



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 10 – relocations that do not result in
significant change to pharmaceutical services
provision

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

1. This chapter deals with *excepted applications* submitted by contractors who wish to relocate to different premises either within the area of the relevant Health and Wellbeing Board (HWB) or to another HWB's area and the relocation would not result in significant change to *pharmaceutical services* or *local pharmaceutical services*. For these purposes, *pharmaceutical services* does not include dispensing services provided by dispensing doctors.

Introduction

2. Part 4 of the 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 to relocate to different premises fall within this category of applications where the move would not result in significant change to the arrangements that are in place for the provision of *pharmaceutical services* or *local pharmaceutical services*. They therefore differ from *routine applications* to relocate that would result in significant change and are to meet an identified need, improvement or better access (submitted under **regulation 12(b)(ii)**).
4. *Excepted applications* to relocate to new premises are required to meet certain criteria and these are listed in **regulation 24**. If an *excepted application* fails to meet any one of these criteria, it must be refused.
5. **Regulation 24** makes provision for the applications to relocate (that would not result in significant change) within the area of the relevant HWB (**Regulation 24(1)**) or to the area of a neighbouring HWB (**Regulation 24(2)**) that are not combined with a change of ownership, and also includes circumstances when NHS England must refuse such an *excepted application* (**Regulation 24(3)**).

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

6. Part 1 of Schedule 2 sets out the information that is to be provided in the application to NHS England. Some of the requirements relate to all applications, whereas others are for specific types of application.
7. When submitting an *excepted* application to relocate, the following information must be included (**paragraph 1 of Schedule 2**):
 - the name of the relevant HWB for the area where the application is made;
 - the type of application being made, for example, an application *to relocate* to new premises;
 - 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 pharmacist sole trader, their General Pharmaceutical Council (GPhC) registration number. A pharmacist does not have to provide their GPhC registration number if their business is as a dispensing appliance contractor (DAC) and not a pharmacy contractor;
 - if the applicant is a partnership, each partner's GPhC registration number². A pharmacist does not have to provide their GPhC registration number if their partnership is as a DAC and not a pharmacy contractor;
 - if the applicant is a body corporate for the purposes of Medicines Act registration, the name and GPhC registration number of the superintendent pharmacist. If the applicant is a DAC, they are not required to have a superintendent pharmacist;
 - with regards to the premises where the applicant wishes to relocate to:
 - the address of those premises;
 - whether the applicant is currently in possession of the premises;
 - the proposed *core opening hours* for the premises; and
 - the total proposed opening hours for the premises (i.e. both *core opening* and *supplementary opening hours*);
 - where the application includes the provision of *directed services* which are provided at the current premises:
 - details of the *directed services* to be provided;

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.

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- 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.

8. As contractors may only change their *core opening hours* following a successful application to NHS England, the *core opening hours* will be the same as those at the existing premises. If the applicant wishes to change their *core opening hours*, they would need to complete the relocation (if approved) and then submit an application to change their *core opening hours*.

Extended core hours

Regulation 65 sets out core opening hours conditions where:

- a pharmacy relocates its premises and was previously included in a pharmaceutical list under the 100 hours per week exemption – the pharmacy must continue to provide these 100 core hours (**regulation 65(1)-(3)**); and
- a pharmacy or appliance contractor is invited or wishes to provide *core opening hours* of more than 40 (or 30 for an appliance contractor) (**regulation 65(4)+(5)**). This may not be varied within three years of a direction being given by NHS England or previously a PCT (**regulation 65(7)**).

9. Similarly, the *supplementary opening hours* listed in the application will be the same as for the existing premises. If the applicant wishes to vary their *supplementary opening hours*, they would need to complete the relocation (if approved) and then notify of a change to their *supplementary opening hours*.
10. The applicant must confirm 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 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.
11. Where an applicant submits an *excepted application* for premises which are:
- already *listed chemist premises*; or
 - are adjacent to or in close proximity to *listed chemist premises*.

