the services are commissioned by NHS England, 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

NHS England receives an *excepted application* for a change of ownership. The current owner of the pharmacy provides *advanced services*, witnessed methadone, a needle exchange service and a minor ailments service. The applicant must therefore also offer to provide these services, and give an undertaking that if NHS England 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) of Schedule 2**. Where this is the case, NHS England 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.

26. 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 NHS England is satisfied that no relevant information or documentation is missing (**paragraph 10 of Schedule 2**). NHS England 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

27. On receipt of an *excepted application* for a change of ownership, there are a number of preliminary matters which NHS England must consider before proceeding with it. These matters are set out in **Part 2 of Schedule 2**.

## Failure to provide undertakings

28. On receipt of an application, NHS England 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, NHS England must, prior to notifying the application, request them to do so within a reasonable timescale (**paragraph 12(1) of Schedule 2**).
29. If the applicant fails to comply with this request within NHS England's timescale, the application is to be treated as withdrawn (**paragraph 12(2) of Schedule 2**).

## Missing relevant information or documents

30. Where NHS England 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**). NHS England should only request information or documentation that is required to determine the application i.e. information or documentation that is relevant to the application. NHS England should not request information that is not relevant to the application (see the example below).
31. 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.
32. NHS England may make the request at any time between receiving and determining the *excepted application* for a change of ownership. It is suggested that requests are made as early as possible in order that NHS England does not delay the transfer of the business.
33. 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 NHS England of the delay (**paragraph 11(1)(b)(i) and (ii) of Schedule 2**). Additionally, they must tell NHS England 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**). NHS England must be satisfied that the delay and the length of the delay are for good cause (**paragraph 11(2)(a)(ii) of Schedule 2**).
34. If the applicant refuses to comply with a request for missing information or documentation within the timescale specified by NHS England, or by any subsequent date specified by the applicant and agreed with NHS England, the application is to be treated as withdrawn by the applicant (**paragraph 11(1)(b)(iii) of Schedule 2**).

35. If the applicant considers that NHS England's request is not reasonable, they may notify NHS England of that and seek a review by NHS England of the reasonableness of the request – see box below (**paragraph 11(2)(a) of Schedule 2**).
36. If the applicant seeks a review, NHS England is required to reconsider its request for missing information or documentation. The 2013 Regulations are silent as to the procedure for this review. 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.
37. If following the review, it is determined that any or all of the requested information or documentation 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**).
38. 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. 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 pharmacy application panel considers the request for a review and agrees that as this information is outside the requirements of the 2013 Regulations, the request is unreasonable. The applicant is advised that the request for that information is withdrawn.

## Determination and deferral of applications

### Flexibility with regard to determining or deferring applications

39. NHS England is able to determine an *excepted application* for a change of ownership 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.

40. NHS England 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.
41. NHS England 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 NHS England decides after the notification exercise that it wishes to consider two or more applications together then it may do so but it must give *notice* of this to the applicants concerned before determining the applications.

## Oral hearings

42. Oral hearings are not required to be held for every application decision and a judgement should be made 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.
43. If NHS England 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 NHS England has decided to determine two or more applications together (**paragraph 25(1) of Schedule 2**)
44. If NHS England 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 NHS England 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

45. **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

46. **Paragraph 27 of Schedule 2** requires NHS England to determine the *excepted application* as soon as it is practicable to do so and within 30 days of the date on which all the required information and documentation was received by NHS England (**paragraph 27(b)(i) of Schedule 2**).
47. The only exceptions to this timescale are where NHS England has deferred the application under the 2013 Regulations or where it has good cause for a delay. The table below summarises when the timescale starts and stops.

Scenario	Point at which the 30 day time period starts
NHS England receives a deficient <i>excepted application</i>	The 30 day time period initially starts at the point the application is received. It stops at the point NHS England discovers it is deficient, for example, not all the relevant information or documentation is received. It restarts at the point all the relevant information or documentation is received.
NHS England defers an application for inclusion in a pharmaceutical list by a person not already included in it on fitness to practise grounds ( <b>Regulation 34</b> ).	The 30 day time period initially starts at the point the application is received. It then stops at the point NHS England decides to defer it on fitness to practise grounds set out in <b>regulation 34</b> . It then restarts when the outcome of the cause for deferral is known.

