NHS England

Pharmacy Manual

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CHAPTER 1

Introduction and Glossary

1. Introduction

1.1. NHS England is responsible for direct commissioning of services beyond the remit of clinical commissioning groups, namely primary care, offender health, military health and specialised services.

1.2. Under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the Regulations"), NHS England is responsible for preparing, maintaining and publishing (for each Health & Wellbeing Board area) the following lists of persons (whether sole traders, partnerships or bodies corporate) who undertake to provide pharmaceutical services from premises located in England:

- a list of those persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs, i.e. pharmacy contractors; and
- a list of those persons who undertake to provide pharmaceutical services in particular by way of the provision of appliances, i.e. dispensing appliance contractors.

The above lists are referred to as pharmaceutical lists.

1.3. NHS England is also responsible for the following lists:

- a list of doctors who undertake to provide pharmaceutical services;
- in certain circumstances, a list of all the NHS chemists situated in that area who participate in the Electronic Prescription Service (EPS); and
- a list of the Local Pharmaceutical Services (LPS) chemists (if there are any) who provide local pharmaceutical services at or from premises situated in that area.

1.4. Persons wishing to provide pharmaceutical services in England must be included in one of the pharmaceutical lists held by NHS England.

The Pharmacy Manual

1.5. This Manual complements the Regulations and any Directions issued by the Secretary of State and should be read alongside them (and not in place of them).

1.6. If relevant, a chapter in this Manual will make reference to corresponding guidance issued by the Department of Health (the DH guidance). The content of the DH Guidance is not repeated in the Manual and the DH guidance should

therefore also be read alongside the Manual in order to ensure fair, proportionate and consistent decisions.

1.7. If the term "working day" is used, this refers to any day other than a Saturday, Sundays, public or bank holiday. Otherwise, references to "days" means calendar days.

Fees, records and appeals

1.8. Certain types of application must be accompanied by the fee set out in the Pharmaceutical Services (Fees for Applications) Directions 2013. Fees must be paid by Bankers' Automated Clearing Services (BACS) or cheque at the point at which the application is submitted. Applicants who indicate on their application form that they have paid the required fee will have their application processed in good faith. No decision will be made, however, until payment has cleared. NHS England will reimburse the applicant's fee when a decision is made to defer their application in order to invite other routine applications under Regulation 13, 15, 17, 18 or 20.

1.9. All documentation received (and subsequent communications) must be filed in a separate file kept in relation to the contractor in question. A robust audit trail must be maintained and the reasons for all decisions recorded in writing.

1.10. Decisions made by NHS England can generally be appealed to the NHS Litigation Authority's Family Health Services Appeal Unit (FHSAU), although some appeals on fitness issues are heard by the First-tier Tribunal. If the Regulations make no provision for an appeal, or if someone is dissatisfied with a decision of the FHSAU, any challenge would need to be made through the courts.

The Commissioner

1.11. The Manual mainly uses the term Commissioner in place of NHS England. References to the Commissioner should be read as references to NHS England or to any organisation to which NHS England has delegated the exercise of any part of relevant duties, powers or functions.

Glossary

1.12.

AUR	Appliance Use Reviews
CCG	Clinical Commissioning Group
CPAF	Community Pharmacy Assurance Framework
DAC	Dispensing Appliance Contractor
Days	Calendar days unless working days is specifically stated
DBS	Disclosure and Barring Service
DH	Department of Health
DH Guidance	Guidance issued by the DH to help NHS England in assessing applications to provide NHS pharmaceutical services
EPS	Electronic Prescription Service
FHSAU	NHSLA Family Health Services Appeal Unit
FPC	Family Practitioner Committees
GP	General Practitioner
GPhC	General Pharmaceutical Council
HWB	Health and Wellbeing Board
IELTS	International English Language Testing System
LLP	Limited Liability Partnership
LPC	Local Pharmaceutical Committee
LPS	Local Pharmaceutical Services
MUR	Medicines Use Review And Prescription Intervention Services
NHS Act	National Health Service Act 2006

NHS BSA	NHS Business Services Authority
NHS England	NHS Commissioning Board (operating as NHS England)
NHS LA	NHS Litigation Authority
NMS	New Medicine Service
PCM	Pharmacy Contracts Manager
PDS NBO	Personal Demographic Service National Back Office
PLDP	Performers Lists Decision-making Panel
PNA	Pharmaceutical Needs Assessment
PSRC	Pharmaceutical Services Regulations Committee
Regulations	The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended

CHAPTER 2

Decision Making Structures

Introduction

1. This chapter sets out:

- General principles for decision making;
- Pharmaceutical Services Regulation Committee Terms of Reference;
- Pharmacy Contract Manager decision making;
- The role of a specially constituted Performers List Decision making Panel;
- The role of the primary care support service provider; and
- Managing versions of Pharmaceutical Needs Assessments.

General Principles for Decision-Making

2. All decisions will be:

- made in line with the timescales set out within the Regulations;
- fully reasoned; and
- documented within the minutes of the relevant Pharmaceutical Services Regulation Committee meeting (if the decision has been made by that committee) or, otherwise, in a note made by the Pharmacy Contracts Manager.

Pharmaceutical Services Regulations Committee Terms of Reference

3. NHS England has established local committees to be known as Pharmaceutical Services Regulations Committees ("PSRC"). Each PSRC is authorised by NHS England to undertake any activity within these terms of reference.

4. NHS England has delegated decision making to each PSRC in relation to matters under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations") listed in Chapter 3 where the decision maker is listed as the PSRC.

5. The voting membership of each PSRC shall be as follows:

- Director of Commissioning (or equivalent) (who will chair the meeting in the absence of the Head of Primary Care);

- Head of Primary Care (or equivalent) (who will chair the meeting); and
- Lay member (or equivalent).

6. No deputies may be appointed unless there is good cause - for example, long-term sick leave. Where deputies are required they must have a good understanding of the Regulations.

7. Each member of a PSRC has a vote and the Chair has the casting vote, if necessary.

8. Each PSRC will be quorate if any 2 of the voting members are present.

9. Each PSRC may obtain such legal or other independent professional advice as it considers necessary and may co-opt persons with relevant experience and expertise if required. Each PSRC must follow current NHS England processes for obtaining legal advice.

10. The following persons will be co-opted to each PSRC:

    - Pharmacy contracts manager (or equivalent); and
    - Pharmacy professional adviser (or equivalent) (if applicable).

11. Persons ineligible to be voting or co-opted members of a PSRC are listed in Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations. All voting and co-opted members must sign a declaration to confirm that they are not barred by virtue of this paragraph. The Chair can require any co-opted member to leave the room before discussion of a matter and not return until the relevant decision has been made. The minutes will record the absences of the relevant co-opted member.

12. No member may take part in a decision if, in the opinion of the remaining voting members, the circumstances set out in paragraph 26(2) of Schedule 2 to the Regulations apply (*reasonable suspicion of bias*).

13. Members must advise the Chair of any potential conflict of interest upon receipt of the papers for a meeting. Discussion of those potential conflicts will take place at the beginning of each meeting and will be recorded. Where a conflict is perceived to exist in relation to a matter, the member with that conflict will leave the room before discussion of that matter and will not return until the relevant decision has been made and the reasons for it have been recorded.

14. Each PSRC shall secure such administrative support as is reasonably necessary to carry out its functions.

15. Each PSRC will meet monthly (or earlier if needed in order to discuss a case urgently).

16. Each PSRC will report at least every 6 months to an appropriate senior management committee (to be determined locally) on the decisions taken and the outcome of any appeals on those decisions.

Pharmacy Contracts Manager ("PCM") Decision Making

17. NHS England has established local Pharmacy Contract Managers ("PCM").

18. Persons ineligible to be a PCM are listed in in Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations. The PCM will sign a declaration to confirm that he or she is not barred by virtue of this paragraph.

19. NHS England has delegated decision making through the PSRC to each PCM in relation to matters under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations") listed in Chapter 3 where the decision maker is listed as "PCM or PSRC".

20. The PCM will be responsible for such matters listed in Chapter 3 where the decision maker is listed as "PCM or PSRC". If, for whatever reason, the PCM is unable to make a decision within the required timeframe (or at all), that decision shall be taken by the PSRC.

21. The PCM will report monthly to the PSRC on decisions taken and the outcome of any appeals on those decisions.

The Role of the Performers List Decision Making Panel

22. NHS England has established local Performers List Decision making Panels ("PLDP").

23. NHS England may delegate decision making through the PSRC to each PLDP in relation to matters under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations") listed in Chapter 3 where the decision maker is listed as "PSRC or PLDP".

24. The PSRC must ensure that the members of the PLDP are eligible to take part in the matter by ensuring that no members are a type of person listed in Regulation 62 and in paragraph 26 of Schedule 2 to the Regulations.

25. The PSRC will be responsible for such matters listed in Chapter 3 where the decision maker is listed as "PSRC or PLDP". The PSRC may delegate such matters to the PLDP for whatever reason.

26. The PLDP will report monthly to the PSRC on decisions taken and the outcome of any appeals on those decisions

Primary Care Support Service Provider

27. NHS England will contract with a primary care support service provider to provide administrative assistance for certain matters including pharmacy matters.