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

12. For an *excepted application* to relocate, **paragraph 8 of Schedule 2** requires the applicant to include details that explain:
- why they believe the application satisfies the criteria set out in **regulation 24(1)** or **(2)**; and
 - why the application should not be refused under **regulation 24(3)**(see the box below for further information on this).

Example

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

- that the pharmacy is not significantly less accessible to the patient groups that are accustomed to accessing *pharmaceutical services* at the current premises (see table below for more information on “patient groups”;
- why it will not cause a significant change to the arrangements for the provision of Local Pharmaceutical Services (LPS) or *pharmaceutical services* in any part of the area of the relevant HWB or in a *controlled locality* of a neighbouring HWB, where that *controlled locality* is within 1.6 km of the proposed premises;
- why it would not cause significant detriment to the proper planning of *pharmaceutical services* in the area of the relevant HWB;
- confirm that the applicant undertakes to provide the same services (whether or not, in the case of *enhanced services*, they will be commissioned); and
- whether there is to be an interruption of service, and if there is the reasoning for this and why this reasoning amounts to good cause.

In addition, they must explain why 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 existing pharmacy on that site should not be considered to be the same as the services that will be provided if the proposed relocation takes place.

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

13. In addition to the information required in **Paragraphs 1 to 6 and 8 of Schedule 2** applicants are required to provide the following undertakings:
- to notify 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;
 - the application is finally determined, be that by NHS England, or on appeal the FHS AU, 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 of another primary care organisation* (**paragraph 9(b) of Schedule 2**). This undertaking applies until whichever of the following events is the latest to take place:
 - the application is withdrawn;
 - the application is finally determined, be that by NHS England, or on appeal the FHS AU, 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 currently providing *directed services*, an undertaking:
 - that they will provide the *directed services* if NHS England commissions them within three years of the date the premises are listed in relation to the applicant 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**).

Directed services and relocations

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

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

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

14. The applicant is also required by **regulation 24(1)(e)** (relocations within the area of the relevant HWB) and **regulation 24(2)(e)** (relocations to a neighbouring HWB area) to undertake to provide the same services at the new premises as those they provide at the existing premises.
15. The obligation on the applicant to provide information or documentation required by **paragraphs 1 to 6 and 8 to 9 of Schedule 2** is only discharged if 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

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

Missing relevant information or documents

17. 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).
18. NHS England may make the request at any time between receiving and determining the *excepted application* to relocate, but it must consider whether or not it needs to request missing information or documentation prior to notifying the application as required by **paragraph 18 of Schedule 2 (paragraph 11(3) of Schedule 2)**. In the interests of

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19. 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.
20. 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**).
21. 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**).
22. 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**).
23. 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.
24. 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, the application is to be treated as withdrawn by the applicant (**paragraph 11(2)(b)(i) of Schedule 2**).
25. If following the review, it is determined that the information or documentation need not be provided, the original request made under **paragraph 11(1) of Schedule 2** is to be treated as withdrawn i.e. the applicant is not required to provide it (**paragraph 11(2)(b)(ii) of Schedule 2**).

Example

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

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

The 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.

Failure to provide undertakings

26. 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**).
27. 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**).

Excepted applications to relocate

28. There are two types of *excepted application* to relocate premises. The first is within the area of the relevant HWB and the second is to the neighbouring HWB area.

