



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 5 - distance-selling premises

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Chapter 11: Distance-selling premises

1. This chapter deals with pharmacy applications for *distance-selling premises*. *Distance-selling premises* are defined in the 2013 Regulations as ‘*listed premises*, or potential pharmacy premises, at which *essential services* are or are to be provided but the means of providing those services are such that all persons receiving those services do so otherwise than at those premises’ (**Regulation 2**).

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 *distance-selling premises* fall within this category of applications but must meet certain criteria and these are listed in **regulation 25**. There are also specific conditions in place for those who are granted inclusion in an NHS pharmaceutical list (**Regulation 64(3)**). These apply to those who apply under this exception under the 2013 Regulations and, subject to a transitional provision, those who were granted inclusion under the 2012 and 2005 Regulations (**Regulation 64(1)**)
4. If an *excepted application* fails to meet any one of these criteria, it must be refused (**Regulation 25(2)**).

Distance-selling premises

Key points

- must provide the full range of *essential services* during opening hours to all persons in England presenting prescriptions;
- cannot provide *essential services* face to face;
- must have a responsible pharmacist in charge of the business at the premises throughout *core* and *supplementary opening hours*;
- must be registered with the General Pharmaceutical Council (GPhC); and
- must have premises within a relevant HWB area.

5. *Distance-selling premises* are *excepted applications* because such applications can face obstacles in proving a need for their services within a locality, as they tend to serve populations living across a much wider area. Previously, businesses providing such services did so from established premises. A new applicant for such a pharmacy would face difficulty in proving a need for a purely postal (in the case of mail order) or remote

delivery (in the case of internet-based) pharmacy service by reference to the area in which it proposed to locate. Demand would likely be very small. Patients drawn from a much wider catchment area, extending beyond the boundaries of a particular HWB area, may well value such a service offering both improved convenience and choice.

6. The definition in **regulation 2** of “distance-selling premises” covers more than just internet pharmacies, but there is no definition of an “internet pharmacy” in law. In effect, an internet-based pharmacy is a registered pharmacy business that operates like any mail order company in that it receives and fulfils orders for medicines “remotely” from a patient or customer rather than face to face as in a traditional pharmacy.
7. Thus, to qualify as an *excepted application*, a wholly mail order or internet-based pharmacy must not provide NHS *essential services* direct to patients on the premises. It may, however, sell or supply goods that are not NHS-related. It may also provide *advanced or enhanced services* from its premises where these services can be provided wholly separately from the provision of *essential services* at the premises.
8. As with traditional retail pharmacies, wholly mail order or internet-based pharmacies must have premises that are registered with GPhC. All pharmacies, whether or not they provide online services, are subject to the same statutory requirements, including the requirements relating to responsible pharmacists.
9. *Distance-selling premises* must be included in a pharmaceutical list in the HWB area where the premises are located in order to provide NHS *pharmaceutical services*. If they are not included in such a list, they may not provide NHS *pharmaceutical services*.
10. All such pharmacies will also need to provide the complete range of *essential services* as set out in **Schedule 4**. As indicated above, these *essential services* cannot be provided on a face-to-face basis. Therefore, the means of delivery of such services will inevitably vary from traditional shop-front pharmacies. The full range of *essential services* must, however, be available from such pharmacies for their weekly 40 core contractual hours though many may be available for longer (supplementary hours).
11. Adequate monitoring arrangements should be put into place for ensuring such pharmacies are not providing *essential services* to people from or in the vicinity of the registered pharmacy premises, for example by having a “shop-front” to the registered pharmacy or delivering medicines to customers waiting in the premises’ car park.
12. NHS England may contract with such pharmacies for the provision of *directed services* that can be provided face-to-face, but should ensure no element of *enhanced services* requires the provision of *essential services*. For example, the *enhanced service* of supervised consumption of methadone would require the pharmacy to dispense the methadone for subsequent consumption. The dispensing of methadone is an *essential*

service and therefore this *enhanced service* could not be provided at the contractor's premises.