28. It is not intended that the primary care support service provider makes decisions on pharmacy matters.

29. Certain elements of the procedures found in this Manual may be carried out by primary care support service provider.

30. A service specification setting out the administrative tasks to be undertaken by the primary care support service provider is provided at Annex 1. It should be noted that this is only a draft specification. It may be updated or amended form time to time. If any person is intending to rely on this document, it should be clarified whether this document has been superseded by any updated documents.

Managing version of Pharmaceutical Needs Assessments

31. The Regulations usually require NHS England to have regard to the relevant Pharmaceutical Needs Assessment ("PNA") defined as the PNA that is current at the time that the decision is made.

32. If a new PNA is published and the applicant prepared its submission in accordance with the old PNA, the applicant could claim that the appeal has not been dealt with justly.

33. The Regulations require the decision to be made against the new PNA unless in NHS England's opinion the only way to determine the application justly is with regard to an earlier PNA.

34. Where a new PNA has been published and NHS England has regard to the new PNA when making the decision, it may mitigate the risk of challenge if the decision sets out why NHS England decided that this would lead to an application being determined justly.

35. Where a new PNA has been published that may have an impact on the determination, NHS England should consider whether to inform parties that it intends to determine the application having regard to the new PNA and invite comments.

CHAPTER 3

Delegated Decision Making

Delegated Decision Making

1.13. If the decision maker is listed as "PSRC", only the local PSRC may make that decision.

1.14. If the decision maker is listed as "PCM or PSRC", the decision may be made by the local PCM or (in circumstances described in Chapter 2) by the local PSRC.

1.15. If the decision maker is listed as the "PSRC or PLDP", the decision may be made by the local PSRC or (in circumstances described in chapter 2) by the local PLDP.

Action		Decision Maker	Chapter of Manual
1.	Regulation 13 – determination of application (current need)	PSRC	Chapter 5 Chapter 14
2.	Regulation 15 – determination of application (future need)	PSRC	Chapter 6 Chapter 14
3.	Regulation 17 – determination of application (current improvement/better access)	PSRC	Chapter 7 Chapter 14
4.	Regulation 18 – determination of application (unforeseen benefits)	PSRC	Chapter 8 Chapter 14
5.	Regulation 20 – determination of application (future improvement / better access)	PSRC	Chapter 9 Chapter 14
6.	Regulation 23 – determination of application (application from NHS chemist in respect of providing directed services)	PSRC	Chapter 17
7.	Regulation 24 – determination of application (relocation involving no significant change)	PSRC	Chapter 10 Chapter 14
8.	Regulation 25 – determination of application (distance selling pharmacies)	PSRC	Chapter 11 Chapter 14
9.	Regulation 26(1) – determination of application (change of ownership)	PCM or PSRC	Chapter 12 Chapter 14

Action		Decision Maker	Chapter of Manual
10.	Regulation 26(2) – determination of application (relocation involving no significant change/change of ownership)	PSRC	Chapter 13 Chapter 14
11.	Regulation 27 – determination of application (for temporary listing arising out of suspension)	PSRC	Chapter 17A
12.	Regulation 28 – determination of application (exercising right of return to the pharmaceutical list)	PCM or PSRC	Chapter 17B
13.	Regulation 29 – determination of application (temporary arrangements during emergencies / because of circumstances beyond the control of NHS chemists)	PCM or PSRC	Chapter 17C
14.	Regulation 33 – determination of suitability of an applicant to be included in a pharmaceutical list on fitness grounds	PSRC or PLDP	Chapter 4
15.	Regulation 24 – determination of deferral of application to be included in a pharmaceutical list on fitness grounds	PSRC or PLDP	Chapter 4
16.	Regulation 36 – determination of whether an area is a controlled locality (or is part of a controlled locality), as a result of a local medical committee or local pharmaceutical committee request for such a determination or because the Commissioner is satisfied that such a determination is required (and make arrangements for any controlled locality to be clearly delineated on a published map)	PSRC	Chapter 14
17.	Regulations 41 and 42 – determination of whether premises are (or a best estimate is) in a reserved location (and make arrangements for any reserved location to be clearly delineated on a published map)	PSRC	Chapter 14
18.	Regulation 48(2) - determination of patient application ('serious difficulty' applications)	PCM or PSRC	Chapter 15
19.	Regulation 50 – consideration of 'gradualisation' (i.e. the postponement of the discontinuation of	PSRC	Chapter 15

Action		Decision Maker	Chapter of Manual
	services by dispensing doctors) for an application in relation to premises in, or within 1.6 kilometres of, a controlled locality		
20.	Regulations 51 to 61 except those regulations set out in this Chapter 3 – determination of doctor application (outline consent and premises approval) including relocations	PSRC	Chapter 15
21.	Regulation 69 – determination of whether there has been a breach of terms of service	PSRC	Chapter 19
22.	Regulation 70 – determination of whether to issue a breach notice / withhold payments in connection with a breach of terms of service	PSRC	Chapter 19
23.	Regulation 71 – determination of whether issue a remedial notice / withhold payments in connection with a breach of terms of service	PSRC	Chapter 19
24.	Regulation 72 – determination of whether to withhold remuneration	PSRC	Chapter 19
25.	Regulation 73 – determination of whether to remove premises or a chemist from the pharmaceutical list (following remedial or breach notice)	PSRC	Chapter 19
26.	Regulation 74 – determination of whether to remove premises or a chemist from the pharmaceutical list (death, incapacity or cessation of service)	PSRC	Chapter 19
27.	Regulation 81 and 82 – determination of the continued suitability of a body corporate to be included in the relevant pharmaceutical list, in the event of a new director and/or superintendent being appointed	PSRC	Chapter 4
28.	Regulation 99 – designation of an LPS area	PSRC	Chapter 20
29.	Regulation 100 – review of designation of an LPS area	PSRC	Chapter 20
30.	Regulation 101 – cancellation of an LPS area	PSRC	Chapter 20

Action		Decision Maker	Chapter of Manual
31.	Regulation 104 – selection of an LPS proposal for development and decision to adopt proposal	PSRC	Chapter 20
32.	Regulation 108 – right of return for LPS contractor	PSRC	Chapter 20
33.	Schedule 2, paragraph 1(10) – whether best estimate is acceptable	PCM or PSRC	Chapters 5 - 9
34.	Schedule 2, paragraph 11(2)(b) – determination of review of reasonableness of request for missing information	PCM or PSRC	Chapters 4 to 13 and 17 to 17C
35.	Schedule 2, paragraph 14 – whether to defer consideration of application	PCM or PSRC	Chapters 5 to 9 and 14
36.	Schedule 2, paragraph 19 – determination of who is to be provided with notice of a notifiable application	PSRC	Chapters 5 to 11 and 13
37.	Schedule 2, paragraph 22(2) – whether oral representations are to be provided and who may be additional presenters as defined in Schedule 2, paragraph 25(2)	PCM or PSRC	Chapters 5 to 11 and 13
38.	Schedule 2, paragraph 31 – consideration of a notification of address following a 'best estimate' routine application. Where this may lead to a refusal under regulation 31, the matter should be escalated to the PSRC	PCM or PSRC	Chapter 5 to 9 and 14
39.	Schedule 2, paragraph 31(4)(c)(i) – extension of latest date for receipt of notice of commencement	PCM or PSRC	Chapters 5 to 13 and 17 to 17C
40.	Schedule 4, paragraph 23(1) / Schedule 5, paragraph 13(1) – consideration of a request to temporarily suspend the provision of services (fixed period)	PSRC	Chapter 18
41.	Schedule 4, paragraph 23(7) / Schedule 5, paragraph 13(6) – consideration of a notification of a change of supplementary opening hours where the number of supplementary hours is reduced and the change is intended to come	PSRC	Chapter 18

Action		Decision Maker	Chapter of Manual
	into effect sooner than three months after receipt of notification of the change		
42.	Schedule 4, paragraph 23(7) / Schedule 5, paragraph 13(6) – consideration of a notification of a change of supplementary opening hours where the number of supplementary hours is increased and the change is intended to come into effect sooner than three months after receipt of notification of the change	PCM or PSRC	Chapter 18
43.	Schedule 4, paragraph 23(7) / Schedule 5, paragraph 13(6) – arranging for amendments to be made to the relevant pharmaceutical list following notification of a change of supplementary opening hours (where change is not intended to come into effect sooner than three months after receipt of notification of change	PCM or PSRC	Chapter 18
44.	Schedule 4, paragraph 23-25 / Schedule 5, paragraph 13-15 – decision to direct a contractor to open at certain times on certain days	PSRC	Chapter 18
45.	Schedule 4, paragraph 23 (10) / Schedule 5, paragraph 9 – review of reason for temporary suspension within the control of the contractor	PSRC	Chapter 18
46.	Determination of applications to provide MURs at locations other than listed premises	PCM or PSRC	Chapter 16
47.	Approval of responses to an appeal against, or challenge to, decisions of the PSRC	PSRC	All chapters
48.	Approval of responses to an appeal against, or challenge to, decisions of the PCM	PCM or PSRC	All chapters
49.	Determination of further action where CPAF identifies concerns	PCM or PSRC	Chapter 19
50.	Determination of further action where the contractor fails or refuses to agree a date and time for a visit	PCM or PSRC	Chapter 19

Action		Decision Maker	Chapter of Manual
51.	Determination of action where any of the following are identified: • Patient safety issues; • NHS England is at risk of material financial loss; and/or • Possible fraudulent or criminal activity.	PCM or PSRC	Chapter 19
52.	Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report	PCM or PSRC	Chapter 19
53.	Determination of action where the contractor exceeds the maximum number of AURs that may be done in any one year	PSRC	Chapter 19

CHAPTER 4

Fitness

Chapter Aims and Objectives

1. This chapter provides information on how to manage fitness matters in accordance with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the "Regulations").