Relocations within the area of the relevant HWB

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

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Regulation 24(1) criteria	Explanation
<p><i>(a) for the patient groups that are accustomed to accessing pharmaceutical services at the existing premises, the location of the new premises is not significantly less accessible;</i></p>	<p>NHS England should consider whether the new premises are significantly less accessible for those patient groups who use the current premises or not.</p> <p>The term “patient group” reflects the requirement for HWBs, when developing their PNAs, to have regard to the demography of their area and the different needs of people in their area who share a <i>protected characteristic</i>, for example, a large travellers’ site, a large sheltered housing complex.. These are the characteristics such as age, sex and disability that form the basis of the public sector equality duty under the Equality Act 2010.</p> <p>When deciding whether the new premises are significantly less accessible, NHS England will need to consider whether there are any physical barriers or other geographical, transport or communication factors which would affect the accessibility of the new premises.</p> <p>Relocations should result in improved access for those patient groups who use the current premises. However there may be occasions where this may not be the case. For example, the lease on the premises is due to expire and the pharmacy has to secure new premises at short notice. In this instance, the pharmacy may have to move into premises that do not offer the same level of access as at the current site and NHS England will need to exercise its judgement and decide whether this reduction in access is significant or not.</p>

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<p><i>(b) in the opinion of NHS England, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—</i></p> <p><i>(i) in any part of the area of the relevant HWB, or</i></p> <p><i>(ii) in a controlled locality of a neighbouring HWB, where that controlled locality is within 1.6 kilometres of the premises to which the applicant is seeking to relocate;</i></p>	<p>Having looked at any impact on patient groups, NHS England will need to consider whether the relocation would impact on the arrangements that are in place for the provision of local pharmaceutical services and <i>pharmaceutical services</i> in any part of the area of the relevant HWB.</p> <p>NHS England would need to be satisfied that any impact would not result in a significant change taking into account the particular circumstances.</p> <p>It should be noted that it is not required to consider the impact on the provision of <i>pharmaceutical services</i> by persons on the dispensing doctor list. Additionally NHS England must consider the impact on <i>pharmaceutical services</i>, provided in a <i>controlled locality</i> of a neighbouring HWB where that <i>controlled locality</i> is within 1.6 km of the proposed new premises. This provision therefore looks at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision.</p>
<p><i>(c) NHS England is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in its area;</i></p>	<p>Finally, NHS England is required to examine whether the relocation would affect its planning of <i>pharmaceutical services</i> in its area.</p> <p>Example – NHS England decides to amalgamate a number of GP practices in a non-controlled locality at a new large health centre, decides to include a pharmacy in the centre and invites applications. A number of applications from potential occupants for the pharmacy site at the centre are considered and the particular pharmacy was one of the unsuccessful applicants. As an alternative, the particular pharmacy attempts to relocate to a site nearer to the centre – and if that application was granted, it would compromise the viability of the plans for <i>pharmaceutical services</i> at the centre that NHS England has put in place. In these circumstances, NHS England could refuse the application on the basis of detriment to proper planning.</p>
<p><i>(d) the services the applicant undertakes to provide at the new</i></p>	<p>The applicant is obliged to undertake to provide the same services at the new premises. If the application is approved, the applicant would be required to provide <i>essential</i></p>

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

30. The following table sets out the criteria for relocations to a neighbouring HWB area (**Regulation 24(2)**) along with an explanation of each. The first three criteria look at the impact of the relocation at different levels:
- the impact on patient groups (**Regulation 24(2)(b)**);
 - the impact on the provision of local pharmaceutical services and *pharmaceutical services* (but not on the provision of such services by persons on the dispensing doctor list) in the area of a neighbouring HWB or in a *controlled locality* of a neighbouring HWB area (including the original relevant HWB area) that is within 1.6 km of the proposed premises (**Regulation 24(2)(c)**);
 - the impact on NHS England's planning for the provision of *pharmaceutical services* in its area (**Regulation 24(2)(d)**).
31. Throughout the explanations, HWB2 is the neighbouring HWB area into whose area the pharmacy wishes to relocate.

