



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 15 – dispensing doctors provision

Contents

Contents.....	2
Chapter 15: Dispensing doctors service provision	3
Introduction.....	3
Approval to provide pharmaceutical services – pre 1983	4
Approval to provide pharmaceutical services – post 1983.....	5
Dispensing doctor lists.....	5
Terms of service of dispensing doctors	8
Persons barred from taking part in decision making on applications submitted under Part 8...	9
Applications by patients.....	9
Discontinuation of arrangements to provide pharmaceutical services.....	12
Preliminary matters following receipt of an application for outline consent and premises approval.....	17
Notification of applications for outline consent and premises approval	17
Applications by doctors for outline consent and premises approval - refusal	21
Decisions on outline consent and premises approval applications.....	21
Taking effect of decisions on outline consent and premises approval applications	22
Premises approval – relocations which are not significant before outline consent takes place	26
Premises approval – relocations which are not significant after outline consent has taken effect.....	27
Taking effect of premises approval where there is no related application for outline consent	30
Gradual introduction of premises approval	32
Temporary provision in cases of relocations or additional premises where premises approval has not taken effect.....	34
Practice amalgamations	35
Lapse of outline consent and premises approval	37
Appeals against decisions	38

Chapter 15: Dispensing doctors service provision

Summary of Chapter

- For the purposes of this chapter, the term *pharmaceutical services*, used in the context of the provision of services by a medical practitioner, means the dispensing of drugs and appliances, but not the other *pharmaceutical services* that contractors on a pharmaceutical list could provide.
- Chapter 14 gives further information on *controlled localities* and *reserved locations* and should be read in conjunction with this chapter.

1. This chapter deals with the provision of *pharmaceutical services* by *dispensing doctors*. Regulations governing how doctors may be approved to provide *pharmaceutical services* are set out in Part 8 of the 2012 Regulations. Schedule 6 sets out the terms of service for *dispensing doctors*.

Introduction

2. Dispensing by doctors has been subject to regulations since at least the 1920s and probably since the First World War. Provision for doctors to provide *pharmaceutical services* in certain circumstances has been made in various NHS Acts and Regulations ever since. These circumstances are in summary:
 - a patient satisfies NHS England or a predecessor organisation that they would have serious difficulty in obtaining any necessary drugs or appliances from an *NHS pharmacist* by reason of distance or inadequacy of means of communication (colloquially known as the “serious difficulty” test which can apply anywhere in the country); or
 - a patient is resident in an area which is rural in character, known as a *controlled locality*, at a distance of more than one mile¹ (1.6 km) from *pharmacy premises* (excluding any *distance selling premises*). The *pharmacy premises* do not have to be in a *controlled locality*.

¹ This distance progressively reduced from 2 miles to 1 mile over the years.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

3. The Regulations have been amended and expanded over time with significant amendments being made in 1983, 1992 and 2005. Doctors may therefore have been approved to provide *pharmaceutical services* under one of several sets of Regulations.
4. The terms of service for doctors who have been approved to provide *pharmaceutical services* under the Pharmaceutical Services Regulations are set out in Schedule 6. Their terms of service differ from those of pharmacy and appliance contractors, but under the 2013 Regulations all three types of contractors provide *pharmaceutical services*.
5. NHS England should have records of the applications that have been made by doctors, and these records should also show the area or areas that each doctor has been approved to dispense to. However, it is recognised that these may not be easily accessed or may have been misplaced over time. It is therefore recommended that where NHS England has incomplete records that it works with the LMC, LPC and practices in the relevant Health and Wellbeing Board (HWB) area in order to establish when doctors were approved, under which set of Regulations and to which area or areas they may provide *pharmaceutical services* to.

Approval to provide pharmaceutical services – pre 1983

6. Those doctors who were providing services prior to 1 April 1983 have what has become known as “historic rights” to provide drugs or appliances. They were approved by the Family Practitioners Committee (FPC) to provide *pharmaceutical services* to patients:
 - who either satisfied the serious difficulty test; or
 - who lived in an area which in the FPC’s opinion was rural in character, more than one mile from the premises of any chemist.
7. NHS England should be able to identify those doctors with historic rights and should have records showing the areas to which the FPC approved them to provide *pharmaceutical services*. This is important as any patient living in one of these areas and who registered with the practice from 1 April 1983 onwards will have to meet additional criteria set out in **regulation 48(3)(b)(ii)**. [NHS England should therefore ensure their procedures include a requirement to check that new patients are indeed eligible to receive *pharmaceutical services*.] Practices which have historic rights to dispense will also wish to ensure that they check patient eligibility before requesting approval to provide *pharmaceutical services*.
8. Should the doctor wish to dispense to patients living in areas other than those for which they were approved to provide services to by the FPC, they will have to apply to NHS England for *outline consent* and *premises approval* (see below).

Approval to provide pharmaceutical services – post 1983

9. From 1 April 1983 when patients living in *controlled localities* requested their doctor to provide them with *pharmaceutical services*, the doctor would have had to apply for *outline consent* (unless the doctor had a historic right to dispense to that area and the patient fell within certain criteria). The doctor would have also had to specify within the application the area to which they wished *outline consent* to be granted to. NHS England should therefore have records of these areas.
10. From 1 April 2005, all doctors were required to have approval from NHS England for those premises at which they wish to provide *pharmaceutical services*. This applied to all doctors providing *pharmaceutical services* irrespective of which Regulations they were granted approval to do so. The requirement for *premises approval* does not however require the premises to meet any particular standards, and such premises are not required to be registered with the General Pharmaceutical Council.
11. Approval to provide *pharmaceutical services* was still granted to individual GPs, but if there were other GPs working at the approved GP's practice, those other doctors were also entitled to provide dispensing services to the patients to whom the approved GP could provide those services. Should, however, any of these other GPs leave the practice they were not able to take the right to provide *pharmaceutical services* with them. This right remained with the approved GP. The option of practice-based listing was introduced in the 2013 Regulations.
12. Throughout the Regulations and this guidance, the term “provider” is used to describe the signatories to a primary medical services contract with NHS England.

Dispensing doctor lists

13. NHS England must prepare and publish a list of any *dispensing doctors* in the relevant HWB area (**Regulation 46(1)**). This will generally include doctors who are signatories to general medical services (GMS), personal medical services (PMS) or alternative provider medical services (APMS) contracts. However, it may also include doctors who are not *providers of primary medical services*, but who provide *pharmaceutical services* from premises in the relevant HWB area. Primary medical services is the collective term for the provision of services under one of these contracts by a GP and is used throughout the Regulations and this guidance.
14. Each *dispensing doctor list* must include the following information:
 - the address of any premises within the relevant HWB area for which the *dispensing doctor* has *premises approval*, or if the doctor does not have *premises approval* (for

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

example they are a salaried GP), the address of the premises from which they perform or provide primary medical services; and

- any area in relation to which the *dispensing doctor* has *outline consent* to dispense. Where a doctor has historic rights to dispense, they will not necessarily have such an area, as they will not have applied for *outline consent* for the areas covered by the historic rights. However, even if they have areas for which they have historic rights to dispense, they may also have been granted *outline consent* for additional areas or indeed for the historic rights area (in the latter case so that they can dispense to a wider range of patients in that area than their historic rights will permit).

(Regulation 46(2))

15. NHS England must remove a *dispensing doctor* from its list if any of the following occur:
 - in the case of a provider, if the doctor or their partnership ceases to be a *provider of primary medical services*, or ceases to be a provider of those services to NHS England i.e. their primary medical services contract with NHS England comes to an end;
 - in the case of an individual doctor, where they are no longer on a medical performers list or no longer performs primary medical services within the relevant HWB area; or
 - more than six months have elapsed since the doctor or their *provider of primary medical services* last provided drugs or appliances as part of the arrangements with NHS England to provide *pharmaceutical services* i.e. they have stopped providing *pharmaceutical services* to the practice's registered patients (**Regulation 46(3)**).
16. **Regulation 46(4)** gives the doctors within a practice the choice of whether they wish to be included in the *dispensing doctors list* as a practice or as individuals. If only one doctor within the practice is on the *dispensing doctors list*, the choice is that doctor's, but if more than one doctor is on the list, all the listed doctors have to agree. Should a practice wish to be included as a provider, they may request this in writing.
17. NHS England is required to agree to the request, and the arrangements NHS England had with the individual doctor or doctors become instead arrangements with the practice. Additionally, the related *outline consent(s)* and *premises approval(s)* of that doctor or those doctors become the *premises approval(s)* and *outline consent(s)* of the provider (**Regulation 46(5)**).
18. Where a practice is listed in the *dispensing doctors list*, the practice must notify NHS England:
 - of any GP who is employed by the practice to perform primary medical services and who will also perform *pharmaceutical services*; and
 - when such a GP no longer performs *pharmaceutical services* for the practice (**Regulation 46(6)(a)**).