2. Procedures are set out in the following chapters for the different types of applicants:

    - Chapter 4A – Pharmacy – Individual
    - Chapter 4B – Pharmacy – Partnership
    - Chapter 4C – Pharmacy – Body Corporate
    - Chapter 4D – Dispensing Appliance Contractor – Individual
    - Chapter 4E – Dispensing Appliance Contractor – Partnership
    - Chapter 4F – Dispensing Appliance Contractor – Body Corporate

3. This document should be read in conjunction with the Regulations.

4. This document sets out an overview of the fitness checks and the Commissioner's policy on the following aspects of the fitness checks:

    - The scope of the fitness checks;
    - English language testing;
    - References;
    - Mandatory refusal of applications on fitness grounds;
    - Discretionary refusal of applications on fitness grounds;
    - Deferral of applications on fitness grounds;
    - Granting applications subject to conditions; and
    - Notification of fitness decisions.

5. The PSRC will consider and determine fitness matters but may delegate a matter to a specially constituted PLDP in recognition of the PLDP's expertise in fitness matters. Details of the constitution of the PLDP are set out in Chapter 2.

Scope

6. This chapter applies to the assessment of applications for inclusion in a pharmaceutical list. Those applying for inclusion in dispensing doctor lists are not subject to fitness / suitability checks. Those who wish to provide local pharmaceutical services are subject to the fitness checks set out in Chapter 20.

7. Pharmaceutical list applicants must, unless already included in a relevant pharmaceutical list in relation to other premises, provide fitness information as part of their application. The Regulations allow applicants to rely on information already provided. Each application form asks the applicant whether information has been previously submitted. Where partial information has been submitted, the applicant must set out what information NHS England has and provide missing information in the application form. Where no information has been provided previously, applicants are required to complete and submit the relevant fitness information form. If NHS England cannot locate the information previously provided after using reasonable efforts, NHS England will need to request the relevant information.

8. Applicants must first be assessed as suitable to be included and only then can the 'market entry' aspect of their application be considered.

9. Lasting damage can be caused to a contractor's reputation and future career by unfounded or malicious allegations. When determining applications for inclusion in pharmaceutical lists, information provided, and the sources of it, must be assessed carefully.

10. There is no place for discrimination on the grounds of gender, religion, race, disability, age or sexual orientation and utmost care must be taken to avoid imposing preferences or prejudices.

11. Applicants for inclusion in the pharmaceutical list of those undertaking to provide pharmaceutical services in particular by way of the provision of drugs, must meet the requirements of the Medicines Act 1968 and so must demonstrate that:

    - pharmacists are registered with the GPhC;
    - if a body corporate, it has a superintendent pharmacist (who may act for another body corporate only for the purposes of submitting an application and not operating any pharmacies).

12. Where a body corporate appoints a new director or superintendent, it must notify the office of the Commissioner that is local to its registered office and provide the required fitness information on that individual within 30 days. A fitness information form where a new director or superintendent is appointed is set out at Annex 1 for pharmacies and for a new director for DACs at Annex 2. The PSRC will consider the fitness information (and may delegate to a specially constituted PLDP) to determine whether the body corporate remains suitable to be included in a pharmaceutical list. The office of the Commissioner that deals with the matter must inform other offices of the Commissioner of details of the change.

13. The Regulations require contractors to provide information about fitness matters as they arise. Where such matters arise in relation to a body corporate, it should notify the office of the Commissioner that is local to its registered office which shall deal with the matter. The office of the Commissioner that deals with the matter must inform other offices of the Commissioner of details of the change.

14. LLPs (who may have non-pharmacist partners) are bodies corporate and are therefore required to have a superintendent pharmacist.

15. The Companies House registration of bodies corporate should be checked to ensure that it is current and that no director is disqualified. This can be done through Companies House Direct.

16. Where a procedure in chapters 4A to 4F requires the Commissioner to contact an organisation for information, this can be done via email if deemed appropriate.

English Language Testing

17. Individuals (which includes partners where the applicant is a partnership) applying for inclusion in a pharmaceutical list who qualified as a pharmacist in Switzerland or a European Economic Area (EEA) member state other than the United Kingdom must have their English language assessed in accordance with regulation 30 (i.e. to be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people making use of the services to which the application relates, is necessary for the provision of those services).

18. The Commissioner requires pharmacists to show that they have a score of at least seven in the academic level of the International English Language Testing System (IELTS).

References

19. References must be provided for individual pharmacist applicants, pharmacists who are members of a partnership applicant, and the superintendent pharmacist and each director who is a pharmacist of a body corporate applicant.

20. References should be provided from two recent posts (which may include a current post as a pharmacist) which lasted at least three months without a significant break. Recent posts should be posts within the previous two years although posts from before this time are acceptable if there are good reasons.

21. The referee should be a pharmacist registered with the GPhC and must be able to comment on the pharmacist's knowledge, skills and competence.

22. The Commissioner should not, without good reason, accept references from:

    - family members;
    - business partners providing references for each other;
    - any person with a financial interest in the application; or
    - pre-registration trainees.

Mandatory Refusal of Applications on Fitness Grounds

23. Applications for inclusion in a pharmaceutical list must be refused if any of the grounds set out in regulation 33(1) are satisfied.

Discretionary refusal of applications on fitness grounds

24. Applications for inclusion in a pharmaceutical list may be refused if any of the grounds set out in regulation 33(2) are satisfied.

25. When considering a refusal on discretionary grounds the decision-maker will take into account the matters set out in regulation 33(3).

26. When taking these matters into consideration, the decision-maker must consider the overall effect of all the matters considered (pursuant to regulation 33(4)).

Deferral of applications on fitness grounds

27. Applications for inclusion in a pharmaceutical list may be deferred by the decision-maker for any of the reasons set out in regulation 34 of the 2013 regulations.

28. Deferral will only be appropriate where the outcome, if adverse, would be likely to lead the decision-maker to remove the applicant from a pharmaceutical list if they were included in it. The word ‘likely’ is crucial. The decision-maker must therefore have robust, evidence-based grounds to come to this decision.

29. An application may only be deferred on fitness grounds in accordance with regulation 34(2).

Granting applications subject to conditions

30. As an alternative to refusing an application, the decision-maker may (except in 'suitability cases') decide to grant the application for inclusion subject to conditions, in accordance with regulation 35, which are made with a view to preventing:

- any prejudice to the efficiency of all or any of the services that the applicant has undertaken to provide; or
- fraud.

31. Conditions must be specific and relevant to the particular concern or issue that has been identified.

Notification of Fitness Decisions

32. Where an application for inclusion in a pharmaceutical list is refused on fitness grounds or is granted subject to conditions, the Commissioner must notify the persons listed in regulation 88(2).

33. Notifications to the person/organisation shown in the left hand column of the table below should be sent to the address shown in the right hand column.

Person / Organisation	Notifications sent to:
Secretary of State for Health	NHS Litigation Authority Family Health Services Appeal Unit, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE
The Scottish Ministers	Chief Pharmaceutical Officer, Scottish Government, St Andrews House, Regent Road, Edinburgh, EH1 3DG
The Welsh Ministers	Chief Pharmaceutical Officer, National Assembly for Wales, Cathays Park, Cardiff, CF1 3NQ
The Northern Ireland Executive	Chief Pharmaceutical Officer, Room D4.7, Castle Buildings, Upper Newtownards Road, Belfast, BT4 3SQ
In relation to a 'fraud' case, the NHS Business Services Authority	NHS Protect, Weston House, 246 High Holborn, London, WC1V 7EX
Other primary care organisations	Local health boards (in Wales), Regional health boards (in Scotland), and the Regional Health and Social Care Board (in Northern Ireland)

1.16.

CHAPTER 4A

Procedure for Application to Join the Pharmaceutical List – Pharmacy – Sole Trader

Chapter aims and objectives

34. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by pharmacy sole traders alongside their application for inclusion in a pharmaceutical list for the first time.

35. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

36. This document must be read in conjunction with the Regulations.

37. A checklist for noting the status of the application is provided at the end of this procedure.

38. A flowchart summarising the procedure below is provided at Annex 1.

39. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of receipt of information) can be sent to the		

Action		Complete?	Notes
	applicant. Go to step 12. If not all the information, documentation or undertakings have been provided, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided send Annex 5 (notification of outcome of review and request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided send Annex 6 (notification of outcome of review and withdrawal of request) and go to step 9.		

Action		Complete?	Notes
8.	If the information and/or documentation is received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	If the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 13. If the applicant qualified as a pharmacist in the United Kingdom, go to step 14.		