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

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	<p>same level of access as at the current site and NHS England will need to exercise its judgement and decide whether this reduction in access is significant or not.</p> <p>Example – a pharmacy is located on one side of a road which is the boundary between two HWB areas. The pharmacist applies to relocate across the road to a neighbouring HWB area and undertakes to provide the same services. There is a zebra crossing outside the new premises which are easy to access from the pavement. NHS England is therefore satisfied that the location of the new premises is as accessible as the current premises and approves the application. Conversely, if the road is a major arterial route which can only be crossed with difficulty, NHS England may not be so satisfied.</p>
<p><i>(c) in the opinion of NHS England, granting the application would not result in a significant change to the arrangements that are in place for the provision of local pharmaceutical services or of pharmaceutical services other than those provided by a person on a dispensing doctor list—</i></p> <p><i>(i) in any part of the area of a neighbouring HWB; or</i></p> <p><i>(ii) in a controlled locality of a neighbouring HWB (including the original HWB area), where that controlled locality is within 1.6 kilometres of P2;</i></p>	<p>Having looked at any impact on patient groups, NHS England will then need to consider whether the relocation would impact on the arrangements that are in place for the provision of local pharmaceutical services and <i>pharmaceutical services</i> in any part of the relevant HWB area.</p> <p>NHS England would need to be satisfied that any impact would not result in a significant change taking into account the particular circumstances.</p> <p>NHS England should note that they are not required to consider the impact on the provision of <i>pharmaceutical services</i> by persons on the dispensing doctor list.</p>

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	<p>Additionally NHS England must consider the impact on <i>pharmaceutical services</i>, provided in a <i>controlled locality</i> of the area of a neighbouring HWB (which could include the HWB area from where the applicant wishes to relocate) where that <i>controlled locality</i> is within 1.6 km of the proposed new premises.</p> <p>This provision therefore looks at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision.</p> <p>Example – a pharmacy is located on one side of a road which is the boundary between two HWB areas. The pharmacist applies to relocate across the road to a neighbouring HWB area and undertakes to provide the same services. There are no other pharmacies in the vicinity. As there would be no change to the arrangements in place for the provision of <i>pharmaceutical services</i>, NHS England approves the application.</p>
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<p><i>(d) NHS England is satisfied that granting the application would not cause significant detriment to proper planning in respect of the provision of pharmaceutical services in the area of the relevant HWB;</i></p>	<p>Finally, NHS England is required to examine whether the relocation would affect its planning of <i>pharmaceutical services</i> in its area.</p> <p>Example – NHS England receives a <i>routine application</i> to meet an identified current need and decides under regulation 14(1) to defer that <i>routine application</i> and invite other applications to meet that same need for a new pharmacy offering a range of <i>essential</i> and <i>directed services</i> in that locality. NHS England receives no other applications and approves the initial <i>routine application</i>. NHS England then receives an <i>excepted application</i> from a pharmacy just over the border in a neighbouring HWB area to relocate close to the premises for which it had just approved the <i>routine application</i>. NHS England decides to refuse the <i>excepted application</i> to relocate as it would cause significant detriment to its proper planning for <i>pharmaceutical services</i>.</p>
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<p><i>(e) the services the applicant undertakes to provide at P2 are the same as the services the applicant has been providing at P1 (whether or not, in the case of enhanced services, NHS England chooses to commission them);</i></p>	<p>The applicant is obliged to undertake to provide the same services at the new premises. If the application is approved, the applicant would be required to provide <i>essential services</i>. They would also be required to continue to provide <i>advanced services</i> and any <i>enhanced services</i> they were providing at the old premises if NHS England chooses to commission them at the new premises. This gives NHS England the flexibility to commission only the <i>enhanced services</i> that are required.</p> <p>The applicant would also be required to be open for the same core and supplementary hours at the new premises. Once the relocation is complete, they could then apply to NHS England to change their <i>core opening hours</i>, or <i>notify</i> of a change in <i>supplementary opening hours</i>.</p> <p>NHS England cannot however, require the contractor to provide additional <i>directed services</i> as a condition of granting the relocation application; they can only require the current <i>directed services</i> to be provided at the new premises.</p> <p>Example - a pharmacy wishes to relocate from the area of HWB1 to the area of HWB2. The pharmacy is commissioned to provide emergency hormonal contraception at its current premises by NHS England and undertakes to do so at the new premises. However, NHS England does not commission that service in the area to which the pharmacy wishes to relocate. The pharmacy has fulfilled its obligation under this regulation by undertaking to provide the service, but is not required to do so because NHS England does not commission it.</p>
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<p><i>(f) the provision of pharmaceutical services will not be interrupted (except for such period as NHS England may for good cause allow);</i></p>	<p>NHS England must be satisfied that the provision of <i>pharmaceutical services</i> will not be interrupted, except for such period as it may for “good cause” allow.</p> <p>What constitutes “good cause” is ultimately for NHS England to assess on the facts of the case. For example, there may be a temporary delay in handing over the premises to the new leaseholder. Alternatively, the applicant may request a short interruption to transfer stock and supplies from the old to the new premises and test computer systems etc before opening and NHS England may decide that this is good cause for service provision to be interrupted.</p>
<p><i>(g) the applicant consents to—</i></p> <p><i>(i) where the applicant has only one set of listed chemist premises in the pharmaceutical list for the area of the HWB, the removal of the applicant’s name from that pharmaceutical list, or</i></p> <p><i>(ii) where the applicant has more than one set of listed chemist premises in the pharmaceutical list, the removal of P1 from being listed in relation to the applicant in that pharmaceutical list,</i></p> <p><i>with effect from the date on which the applicant undertakes to provide pharmaceutical services from P2.</i></p>	<p>The final criterion for NHS England to consider is the applicant’s consent to the removal of its existing premises (P1) from a pharmaceutical list for the original relevant HWB area. Where this consent is withheld or not given by the applicant, then the application cannot be finally determined.</p> <p>Clarity is provided as to which set of premises are to be removed from a pharmaceutical list for the relevant HWB area where the applicant has multiple premises included in that list.</p>