Information to be included in all excepted applications for distance-selling premises

13. 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.
14. When submitting an *excepted* application for *distance-selling premises*, the following information must be included (**paragraph 1 of Schedule 2**):
 - the name of the relevant HWB for the area where the application is made;
 - the type of application being made, for example, a *distance-selling* application;
 - 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/partnership¹/body corporate;
 - if the applicant is a pharmacy sole trader, their GPhC registration number;
 - if the applicant is a partnership, each partner's GPhC registration number²;
 - 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;
 - 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*:
 - 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.
15. The applicant must confirm that the application is an *excepted* rather than a *routine 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**

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. Partners in limited liability partnerships should be dealt with as bodies corporate.

Schedule 2). Should the applicant 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].

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

paragraph 6 of Schedule 2 requires the applicant to include in their application, details that explain why the application should not be refused pursuant to **regulation 31**

18. **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 25**, read with the definitions in **regulation 2**; and
 - why the application should not be refused under **regulation 25(2)** (see box below for further information on this).

Example

NHS England receives an *excepted application* for *distance-selling premises*. The location for the premises is the same as another pharmacy run by the applicant.

Regulation 25(2) requires the applicant to explain how the pharmacy procedures will secure:

- the uninterrupted provision of *essential services* during opening hours to persons anywhere in England who request those services; and
- the safe and effective provision of *essential services* without face to face contact between any person receiving the services, whether on their own behalf or on behalf of someone else, and the applicant or the applicant's staff.

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

Therefore, in this case, the applicant would need to explain why the services provided at existing pharmacy on that site should not be considered part of the same service as the services that will be provided if the *excepted application* was approved.

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

19. **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.
20. 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, conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968.
21. Where the applicant is a body corporate they are required to provide:
 - the registered name and any other name under which the applicant trades;
 - the company's registration number (this is their Companies House registration number);
 - 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;
 - 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; and
 - if the applicant has other premises registered with the GPhC, the registration number(s) for those premises.
22. **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.

23. **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.
24. 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 distance-selling premises*.
25. 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**).
26. 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

27. 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 FHSU 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 FHS AU 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)**;
- in particular, to provide all the services and perform all the activities at those proposed *pharmacy premises* that are required under the terms of service to be provided or performed as, or in connection with, *essential services (paragraph 9(c)(ii) of Schedule 2)*;
- if the applicant 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 a 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**)

Agreed service specifications

Where the applicant is offering to provide a *directed service* (where NHS England wishes to commission this) and the HWB has indicated within its PNA that there is a need for that *directed service*, where that service is an *enhanced service* NHS England should have a service specification.

There is already likely to be such a specification and NHS England is advised to send that to the applicant at the point the *excepted application for distance-selling premises* is received so that the applicant is aware of what they will be required to provide should the application be successful. 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 request the applicant to give the required undertakings and only begin to process the application once these are received.

Where there is no such service specification, NHS England must be able to describe the service in broad enough terms to allow itself flexibility, but narrow enough to allow the applicant to give the required undertakings in **paragraph 9(d) of Schedule 2**. Failure by NHS England to give sufficient information to allow the applicant to give the undertakings is not sufficient reason to delay the processing of the application.

Where the applicant offers to provide a *directed service* for which there is no identified need within the PNA, NHS England is under no obligation to commission this.

28. 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 must not use this provision simply to avoid determining, or to delay determining, an application.

Preliminary matters to consider following receipt of an application

29. On receipt of an *excepted application for distance-selling premises*, 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

30. 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**).
31. 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

32. 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).
33. The timescale must be reasonable and will depend on what information or documentation is required, for example, a timescale of one week may be reasonable to provide the GPhC registration number of the superintendent pharmacist required under **paragraph 1(6) of Schedule 2** but a longer period may be required to provide any

fitness to practise information required under **paragraph 3 of Schedule 2** for all the partners in a partnership.

34. NHS England may make the request at any time between receiving and determining the *excepted application* for *distance-selling premises* but it must consider whether or not it needs to request missing information or documentation prior to notifying the application as required by **paragraph 18 of Schedule 2 (paragraph 11(3) of Schedule 2)**. In the interests of fairness and transparency and to make sure those notified of the application have all the relevant information, NHS England may wish to ensure they have any missing information or documentation prior to notifying the application.
35. The applicant is required to provide the information or documentation within the specified timescale and where they are unable to meet the timescale, they must notify 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**).
36. 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(2)(a)(ii) of Schedule 2**).
37. 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(1)(b)(iii) of Schedule 2**).
38. 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.
39. 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**).
40. If following the review, it is determined that the information or documentation need not be provided, the original request made under **paragraph 11(1) of Schedule 2** is to be treated as withdrawn i.e. the applicant is not required to provide it (**paragraph 11(2)(b)(ii) of Schedule 2**).