Action		Complete?	Notes
13.	Where the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the Commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services. Ensure the applicant has provided evidence of achieving a score of at least 7 in the academic level of the International English Language Testing System (IELTS). If the applicant has provided such evidence, go to step 14. If the applicant has not provided such evidence, refer the matter to the medical director.		
14.	Send Annex 12 (letter to the GPhC) to check the registration status of the applicant.		
15.	If registration of the applicant with the GPhC is confirmed, go to step 16. If registration of the applicant with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Send Annex 14 by email to NHS Protect, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary.		
17.	Initiate an online enquiry to the NHS Litigation Authority in respect of past or		

Action		Complete?	Notes
	current investigations relating to the applicant (http://www.nhsla.com/fhsau/Pages/Home.aspx). Diarise date for receipt of response and follow up if necessary.		
18.	Check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 15 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 16 (reference request) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 17 (letter to referee – chasing response) to that referee and if there is still no response send Annex 18 (non-receipt of reference) to the applicant. Diarise the date for receipt of responses. Liaise with the officer dealing with the market entry application so they are aware		

Action		Complete?	Notes
	there may be a delay.		
21.	Once all the checks are completed, prepare the committee report (Annex 19) on the applicant for the decision-maker and send to the relevant administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the application is approved subject to conditions, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 20 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		
24.	If the application is refused: • Under regulation 30 (language requirement), send Annex 21 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 22 (mandatory refusal) to the applicant and Annex 23 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 24 (discretionary		

Action		Complete?	Notes
	refusal) to the applicant and Annex 25 (notification of discretionary refusal) to the relevant bodies set out in regulation 88. Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the decision-maker is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 26 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 27 (conditions) to the applicant and Annex 28 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 29 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 30 (no further grounds to defer) to the applicant.		

Action		Complete?	Notes
27.	If the applicant fails to respond, or if they confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 31 (application withdrawn) to the applicant and advise the officer dealing with the market entry application. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed send Annex 32 (application proceeding), refer to the decision-maker and return to step 21 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

40. A checklist for noting the status of the application is provided on the next page.

Checklist for applications to join the pharmaceutical list – fitness to practise – pharmacy sole trader

Name of applicant	
Legal form	Sole trader (pharmacy)
Address/best estimate of proposed premises	
Date application received	
Timescale for determination of application	30 days / 4 months
English language knowledge a) Required? b) Satisfactory?	 Yes / No Yes / No
Confirmation of registration with GPhC a) Request sent b) Date response due c) Date response received	
NHS Protect check a) Request sent b) Date response due c) Date response received	
NHSLA check a) Request sent	

b) Date response due c) Date response received	
References a) Requests sent b) Date responses due c) Date responses received	
Decision a) Information sent b) Date decision due c) Date decision received	
Decision	Approved / deferred / refused / conditional inclusion
If deferred, final decision	Approved / refused / conditional inclusion
Date applicant notified of decision	
Date relevant bodies notified (where relevant)	
End of 30 day appeal period	
Appeal received?	Yes/No
Outcome of appeal (where relevant)	Appeal upheld/dismissed

Completed by

Name:

Signature: Date:

CHAPTER 4B

Procedure for Application to Join the Pharmaceutical List – Pharmacy – Partnership

Chapter aims and objectives

41. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by pharmacy partnerships alongside their application for inclusion in a pharmaceutical list for the first time.

42. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

43. This document must be read in conjunction with the Regulations.

44. A checklist for noting the status of the application is provided at the end of this procedure.

45. A flowchart summarising the procedure below is provided at Annex 1.

46. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that each partner has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of receipt of information) can be sent to the applicant. Go to step 12.		

Action		Complete?	Notes
	If any of the information, documentation or undertakings are missing, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided, send Annex 5 (notification of outcome of review and request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided, send Annex 6 (notification of outcome of review and withdrawal of request) and go to step 9.		
8.	If the information and/or documentation is received by the due date, send Annex 7		

Action		Complete?	Notes
	(confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	If a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 13. If a partner of the applicant qualified as a pharmacist in the United Kingdom, go to step 14.		

Action		Complete?	Notes
13.	Where a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the Commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services. Ensure the pharmacist has provided evidence of achieving a score of at least 7 in the academic level of the International English Language Testing System (IELTS). If the pharmacist has provided such evidence, go to step 14. If the pharmacist has not provided such evidence, refer the matter to the medical director.		
14.	Send Annex 12 (letter to the GPhC) to check the registration status of each partner.		
15.	If registration of the partners with the GPhC is confirmed, go to step 16. If registration of a partner with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Send Annex 14 (enquiry) by email to NHS Protect, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary.		
17.	Initiate an online enquiry to the NHS Litigation Authority in respect of past or		

Action		Complete?	Notes
	current investigations relating to the applicant. (http://www.nhsla.com/fhsau/Pages/Home.aspx). Diarise date for receipt of response and follow up if necessary.		
18.	Check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 15 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 16 (request letter and pro forma) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 17 (letter to referee – chasing response) to that referee and if there is still no response send Annex 18 (non-receipt of reference) to the applicant. Diarise the date for receipt of responses. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		

Action		Complete?	Notes
21.	Once all the checks are completed, prepare the committee report (Annex 19) on the applicant for the performers list decision panel and send to the panel administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the panel that in the event of a refusal or conditional inclusion this applies collectively to the partnership as on entity and not to an individual.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the panel is minded to conditionally include the applicant, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 20 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		
24.	If the application is refused: • Under regulation 30 (language requirement), send Annex 21 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 22 (mandatory refusal) to the applicant and Annex 23 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 24		

Action		Complete?	Notes
	(discretionary refusal) to the applicant and Annex 25 (notification of discretionary refusal) to the relevant bodies set out in regulation 88. Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the performers list decision panel is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 26 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 27 (conditions) to the applicant and Annex 28 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 29 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 30 (no further grounds to defer) to the applicant.		
27.	If the applicant fails to respond, or if they		

Action		Complete?	Notes
	confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 31 (application withdrawn) to the applicant and advise the officer dealing with the market entry application. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 32 (application proceeding) refer to the performers list decision panel and return to step 19 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the performers list decision panel and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

47. A checklist for noting the status of the application is provided below.

Checklist for Applications to join the Pharmaceutical List

Fitness to Practise – Pharmacy Partnership

Name of applicant				
Legal form	Partnership (pharmacy)			
Address/best estimate of proposed premises				
Date application received				
Timescale for determination of application	30 days / 4 months			
English language knowledge a) Required? b) Satisfactory?	 Yes / No Yes / No			
Confirmation of registration with GPhC a) Request sent b) Date response due c) Date response received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
NHS Protect check a) Request sent b) Date response due c) Date response received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
NHSLA check a) Request sent b) Date response due c) Date response received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**

References a) Requests sent b) Date responses due c) Date responses received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
Decision a) Information sent b) Date decision due c) Date decision received				
Decision	Approved / deferred / refused / conditional inclusion			
If deferred, final decision	Approved / refused / conditional inclusion			
Date applicant notified of decision				
Date relevant bodies notified (where relevant)				
End of 30 day appeal period				
Appeal received?	Yes/No			
Outcome of appeal (where relevant)	Appeal upheld/dismissed			

Completed by

Name:

Signature: Date:

CHAPTER 4C

Procedure for Application to Join the Pharmaceutical List – Pharmacy – Body Corporate

Chapter aims and objectives

48. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by pharmacy bodies corporate alongside their application for inclusion in a pharmaceutical list for the first time.

49. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

50. This document must be read in conjunction with the Regulations.

51. A checklist for noting the status of the application is provided at the end of this procedure.

52. A flowchart summarising the procedure below is provided at Annex 1.

53. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of receipt of information) can be sent to the		

Action		Complete?	Notes
	applicant. Go to step 12. If any of the information, documentation or undertakings are missing, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided, send Annex 5 (notification of outcome of review and request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided, send Annex 6 (notification of outcome of review and withdrawal of request) and go to step 9.		

Action		Complete?	Notes
8.	If the information and/or documentation is received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	Check that the company is registered on the Companies House website (http://www.companieshouse.gov.uk) and that the date of incorporation of the company is before the date of the application for inclusion in the relevant		

Action		Complete?	Notes
	pharmaceutical list. Check also that no directors have been disqualified.		
13.	If the company is not registered send Annex 12 (Companies House registration not confirmed) and diarise follow-up action. Advise the officer dealing with the market entry application. If the date of incorporation is after the date of the application for inclusion in the relevant pharmaceutical list send Annex 13 (Companies House registration post-dates application) and diarise follow-up action. Advise the officer dealing with the market entry application.		
14.	Send Annex 14 (letter to the GPhC) to check the registration status of the superintendent pharmacist and of any director of the company who is a registered pharmacist.		
15.	If registration of the applicant with the GPhC is confirmed, go to step 16. If registration of the superintendent with the GPhC is not confirmed, send Annex 15 (unable to confirm registration of superintendent). If registration of any director that state they are registered with the GPhC cannot be confirmed, send Annex 16 (unable to confirm registration of director). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Send Annex 17 (enquiry) by email to NHS Protect, requesting a fraud check to be carried out on the company, superintendent and any director. Checks on the superintendent and any director who is a registered pharmacist		

Action		Complete?	Notes
	should include checks on other companies where they have been a superintendent or director. Diarise date for receipt of response and follow up if necessary.		
17.	Initiate an online enquiry to the NHS Litigation Authority in respect of past or current investigations relating to the company, superintendent and any director (http://www.nhsla.com/fhsau/Pages/Home.aspx). Checks on the superintendent and any director should include checks on other companies where they have been a superintendent or director. Diarise date for receipt of response and follow up if necessary.		
18.	Check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 18 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 19 (reference request) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to		

Action		Complete?	Notes
	provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 20 (letter to referee – chasing response) to that referee and if there is still no response send Annex 21 (letter to applicant – non-receipt of reference) to the applicant. Diarise the date for receipt of responses. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
21.	Once all the checks are completed, prepare the committee report (Annex 22) on the applicant for the performers list decision panel and send to the committee administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the panel is minded to conditionally include the applicant, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 23 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		