Notification

32. Once all the above preliminary checks are completed, NHS England may then move on to give *notice* of the *excepted application* to relocate to new premises.
33. NHS England must give *notice* of the *excepted application* to relocate 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**).
34. 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**).
35. It is recommended that NHS England records its reasoning for why it believes persons have a significant interest in the outcome of the application.

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36. 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 were 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* to relocate and after completing its preliminary checks is ready to notify it as required by **paragraph 19 of Schedule 2**. The application is for premises on the outskirts of a town and is within 1 km of a *controlled locality*. Using the Exeter system, 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 the 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.

37. 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

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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**).

Possible need for parallel notifications

38. There may be occasions where an *excepted application* to relocate will result in a pharmacy moving into an area that is or may be a *controlled locality*. It should be noted that the two grounds for refusing applications in Part 7 of the 2013 Regulations – the “5 year rule” in **regulation 40** and the “prejudice test” in **regulation 44** – do not apply to determinations of *excepted applications*. Accordingly, NHS England is not required under **regulation 38(4)** to defer consideration of *excepted applications* to locate pharmacies in areas that are, or might become, *controlled localities*. If the area in question is the subject of a process for determining whether or not it is a *controlled locality*, it is advisable to keep the two notifications separate so as not to unintentionally misrepresent to those who are notified that the decisions are linked. See chapter 14 for further information on *controlled localities*.
39. Similarly, it is possible that NHS England may receive an *excepted application* for a relocation that, if the application were a *routine application*, would result in consideration of whether or not the proposed premises are within a *reserved location*. However, the rules relating to *reserved locations* only apply in relation to new premises that are included in a pharmaceutical list as a consequence of a *routine application*. If a relocation application is granted under **regulation 25** and the new premises are within 1.6 km of *medical practice premises* of a *dispensing doctor*, the rules on “gradualisation” in **regulation 50(3)** will however apply. See chapter 14 for further information on *reserved locations*.
40. If NHS England wishes to consider two or more applications together and in relation to each other, for example, where it has deferred a *routine application* to consider it alongside an *excepted application* to relocate, it is required by **paragraph 22(3) of Schedule 2** to give *notice* of its intention to do so.