Example

A shared service agency receives an *excepted application* for *distance-selling premises*. 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.

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

41. Where NHS England receives an *excepted application* for *distance-selling premises*, 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**).
42. If the *excepted application* for *distance-selling premises* is from a person who is not already included in a pharmaceutical list at other premises, then 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 a pharmaceutical list at other premises.

Prior to notification, 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 as a pharmacist.

Refusal of applications on fitness to practise grounds prior to notification

43. Where NHS England receives an *excepted application* for *distance-selling premises* from a person who is not already included in a pharmaceutical list at other premises, prior to notification it must consider whether or not it must refuse that application under **regulation 33(1)** – mandatory refusal on fitness to practise grounds (**paragraph 16 of Schedule 2**).

Example

NHS England receives an *excepted application for distance-selling premises* from a pharmacist that is not already included in a pharmaceutical list. Prior to notifying the application to interested parties, it checks the fitness to practise information and it is noted that the pharmacist is the subject of a national disqualification. NHS England therefore refuses the application under **regulation 33(1)**.

Deferral of applications prior to notification on fitness to practise grounds

44. When NHS England receives an *excepted application* for distance-selling 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** i.e. on fitness to practise grounds (**paragraph 14(1) of Schedule 2**).
45. If NHS England decides to defer consideration of the application on fitness to practise grounds before notification, 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 NHS England is required to treat it as withdrawn (see below).

Action following decisions to defer an excepted application for distance-selling premises

46. Where NHS England decides to defer consideration or determination of an *excepted application* for *distance-selling premises*, 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**).
47. NHS England 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.
48. Where the applicant is not already included in a pharmaceutical list and NHS England decides to defer the *excepted application* 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**).
49. If the applicant informs NHS England within the specified period that they do not wish to proceed with the *excepted 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.

Notification

50. Once NHS England has considered the matters listed in **paragraphs 11 to 17 of Schedule 2** and has decided not to refuse the application under **paragraph 15 or 16 of Schedule 2**, or to defer it, NHS England must give notice of an *excepted application* for *distance-selling premises* to:
- any 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 Local Medical Committee (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;
 - any person in a pharmaceutical list whose interests NHS England believes might be significantly affected if the application were granted;
 - any person who is entitled to be included in a list because of the grant by NHS England or on appeal by the FHSAU, of a *routine* or *excepted application*, but who is not (yet) included, and whose interests NHS England believes might be significantly affected if the application were granted;
 - 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 if the application were granted;

- any Local Healthwatch organisation for the area of the relevant HWB, and any other patient, consumer or community group in the relevant area (for example Parish and Town Councils) which NHS England 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 the area of the HWB, any provider of primary medical services or any other person on the dispensing doctor list for the area of the relevant HWB if there is one (i.e. doctors on the list who are performers as opposed to providers) who NHS England believes has a significant interest in the outcome of the application; and
 - any other Local Health Board (LHB) any part of whose area is within 2 km of the proposed premises (**paragraph 19(1) of Schedule 2**).
51. Persons in the above list must receive *notice* of the application. NHS England 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**).
52. It is recommended that NHS England records its reasoning for why it believes persons have a significant interest in the outcome of the application.
53. For *distance-selling applications*, it is sufficient to *notify* those persons listed above along with those in the nearest neighbouring HWB area(s) as relevant.
54. Other than LPCs, LMCs and LHBs, NHS England should note the requirement to *notify* only those who it believes might be significantly affected if the application was granted, or those it believes have a significant interest in the outcome. NHS England will therefore need to identify those relevant persons rather than automatically notifying everyone on a pharmaceutical list, dispensing doctor list and all providers of primary medical services.

Example

NHS England receives an *excepted application* for *distance-selling premises* 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, NHS England 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. NHS England 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.