Action		Complete?	Notes
24.	If the application is refused: • under regulation 33(1) (mandatory refusal), send Annex 24 (mandatory refusal) to the applicant and Annex 25 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 26 (discretionary refusal) to the applicant and Annex 27 (notification of discretionary refusal) to the relevant bodies set out in regulation 88. Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the performers list decision panel is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 28 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 29 (conditions) to the applicant and Annex 30 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 31 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be		

Action		Complete?	Notes
	deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 32 (no further grounds to defer) to the applicant.		
27.	If the applicant fails to respond, or if they confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 33 (application withdrawn) to the applicant and advise the officer dealing with the market entry application. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed send Annex 34 (application proceeding) refer to the performers list decision panel and return to step 21 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the performers list decision panel and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

54. A checklist for noting the status of the application is provided below.

Checklist for Applications to Join the Pharmaceutical List

Fitness to Practise – Pharmacy Body Corporate

Name of applicant				
Legal form	Body corporate			
Address/best estimate of proposed premises				
Date application received				
Timescale for determination of application	30 days / 4 months			
Check the company is registered with Companies House	Yes / No. Registration number -			
The following checks are only to be undertaken on directors if they are also pharmacists.				
Confirmation of registration with GPhC a) Request sent b) Date response due c) Date response received	**Superintendent pharmacist**	**Director 1**	**Director 2**	**Director 3**
NHS Protect check a) Request sent b) Date response due	**Superintendent pharmacist**	**Director 1**	**Director 2**	**Director 3**

c) Date response received				
NHSLA check a) Request sent b) Date response due c) Date response received	**Superintendent pharmacist**	**Director 1**	**Director 2**	**Director 3**
References a) Requests sent b) Date responses due c) Date responses received	**Superintendent pharmacist**	**Director 1**	**Director 2**	**Director 3**
Decision a) Information sent b) Date decision due c) Date decision received				
Decision	Approved / deferred / refused / conditional inclusion			
If deferred, final decision	Approved / refused / conditional inclusion			
Date applicant notified of decision				
Date relevant bodies notified (where relevant)				
End of 30 day appeal period				

Appeal received?	Yes/No
Outcome of appeal (where relevant)	Appeal upheld/dismissed

Completed by

Name:

Signature: Date:

1.17.

CHAPTER 4D

Procedure for Application to Join the Pharmaceutical List – from a Dispensing Appliance Contractor – Sole Trader

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by dispensing appliance contractor sole traders alongside their application for inclusion in a pharmaceutical list for the first time.

2. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

3. This document must be read in conjunction with the Regulations.

4. A checklist for noting the status of the application is provided at the end of this procedure.

5. A flowchart summarising the procedure below is provided at Annex 1.

6. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out at Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of receipt of information) can be sent to the applicant. Go		

Action		Complete?	Notes
	to step 12. If not all the information, documentation or undertakings have been provided, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided, send Annex 5 (notification of outcome of review – request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided, send Annex 6 (notification of outcome of review – request withdrawn) and go to step 9.		

Action		Complete?	Notes
8.	If the information and/or documentation is received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	If the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 13. If the applicant qualified as a pharmacist in the United Kingdom, go to step 14.		

Action		Complete?	Notes
13.	Where the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the Commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services. Ensure the applicant has provided evidence of achieving a score of at least 7 in the academic level of the International English Language Testing System (IELTS). If the applicant has provided such evidence, go to step 14. If the applicant has not provided such evidence, refer the matter to the medical director.		
14.	Where the applicant is a pharmacist, send Annex 12 (letter to the GPhC) to check the registration status of the applicant.		
15.	If registration of the applicant with the GPhC is confirmed, go to step 16. If registration of the applicant with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Where the applicant is a pharmacist, GP, dentist or optometrist, send Annex 14 (enquiry) by email to NHS Protect, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary.		
17.	Where the applicant is a pharmacist, GP,		

Action		Complete?	Notes
	dentist or optometrist, initiate an online enquiry to the NHS Litigation Authority in respect of past or current investigations relating to the applicant (http://www.nhsla.com/fhsau/Pages/Home.aspx). Diarise date for receipt of response and follow up if necessary.		
18.	Where the applicant is a pharmacist, check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 15 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 16 (reference request) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 17 (letter to referee – chasing response) to that referee and if there is still no response send Annex 18 (non-receipt of reference) to the applicant. Diarise the date for receipt of responses. Liaise with the officer dealing with the market entry application so they are aware there		

Action		Complete?	Notes
	may be a delay.		
21.	Once all the checks are completed, prepare the committee report (Annex 19) on the applicant for the performers list decision panel and send to the committee administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the panel is minded to conditionally include the applicant, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 20 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		
24.	If the application is refused: • where the applicant is a pharmacist, under regulation 30 (language requirement), send Annex 21 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 22 (mandatory refusal) to the applicant and Annex 23 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 24 (discretionary refusal) to the applicant and Annex 25		

Action		Complete?	Notes
	(notification of discretionary refusal) to the relevant bodies set out in regulation 88. Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the performers list decision panel is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 26 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 27 (conditions) to the applicant and Annex 28 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 29 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 30 (no further grounds to defer) to the applicant.		
27.	If the applicant fails to respond, or if they confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 31 (application withdrawn) to		

Action		Complete?	Notes
	the applicant and advise the officer dealing with the market entry application. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 32 (application proceeding) refer to the performers list decision panel and return to step 21 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the performers list decision panel and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

7. A checklist for noting the status of the application is provided below.

Checklist for Applications to Join the Pharmaceutical List

Fitness to Practise – Dispensing Appliance Contractor - Sole Trader

Name of applicant	
Legal form	Sole trader (DAC)
Address/best estimate of proposed premises	
Date application received	
Timescale for determination of application	30 days / 4 months
English language knowledge a) Required (pharmacists only)? b) Satisfactory	 Yes / No Yes / No
Confirmation of registration with GPhC (pharmacists only) a) Request sent b) Date response due c) Date response received	
NHS Protect check (only if a pharmacist, GP, dentist or optometrist) a) Request sent b) Date response due c) Date response received	
NHSLA check (only if a pharmacist, GP, dentist or optometrist)	

a) Request sent b) Date response due c) Date response received	
References (pharmacists only) a) Requests sent b) Date responses due c) Date responses received	
Decision a) Information sent b) Date decision due c) Date decision received	
Decision	Approved / deferred / refused / conditional inclusion
If deferred, final decision	Approved / refused / conditional inclusion
Date applicant notified of decision	
Date relevant bodies notified (where relevant)	
End of 30 day appeal period	
Appeal received?	Yes/No

Completed by

Signature: Date:

Name:

CHAPTER 4E

Procedure for Application to Join the Pharmaceutical List – Dispensing Appliance Contractor – Partnership

Chapter aims and objectives

8. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by dispensing appliance contractor partnerships alongside their application for inclusion in a pharmaceutical list for the first time.

9. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

10. This document must be read in conjunction with the Regulations.

11. A checklist for noting the status of the application is provided at the end of this procedure.

12. A flowchart summarising the procedure below is provided at Annex 1.

13. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that each partner has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out at Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of		

Action		Complete?	Notes
	receipt of information) can be sent to the applicant. Go to step 12. If any of the information, documentation or undertakings are missing, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided, send Annex 5 (notification of outcome of review and request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided, send Annex 6 (notification of outcome of review and withdrawal of request) and go to step 9.		

Action		Complete?	Notes
8.	If the information and/or documentation is received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	If a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 13. If a partner of the applicant qualified as a pharmacist in the United Kingdom, go to		

Action		Complete?	Notes
	step 14.		
13.	Where a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the Commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services. Ensure the pharmacist has provided evidence of achieving a score of at least 7 in the academic level of the International English Language Testing System (IELTS). If the pharmacist has provided such evidence, go to step 14. If the pharmacist has not provided such evidence, refer the matter to the medical director.		
14.	Where a partner is a pharmacist, send Annex 12 (letter to the GPhC) to check the registration status of each partner.		
15.	If registration of the partners with the GPhC is confirmed, go to step 16. If registration of a partner with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Send Annex 14 (enquiry) by email to NHS Protect, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary.		

Action		Complete?	Notes
17.	Initiate an online enquiry to the NHS Litigation Authority in respect of past or current investigations relating to the applicant. (http://www.nhsla.com/fhsau/Pages/Home.aspx) Diarise date for receipt of response and follow up if necessary.		
18.	Where a partner is a pharmacist, check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 15 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 16 (request letter and pro forma) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 17 (letter to referee – chasing response) to that referee and if there is still no response send Annex 18 (non-receipt of reference) to the applicant. Diarise the date for receipt of responses.		