19. NHS England must include all the names of any GP notified to them in a *dispensing doctor list*, as part of the listing for the practice, until such time as it is advised that a GP is no longer performing *pharmaceutical services* for the practice (**Regulation 46(6)(b)**). The list remains essentially a list of names of individual names, even though it has become possible to have a practice listing.

Example

Doctors Smith, Jones and Taylor are partners at a practice and employ Dr Wells as a salaried GP. The partners have all previously been approved by NHS England to provide *pharmaceutical services* and all four doctors are currently listed in a *dispensing doctor list* for the relevant HWB area. They agree that they would like to be included in the list as the practice which is known as High Street Medical Centre. The practice and Dr Wells write collectively to NHS England and request this change, providing all four names as required by **regulation 46(6)(a)(i)**.

NHS England includes the practice, High Street Medical Centre, on the relevant *dispensing doctor list* and lists Dr Wells as part of the practice entry. A *dispensing doctor list* records this as:

High Street Medical Centre, Medical Way, Makeyouwell.

Dr Smith

Dr Jones

Dr Taylor

Dr Wells

Area for which *outline consent* has been granted – the village of Makeyouwell. Bounded to the east and south by the river Babblebrook, to the north by the A999 and to the west by the railway.

Six months later Dr Wells leaves the practice and Dr Hill joins as a salaried GP. The practice notifies NHS England who amends a *dispensing doctor list* to remove Dr Wells and add Dr Hill. Dr Wells is removed, even if he/she continues to be a performer of primary medical services in the relevant HWB area. Ten months later Dr Smith retires from the practice and the practice notifies NHS England of his/her retirement.

Terms of service of dispensing doctors

20. NHS England is required to ensure that the arrangements under which a *dispensing doctor* undertakes to provide *pharmaceutical services* are to include any provisions affecting their rights and obligations that -
- are included in the 2013 Regulations including:
 - the terms of service set out in Schedule 6;
 - any obligation that is only applicable in prescribed cases, if the *dispensing doctor* is a person to whom the obligation is applicable²;
 - were imposed by virtue of regulation 20(2) of the 2005 Regulations and regulation 50(2) of the 2012 Regulations³;
 - are included in the determinations of remuneration for services provided by *dispensing doctors* referred to in **regulation 92**, in so far as those rights and obligations are applicable in the case of the *dispensing doctor*⁴;
 - are included in regulation 3 of the Local Involvement Networks (Duty of Services-Providers to Allow Entry) Regulations 2008 [**DN: updated?**] in so far as it applies to the *dispensing doctor* (**Regulation 47(1)**).
21. The above all form the terms of service for the doctor's practice and NHS England must ensure that they are all included in the relevant primary medical services contract (**Regulation 47(2)(a)**). In the case of a doctor who does not have such a contract, NHS England must ensure that they are enforced under the contract it holds with the practice that the doctor works for (**Regulation 47(2)(b)**). If the doctor works at a PCTMS practice, the above are to be terms of service of the arrangements under which that practice provides primary medical services.

² An example of this is where under regulation 50(2) NHS England postpones the termination of arrangements for the provision of *pharmaceutical services* for a period of time following the opening of a pharmacy in a *controlled locality*. In this instance, it is only the *dispensing doctors* with patients living within 1.6 km of those premises that are affected, and only for a certain period of time.

³ This is similar to Regulation 50(2) - conditions to postpone the making or termination of arrangements for the provision of *pharmaceutical services* by the doctor

⁴ This requirement makes the remuneration terms in the GMS Statement of Financial Entitlement terms of service for all *dispensing doctors* irrespective of whether they have a GMS contract or a PMS or APMS agreement.

Persons barred from taking part in decision making on applications submitted under Part 8

22. **Regulation 62** sets out a list of persons who may take no part in determining or deferring any application under Part 8. Further information on this can be found in Chapter 3.

Applications by patients

23. Any application from a doctor to provide *pharmaceutical services* or to vary the area to which they provide such services must be in response to a patient requesting them to provide such services. There is no provision within the Regulations for doctors to simply apply to provide *pharmaceutical services*.
24. A patient may at any time request in writing that a doctor provides them with *pharmaceutical services*. However, the patient must meet one or more of the three conditions set out in **regulation 48(2) to (4)** and they must be on the doctor's patient list, or the patient list of the practice at which the doctor provides or performs primary medical services (i.e. the doctor is either a partner at the practice, or is employed or engaged by the practice) (**Regulation 48(1)**).
25. Condition 1 is that the patient satisfies NHS England with whom the doctor has the relevant contract that they would have serious difficulty in obtaining any necessary drugs or appliances from *pharmacy premises* because of distance or inadequacy of means of communication (**Regulation 48(2)**). Lack of transport is not a reason to approve an application under this regulation.
26. Condition 2 is that the patient lives in a *controlled locality* at a distance of more than 1.6 km from any *pharmacy premises* (with the exception of *distance selling premises*) and the doctor has *outline consent* and *premises approval* for the premises from which they would provide services from (**Regulation 48(3)(a)**).
27. If the doctor or the practice has historic rights and the patient needs to rely on those (**Regulation 48(3)(b)(i)**), as well as living in a *controlled locality* at a distance of more than 1.6 km from any *pharmacy premises* (with the exception of *distance selling premises*) the patient must meet one of the following criteria (**Regulation 48(3)(b)(ii)**):
- they have not previously been included in a patient list in the relevant HWB area, for example babies; or
 - they have been so included but have changed their address in the meantime; or
 - have not changed their address but immediately before joining the doctor's list they were being provided with *pharmaceutical services* by another doctor under arrangements with NHS England.

28. Additionally, there must be *premises approval* in effect in relation to the premises from which the doctor plans to provide *pharmaceutical services* to the patient (**Regulation 48(3)(b)(iii)**). This condition applies whether the patient is relying on *outline consent* or historic rights.
29. For practices with historic rights, NHS England should ensure that all three strands of Condition 2 set out in **regulation 48(3)(b)** are met. It is therefore important that records of when doctors were approved to provide *pharmaceutical services* are maintained and easily accessible.

Example

Mrs Smith moves from London to a Hertfordshire village in a *controlled locality*. The nearest pharmacy is 5 km away so she asks her doctor to provide her with *pharmaceutical services*. Her doctor was granted *outline consent* to provide *pharmaceutical services* to the village in which Mrs Smith lives in 1988 and was granted *premises approval* for his medical premises in 2005. Mrs Smith therefore meets the requirements of Condition 2 – she lives in a *controlled locality*, more than 1.6 km from a pharmacy, her doctor has *outline consent* to provide *pharmaceutical services* and has had *premises approval* since 2005.

Mrs Smith subsequently changes to another practice which has historic rights and *premises approval*. That practice can also provide her with *pharmaceutical services* because although Mrs Smith has not changed her address, she received such services from her previous GP.

Mr Hall lives next door to Mrs Smith and he decides to change his practice and register at the same practice as Mrs Smith. However, his previous doctor did not provide *pharmaceutical services*. Mr Hall would not be able to receive *pharmaceutical services* as he has previously been included in a practice list in the relevant area of the HWB, has not changed his address and was not receiving *pharmaceutical services* from his previous practice.

30. Condition 3 is that the patient is resident in a *controlled locality* and within a distance of 1.6 km of a pharmacy (excluding *distance selling premises*), but they are resident in a *reserved location* and either **regulation 48(3)(a)** or **(b)** is satisfied.
31. Where a doctor receives an application from a registered patient, they must apply in writing, enclosing a copy of the patient's request, to NHS England (**Regulation 48(5)(a)**) for approval to provide *pharmaceutical services* to the patient.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

32. NHS England must then make arrangements with the doctor to provide *pharmaceutical services* either from their *medical practice premises* (where Condition 1 applies i.e. a serious difficulty application), or from their *listed dispensing premises* (in the case of an application to which Condition 2 or 3 applies i.e. the doctor has already been approved to provide *pharmaceutical services*) (**Regulation 48(5)(a)(i) and (ii)**). These arrangements take effect from the date of the patient's written request (**Regulation 48(7)(a)**).
33. If the doctor does not respond to the patient's request within 30 days, NHS England may require the doctor to undertake to provide *pharmaceutical services* to the patient. NHS England should give notice to this effect and give reasonable notice of when the requirement is to take effect (**Regulation 48(5)(b)**).
34. **Regulation 48(9)** requires the *notice* to include explanation of:
- the reasons for the imposition of the requirement; and
 - the doctor's right of appeal under **regulation 63(1)(a)** to the FHSU.
35. If the *notice* does not include this explanation then it is not valid.
36. Information on the FHSU's contact details including address, e-mail and fax and telephone numbers can be found on the NHSLA's website⁵
37. In order to be valid the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).
38. NHS England must not require a doctor to provide *pharmaceutical services* to the patient if the doctor satisfies NHS England that:
- they do not normally provide *pharmaceutical services*; or
 - the patient would not have serious difficulty in obtaining *pharmaceutical services* from a pharmacy by reason of distance or inadequacy of means of communication (**Regulation 48(6)**)
39. These arrangements take effect from the date specified in NHS England's *notice*, unless the doctor appeals in which case they take effect from the date on which the appeal reaches its final outcome, if unsuccessful (**Regulation 48(7)(b)**).