55. Where any part of the area of another HWB other than the relevant HWB is within 2 km of the premises or location to which the application relates, NHS England must also give *notice* to:
- any LPC whose area includes that part of the area and that is not given *notice* of the application under paragraph (1)(a) and (b) of Schedule 2;
 - any LMC whose area includes that part of the area and that is not given *notice* of the application under paragraph (1)(a) and (b) of Schedule 2;
 - any person in a pharmaceutical list whose interests NHS England believes might be significantly affected if the application were granted;
 - any person who is entitled to be included in a list in the second HWB area because of the grant of a *routine* or *excepted application*, but who is not (yet) included, and whose interests NHS England believes might be significantly affected if the application were granted;
 - any LPS chemist with whom NHS England made arrangements for the provision of any local pharmaceutical services in the area of the second HWB and whose interests NHS England believes might be significantly affected if the application were granted;
 - any Local Healthwatch organisation for the area of the second HWB, and any other patient, consumer or community group in that area which NHS England believes has a significant interest in the outcome of the application; and
 - if the proposed premises within the application are within 1.6 km of a *controlled locality* in the area of the second HWB, any provider of primary medical services or any other person on the dispensing doctor list for the area of the second HWB where there is one (i.e. doctors on the list who are performers as opposed to providers) who NHS England believes has a significant interest in the outcome of the application (**paragraph 19(3)(a) of Schedule 2**).
56. Those persons who have been notified may make written representations about the application to NHS England within 45 days of the date on which *notice* of the application was given to them (**paragraph 19(4) of Schedule 2**)

Parallel notifications

57. If NHS England wishes to consider two or more applications together and in relation to each other, it is required by **paragraph 22(3) of Schedule 2** to give *notice* to the applicants of its intention to do so.

Content of notifications

58. **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, NHS England 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 NHS England subsequently decide to hold an oral hearing; and
 - where NHS England intends to consider the application at the same time as another application, notification of that intention (**paragraph 21(1)(a) of Schedule 2**)

59. When *notifying* of applications NHS England 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**). NHS England is not, however, required to provide copies or excerpts of their PNA with the notification letter (**paragraph 21(2) of Schedule 2**).

60. NHS England must not send any private personal information or fitness to practise information provided by the applicant under **paragraphs 3 and 4 (paragraph 21(3) of Schedule 2)**. This includes any private addresses, private telephone numbers or dates of birth that may have been supplied.

61. If the applicant advises NHS England that they consider:
- any information to be confidential; and
 - that they do not consent to that information being disclosed as part of the notification

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

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

Example

A pharmacist who is currently employed at a local pharmacy submits an *excepted application* for *distance-selling premises*. They request that their name is removed from the documentation before it is circulated as they do not wish their employer to know they are applying.

The full disclosure principle applies in this case and therefore NHS England is required to disclose who is applying.

Determination of applications

Flexibility with regard to determining applications

63. NHS England is able to determine an *excepted application* for *distance-selling premises* 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).
64. 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.
65. 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

66. 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.

67. 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**)
68. **Paragraph 25(2) of Schedule 2** defines a person as an *additional presenter* if:
- the application to which the hearing applies is a *notifiable application* (which *excepted applications* for *distance-selling premises* are);
 - they were given *notice* of the application and made representations in accordance with **paragraph 19(4)**. As part of the representations the person must have indicated that they would wish to make oral representations if an oral hearing took place, and they must have identified a matter about which NHS England considers it would be desirable to hear further evidence from the person at the oral hearing; and
 - NHS England is satisfied that the person made a reasonable attempt to express their views on the application in their written representation.
69. 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 NHS England to then decide whether they wish to hear further evidence on those reasons at the oral hearing. It should be noted 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, NHS England is not required to invite them to an oral hearing if it decides to hold one.
70. 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

71. **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

72. **Paragraph 27 of Schedule 2** requires NHS England to determine *excepted applications* which are *notifiable applications* as soon as it is practicable to do so and within four months of the date on which all the required information and documentation was received by NHS England (**paragraph 27(b)(i) of Schedule 2**).
73. 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 four month time period starts
NHS England receives a deficient <i>excepted application</i> for <i>distance selling premises</i>	The four month time period initially starts at the point the application is received. It then stops at the point NHS England discovers it is deficient, for example not all the relevant information or documentation is received. It then restarts, back at the beginning, 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 (Regulation 34).	The four month time period initially starts at the point the application, and all relevant information, is received. It then stops at the point NHS England 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, the applicant has updated their application and has indicated that it wishes the application to proceed.