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

## Refusal, deferral and conditional inclusion in a pharmaceutical list of chemists on fitness to practise grounds

49. Where the applicant is not already included in a pharmaceutical list, they will also have to have submitted information on their fitness to practise (**paragraphs 2 to 4 of Schedule 2**). NHS England may process this information either in advance of processing the *excepted application* for a change of ownership, or alongside. Whichever course of action is taken, NHS England must come to a decision on the fitness to practise information in advance of the *excepted application*. It is not possible for NHS England to

approve the *excepted application*, subject to the satisfactory approval of the fitness to practise information.

50. Part 6 of the 2013 Regulations sets out the grounds on which NHS England:
- must or may refuse the *excepted application* for inclusion in a pharmaceutical list on fitness to practise grounds (**Regulation 33**);
  - may defer consideration of the *excepted application* for inclusion in a pharmaceutical list on fitness to practise grounds (**Regulation 34**); and
  - may grant the *excepted application* for inclusion in a pharmaceutical list subject to efficiency conditions and conditions to combat fraud (**Regulation 35**).
51. Further information on these provisions can be found in guidance issued by DH.
52. Where the *excepted application* has been made by someone who is not already included in a pharmaceutical list, there are additional actions that NHS England must undertake prior to determining the *excepted application*. **Paragraph 23(1) of Schedule 2** requires NHS England to:
- where the applicant is an individual, check with the Business Services Authority Counter Fraud Service, now better known as NHS Protect<sup>3</sup> whether the applicant has any record of, or is under investigation for, fraud;
  - where the applicant is a body corporate, check with NHS Protect whether any director or the superintendent pharmacist has any record of, or is under investigation for, fraud;
  - where the applicant is an individual, check whether the Secretary of State (who has delegated this function to the NHSLA<sup>4</sup>) holds any information on the applicant that is relevant to NHS England'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 NHS England 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 NHS England via a secure website; and
  - take up references from the referees provided under **paragraph 3(8) of Schedule 2** and check those references.

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<sup>3</sup> <http://www.nhsbsa.nhs.uk/fraud>

<sup>4</sup> <http://www.fhsaa.tribunals.gov.uk/index.htm>

53. Once NHS England 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**.
54. If NHS England 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 NHS England makes its decision (**paragraph 23(2) of Schedule 2**).
55. If NHS England decides to defer consideration of the application, as soon as it no longer has grounds to defer the application, it must proceed to determining it. The only exception to this would be where the application has been withdrawn or NHS England is required to treat it as withdrawn.

#### Example

NHS England has received an *excepted application* for a change of ownership. The new owner is a sole trader who is not currently included in a pharmaceutical list and so has provided the required fitness to practise information.

On checking the information that has been provided, it is noted that the pharmacist is currently being investigated by the GPhC. Based on the nature of the investigation it is possible that the individual will be removed from the GPhC's register. NHS England therefore decides to defer the *excepted application* under **Regulation 34(1)(c)** until such time as the investigation is concluded.

Three months later the investigation is concluded and the individual is removed from the GPhC's register and the *excepted application* is withdrawn by the pharmacist.

56. If NHS England decides to defer consideration or determination of an *excepted application* for a change of ownership then 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 NHS England can refer to a future event as opposed to a period of time (**paragraph 24(1) of Schedule 2**)



57. Where the applicant is not already included in a pharmaceutical list and NHS England decides to defer the *excepted application* for a change of ownership under **regulation 34**, once the outcome of the cause of that deferral is known NHS England must notify the applicant that they must within a specified period of not less than 30 days update their application and notify NHS England whether or not they still wish to proceed with it (**paragraph 24(2)(f) of Schedule 2**).
58. If the applicant informs NHS England within the specified period that they do not wish to proceed with the application, 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.
59. Until such time as the application is determined the current owner remains included in a pharmaceutical list.

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

60. Where NHS England receives an *excepted application* for a change of ownership, if the applicant has qualified as a pharmacist in Switzerland or an European Economic Area State other than the UK, NHS England must be satisfied that the applicant has the level of knowledge of English which is necessary for the provision of services in the relevant HWB area (unless the applicant is already on a pharmaceutical list) (**Regulation 30**).

### Example

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

NHS England checks the fitness to practise information that is submitted with the application and it is noted that the pharmacist grew up in Argentina but qualified in Switzerland.

NHS England requests evidence of the level of knowledge of English and then meets with the pharmacist. After considering all the evidence, NHS England is not satisfied that the pharmacist has the level of knowledge of English which is necessary for the provision of pharmaceutical services in the relevant HWB area. It therefore refuses the *excepted application* under regulation 30 and notifies the applicant of its decision and the reasons for it. Had the applicant qualified in Argentina, this regulation would not have applied as it would have been for the GPhC to resolve the issue of language competency prior to registration.