⁵ <http://www.nhsla.com/ContactUs/>

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

40. **Regulation 48(8)** requires the provision of services to continue for as long as the arrangements remain in place. Where the arrangements are with a GP practice, any doctor performing primary medical services on behalf of that practice may also provide *pharmaceutical services* to that patient (**Regulation 48(8)(a)**). Where the arrangements are with an individual doctor who performs primary medical services on behalf of a GP practice, that doctor or any other doctor who performs primary medical services on behalf of that practice may provide *pharmaceutical services* to the patient (**Regulation 48(8)(b)**).
41. Where a doctor provides *pharmaceutical services* to patients on their registered list, they may also provide such services, where it is necessary to do so, to persons who have been taken on as temporary patients (**Regulation 49**).
42. Where a new patient does not request a doctor to provide them with *pharmaceutical services* when they apply to join the practice but subsequently wishes to do so, they can do so providing they meet one or more of the conditions set out in **regulation 48(2) to (4)**.

Discontinuation of arrangements to provide pharmaceutical services

43. There are certain circumstances when the doctor must terminate the provision of *pharmaceutical services* to one or more patients, subject to any postponement of that termination by NHS England in accordance with **regulation 50(2) to (6)**. Postponement of termination under those provisions is one of a set of actions that has become known as “gradualisation”. The circumstances in which this particular form of gradualisation might be appropriate are set out in **regulation 50(1)** and are as follows:
 - by NHS England determines that condition 1 (serious difficulty) no longer applies to the patient;
 - the patient lived in a *controlled locality*, however by NHS England has determined that the area is no longer in, or part of, a *controlled locality* and the patient was only eligible because they lived in a *controlled locality*;
 - the patient has changed address and no longer lives in a *controlled locality*, and they were only eligible because they lived in a *controlled locality*;
 - the patient lives in a *controlled locality* but is no longer more than 1.6 km from a pharmacy (excluding *distance selling premises*), and either does not live in a *reserved location* or does live in a *reserved location* but has advised by NHS England that they wish to receive *pharmaceutical services* from a person on a pharmaceutical list and not from their doctor;
 - the patient lives within a *reserved location* and previously informed by NHS England that they wished to receive *pharmaceutical services* from their doctor, but has since informed by NHS England that they wish to receive *pharmaceutical services* from a person on a pharmaceutical list; or

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

- the patient lives in an area that was a *reserved location* but it is no longer designated as such.
44. NHS England may postpone the discontinuation until all proceedings relating to the discontinuation, including those that arise out of the granting of a *routine* or *excepted application* have reached their final outcome – see the example below (**Regulation 50(2)(a)**).
45. **Regulation 50(3)** also allows by NHS England to postpone the discontinuation where:
- by NHS England grants a *routine* or *excepted application* which results in the inclusion in a pharmaceutical list of pharmacy premises that are not already listed in relation to an *NHS pharmacist*, for example a new pharmacy but not a change of ownership;
 - the *pharmacy premises* to which the application relates are not *distance selling premises* but are in a *controlled locality* or are within 1.6 km of a part of a *controlled locality* in which patients of a *dispensing doctor* reside and those patients are receiving *pharmaceutical services* from that doctor; and
 - granting the application results, in by NHS England's opinion, in a significant change to the arrangements that are in place for the provision of *pharmaceutical services* (including by a person on a *dispensing doctor list*) or LPS in any part of a *controlled locality*.
46. In this instance, by NHS England may postpone the discontinuation for such period as it thinks fit (**Regulation 50(3) and (5)**).
47. NHS England may also postpone discontinuation for such period as it thinks fit in circumstances where a patient lives in an area that has been designated as a *reserved location* but there has been a redetermination by NHS England and the area in which the patient lives is no longer classed as a *reserved location*. Typically, this will happen where the number of people in the area who are on a patient list exceeds the threshold total of 2,750 and NHS England is satisfied that the reclassification will not prejudice the proper provision of NHS services (**Regulation 50(4) and (5)**).
48. In addition to the circumstances in which NHS England may postpone the discontinuation, there are circumstances where it must do so. NHS England must postpone the discontinuation whilst it is deciding whether or not there will be a significant change to the arrangements that are in place for the provision of *pharmaceutical services*, as the result of the grant of a *routine* or *excepted application*. If it decides that there will be a significant change, then NHS England may postpone the discontinuation for such period as it considers necessary in order to give the doctor reasonable notice of the discontinuation (**Regulation 50(6)**). NHS England could form this opinion at the same time as determining the *routine* or *excepted application* that triggered the possible postponement.

49. NHS England must also postpone the discontinuation in any case where it makes a decision to discontinue, for such period as it considers necessary in order to give the doctor reasonable notice of the discontinuation. This applies even in cases where NHS England declines to use its discretion to postpone for a potentially longer period under **regulation 50(5)**.
50. It is for NHS England to decide what period of time is reasonable when postponing the discontinuation of service provision, either in the necessary circumstances or in the discretionary circumstances, taking into account the facts of each case.

Example

A *routine application* is received to open a new pharmacy within a village that is in a *controlled locality*. Within the village, there is a GP practice that provides *pharmaceutical services* to the residents and surrounding area. NHS England determines that at the date the application is received there are 3,000 registered patients living within 1.6 km of the proposed premises.

If the application is approved, and the pharmacy subsequently opens the practice will no longer be able to provide *pharmaceutical services* to those 3,000 patients. This would lead to a 40% reduction in the practice's dispensing patient list.

When considering the *routine application*, NHS England also considers whether to postpone the discontinuation of *pharmaceutical services* to those patients by the practice, beyond the period that it thinks it needs to postpone the discontinuation simply to give the practice reasonable notice of the discontinuation. It will need to balance the impact of the loss of such a large number of dispensing patients by the practice against the financial requirements of the pharmacy. It must also consider the needs of the patients and their ability to adjust to a change in the way their prescriptions are dispensed.

NHS England could at the point it determines the *routine application* therefore decide whether to postpone the discontinuation of *pharmaceutical services* to those patients who were willing to continue to receive services from the practice. The postponement would commence at the point the pharmacy is included in a pharmaceutical list i.e. when it opens.

Due to the lead in time to the pharmacy opening, by making the decision on postponement at this early stage additional time is given to allow the patients to

adjust to the new system of receiving their drugs and appliances. It would also give the doctors time to reduce stock levels and discuss potential redundancy for affected staff, and it would allow the pharmacy to plan for a gradual increase in work.