74. 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

75. 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 *distance-selling premises*, or alongside. Whichever course of action is taken, NHS England must come to a decision on the fitness to practise information in advance of determining 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.
76. 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**).
77. Further information on these provisions can be found in guidance issued by DH.
78. 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 NHS Business Services Authority Counter Fraud Service, now better known as NHS Protect³ 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 NHSLA⁴) 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 is accessed by NHS England via a secure website;

³ <http://www.nhsbsa.nhs.uk/fraud>

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

- 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 is 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.
79. 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**.
80. 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**).

Refusal: same or adjacent premises

81. Where the premises within an *excepted application* for *distance-selling premises* are:
- already included in a pharmaceutical list; or
 - adjacent to or in close proximity to premises that are already included in a pharmaceutical list,

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

82. NHS England must refuse an *excepted application* for *distance-selling premises* where:
- a person on a pharmaceutical list (which does not have to be the applicant) is providing (or has undertaken to provide) *pharmaceutical services* from the premises mentioned in the application or from adjacent premises; and
 - NHS England 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)**).
83. The purpose of this regulation is to prevent a contractor from applying for multiple inclusions in a pharmaceutical list at the same address with no benefit to patients.

Refusal of distance-selling applications

84. **Regulation 25(2)** sets out two circumstances when NHS England must refuse *excepted applications* for *distance-selling premises*.
85. **Regulation 25(2)(a)** requires NHS England to refuse applications if the premises to which the application relates are on the same site or in the same building as a provider of primary medical services with a patient list. This is one of the safeguards previously promised in connection with this type of application to avoid circumstances arising where patients of the provider of primary medical services inadvertently present prescriptions for dispensing at the pharmacy, even though such dispensing to patients on the site is not permitted.
86. The second reason for refusing such an application is where NHS England is not satisfied that the *pharmacy procedures* for the premises are likely to secure:
- the uninterrupted provision of *essential services* throughout the opening hours of the premises to persons anywhere in England who request those services (**Regulation 25(2)(b)(i)**); and
 - the safe and effective provision of *essential services* without face to face contact between any person receiving these services, whether on their own or on someone else's behalf, and the applicant or the applicant's staff (**Regulation 25(2)(b)(ii)**).

Distance-selling premises: conditions limiting service provision to distance selling

87. When considering an *excepted application* for *distance-selling premises*, **regulation 25(2)** sets two specific conditions that applications must meet. Once such applications are approved and the applicant is included in a pharmaceutical list, **regulation 64(3)** places further conditions on that inclusion. It also applies to applications for *distance-selling premises* that were approved under **regulation 13(1)(d)** of the 2005 Regulations.
88. These conditions remain even if the pharmacy successfully applies to relocate to new premises (**Regulation 64(2)(b)**). The conditions are:
- the contractor must not offer to provide *pharmaceutical services*, other than *directed services*, to persons who are present at the *listed chemist premises* (**Regulation 64(3)(a)**). For these purposes, a person is “present at” the premises if they are in the vicinity of those premises;
 - the means by which the contractor provides *pharmaceutical services*, other than *directed services* must be such that any person receiving those services does so otherwise than at the *listed chemist premises* (**Regulation 64(3)(b)**);
 - the *listed chemist premises* must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list (**Regulation 64(3)(c)**);
 - in the case of *pharmacy premises*, the *pharmacy procedures* (as required by section 72A(3) of the Medicines Act 1968⁵) for the premises must be such as to secure:
 - the uninterrupted provision of *essential services* during opening hours to persons anywhere in England who request those services; and
 - the safe and effective provision of *essential services* without face to face contact between any person receiving the services (whether it is on their own or on someone else’s behalf) and the contractor or the contractor’s staff (**Regulation 64(3)(d)**); and
 - there should be nothing in a distance selling contractor’s practice leaflet, publicity material, or in direct communications with patients to suggest that the *essential services* the contractor is supplying are for particular areas of England, i.e. are anything other than a nationwide operation. Also that they do not only dispense drugs or appliances ordered on NHS prescription forms or repeatable prescriptions presented by particular categories of patient. This is to ensure that the contractor provides *essential services* to all categories of patient and not, for example, that their business is tailored towards servicing care homes (**Regulation 64(3)(e)**).
89. NHS England may not vary or remove these conditions (**Regulation 64(4)**).