Action		Complete?	Notes
	Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
21.	Once all the checks are completed, prepare the committee report (Annex 19) on the applicant for the performers list decision panel and send to the panel administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the panel that in the event of a refusal or conditional inclusion this applies collectively to the partnership as on entity and not to an individual.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the panel is minded to conditionally include the applicant, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 20 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		
24.	If the application is refused: • where the applicant is a pharmacist, under regulation 30 (language requirement), send Annex 21 (refusal – language requirement); • under regulation 33(1) (mandatory		

Action		Complete?	Notes
	refusal), send Annex 22 (mandatory refusal) to the applicant and Annex 23 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 24 (discretionary refusal) to the applicant and Annex 25 (notification of discretionary refusal) to the relevant bodies set out in regulation 88. Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the performers list decision panel is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 26 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 27 (conditions) to the applicant and Annex 28 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 29 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to		

Action		Complete?	Notes
	recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 30 (no further grounds to defer) to the applicant.		
27.	If the applicant fails to respond, or if they confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 31 (application withdrawn) to the applicant and advise the officer dealing with the market entry application. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 32 (application proceeding), refer to the performers list decision panel and return to step 19 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the performers list decision panel and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

14. A checklist for noting the status of the application is provided below.

Checklist for Applications to Join the Pharmaceutical List

Fitness to Practise – Dispensing Appliance Contractor Partnership

Name of applicant				
Legal form	Partnership (dispensing appliance contractor)			
Address/best estimate of proposed premises				
Date application received				
Timescale for determination of application	30 days / 4 months			
English language knowledge a) Required (pharmacists only)? b) Satisfactory?	 Yes / No Yes / No			
Confirmation of registration with GPhC (pharmacists only) a) Request sent b) Date response due c) Date response received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
NHS Protect check (only if a pharmacist, GP, dentist or optometrist) a) Request sent	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**

b) Date response due c) Date response received				
NHSLA check (only if a pharmacist, GP, dentist or optometrist) a) Request sent b) Date response due c) Date response received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
References (pharmacists only) a) Requests sent b) Date responses due c) Date responses received	**Partner 1**	**Partner 2**	**Partner 3**	**Partner 4**
Decision a) Information sent b) Date decision due c) Date decision received				
Decision	Approved / deferred / refused / conditional inclusion			
If deferred, final decision	Approved / refused / conditional inclusion			
Date applicant notified of decision				
Date relevant bodies notified (where relevant)				

End of 30 day appeal period	
Appeal received?	Yes/No
Outcome of appeal (where relevant)	Appeal upheld/dismissed

Completed by

Name:

Signature: Date:

1.18.

CHAPTER 4F

Procedure for Application to Join the Pharmaceutical List – Dispensing Alliance Contractor Body Corporate

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications for inclusion in one of the pharmaceutical lists for the first time are dealt with in line with the requirements of the Regulations. It focuses on the processing of the fitness information that is to be provided by dispensing alliance contractor bodies corporate alongside their application for inclusion in a pharmaceutical list for the first time.

2. Fitness procedures must be completed before the market entry application is determined under the relevant procedure (including where deferred on fitness grounds). Market entry applications must be determined within either 30 days or four months of receipt depending on the type of application.

3. This document must be read in conjunction with the Regulations.

4. A checklist for noting the status of the application is provided at the end of this procedure.

5. A flowchart summarising the procedure below is provided at Annex 1.

6. A fitness information form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 2.		
2.	Where all relevant information, documentation and undertakings have been provided, liaise with the officer dealing with the market entry application to ensure that Annex 3 (confirmation of receipt of information) can be sent to the applicant. Go to step 12.		

Action		Complete?	Notes
	If any of the information, documentation or undertakings are missing, go to step 3.		
3.	If information and/or documents have not been provided, go to step 4. If undertakings have not been provided, go to step 9.		
4.	Where there is missing information and/or documentation send Annex 4 (request for missing information). The amount of time to be given for submission is 10 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
5.	Diarise the date for the missing information and/or documentation to be submitted.		
6.	If the applicant requests a review of the request, go to step 7. If the applicant does not request a review of the request, go to step 8.		
7.	If the applicant requests a review of the request, forward this to the Pharmacy Contracts Manager for a decision. If the outcome is that the information/documentation is to be provided, send Annex 5 (notification of outcome of review and request for missing information) and go to step 8. If the outcome is that the information/documentation is not to be provided, send Annex 6 (notification of outcome of review and withdrawal of request) and go to step 9.		
8.	If the information and/or documentation is received by the due date, send Annex 7		

Action		Complete?	Notes
	(confirmation of receipt of missing information) to the applicant. Go to step 9. If the information and/or documentation is not received by the due date, liaise with the officer dealing with the market entry application and send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. No further action is necessary.		
9.	Where there are missing undertakings, complete and send to the applicant Annex 9 (request for missing undertakings). The amount of time to be given for submission is 5 working days. Liaise with the officer dealing with the market entry application so they are aware there may be a delay.		
10.	Diarise the date for the missing undertakings to be submitted.		
11.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 12. If the missing undertakings are not received by the due date, liaise with the officer dealing with the market entry application and send Annex 11 (missing undertakings not received). Treat the application as withdrawn. No further action is necessary.		
12.	Check that the company is registered on the Companies House website (http://www.companieshouse.gov.uk) and that the date of incorporation of the company is before the date of the application for inclusion in the relevant pharmaceutical list. Check also that no directors have been disqualified.		

Action		Complete?	Notes
13.	If the company is not registered send Annex 12 (Companies House registration not confirmed) and diarise follow-up action. Advise the officer dealing with the market entry application. If the date of incorporation is after the date of the application for inclusion in the relevant pharmaceutical list send Annex 13 (Companies House registration post-dates application) and diarise follow-up action. Advise the officer dealing with the market entry application.		
14.	Where a director is also a pharmacist, send Annex 14 (letter to the GPhC) to check the registration status.		
15.	If registration of the director(s) with the GPhC is confirmed, go to step 16. If registration of a director that is claiming to be a registered pharmacist cannot be confirmed, send Annex 15 (unable to confirm registration of director). Diarise follow-up action. Liaise with the officer dealing with the market entry application as appropriate.		
16.	Send Annex 16 (enquiry) by email to NHS Protect, requesting a fraud check to be carried out on the company and the director(s). Checks on the superintendent and any director should include checks on other companies where they have been a superintendent or director. Diarise date for receipt of response and follow up if necessary.		
17.	Where a director is also a pharmacist, initiate an online enquiry to the NHS Litigation Authority in respect of past or current investigations relating to the company and		

Action		Complete?	Notes
	the directors (http://www.nhsla.com/fhsau/Pages/Home.aspx). Checks on the directors should include checks on other companies where they have been a director or, where they are a pharmacist, a superintendent. Diarise date for receipt of response and follow up if necessary.		
18.	Where a director is also a pharmacist, check that referees who are pharmacists are registered with the GPhC and that there are no fitness to practise proceedings against that individual by sending Annex 17 (letter to GPhC – referees). Where the response is unsatisfactory, refer the matter to the medical director. Where the response is satisfactory, send Annex 18 (reference request) to each referee nominated by the applicant and go to step 19. If alternative referees have been nominated because the applicant is unable to nominate two referees in respect of two recent posts, refer to this in the committee report.		
19.	Diarise date for receipt of responses and follow-up action as below.		
20.	If a reference is received, got to step 21. If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the applicant to nominate an alternative person. Go back to step 18. If no response is received, send Annex 19 (letter to referee – chasing response) to that referee and if there is still no response send Annex 20 (letter to applicant – non-receipt of reference) to the applicant. Diarise the date for receipt of responses. Liaise with the officer dealing with the market		

Action		Complete?	Notes
	entry application so they are aware there may be a delay.		
21.	Once all the checks are completed, prepare the committee report (Annex 21) on the applicant for the performers list decision panel and send to the committee administrator/secretary. Set the date for return of the decision in order to ensure the overall decision (i.e. including market entry provisions) is made within 30 days or four months of receipt as appropriate.		
22.	If the application is approved, go to step 23. If the application is refused, go to step 24. If the panel is minded to conditionally include the applicant, go to step 25. If the application is deferred, go to step 26.		
23.	If the applicant is suitable for inclusion on fitness grounds, send Annex 22 (approval letter) to the applicant. Advise the officer dealing with the market entry application that the application has been approved on fitness grounds. No other steps are necessary.		
24.	If the application is refused: • under regulation 33(1) (mandatory refusal), send Annex 23 (mandatory refusal) to the applicant and Annex 24 (notification of mandatory refusal) to the relevant bodies set out in regulation 88; or • under regulation 33(2) (discretionary refusal), send Annex 25 (discretionary refusal) to the applicant and Annex 26 (notification of discretionary refusal) to the relevant bodies set out in regulation 88.		

Action		Complete?	Notes
	Advise the officer dealing with market entry application that the application has been refused on fitness grounds. Go to step 28.		
25.	If the performers list decision panel is minded to conditionally include the applicant, arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 27 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 28 (conditions) to the applicant and Annex 29 (notification of conditions) to the relevant bodies set out in regulation 88. Advise the officer dealing with the market entry application that if the market entry application is approved, the applicant is to be conditionally included in the relevant pharmaceutical list on fitness grounds. Go to step 28.		
26.	If the application is deferred send Annex 30 (deferral) to the applicant and advise the officer dealing with the market entry application that the application is to be deferred on fitness grounds. Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the fitness information at the relevant time. Once the outcome of the investigation is known send Annex 31 (no further grounds to defer) to the applicant.		
27.	If the applicant fails to respond, or if they confirm that they do not wish to proceed, the application is to be treated as withdrawn. Send Annex 32 (application withdrawn) to the applicant and advise the officer dealing with the market entry application. No further steps are necessary.		