51. Where NHS England decides to terminate the arrangements for the provision of *pharmaceutical services* it must notify that decision to:
- the doctor;
 - the LPC whose area includes the listed dispensing premises at or from which the *dispensing doctor* has been providing *pharmaceutical services*; and
 - the LMC whose area includes the listed dispensing premises at or from which the *dispensing doctor* has been providing *pharmaceutical services* (**Regulation 50(7)**)
52. If there is any postponement of the discontinuation NHS England must also notify the applicant or pharmacy contractor whose application or pharmacy triggered NHS England's decision as well as the three persons listed above (**Regulation 50(7)(b)**).
53. Each notification must include a statement of the reasons for the decision and if the person has appeal rights under **regulation 63(1)(b)**, an explanation of how those rights may be exercised (**Regulation 50(8)**). Information on the FHSAU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website.
54. **Regulation 63(1)(b)** gives appeal rights to:
- the doctor who is being required to terminate arrangements, subject to any postponement; and
 - if there is any postponement, the applicant or pharmacy contractor whose application or pharmacy triggered NHS England's decision.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

55. In order to be valid, the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

Applications by doctors for outline consent and premises approval

56. If a patient requests their doctor to provide them with *pharmaceutical services* on the basis of Condition 2 or 3 and the doctor does not already have approval to provide services in that area, then the doctor will need to apply under **regulation 51**. In the application the doctor will need to:
- request consent to provide *pharmaceutical services (outline consent)* to patients who request those services and who reside in the area specified in that application;
 - specify the area to which they wish to provide services to; and
 - request approval for those practice premises (*premises approval*) from which they wish to dispense (**Regulation 51(1)**).
57. As all applications to NHS England must be triggered by a request from a patient, the doctor will need to apply for *outline consent* for individual areas, rather than their entire practice area. The only exception to this would be where they have received applications from patients across a wide area.
58. Generally, *premises approval* applications will require a related *outline consent* application to be submitted at the same time, but there are two exceptions to this. The first of these is where a doctor already has *outline consent* for an area, and this has taken effect, and they apply for *premises approval* for additional practice premises in order to provide *pharmaceutical services* from those premises to patients living in the area for which they have *outline consent* to provide services (**Regulation 51(2)(a)**).
59. The second instance is if a doctor wishes to relocate to premises to provide services to patients who reside in the area for which they have *outline consent* and the relocation does not meet the requirements of a relocation under **regulation 55(2) (Regulation 51(2)(b))** (that is, a relocation that does not result in significant change to service provision or significant detriment to proper planning).
60. An application for *premises approval* must include the address of the premises and whether those premises are already listed in relation to a different area for which the doctor has *outline consent* (**Regulation 51(3)**). Each time a doctor wishes to apply for *outline consent* for a new area they must also apply for *premises approval* for those premises even if they have already been given it in respect to another area.

Example

Dr Smith and Jones have *outline consent* to provide *pharmaceutical services* to the village of Little Snoring and *premises approval* for their practice premises. Following applications from patients living in the village of Big Snoring, they apply to NHS England for *outline consent* for that village and also submit an application for *premises approval* for their practice premises.

61. NHS England is able to determine or defer applications for *outline consent* and *premises approval* in such manner (including with regard to procedures) as it sees fit, unless the 2013 Regulations indicate otherwise. An example of this is **regulation 62** which sets out who may not take part in the determination of any application under Part 8 of the 2013 Regulations.

Preliminary matters following receipt of an application for outline consent and premises approval

62. If NHS England receives an application for *outline consent* and *premises approval*, the first thing it must check is that the area described in the application is, or is part of, a *controlled locality*.
63. Where as a result of the application, NHS England is considering making or revising a determination as to whether or not an area is or is not to be part of a *controlled locality*, **regulation 52(5)** requires it to give *notice* of the application at the same time as it gives notice under **regulation 38(1)**.
64. Further information on determining *controlled localities* can be found in chapter 14.

Notification of applications for outline consent and premises approval

65. If NHS England receives an application for *outline consent* or *premises approval* (including an application for *premises approval* under **regulation 54** or **55** – “no significant change” relocations), **regulation 52(1)** requires it to give *notice* of that application as soon as practicable to:
- the LPC whose area includes the medical practice premises or all or part of the area to which the application relates, or any part of whose area is within 2 km of the medical practice premises to which the application relates;

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

- the LMC whose area includes the medical practice premises or all or part of the area to which the application relates, or any part of whose area is within 2 km of the medical practice premises to which the application relates;
 - any person who is included in a pharmaceutical list for the area of the relevant HWB, or who is entitled to be because their application has been granted but they have not yet been included, and whose interests NHS England believes might be significantly affected if the application were granted;
 - any LPS chemist with whom NHS England has a contract and whose interests NHS England believes might be significantly affected if the application were granted;
 - any *Local Healthwatch organisation* for the relevant HWB area any other patient, consumer or community group in the relevant HWB area which NHS England believes has a significant interest in the outcome of the application;
 - any *provider of primary medical services* or any other person on a *dispensing doctors list*, if there is one (i.e. a doctor who is a performer but not a *provider of primary medical services*), who NHS England believes has a significant interest in the outcome of the application;
 - any other Local Health Board any part of whose area is within 2 km of the proposed premises to which the application relates.
66. NHS England may also give notice to any other person who it believes has a significant interest in the outcome of the application, for example. Parish Councils (**Regulation 52(2)**).

Example

NHS England receives an application for *outline consent* and *premises approval* for a village on the outskirts of a town. The village has previously been determined as being part of a *controlled locality* however over the past few years the town has expanded considerably and there is now no longer a clear distinction between the two. The number of retail units in the village has increased and the school has been expanded in size and its catchment area includes a large part of the town.

NHS England therefore decides that it wishes to determine whether the village is still part of the *controlled locality*. It duly notifies the application for *outline consent* and *premises approval* to those persons listed in **regulation 52(1)** and it also notifies those listed at **regulation 38(1)** of its decision also to determine whether the village is still part of the *controlled locality* or not.

67. If any part of the area of a notified HWB, other than the relevant HWB is within 2 km of the proposed practice premises to which the application relates, NHS England must also give notice of the application to:
- any person included on a pharmaceutical list in the second HWB area, or who is entitled to be included in this list because of the grant of a *routine or excepted application*, but who is not (yet) included, or whose interests NHS England believes might be significantly affected if the application was granted;
 - any LPS chemist with whom NHS England has a contract and whose interests NHS England believes might be significantly affected if the application was granted;
 - any *local Healthwatch organisation* for the area of the second HWB, and any other patient, consumer or community group in this area which NHS England believes has a significant interest in the outcome of the application; and
 - any *provider of primary medical services* or any other person on its *dispensing doctor list* if it has one (i.e. doctors on the list who are performers as opposed to providers) who NHS England believes has a significant interest in the outcome of the application **(Regulation 52(3))**.

Significantly affected

NHS England needs to identify those contractors it feels will be significantly affected rather than automatically notifying everyone on a pharmaceutical list, *dispensing doctor list* and all *providers of primary medical services*.

For example, NHS England receives an application for *outline consent and premises approval* from a practice that wishes to provide *pharmaceutical services* from its surgery in a village in its area. It is within a *controlled locality* and NHS England is satisfied that there is no reason to re-establish that fact. Within the village, there is also a pharmacy. The proposed premises are not within 2 km of the neighbouring HWB area.

Using ePACT, NHS England looks at where the prescriptions currently written by the practice are dispensed and identifies that 70% are dispensed at the pharmacy in the village with the majority of the remaining 30% going to two other pharmacies about five miles away.

Looking at the Exeter system NHS England identifies that 90% of the village residents are registered with the practice with a further 9% at a practice in a neighbouring village.

NHS England therefore only notifies those three pharmacies of the application as well as the LPC, LMC, Healthwatch, Parish Council, and the practice in the neighbouring village.

68. A person notified under **regulation 52(1) to (3)** may make representations in writing about the application provided that they do so:
- within 45 days of the date on which notice of the application was given to them; or
 - in the case of notifications under **regulation 52(2) or (3)** within such longer period as NHS England that received the application may specify (**Regulation 52(4)**)
69. As well as sending information about the application, NHS England must inform those it is notifying of their right to make representations under **regulation 52(4) (Regulation 52(6)(a))**.
70. When notifying of the application NHS England must ensure that it sends sufficient information, from the information provided by the applicant, to enable those notified to make informed representations as to whether or not the application should be granted (**Regulation 52(6)(b)**). NHS England is not required to provide any information that is published as part of the HWB's PNA with the notification (**Regulation 52(7)**).
71. NHS England must ensure it does not include any private addresses, private telephone numbers or dates of birth that may have been supplied by the applicant (**Regulation 52(8)**).
72. When notifying of applications 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 (**Regulation 52(9)**). If NHS England does withhold any information, it must inform those notified of the application of the nature of the information that is being withheld (**Regulation 52(11)**).

73. The full disclosure principle means that information that is relevant to the determination of an application should be available to any individual who has a significant interest in the outcome of the application. The only exception is where it is fair and proper for that information to be withheld (**Regulation 52(10)**). Where NHS England is in any doubt as to whether the full disclosure principle applies, it should seek legal advice.