Content of notifications

41. **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

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- 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**)
42. 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 the PNA with the notification letter (**paragraph 21(2) of Schedule 2**).
43. NHS England must not send any private personal information provided by the applicant under **paragraphs 3 and 4**, where relevant (**paragraph 21(3) of Schedule 2**). This includes any private addresses, private telephone numbers or dates of birth that may have been supplied.
44. 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**).

45. 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.

Determination and deferral of applications

Flexibility with regard to determining or deferring applications

46. NHS England is able to determine an *excepted application* to relocate as it sees fit, unless the Regulations provide to the contrary (**paragraph 22(1) of Schedule 2**). An example of this is **paragraph 26 of Schedule 2** which sets out who cannot take part in the decision-making process.
47. 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.
48. 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

49. 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.
50. If NHS England decides to hear oral representations prior to determining an *excepted application* to relocate then it must:
 - give the applicant and any *additional presenters* not less than 14 days *notice* of the time and place for the oral hearing; and
 - advise the applicant who else has been invited to make representations at the hearing. This may include other applicants where NHS England has decided to determine two or more applications together (**paragraph 25(1) of Schedule 2**)

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51. **Paragraph 25(2) of Schedule 2** defines a person as an *additional presenter* if:
- the application to which the hearing applies is a *notifiable application* (which *excepted applications* to relocate are);
 - they were given *notice* of the application and made representations in accordance with **paragraph 19(4)**. As part of the representations the person must have indicated that they would wish to make oral representations if an oral hearing took place, and they must have identified a matter about which NHS England considers it would be desirable to hear further evidence about 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.
52. 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.
53. 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

54. **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

55. **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 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**).

56. The only exceptions to this timescale are:

- where the application is deferred in accordance with a provision of the Regulations, for example fitness to practise reasons such as an ongoing investigation for fraud; or
- there is good cause for the delay, for example where the application is deficient i.e. there is missing relevant information or documentation. In this case the four month time period initially starts at the point the application is received. It then stops at the point NHS England discovers it is deficient e.g. not all the relevant information or documentation is received. It then restarts at the point all the relevant information or documentation is received.

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

Example

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

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

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

Refusal: same or adjacent premises

58. Where the premises within an *excepted application* to relocate 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**.

59. NHS England must refuse an *excepted application* to relocate 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)**).

60. 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 excepted applications to relocate

61. **Regulation 24(3)** provides for three specific situations where NHS England must refuse to approve an *excepted application* to relocate.

62. The first of these is pharmacies that successfully applied under **regulation 13(1)(a)** of the 2005 Regulations and were included in a pharmaceutical list on the basis of that exemption, namely pharmacies in approved retail areas that fell within **regulation 15** of those Regulations. **Regulation 24(3)(a)** requires NHS England to refuse *excepted applications* from such pharmacies wishing to relocate outside of the approved retail area.

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63. The second situation relates to exempt applications successfully made under **regulation 13(1)(c)** of the 2005 Regulations, namely premises which are in a new one stop primary care centre (within the definition of **regulation 16** of those Regulations). **Regulation 24(3)(b)** requires NHS England to refuse *excepted applications* from such pharmacies wishing to relocate unless the following criteria are met:
- i. the provider or providers of primary medical services at the one stop primary care centre are relocating with the applicant to a new discrete site or building,
 - ii. at that new discrete site or building primary medical services are or will be provided by one or more providers of primary medical services with a patient list of, or patients lists with a combined total of 18,000 patients, and
 - iii. at that site or building the services of a broad range of health care professionals are or will be regularly and frequently provided (together with other health and social services where appropriate).
64. **Regulation 24(3)(b)** therefore ensures that pharmacies that had previously been included in a pharmaceutical list under **regulation 13(1)(c)** of the 2005 Regulations remain under the same conditions as at the point they were included in a pharmaceutical list.
65. Once an *excepted application* to relocate has been granted under the 2013 Regulations, **regulation 24(3)(c)** requires the applicant to trade for a minimum period of 12 months from the new premises before any further *excepted application* for a relocation can be made unless NHS England for good cause allows the applicant do so before the end of that period, for example on grounds of health and safety, or because the pharmacy temporarily relocated to premises while the original premises were being upgraded and the return to those premises was part of the planned refurbishment.
66. It should be noted that the onus is on the applicant to demonstrate good cause within their application (**Regulation 24(3)(c)(iii)**).