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

61. Once NHS England 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**).
62. The 2013 Regulations make provision for certain persons to have a right of appeal against NHS England'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 NHS England's letter;
  - information on the FHSAU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website<sup>5</sup>. If there is a right of appeal on a matter related to fitness to practise, the appeal is to the FTT and its contact details must instead be provided by NHS England.
63. 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

64. Once NHS England 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;
  - the LPC whose area includes the premises or location to which the application relates, or any part of whose area is within 2 km of the premises or location to which the application relates;
  - the LMC whose area includes the premises or location to which the application relates, or any part of whose area is within 2 km of the premises or location to which the application relates;

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<sup>5</sup> <http://www.nhs.uk/ContactUs/>

- any person who is included in a pharmaceutical list, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests NHS England believes might be significantly affected by the decision;
  - any LPS chemist with whom NHS England has made arrangements for the provision of any local pharmaceutical services in the area of the relevant HWB and whose interests NHS England believes might be significantly affected by the decision;
  - any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in the relevant area and which NHS England believes has a significant interest in the decision;
  - if the proposed premises are in or within 1.6 km of a *controlled locality* in the area of the relevant HWB, any provider of primary medical services or any other person (who is a performer but not a provider of primary medical services) on the dispensing doctors list for the area of the relevant HWB if there is one, who NHS England believes has a significant interest in the decision;
  - any other persons that NHS England notified under **paragraph 19(2) of Schedule 2** (other persons who in the opinion of NHS England have a significant interest in the outcome of the application) and who made representations about the application under **paragraph 19(4) of Schedule 2**; and
  - any other LHB any part of whose area is within 2 km of the proposed pharmacy premises to which the decision relates (**paragraph 28(1) of Schedule 2**).
65. The requirement is to notify the decision as soon as is practicable. NHS England 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 NHS England of the reasons for that decision (**paragraph 28(6) of Schedule 2**).
66. NHS England should note the requirement to notify only 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. NHS England 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**

NHS England receives and approves an *excepted application* for a change of ownership of a DAC. It notifies the LPC, LMC and Healthwatch. There are no LPS chemists in the relevant HWB area and no other DACs on a pharmaceutical list. The DAC provides specialist appliances which NHS England 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 the relevant HWB area.

67. If NHS England decides 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

68. If NHS England 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**).
69. NHS England may wish to pre-populate the form where it holds the information.

## Appeals to the Secretary of State by the applicant

70. **Paragraph 36(1) of Schedule 2** gives the applicant rights of appeal against certain NHS England 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 NHS England:
- to refuse the application on grounds set out in **regulation 26**;
  - to refuse the application on grounds set out **regulation 31** (refusal same or adjacent premises) of the 2013 Regulations; or
  - to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**.
71. 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

72. **Paragraph 30(1) of Schedule 2** gives third party rights of appeal against certain NHS England decisions. The 2013 Regulations refer to these as third party rights of appeal as they are persons other than those who are party to the application and decision i.e. persons other than the applicant and NHS England. The right of appeal is to the Secretary of State who has delegated this function to the FHSAU.
73. If NHS England 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**).
74. **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 with and in relation to the application to which the decision letter relates.
75. Other persons with third party rights of appeal are those:
- who were required to be notified of the application because they are on a pharmaceutical list or are entitled to be because their application has been granted but they have not yet been included, and whose interests NHS England believed might be significantly affected by the decision. This could be those in the original HWB area and those notified of the application in the area of the second HWB, any part of whose area is within 2 km of the proposed premises and was given *notice* of the application;
  - had made written representations about the application under **paragraph 19(4) of Schedule 2**; and
  - where NHS England was satisfied that within their written or oral representations they had 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 HWB or Primary Care Trust (PCT)'s PNA or to the fairness of the process by which the HWB or PCT undertook that assessment and must not be vexatious or frivolous (**paragraph 30(3) of Schedule 2**)
76. NHS England should not give third party rights of appeal to all persons included in a pharmaceutical list or entitled to be included in that list who made representations. NHS England must consider carefully 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.