Applications by doctors for outline consent and premises approval - refusal

74. There are three instances when NHS England must refuse an application for *outline consent* and/or *premises approval*.
75. Firstly, NHS England must refuse an application for *premises approval* under **regulation 51(1)(b)** if the proposed premises are within 1.6 km of *pharmacy premises* that are not *distance selling premises* (**Regulation 51(5)**).
76. Secondly, NHS England must refuse an application for *outline consent* to the extent that any part of the area specified in the application is not a *controlled locality*, or is not part of a *controlled locality*, or is within 1.6 km of *pharmacy premises* that are not *distance selling premises* (**Regulation 51(6)**).
77. If NHS England believes that part of the area specified in the application for *outline consent* may be a *controlled locality*, or may be part of a *controlled locality*, but no formal determination has been made, it may defer the application until such time as it has made such a determination under **regulation 36** (**Regulation 51(7)**).
78. Thirdly, NHS England is required to refuse an application submitted under **regulation 51(1)** where, in its opinion, granting it would prejudice the proper provision of *relevant NHS services* in the relevant HWB area or in the area of a neighbouring HWB (**Regulation 51(8)**).
79. However, instead of refusing the application in whole, where NHS England is satisfied that granting the application in respect of a smaller area would not prejudice the proper provision of *relevant NHS services* in that smaller area, then it may grant the application in respect of that smaller area (**Regulation 51(9)**).

Decisions on outline consent and premises approval applications

80. When considering an application for *outline consent* and *premises approval*, NHS England will also need to consider whether the provision of *pharmaceutical services* by any *NHS pharmacist* or LP services by any LPS chemist would be adversely affected by the grant of such an application. If NHS England considers this would happen then it may by conditions gradually introduce the *premises approval* (**Regulation 57**).
81. Once it has determined an application for *outline consent* or *premises approval*, NHS England is required to give notice of that decision as soon as practicable to:

- the applicant; and
 - any person notified of the application under **regulation 52(1), (2) or (3) (Regulation 53(1))**.
82. Each notification must include a statement of the reasons for the decision, and if the person notified of the decision has appeal rights under **regulation 63(1)(c) or (d)**, the notification must also include an explanation of how those rights may be exercised (**Regulation 53(3)**). Information on the Family Health Service Appeal Unit(FHSAU)'s contact details, including address, e-mail and fax and telephone numbers, can be found on the NHS Litigation Authority's website.
83. Appeal rights are to be given where:
- the application for *outline consent* and *premises approval* is refused – the applicant; and
 - the application for *outline consent* and *premises approval* is approved – persons with third party appeal rights. These persons are, broadly speaking, pharmacy or primary medical services contractors with a significant interest who made representations about the application, and NHS England is satisfied that they made a reasonable attempt to explain their grounds for opposing to the application in those representations. Those grounds, however, must not be grounds instead for judicial review, or be vexatious or frivolous.
84. In order to be valid the notice of appeal must be sent to the FHSAU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

Taking effect of decisions on outline consent and premises approval applications

85. When *outline consent* is granted, NHS England must determine when it will take effect, i.e. when the doctor can start the provision of *pharmaceutical services* (**Regulation 53(4)**). This is subject to **regulation 53(12) and (14)(b)**.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

86. Where a *premises approval* application is accompanied by a related *outline consent* application, the former takes effect when the latter takes effect (**Regulation 53(5)**). If it is not accompanied by a related *outline consent* application, it takes effect in accordance with **regulation 56**.
87. Under **regulation 53(6)**, *outline consent* takes effect on the day the proceedings relating to the grant of it have received their final outcome, unless, on the day before proceedings are concluded there is an *outstanding pharmacy application* for premises that are within 1.6 km of the *relevant practice premises*. In this instance *relevant practice premises* are defined as:
- those that are the subject of any *premises approval* application that accompanied the *outline consent* application; or
 - if there was no related *premises approval* application, the medical practice premises from which the doctor wishes to dispense (**Regulation 53(7)**).
88. An *outstanding pharmacy application* is defined in **regulation 53(8)** as:
- an application, which may be an *excepted application*, for inclusion in a pharmaceutical list which has not yet reached its final outcome i.e. NHS England has yet to make a decision on it, or the decision is subject to an appeal which has not been decided. The *outstanding pharmacy application* could be in a neighbouring HWB area; or
 - an application, *which may be an excepted application* which has been granted but has yet to open, and the grant has not lapsed.
89. Where *outline consent* does not take effect on the date it is granted (any appeal to the FHSAU having run its course) because of an *outstanding pharmacy application*, NHS England must give the doctor written details of the *outstanding pharmacy application* and the earliest date on which the doctor can apply to NHS England to determine when their *outline consent* is to come into effect (**Regulation 53(9)**). NHS England must ensure it has systems in place to ensure that it takes into account any applications that it is notified of by neighbouring HWB areas.
90. The earliest date (referred to in this regulation as the *provisional date*), is the day after a period of one year, starting on the day NHS England determines the doctor's application for *outline consent* or where this determination is appealed, the day on which the appeal reaches its final outcome (**Regulation 53(10)**). NHS England may extend this 12 month period by a further period of not more than three months (**Regulation 53(11)**) and must notify the applicant of its determination.
91. This notification of a change to the provisional date must include an explanation of the reasons for the determination and the applicant's rights of appeal under **regulation**

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

63(1)(e) (Regulation 53(15)). Information on the FHSU's contact details, including address, e-mail and fax and telephone numbers, can be found on the NHSLA's website.

92. In order to be valid the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).
93. *Outline consent* lapses if before the *provisional date*, *pharmaceutical services* are provided as a result of the *outstanding pharmacy application* (**Regulation 53(12)**). The grant of the *outstanding pharmacy application* is not sufficient to annul the grant of *outline consent*. Service provision must have actually started at the pharmacy, and it must have actually started before the provisional date.
94. On or as soon as is reasonably practicable after the *provisional date*, if the doctor has not already asked NHS England for a date on which the doctor can start providing *pharmaceutical services*, NHS England must notify the doctor that they may, within three months of the *provisional date*, request in writing that NHS England determines whether *outline consent* is to come into effect (**Regulation 53(13)**).
95. Where NHS England receives such a request from the doctor, it must determine as soon as is reasonably practicable and notify the doctor that:
- *outline consent* is to come into immediate effect; or
 - that it has lapsed, where on the date of determination (which must be a day from Monday to Friday, except Good Friday, Christmas Day or a bank holiday) primary medical services are not being provided at the relevant premises or because a pharmacy contractor started providing at the pharmacy to which the *outstanding pharmacy application* related before the provisional date (**Regulation 53(14)**).
96. NHS England must notify the applicant of its determination. This notification must include an explanation of the reasons for the determination and the applicant's rights of appeal to the FHSU under **regulation 63(1)(e) (Regulation 53(15))**. Information on the FHSU's contact details including address, e-mail and fax and telephone numbers. These can be found on the NHSLA's website.
97. In order to be valid the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

Example

NHS England receives an application for *outline consent* and *premises approval* from a practice that wishes to provide *pharmaceutical services* to a village. NHS England notifies the application under **regulation 52(1)** and subsequently receives a *routine application* offering unforeseen benefits – the proposed premises are within the same village.

NHS England approves the application for *outline consent* and *premises approval* and a subsequent appeal is dismissed by the FHSAU on 4 April. NHS England writes to the practice to confirm their application has been given final grant but the *outline consent* does not take effect due to the *outstanding pharmacy application*. It gives details of the *outstanding pharmacy application* and advises that the practice may make an application to NHS England for a determination of when the *outline consent* is to come into effect on or after 5 April the following year, unless before that date NHS England has decided to delay the decision for a further period of not more than three months.

Before 5 April, NHS England does indeed write to tell the doctor that the provisional date is to be put back. The unforeseen benefits application was granted on appeal, and NHS England considers it appropriate to put back the *provisional date* for two months to 5 June, to give the contractor longer to open.

On 5 June, the doctor applies to NHS England for a determination of when the *outline consent* is to come into effect. The pharmacy contractor who made the unforeseen benefits application has not yet started providing *pharmaceutical services*, and so NHS England says that the *outline consent* is to come into immediate effect. At that stage, NHS England cannot change the *provisional date* to a later date (i.e. to give the pharmacy contractor one more month to open) because NHS England can only change a provisional date before the date in question.