⁵ <http://www.legislation.gov.uk/ukpga/2006/28/section/30/prospective> as amended by SI 2006/2407

Conditions relating to directed services

90. Where the *excepted application* for *distance-selling premises* is made under the 2013 Regulations and as part of the application, the applicant undertakes:

- to provide the *directed services*, if NHS England commissioned them within three years, of the date the premises are included in a pharmaceutical list;
- if the *directed services* were commissioned by NHS England, 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 pharmaceutical list is subject to the condition set out in **regulation 66(5)**.

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

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

92. However, for the condition to apply, NHS England is required to commission the services within three years of the date on which the new premises are included in a pharmaceutical list.

93. The condition takes effect on the date which NHS England may, under **regulation 66(6)(a)** specify as the date on which service provision is to commence, or alternatively the date that NHS England and contractor can agree a mutually convenient commencement date for the *directed services* (**Regulation 66(6)(b)**), whichever is the sooner.

NHS England may not vary or remove the condition imposed by virtue of **regulations 66(3) to (5) (Regulation 66(7))**.

Notification, taking effect of decisions and rights of appeal

94. 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**).

95. 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 website⁶. 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.
96. 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

97. Once NHS England has made a decision on the *excepted application for distance-selling premises*, 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;
 - the relevant HWB, and if the applicant is relocating to different premises in the area of another HWB, the other HWB, and
 - 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**.
98. 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**).
99. If NHS England 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**).

⁶ <http://www.nhsla.com/ContactUs/>

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

100. 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**).
101. NHS England may wish to pre-populate the form where it holds the information.

Appeals to the Secretary of State by the applicant

102. **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 25**;
 - to refuse the application on some of the grounds set out in Part 5 (**regulations 30 and 31**) or;
 - to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**.
103. 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

104. **Paragraph 30(1) of Schedule 2** gives third party rights of appeal against certain NHS England decisions that are not fitness related. 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 NHSLA's FHSAU.

105. 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**).
106. **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.
107. 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**)
108. 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.
109. 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.

Example

Following notification of an *excepted application for distance-selling premises*, NHS England 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.

110. 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**).
111. 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 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 NHS England following notification of an appeal decision

112. 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**).
113. 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**).
114. 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**).

115. Generally, where the FHSAU grants or confirms the grant of an *excepted application*, NHS England must proceed as soon as is practicable to take such action under **regulation 50(4) or (5)** (postponement of the discontinuation of arrangements for the provision of *pharmaceutical services* by doctors) as it thinks fit, subject to any directions of the FHSAU given under **paragraph 9(2)(b) of Schedule 3**. However, these “gradualisation” arrangements do not apply where the new pharmacy premises are *distance-selling premises*, as the presence of *distance-selling premises* are discounted for the purposes of considering whether a patient can receive services from a dispensing doctor (see Chapter 15 for further information on this).

Taking effect of listing decisions: general

116. If the *excepted application* is granted, the applicant is required to submit a valid *notice of commencement* informing NHS England that they are to 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 its pharmaceutical list as the applicant is not obliged to open on such a day.

117. 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**)

118. 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.

119. 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 notice of NHS England’s decision to approve under paragraph 28 of Schedule 2 , unless the grant is appealed by a person with third party appeal rights, in which case the period starts on the date of determination of an unsuccessful appeal.
Refusal of the application was successfully appealed by the applicant	Date on which the FHS AU 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 on fitness to practise grounds) and that condition is appealed by the applicant to the FTT.	The applicant can temporarily accept the condition and open within the normal timeframes, but if it prefers, it can await the outcome of the decision of the FTT. If the FTT confirms NHS England’s decision or imposes a different condition, the applicant must within 30 days of being notified of the FTT’s decision, <i>notify</i> 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 (or won it on appeal), the six months starts at the date of the FTT’s decision.

120. 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**).
121. 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, then the grant of that application lapses (**paragraph 34(4) of Schedule 2**).
122. 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; or

- the applicant successfully appeals against NHS England’s decision not to allow a longer period under **paragraph 34(4)(c)(i) of Schedule 2**.
123. 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**).
124. Where NHS England 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**).
125. 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, 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 *distance-selling premises*. 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 FHSAU by a person with third party appeal rights. The template *notice of commencement* sent by NHS England ceases to have effect.

The FHSAU 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 FHSAU’s determination within which to open.