77. Third party rights of appeal may not be given to LPCs, LMCs, LPS chemists, GPs, the Local Healthwatch organisation or other patient, consumer or community groups.
78. When a person with third party rights of appeal appeals to the FHS AU, 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 NHS England's decision (**paragraph 30(1) and (5) of Schedule 2**).
79. If a person believes that they should have been given third party rights of appeal by NHS England but were not, they may appeal to the FHS AU against NHS England's determination not to give them rights. They must notify the FHS AU within 30 days of the date on which they were notified of NHS England'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 NHS England's decision on the application (**paragraph 30(6) of Schedule 2**). If their appeal is successful, they will gain third party rights of appeal in relation to the decision to grant the application.

## Action to be taken by NHS England following notification of an appeal decision

80. Once the FHS AU has determined any appeal, NHS England 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**).
81. For the purposes of the 2013 Regulations, the FHS AU's decision becomes NHS England's decision on the matter unless the FHS AU's decision is overruled by a court (**paragraph 11 of Schedule 3**).
82. If the FHS AU has granted or confirmed the grant of the *excepted application*:
  - NHS England must send the applicant a template *notice of commencement*, and
  - the six months within which to open take effect from the date the FHS AU makes its determination (**paragraph 10(2) of Schedule 3**).

## Taking effect of listing decisions: general

83. If the *excepted application* is granted, the applicant is required to submit a valid *notice of commencement* informing NHS England that they will commence the provision of services in the next 14 days (**paragraph 34(2) of Schedule 2**). NHS England then includes the applicant in a 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, NHS England may include the applicant and the premises in a pharmaceutical list as the applicant is not obliged to open on such a day.
84. 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 NHS England with its decision letter (**paragraph 34(3) of Schedule 2**)
85. Where the applicant undertakes to commence the provision of services within a period of less than six months and that undertaking was not withdrawn, the *notice of commencement* must be sent within that period otherwise it will be invalid (**paragraph 34(4)(a) of Schedule 2**). If the applicant fails to submit their *notice of commencement* within this shorter timescale, the grant of the application lapses.
86. 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 NHS England	Date on which the applicant is sent <i>notice</i> of NHS England’s decision to approve under <b>paragraph 28 of Schedule 2</b> .
Refusal of the application was successfully appealed by the applicant	Date on which the FHS AU determines the appeal.
In the course of granting the application a decision was taken to impose a condition in accordance with <b>regulation 35</b> (conditional inclusion) and that condition is successfully appealed by the applicant, unless <b>regulation 35(7)</b> applies.	Date on which the FTT determines the appeal. If at that time, the applicant is not included in a pharmaceutical list and the FTT confirms NHS England’s decision or imposes a different condition, then the applicant must within 30 days of being notified of the FTT’s decision, notify NHS England as

	to whether or not it wishes to withdraw the application. If the applicant notifies that they do not wish to withdraw the application the six months starts at that point.
In the course of granting the application a decision was taken to impose a condition in accordance with <b>regulation 35</b> (conditional inclusion) and that condition is unsuccessfully appealed by the applicant, unless <b>regulation 35(7)</b> applies.	Date on which NHS England made its decision to impose conditions on the applicant's inclusion in a pharmaceutical list.

87. 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**).
88. During the six month period following grant of the *excepted application*, NHS England may approve a longer period not exceeding a further three months (**paragraph 34(4)(c)(i) of Schedule 2**). Should the applicant fail to submit their *notice of commencement* within that extended period, the grant of that application lapses (**paragraph 34(4) of Schedule 2**).
89. Under **paragraph 34(4)(c)(ii) of Schedule 2**, the FHS AU may allow a longer period of time if:
- the grant is appealed by a person with third party appeal rights;
  - the applicant successfully appeals against NHS England's decision not to allow a longer period under **paragraph 34(4)(c)(i) of Schedule 2**.
90. 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**).
91. Where NHS England approves an application and issues a *notice of commencement* and the FHS AU 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**).



92. If, on appeal, the FHS AU grants or confirms the grant of the *excepted application* for an extension of the time period within which to open, NHS England is required to send to the applicant another template of the *notice of commencement* (**paragraph 10(2)(a) of Schedule 3**).

**Example**

NHS England approves an *excepted application* for a change of ownership. 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 NHS England's decision is subsequently made to the FHS AU by a person with third party appeal rights. The template *notice of commencement* sent by NHS England ceases to have effect.

The FHS AU considers the appeal and dismisses it and NHS England sends a second template *notice of commencement* giving the applicant six months from the date of the FHS AU's determination within which to commence service provision.