Premises approval – relocations which are not significant before outline consent takes place

98. If *outline consent* has been granted, but has not taken effect, before the *provisional date* the applicant may apply to NHS England to change the premises from which it wishes to provide services (**Regulation 54(1)**).
99. NHS England must notify the application under **regulation 52(1)-(3)**. **Regulation 52(4) to (11)** then applies in relation to the procedural aspects of that application, and NHS England must take into account any representations received.
100. NHS England may agree to the change where it is satisfied that the relocation is a type described in **regulation 55(2)** – see next section (**Regulation 54(2)**). *Premises approval* would then take effect when the related *outline consent* takes effect, or if later, on the date on which the change is agreed by NHS England (**Regulation 54(3)**).
101. When considering the application, NHS England will also need to consider whether the provision of *pharmaceutical services* by any *NHS pharmacist* or LP services by any LPS chemist would be adversely affected by the grant of such an application. If NHS England considers this would happen then it may by conditions gradually introduce the *premises approval* under **Regulation 57**.
102. NHS England must notify its decision to those persons to whom it notified the application for *outline consent* and *premises approval* and who made representations under **regulation 52(4)**. The notification must include an explanation of the reasons for the decision and if the person notified is a person with rights of appeal under **regulation 63(1)(c) or (d)** an explanation of how those rights may be exercised (**Regulation 54(4)**). Information on the FHSAU's contact details, including address, e-mail and fax and telephone numbers, can be found on the NHSLA's website.
103. Appeal rights are to be given:
 - where the application for *premises approval* is refused – the applicant; and
 - where the application for premises approval is approved – persons with third party appeal rights. These persons are, broadly speaking, pharmacy or primary medical services contractors with a significant interest who made representations about the application, and NHS England is satisfied that they made a reasonable attempt to explain their grounds for opposing to the application in those representations. Those grounds, however, must not be grounds instead for judicial review, or be vexatious or frivolous.
104. In order to be valid, the notice of appeal must be sent to the FHSAU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

(Regulation 63(1)). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid **(Regulation 63(2))**.

105. Where a practice wishes to move to premises and the relocation is significant i.e. it fails to meet the criteria set out in **regulation 55(2)**, the practice would need to complete the relocation and then apply for *outline consent* and *premises consent* following a request by a patient under **regulation 48(1)**.

Premises approval – relocations which are not significant after outline consent has taken effect

106. Where a doctor is providing *pharmaceutical services* from *listed dispensing premises* and wishes to relocate and dispense from new medical practice premises in relation to the area for which they have *outline consent*, they may apply in writing **(Regulation 55(1))**. The application is submitted to NHS England for the relevant HWB area the new medical practice premises are, or are to be, located.
107. NHS England must notify the application under **regulations 52(1)-(3)**. **Regulation 52(4) to (11)** then applies in relation to the procedural aspects of that application, and NHS England must take into account any representations received.
108. The table below sets out the criteria for relocations which are not significant **(Regulation 55(2))** along with an explanation of each. The criteria look at the impact of the relocation at different levels:
- the impact on patient groups **(Regulation 55(2)(a))**;
 - the impact on the provision of *pharmaceutical services* (including by persons on a *dispensing doctor list* for the relevant HWB area) or LPS **(Regulation 55(2)(b))**; and
 - the impact on NHS England's planning for the provision of *pharmaceutical services* in its area **(Regulation 55(2)(c))**.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

109. NHS England must only grant the application if it is satisfied that the application meets all three criteria.

Regulation 55(2) 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 or not the new premises are significantly less accessible for those patient groups who use the current premises. The term “patient group” mirrors the requirement for the HWB to look at the needs of patient groups when developing the PNA. Regulation 9(1)(b) sets out the attributes that may be shared by members of these groups for example age, disability, race, religion or belief. NHS England should not merely treat the practice’s dispensing patients as one group as there will be differing needs within these patients.</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 practice has to secure new premises at short notice. In this instance, the practice may have to move into premises that do not offer the same level of access as at the current site.</p> <p>In this instance, NHS England will</p>

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

	need to exercise its judgement and decide whether this reduction in access is significant or not.
<p><i>(b) granting the application would not result in a significant change to the arrangements that are in place for the provision of pharmaceutical services (including by a person on dispensing doctor list) or of local pharmaceutical services —</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 then need to consider whether the relocation would impact on the arrangements that are in place for the provision of LPS and <i>pharmaceutical services</i> in any part of their area. 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>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.</p> <p>This provision therefore looks at the impact on service provision to ensure that granting the application would not result in a significant change to current service provision.</p>
<p><i>(c) 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 the relevant HWB area, in a manner that would cause significant detriment to that planning.</p>

110. These three requirements mirror the requirements for relocations of pharmacies and dispensing appliance contractors (DACs) under **regulation 24**.
111. When considering the application, NHS England will also need to consider whether the provision of *pharmaceutical services* by any *NHS pharmacist* or LP services by any LPS chemist would be adversely affected by the grant of such an application. If NHS England considers this would happen, it may by conditions gradually introduce the *premises approval* under **regulation 57**.
112. NHS England must notify its decision to those persons to whom it notified the application and who made representations under **regulation 52(4)**. The notification must include an

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

explanation of the reasons for the decision and if the person notified is a person with rights of appeal under **regulation 63(1)(c) or (d)** an explanation of how those rights may be exercised (**Regulation 55(4)**). Information on the FHSAU's contact details, including address, e-mail and fax and telephone numbers, can be found on the NHSLA's website.

113. Appeal rights are to be given:

- where the application for *premises approval* is refused – the applicant; and
- where the application for *premises approval* is approved – persons with third party appeal rights. These persons are, broadly speaking, pharmacy or primary medical services contractors with a significant interest who made representations about the application, and NHS England is satisfied that they made a reasonable attempt to explain their grounds for opposing to the application in those representations. Those grounds, however, must not be grounds instead for judicial review, or be vexatious or frivolous.

114. In order to be valid, the notice of appeal must be sent to the FHSAU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

115. Once a *dispensing doctor* has relocated, generally they cannot apply for a further relocation under **regulation 55** for a period of 12 months. Where such an application is submitted, NHS England must generally refuse it (**Regulation 55(3)**). This bar equally applies to any relocations that were granted under regulation 65(4)(a) of the 2005 and regulation 55 of the 2012 Regulations. NHS England will therefore need to ensure that it has accurate records of all applications from *dispensing doctors*. The exception to the general rule is that NHS England may grant the application if it believes there is good cause to set aside this bar, and it is satisfied that the requirements of **regulation 55(2)** are also met.

Taking effect of premises approval where there is no related application for outline consent

116. **Regulation 56** applies to applications for *premises approval* for additional premises or premises to which the doctor is relocating to (i.e. the new premises are replacing current premises) and there is no related application for *outline consent* (**Regulation 56(1)**).

Example

Examples of such applications are where a practice:

- opens a branch surgery within the area for which it has *outline consent*,
- is moving into new premises and continues to provide *pharmaceutical services* to those areas for which it has *outline consent*, or
- wishes to change the premises prior to *outline consent* taking effect.

As the practice is not seeking to provide *pharmaceutical services* in new areas, they only need to seek *premises approval* for their new premises.

117. In these circumstances, *premises approval* takes effect:

- on the date the application is determined (**Regulation 56(2)(a)**). Where no appeal is made, it is the date on which the period within which to make an appeal expires. Where an appeal is made, it is the date on which the appeal reaches its final outcome; or
- where there is an *outstanding pharmacy application* within 1.6 km of the relevant medical practice premises, the day after the end of the one year period which started on the date on which that *outstanding pharmacy application* reached its final outcome, or such longer period as NHS England may for good cause allow (not exceeding three months) (**Regulation 56(2)(b)**).

118. *Premises approval* lapses if *pharmaceutical services* are provided at the *pharmacy premises* listed within the *outstanding pharmacy application* before the date it would otherwise take effect by virtue of **regulation 56(2)** (**Regulation 56(3)**).

Example

Dr Smith and Partners are relocating to new practice premises on 1 March and apply to NHS England for *premises approval*. As they will be providing *pharmaceutical services* to the same area, they do not need to apply for *outline consent*. The application committee meets to consider the application for *premises approval* and is advised that a *routine application* to meet a current need identified within the PNA has been submitted 1 km away from Dr Smith and Partners' new premises.

The committee approves the application for *premises approval* but this cannot take effect for a period of one year starting on the day the *outstanding pharmacy*

application reaches its final outcome. Dr Smith and Partners cannot therefore provide *pharmaceutical services* from their new premises due to the *outstanding pharmacy application*. NHS England may however grant temporary *premises approval*.

NHS England determines the *outstanding pharmacy application* on 8 May and approves it. No appeal is made and therefore the application reaches *its* final outcome on 6 June. The pharmacy subsequently starts to provide *pharmaceutical services* and the *premises approval* for Dr Smith and Partners lapses.

If however the pharmacy failed to open, then Dr Smith and Partners would be able to start the provision of *pharmaceutical services* on 6 June in the following year.