The minimum period of 12 months in **regulation 24(3)(c)** also applies to pharmacies who may have relocated under the minor relocation provisions in either **regulation 6** or **7** of the 2005 Regulations or **regulation 24** of the 2012 Regulations.

Conditions relating to directed services

67. Where the *excepted application* for a relocation is made under the 2013 Regulations and as part of the application, the applicant undertakes:

- to provide the *directed services* it has been providing at the old premises, 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 a pharmaceutical list is subject to the condition set out in **regulation 66(5)**.

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

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

69. However, 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.

70. NHS England may, under **regulation 66(6)(a)** specify a date on which service provision is to commence, or alternatively 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)**.

Example

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

- minor ailments; and
- witnessed methadone consumption and needle exchange.

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

- out of hours

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

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

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

Postponement of the discontinuation of provision of pharmaceutical services by doctors

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

Notification, taking effect of decisions and rights of appeal

72. 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(3)(b) of Schedule 2**).

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73. 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 website³.
74. 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

75. Once NHS England has made a decision on the *excepted application* to relocate, it must, as soon as is practicable, notify certain persons of its decision (**paragraph 28(3) of Schedule 2**). Those persons are:
- the applicant;
 - 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 person notified under **paragraph 19** (other persons who in the opinion of NHS England have a significant interest in the outcome of the application) who made representations about the application under **paragraph 19(4) of Schedule 2**.
76. 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**).
77. 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

³ <http://www.nhs.uk/ContactUs/>

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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

78. 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**).
79. NHS England may wish to pre-populate the form where it holds the information.

Appeals to the Secretary of State by the applicant

80. **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 FHS AU. The applicant may appeal to the FHS AU against a decision by NHS England:
- to refuse the application on grounds set out in **regulation 24**;
 - to refuse the application on grounds set out **regulation 31** (refusal same or adjacent premises) of the 2013 Regulations;
 - to refuse a request for an extension to the period within which to open under **paragraph 34(4)(c)(i) of Schedule 2**; or
81. 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

82. **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.

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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.

83. 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**).
84. **Paragraph 30(2)** confirms that for the purposes of **Schedule 2** a person has third party rights of appeal if they were entitled to receive notification of the decision to grant the application by virtue of **paragraph 28(5) of Schedule 2** – i.e. they were notified because their application was considered together and in relation to the application to which the decision letter relates.
85. 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**)
86. 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 carefully consider to whom it gives third party appeal rights and should not give them to persons who did not make a reasonable attempt to express their grounds for opposing the application.
87. Third party rights of appeal may not be given to LPCs, LMCs, LPS chemists, GPs, Healthwatch or other patient, consumer or community groups.

Example

Following notification of an *excepted application* to relocate NHS England receives a number of responses. Several responses did not indicate whether or not they supported the application. Such persons are not given third party rights of appeal as they have not attempted to express their grounds for opposing the application, and indeed have not indicated whether they oppose or support the application.

88. Where 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**).
89. 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

90. 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**).
91. 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**).
92. 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**).
93. If the FHS AU 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)**

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(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**. (See Chapter 15 for further information on this).

Taking effect of listing decisions: general

94. 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.
95. 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**)
96. 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.
97. 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 FHSAU determines the appeal.

98. 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**).

99. 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**).
100. 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**.
101. 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**).
102. 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**).
103. 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* to relocate. It issues its decision and template *notice of commencement* to the applicant. It issues its decision to interested parties as required by **paragraph 28 of Schedule 2**.

An appeal against 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 open.