Action		Complete?	Notes
	If the applicant updates the application and confirms that they wish to proceed send Annex 33 (application proceedings), refer to the performers list decision panel and return to step 21 above for a decision and liaise with the officer dealing with the market entry application.		
28.	If notice of an appeal against refusal or conditional inclusion is received, advise the performers list decision panel and assist in the production of a response. Advise the officer dealing with the market entry application that an appeal has been made. Once the outcome of the appeal is known advise the officer dealing with the market entry application accordingly. No further steps are necessary.		

Checklist

7. A checklist for noting the status of the application is provided on the next page.

Checklist for Applications to Join the Pharmaceutical List

Fitness to Practise – Dispensing Appliance Contractor Body Corporate

Name of applicant				
Legal form	Body corporate – dispensing appliance contractor			
Address/best estimate of proposed premises				
Date application received				
Timescale for determination of application	30 days / 4 months			
Check the company is registered with Companies House	Yes / No. Registration number -			
Confirmation of registration with GPhC (pharmacists only) a) Request sent b) Date response due c) Date response received	**Director 1**	**Director 2**	**Director 3**	**Director 4**
NHS Protect check (only if a pharmacist, GP, dentist or optometrist) a) Request sent b) Date response due c) Date response				

received				
NHSLA check (only if a pharmacist, GP, dentist or optometrist) a) Request sent b) Date response due c) Date response received				
References (Pharmacists only) a) Requests sent b) Date responses due c) Date responses received				
Decision a) Information sent b) Date decision due c) Date decision received				
Decision	Approved / deferred / refused / conditional inclusion			
If deferred, final decision	Approved / refused / conditional inclusion			
Date applicant notified of decision				
Date relevant bodies notified (where relevant)				
End of 30 day appeal period				

Appeal received?	Yes/No
Outcome of appeal (where relevant)	Appeal upheld/dismissed

Completed by

Name:

Signature: Date:

CHAPTER 5

Current Needs

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications offering to meet an identified current need are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations). It is to be used where either the address of the proposed premises is known or where a best estimate has been given.

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 5 of the DH Guidance.

4. A flowchart summarising the procedure where the address of the proposed premises is known is provided at Annex 1A.

5. A flowchart summarising the procedure where a best estimate has been given is provided at Annex 1B

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of an application to meet an identified current need, check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, continue with this procedure. If they are, or could be, refer to Chapter 14 before continuing with this procedure. Check the application details have been added to the applications database. Ensure the database is updated as the application		

Action		Complete?	Notes
	progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided liaise with the officer responsible for fitness to practise checks (if applicable) to ensure that an acknowledgement of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant is offering to meet an identified current need for enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with the officer responsible for fitness to practise		

Action		Complete?	Notes
	checks (if applicable).and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; • submission of the required fitness information – 10 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex		

Action		Complete?	Notes
	6). Then go to step 12.		
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to meet an identified current need for enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to meet an identified current need for enhanced services, enclose with the		

Action		Complete?	Notes
	acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Complete the deferral report (Annex 12) and send to the decision-maker (set out in Chapter 3) for a decision on whether the best estimate is acceptable (if relevant) and whether the application should be deferred under Regulation 14(1) to (3) or Regulation 32.		
17.	Refer to the DH guidance for further information on deciding whether the application should be deferred.		
18.	Where an application is not to be deferred on either non-fitness or fitness grounds, interested parties must be notified of the application. Annex 13 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
19.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or		

Action		Complete?	Notes
	personal information.		
20.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
21.	Once the outcome is known and the best estimate is acceptable (if relevant), notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
22.	If the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 15) to the applicant.		
23.	Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the application at the relevant time.		
24.	Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 16) to the applicant.		
25.	If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn.		

Action		Complete?	Notes
	Once the applicant has responded and where they wish to proceed, notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
26.	If the decision-maker (set out in Chapter 3) confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 17) to the applicant.		
27.	Diarise the date for the second best estimate to be submitted.		
28.	On receipt of the second best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.		
29.	If the second best estimate is acceptable, send confirmation that the second best estimate is acceptable to the applicant (Annex 18) and notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) If the second best estimate is not acceptable, write back to the applicant for a further best estimate.		
30.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 19) to the applicant.		
31.	During the 45-day notification period, ensure, if relevant, that a fitness to practise		

Action		Complete?	Notes
	decision has been made (or will be made before the application is determined on market entry grounds).		
32.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 20).		
33.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
34.	Chapter 5 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
35.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 21).		
36.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker wishes to hear from. At least 14 days' notice must be given.		
37.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendation/decision.		

Action		Complete?	Notes
38.	Prepare a report (Annex 24) on the application for the decision-maker (as set out in Chapter 3) and send to the committee administrator/secretary.		
39.	Refer to Chapter 5 of the DH guidance for further information on the determination of applications.		
40.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 25 for information on third party rights of appeal. The granted decision letters for applications where the address of the premises is known are: • Granted – to the applicant (Annex 26); • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • Granted – to the applicant (Annex 29); • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). The refusal decision letters for applications where the address is known or a best estimate has been given are: • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed		

Action		Complete?	Notes
	distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
41.	Diarise the latest date for appeals to be made.		
42.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
43.	Where an address for the proposed premises was provided, if the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 34) to the applicant. Include a copy of the banking mandate.		
44.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 35 where the address of the proposed premises was provided or Annex 36 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate.		
45.	Where the application contains a best estimate of the location of the proposed premises, go to step 46. Where the application contains the address of the proposed premises, go to step 47.		
46.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address check that it was received within the relevant timescale. If it was, forward it to the		

Action		Complete?	Notes
	decision-maker (as set out in Chapter 3) to determine whether or not it is a valid notification. If the notification wasn't received in time send notification of receipt of premises not valid (Annex 37). If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 38) to the applicant and send notification of premises (Annex 39) to those parties notified of the decision on the original application. If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 40). Where the application provided a best estimate of the location of the proposed premises and the NHS Litigation Authority determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 41).		
47.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
48.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send an acknowledgement of receipt (Annex 42).		
49.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
50.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43) advising the applicant of their contractor number when received from NHS Prescription Services.		

Action		Complete?	Notes
51.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date update the list accordingly and advise the relevant HWB.		
52.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 44).		
53.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 45) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • The local PCS provider office; • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 6

Procedure - Future Needs

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications offering to meet an identified future need are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations). It is to be used where either the address of the proposed premises is known or where a best estimate has been given.

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 6 of the DH Guidance.

4. A flowchart summarising the procedure where the address of the proposed premises is known is provided at Annex 1A.

5. A flowchart summarising the procedure where a best estimate has been given is provided at Annex 1B.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of an application to meet an identified future need check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, continue with this procedure. If they are, or could be, refer to Chapter 14 before continuing with this procedure. Check the application details have been added to the applications database. Ensure		

Action		Complete?	Notes
	the database is updated as the application progresses.		
2.	Where the applicant is not already included in the relevant pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided liaise with the officer responsible for fitness to practise checks (if applicable) to ensure that an acknowledgement of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant is offering to meet an identified future need for enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with		

Action		Complete?	Notes
	the officer responsible for fitness to practise checks (if applicable).and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; • submission of the required fitness information – 10 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex		

Action		Complete?	Notes
	6). Go to step 12.		
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to meet an identified future need for enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to meet an identified future need for enhanced services, enclose with the		

Action		Complete?	Notes
	acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Complete the deferral report (Annex 12) and send to the decision-maker (set out in Chapter 3) for a decision on whether the best estimate is acceptable (if relevant) and whether the application should be deferred under Regulation 16(1) to (4) or Regulation 32.		
17.	Chapter 6 of the DH guidance provides further information on deciding whether the application should be deferred.		
18.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, interested parties must be notified of the application. Annex 13 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
19.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, notify the interested parties as of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or		

Action		Complete?	Notes
	personal information.		
20.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
21.	Once the outcome is known and the best estimate is acceptable (if relevant), notify interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
22.	If the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 15) to the applicant.		
23.	Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the application at the relevant time.		
24.	Once the reason for deferral ceases and the best estimate is acceptable (if relevant) send the notification of cessation of deferral – non-fitness grounds (Annex 16) to the applicant.		
25.	If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and		

Action		Complete?	Notes
	where they wish to proceed, notify interested parties of the application using the notification of application to interested parties (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
26.	If the decision-maker (set out in Chapter 3) confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 17) to the applicant.		
27.	Diarise the date for the second best estimate to be submitted.		
28.	On receipt of the second best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.		
29.	If the second best estimate is acceptable, send confirmation that the second best estimate is acceptable to the applicant (Annex 18) and notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) If the second best estimate is not acceptable, write back to the applicant for a further best estimate.		
30.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 19) to the applicant.		
31.	During the 45-day notification period, ensure, if relevant, that a fitness to practise decision has been made (or will be made before the application is determined on		

Action		Complete?	Notes
	market entry grounds).		
32.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 20).		
33.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
34.	Chapter 6 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
35.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 21).		
36.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
37.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendation/decision.		