Gradual introduction of premises approval

119. NHS England may apply the gradual introduction of *premises approval* to all applications for *premises approval* for which there is a related *outline consent*, whether submitted under **regulation 51, 54 or 55**. When it determines the application for *premises approval*, or where there is an *outstanding pharmacy application* when it determines when the outline consent is to come into effect, NHS England must consider whether this will adversely affect the provision of *pharmaceutical services* by any *NHS pharmacist*, or of LP services⁶ by any LPS contractor (**Regulation 57(1) and (2)**).
120. If NHS England decides that such services will be adversely affected, NHS England may place conditions on the doctor so as to either:
- postpone the taking effect of the *premises approval* for such period as it thinks fit; or
 - limit the patients to whom the doctor is able to provide *pharmaceutical services* in such manner and for such periods as it thinks fit.
121. In practice, NHS England would normally make the decision whether or not to impose such conditions when it determines the application for *premises approval* (**Regulation 57(2)(b)**). However, if before proceedings relating to the grant of a related *outline consent* have reached their final outcome, an *outstanding pharmacy application* is submitted in relation to premises within 1.6 km of the relevant medical practice premises, the question of gradualisation will need to be deferred until, or reconsidered when, NHS

⁶ LP services are those services that a LPS contractor may provide that are not essential, advanced or enhanced services.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

England it determines under **regulation 53(14)** that the *outline consent* is to come into effect (**Regulation 57(2)(a)**).

122. The gradual introduction of *premises approval* is therefore the reverse of gradualisation which is granted to a *dispensing doctor* following the opening of a pharmacy which leads to patients living within 1.6 km of it no longer being eligible to be dispensed to by the doctor. See chapter 14 for more information on this.
123. When coming to a decision as to whether or not to postpone the taking effect of the *premises approval*, NHS England will need to balance the impact of the loss of such a large number of dispensing patients by the pharmacy against the financial requirements of the doctor. It must also consider the needs of the patients and their ability to adjust to a change in the way their prescriptions are dispensed.
124. NHS England must notify any decision to impose, or not to impose, conditions under **regulation 57(1)** to the following:
- the doctor concerned;
 - any person with third party appeal rights in relation to the related application for *premises approval*;
 - any LPC whose area includes the medical practice premises to which the decision relates; and
 - any LMC whose area includes the medical practice premises to which the decision relates (**Regulation 57(3)**).
125. The notification must include a statement of the reasons for the decision and if the person notified is a person with rights of appeal under **regulation 63(1)(f)** an explanation of how those rights may be exercised (**Regulation 57(4)**). Information on the FHSAU's contact details, including address, e-mail and fax and telephone numbers, can be found on the NHSLA's website.
126. Appeal rights are to be given:
- when a decision is made to impose conditions – the applicant and an NHS pharmacist or LPS chemist with third party rights of appeal; or
 - where there is a failure to impose conditions – the applicant and an *NHS pharmacist* or LPS chemist with third party rights of appeal.
127. The *NHS pharmacists* and LPS chemists with third party rights of appeal are, broadly speaking, pharmacy contractors with a significant interest who made representations about the *premises approval* application, and NHS England is satisfied that they made a reasonable attempt to explain their grounds for opposing to the application in those

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

representations. Those grounds, however, must not be grounds instead for judicial review, or be vexatious or frivolous.

128. In order to be valid the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

Temporary provision in cases of relocations or additional premises where premises approval has not taken effect

129. Where *premises approval* is granted for additional medical practice premises or for a relocation and there is no related application for *outline consent*, and the *premises approval* has not taken effect due to an *outstanding pharmacy application*, it is possible for NHS England to grant the doctor temporary *premises approval* (**Regulation 58(1)**).
130. NHS England may do this where it considers it is desirable to do so in order to secure the adequate provision of *pharmaceutical services* in the area for which the doctor has *outline consent* (**Regulation 58(1)(a)**). NHS England may grant temporary *premises approval* for a period of up to 12 months. This 12-month period may be extended by up to three months. If NHS England initially granted temporary *premises approval* for less than 12 months it may be renewed more than once for up to a total aggregate period of 15 months (**Regulation 58(1)(b)**).
131. If NHS England does grant temporary *premises approval* it must notify:
- the doctor;
 - the applicant who made the *outstanding pharmacy application* which has led to the *premises approval* not taking (permanent) effect;
 - the LPC whose area includes the medical practice premises for which temporary premises approval has been granted; and
 - the LMC whose area includes the medical practice premises for which temporary premises approval has been granted. (**Regulation 58(2)**)
132. The notification must include a statement of the:
- reasons for the decision; and
 - duration of the temporary *premises approval* and the circumstances in which it might be extended (**Regulation 58(3)**)

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

133. If the application for temporary *premises approval* is refused, NHS England must notify the doctor and include:
- a statement of the reasons for that decision; and
 - an explanation of how their rights of appeal under **regulation 63(1)(c)(iii)** may be exercised (**Regulation 58(4)**)
134. Information on the FHSU's contact details, including address, e-mail and fax and telephone numbers, can be found on the NHSLA's website.
135. Appeal rights are only to be given to the applicant if the application is refused.
136. In order to be valid the notice of appeal must be sent to the FHSU within 30 days of the date on which the person bringing the appeal was notified of NHS England's decision (**Regulation 63(1)**). The notice of appeal must include a concise and reasoned statement of the grounds of appeal in order to be valid (**Regulation 63(2)**).

Practice amalgamations

137. A practice amalgamation occurs when two or more patient lists are combined as a result of the coming together, as a single provider, of two or more *dispensing doctors* (**Regulation 59(1)**).
138. If following a practice amalgamation, all the premises of the single provider are premises which had approval immediately before the amalgamation (and were therefore *listed dispensing premises*), the existing *outline consents* and *premises approvals* shall simply continue to have effect for the single provider (**Regulation 59(2)**).
139. Those patients who were dispensing patients prior to the amalgamation continue to be such as long as they continue to meet one of the three conditions listed in **regulation 48(2) to (4)**. Those patients who were non-dispensing patients prior to the amalgamation may apply to the single provider as long as they meet one of the three conditions.

Example

Two practices (Dr Hill and Partners and Dr Dale and Partners) amalgamate and become the Make You Feel Better Medical Centre with one primary medical services contract with NHS England. They continue to provide services from both premises. Prior to the amalgamation both practices had *premises approval* for their premises (i.e. they were *listed dispensing premises*) and these continue for the single provider, as do the *outline consents*.

140. Where only one practice had *premises approval* prior to the amalgamation, if those premises continue to be used by the single provider, then the *premises approval* for those premises and the related *outline consents* become approvals and consents for the single provider (**Regulation 59(3)(a)(i)**). *Premises approval* for any other premises could be applied for and NHS England would treat such an application as one for additional premises (**Regulation 59(3)(a)(ii)**).

Example

Dr Smith and Partners has *outline consent* and *premises approval*. They amalgamate with Dr Jones who has neither. Following the amalgamation, the single provider retains Dr Smith and Partners' *outline consent* and *premises approval* and Dr Smith applies for *premises approval* for Dr Jones' premises so that the single provider may provide *pharmaceutical services* from those premises to patients living in the area of *outline consent*. NHS England treats this application as one for additional premises.

141. If following the amalgamation, none of the single provider's premises have *premises approval*, the single provider may nominate premises in respect of which it wants to apply for *premises approval* and have that application treated as a relocation from its previous premises. Any other premises for which the single provider wishes to apply for *premises approval* would be dealt with as applications for additional premises (**Regulation 59(3)(b)**).

Example

Dr Smith and Partners and Dr Jones and Partners amalgamate and become the Make You Feel Better Medical Centre. As part of the amalgamation, they move to new premises. The single provider retains the *outline consents* for the two previous practices and nominate Dr Smith and Partners' old premises and apply for a relocation from those premises to the new premises. If they also opened a branch surgery, they could apply for additional *premises approval* for those premises.

142. A *dispensing doctor* who intends to be part of a practice amalgamation may apply in advance where it is known that the single provider will not occupy one of the current *listed dispensing premises* (**Regulation 59(4)**). Where this happens, any *premises approval* granted becomes a *premises approval* granted to the single provider once the amalgamation takes effect (**Regulation 59(4)(a)**). If the amalgamation does not subsequently take place, or if the doctor that applied does not become party to the amalgamation, any *premises approval* that has been granted on the basis of that doctor's application lapses (**Regulation 59(4)(b)**).

143. Any application for *premises approval* that arises from a practice amalgamation that has or is to take place, must include the names of all the medical practitioners and any other providers of primary medical services who are participating in the amalgamation (**Regulation 59(5)**).

Lapse of outline consent and premises approval

144. As well as in the situations described above, *outline consent* lapses when any of the following happen:
- no arrangement has been made under **regulation 48** following a request by an eligible patient for their doctor to provide *pharmaceutical services* to them within six months of the *outline consent* taking effect (**Regulation 60(1)(a)**). No account is to be taken of a period when the doctor is unable to make arrangements to provide *pharmaceutical services* because of a condition imposed by virtue of regulation 20(2) of the 2005 Regulations or **regulation 57** of the 2012 and 2013 Regulations i.e. the gradual introduction of *premises approval*;
 - six months have lapsed since any drugs or appliances have been dispensed (**Regulation 60(1)(b)**). No account is to be taken of a period when the doctor is unable to make arrangements to provide *pharmaceutical services* because of a condition imposed by virtue of regulation 20(2) of the 2005 Regulations or **regulation 57** of the 2012 and 2013 Regulations i.e. the gradual introduction of *premises approval*; and
 - following a *practice amalgamation*, there are no medical practice premises with *premises approval* and no outstanding applications to which **regulation 59(3)(a)** applies i.e. the single provider has not nominated one of its previous premises and subsequently applied for a relocation to the new premises (**Regulation 60(1)(c)**).
145. *Outline consent* ceases in relation to an area, or part of an area, if a *dispensing doctor* is no longer able to provide *pharmaceutical services* to patients on their list living in that area (**Regulation 60(2)**).

Example

A practice has *outline consent* to provide *pharmaceutical services* to a village which is in a *controlled locality*. Following the construction of a housing development with retail units and office accommodation NHS England determines that the village is no longer part of the *controlled locality*. The practice would therefore no longer be able to provide *pharmaceutical services* to patients living within the village and *outline consent* would cease for the village.

Although the arrangements with dispensing patients would have to discontinue, NHS England would be obliged to postpone that discontinuation for such period as it considered was necessary to give the practice reasonable notice of the discontinuation. However, it would not be entitled to postpone the discontinuation for longer, even if NHS England thought it desirable to do so.

146. For the purposes of **regulation 60(1)** where a doctor has historic rights to dispense in place of *outline consent*, those rights are to be treated as *outline consent* for the purposes of lapsing provisions. Accordingly, in the above example, historic rights will lapse if they relate to an area that ceases to be a *controlled locality* (**Regulation 60(4)**).
147. In addition to the circumstances, *premises approval* lapses if:
- the premises are no longer medical practice premises of a dispensing doctor with *outline consent* (**Regulation 60(3)(a)**);
 - six months have elapsed since any drug or appliance was dispensed under the arrangements made pursuant to **regulation 48** although NHS England may for good cause allow a longer period (**Regulation 60(3)(b)**). No account is to be taken of a period when the doctor is unable to make arrangements to provide *pharmaceutical services* because of a condition imposed by virtue of regulation 20(2) of the 2005 Regulations or **regulation 57** of the 2012 and 2013 Regulations i.e. the gradual introduction of *premises approval*;
 - NHS England is notified that doctors at listed dispensing premises have ceased to provide *pharmaceutical services* (**Regulation 60(3)(c)**);
 - the *dispensing doctor* in relation to whom the premises are listed is no longer listed in the *dispensing doctors list* (**Regulation 60(3)(d)**); or
 - the related *outline consent* has lapsed (**Regulation 60(3)(e)**).
148. For the purposes of **Regulation 60(3)** where a doctor has historic rights to dispense in relation to an area, this is treated as *outline consent* for the purposes of the rules relating to the lapsing of *premises approval* (**Regulation 60(5)**).

Appeals against decisions

149. Appeal rights against decisions made under Part 8 of the 2013 Regulations are given in **Regulation 63(1)**. Although covered in the above paragraphs they are summarised in the table below for ease of reference.

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

Regulation to which the decision relates	Persons with appeal rights
Regulation 48(5)(b) – NHS England requires a doctor to undertake to provide <i>pharmaceutical services</i> where a patient has requested such services but the doctor has not applied to do so to NHS England	That doctor.
Regulation 50 – discontinuation of arrangements for the provision of <i>pharmaceutical services</i> by a doctor, subject to any postponement of the discontinuation	That doctor; and if there is any postponement, the <i>NHS pharmacist</i> whose application or pharmacy premises led to NHS England’s determination
Regulation 51 – refusal of <i>outline consent</i> and <i>premises approval</i>	The doctor who made the application
Regulation 51 – grant of <i>outline consent</i> and <i>premises approval</i>	A person with third party rights of appeal
Regulation 54 – refusal of <i>premises approval</i> for an application to relocate (that is not significant) before <i>outline consent</i> takes effect	The doctor who made the application
Regulation 54 – grant of <i>premises approval</i> for an application to relocate (that is not significant) before <i>outline consent</i> takes effect	A person with third party rights of appeal
Regulation 55 - refusal of <i>premises approval</i> for an application to relocate (that is not significant) after <i>outline consent</i> takes effect	The doctor who made the application
Regulation 55 - grant of <i>premises approval</i> for an application to relocate (that is not significant) after <i>outline consent</i> takes effect	A person with third party rights of appeal
Regulation 58 – refusal of temporary <i>premises approval</i>	The doctor who made the application
Regulation 53(11) – a determination of a change to a provisional date	The doctor to whom the relevant <i>outline consent</i> was granted
Regulation 53(14) – a determination of whether <i>outline consent</i> is to come into effect	The doctor to whom the relevant <i>outline consent</i> was granted
Regulation 57 – a decision to impose, or failure to impose, conditions for the gradual introduction of <i>premises approval</i>	The doctor and any <i>NHS pharmacist</i> or LPS contractor who has third party appeal rights in relation to the related application for <i>premises approval</i> .

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

150. Such persons may appeal to the FHSU as long as they send a valid notice of appeal within 30 days of the date on which they were notified of NHS England's decision (**Regulation 63(1)**). The notice is only valid if it includes a concise and reasoned statement of the grounds of the appeal (**Regulation 63(2)**).
151. A person has third party appeal rights if NHS England was required to notify them of the application because they are:
- included in a pharmaceutical list for the relevant HWB area;
 - entitled to be included in a pharmaceutical list for the relevant HWB area because their routine or *excepted application* has been granted but they have not yet been included;
 - a LPS chemist with whom NHS England is in contract; or
 - (except in gradualisation appeals) a *provider of primary medical services* or any other person in its *dispensing doctor list* if it has one (i.e. doctors on the list who are performers as opposed to providers),

and NHS England believes their interests might be significantly affected by the decision (**Regulation 63(3)(a)**).

152. That person must, additionally, have made written representations about the application under **regulation 52(4) (Regulation 63(3)(b))**, and NHS England that made the decision must be satisfied that within their written or oral representations they made a reasonable attempt to express their grounds for opposing the application. Their grounds for opposing the application must not amount to a challenge to the legality or reasonableness of the HWB's PNA or to the fairness of the process by which the HWB undertook that assessment and must not be vexatious or frivolous (**Regulation 63(3)(c)**).
153. NHS England must carefully consider to whom it gives third party appeal rights. They should not give them to persons who did not make a reasonable attempt to express their grounds for opposing the application (**Regulation 63(3)(c)(i)**).
154. Where NHS England considers that a person does have third party appeal rights then it must notify them of that fact when they notify of the decision on the application.
155. If a person believes that they should have been given third party appeal rights by NHS England that made the decision but were not, then they may appeal to the FHSU against NHS England's determination not to give them such rights. They must notify the FHSU within 30 days of the date on which they were notified of NHS England's decision on the application but not given third party appeal rights. 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 appeal rights and also against NHS England's

Market entry by means of pharmaceutical needs assessments – dispensing doctors provision

decision on the application (**Regulation 63(5)**). If their appeal is successful then they will gain third party appeal rights in relation to the decision on the application.

156. For the purposes of the 2013 Regulations, the FHSU's decision becomes NHS England's decision on the matter unless the FHSU's decision is overruled by a court (**paragraph 11 of Schedule 3**).
157. If the appeal is against a decision to grant or refuse an application for *outline consent* or *premises approval*, the FHSU may:
- confirm NHS England's decision;
 - quash NHS England's decision and redetermine the application; or
 - quash NHS England's decision and remit the matter to NHS England for it to redetermine the application, subject to such directions as the FHSU considers appropriate. (**paragraph 9(4)(b) of Schedule 3**).
158. If the appeal relates to any other decision or determination appealed against under **regulation 63**, the FHSU may:
- confirm NHS England's decision or determination;
 - substitute for that decision or determination any that NHS England could have taken or made; or
 - quash NHS England's decision or determination and remit the matter to NHS England for it to redetermine, subject to such directions as the FHSU considers appropriate (**paragraph 9(4)(a) of Schedule 3**).