Action		Complete?	Notes
38.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
39.	Refer to Chapter 6 of the DH guidance for further information on the determination of applications.		
40.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 25 for information on third party rights of appeal. The granted decision letters for applications where the address of the premises is known are: • Granted – to the applicant (Annex 26); • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • Granted – to the applicant (Annex 29); • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). The refusal decision letters for applications where the address is known or a best estimate has been given are: • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed		

Action		Complete?	Notes
	distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
41.	Diarise the latest date for appeals to be made.		
42.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
43.	Where an address for the proposed premises was provided, if the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 34) to the applicant. Include a copy of the banking mandate.		
44.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 35 where the address of the proposed premises was provided or Annex 36 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate.		
45.	Where the application contains a best estimate of the location of the proposed premises, go to step 46. Where the application contains the address of the proposed premises, go to step 47.		
46.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. Ensure this is updated if the Commissioner allows an extension. On receipt of the notification of the address		

Action		Complete?	Notes
	check that it was received within the relevant timescale. If it was, forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification. If the notification wasn't received in time send notification of receipt of premises not valid (Annex 37). If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 38) to the applicant and send notification of premises (Annex 39) to those parties notified of the decision on the original application. If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 40). Where the application provided a best estimate of the location of the proposed premises and the NHS Litigation Authority determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 41).		
47.	Diarise the latest date by which the template notice of commencement can be submitted.		
48.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send an acknowledgement of receipt (Annex 42).		
49.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
50.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43) advising the applicant of their contractor number when received from NHS Prescription Services.		

Action		Complete?	Notes
51.	Diarise the date that the applicant is to be included the pharmaceutical list. On that date update the list accordingly and advise the relevant HWB.		
52.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 44).		
53.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 45) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 7

Procedure - Improvements or Better Access

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications offering to secure identified improvements or better access are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations). It is to be used where either the address of the proposed premises is known or where a best estimate has been given.

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 7 of the DH Guidance.

4. A flowchart summarising the procedure where the address of the proposed premises is known is provided at Annex 1A.

5. A flowchart summarising the procedure where a best estimate has been given is provided at Annex 1B.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of an application to secure identified improvements or better access check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, continue with this procedure. If they are, or could be, refer to Chapter 14 before continuing with this procedure. Check the application details have been		

Action		Complete?	Notes
	added to the applications database. Ensure the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided liaise with the officer responsible for fitness to practise checks (if applicable) to ensure that an acknowledgement of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant is offering to secure identified improvements or better access to enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in		

Action		Complete?	Notes
	the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; • submission of the required fitness information – 10 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10. If the information		

Action		Complete?	Notes
	is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 12.		
10.	On receipt of the information/ documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to secure identified improvements or better access to enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		

Action		Complete?	Notes
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to secure identified improvements or better access to enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Complete the deferral report (Annex 12) and send to the decision-maker (set out in Chapter 3) for a decision on whether the best estimate is acceptable (if relevant) and whether the application should be deferred under Regulation 19(1) to (3) or Regulation 32.		
17.	Refer to the DH guidance for further information on deciding whether the application should be deferred.		
18.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, interested parties must be notified of the application. Annex 13 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		

Action		Complete?	Notes
19.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, notify the interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
20.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
21.	Once the outcome is known and the best estimate is acceptable (if relevant), notify interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
22.	If the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 15) to the applicant.		
23.	Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the application at the relevant time.		
24.	Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 16) to the applicant.		
25.	If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light		

Action		Complete?	Notes
	of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If they fail to respond their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, notify interested parties of the application using the notification of application to interested parties (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
26.	If the decision-maker (set out in Chapter 3) confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 17) to the applicant.		
27.	Diarise the date for the second best estimate to be submitted.		
28.	On receipt of the second best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.		
29.	If the second best estimate is acceptable, send confirmation that the second best estimate is acceptable to the applicant (Annex 18) and notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) If the second best estimate is not acceptable, write back to the applicant for a further best estimate.		
30.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for		

Action		Complete?	Notes
	payment (Annex 19) to the applicant.		
31.	During the 45-day notification period, ensure, if relevant, that a fitness to practise decision has been made (or will be made before the application is determined on market entry grounds).		
32.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 20).		
33.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
34.	Chapter 7 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
35.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 21).		
36.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		

Action		Complete?	Notes
37.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendation/decision.		
38.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
39.	Refer to Chapter 5 of the DH guidance for further information on the determination of applications.		
40.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 25 for information on third party rights of appeal. The granted decision letters for applications where the address of the premises is known are: • Granted – to the applicant (Annex 26); • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • Granted – to the applicant (Annex 29); • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). The refusal decision letters for applications where the address is known or a best estimate has been given are: • Refused – to the applicant (Annex 32);		

Action		Complete?	Notes
	and • Refused – to a third party (Annex 33). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
41.	Diarise the latest date for appeals to be made.		
42.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
43.	Where an address for the proposed premises was provided, if the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 34) to the applicant. Include a copy of the banking mandate.		
44.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 35 where the address of the proposed premises was provided or Annex 36 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate.		
45.	Where the application contains a best estimate of the location of the proposed premises, go to step 46. Where the application contains the address of the proposed premises, go to		

Action		Complete?	Notes
	step 47.		
46.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address check that it was received within the relevant timescale. If it was, forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification. If the notification wasn't received in time send notification of receipt of premises not valid (Annex 37). If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 38) to the applicant and send notification of premises (Annex 39) to those parties notified of the decision on the original application. If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 40). Where the application provided a best estimate of the location of the proposed premises and the NHS Litigation Authority determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 41).		
47.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
48.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send an acknowledgement of receipt (Annex 42).		

Action		Complete?	Notes
49.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
50.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43) advising the applicant of their contractor number when received from NHS Prescription Services.		
51.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date update the list accordingly and advise the relevant HWB.		
52.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 44).		
53.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 45) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and		

Action		Complete?	Notes
	• the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 8

Procedure - Unforeseen Benefits

1.19.

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications offering unforeseen benefits are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations). It is to be used where either the address of the proposed premises is known or where a best estimate has been given.

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 8 of the DH Guidance.

4. A flowchart summarising the procedure where the address of the proposed premises is known is provided at Annex 1A.

5. A flowchart summarising the procedure where a best estimate has been given is provided at Annex 1B.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of an application offering unforeseen benefits check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, continue with this procedure. If they are, or could be, refer to Chapter 14 before continuing with this procedure. Check the application details have been added to the applications database. Ensure		

Action		Complete?	Notes
	the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided liaise with the officer responsible for fitness to practise checks (if applicable) to ensure that an acknowledgement of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant is offering to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with the officer responsible for fitness to practise		

Action		Complete?	Notes
	checks (if applicable) and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; • submission of the required fitness information – 10 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 12.		

Action		Complete?	Notes
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		

Action		Complete?	Notes
15.	If the missing undertakings aren't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Complete the deferral report (Annex 12) and send to the decision-maker (set out in Chapter 3) for a decision on whether the best estimate is acceptable (if relevant) and whether the application should be deferred under Regulation 19(2) to (4) or Regulation 32.		
17.	Refer to the DH guidance for further information on deciding whether the application should be deferred.		
18.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, interested parties must be notified of the application. Annex 13 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
19.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, notify the interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
20.	If the application is to be deferred on fitness to practise grounds, do not progress any		

Action		Complete?	Notes
	further until the outcome of the cause of the deferral is known.		
21.	Once the outcome is known and the best estimate is acceptable (if relevant), notify interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
22.	If the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 15) to the applicant.		
23.	Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the application at the relevant time.		
24.	Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 16) to the applicant.		
25.	If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If they fail to respond their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, notify interested parties of the application using the notification of application to interested parties (Annex 14) enclosing a copy of the application.		

Action		Complete?	Notes
	Do not include any fitness to practise or personal information.		
26.	If the decision-maker (set out in Chapter 3) confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 17) to the applicant.		
27.	Diarise the date for the second best estimate to be submitted.		
28.	On receipt of the second best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.		
29.	If the second best estimate is acceptable, send confirmation that the second best estimate is acceptable to the applicant (Annex 18) and notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) If the second best estimate is not acceptable, write back to the applicant for a further best estimate.		
30.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 19) to the applicant.		
31.	During the 45-day notification period, ensure, if relevant, that a fitness to practise decision has been made (or will be made before the application is determined on market entry grounds).		
32.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded		

Action		Complete?	Notes
	using the notification of circulation of comments (Annex 20).		
33.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
34.	Chapter 8 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
35.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 21).		
36.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
37.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendation/decision.		
38.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		

Action		Complete?	Notes
39.	Refer to Chapter 8 of the DH guidance for further information on the determination of applications.		
40.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 25 for information on third party rights of appeal. The granted decision letters for applications where the address of the premises is known are: • Granted – to the applicant (Annex 26); • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • Granted – to the applicant (Annex 29); • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). The refusal decision letters for applications where the address is known or a best estimate has been given are: • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		

Action		Complete?	Notes
41.	Diarise the latest date for appeals to be made.		
42.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
43.	Where an address for the proposed premises was provided, if the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 34) to the applicant. Include a copy of the banking mandate.		
44.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 35 where the address of the proposed premises was provided or Annex 36 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate.		
45.	Where the application contains a best estimate of the location of the proposed premises, go to step 46. Where the application contains the address of the proposed premises, go to step 47.		
46.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address check that it was received within the relevant timescale. If it was, forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification. If the notification wasn't received in time send notification of receipt of premises not		

Action		Complete?	Notes
	valid (Annex 37). If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 38) to the applicant and send notification of premises (Annex 39) to those parties notified of the decision on the original application. If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 40). Where the application provided a best estimate of the location of the proposed premises and the NHS Litigation Authority determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 41).		
47.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
48.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send an acknowledgement of receipt (Annex 42).		
49.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
50.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43) advising the applicant of their contractor number when received from NHS Prescription Services.		
51.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date update the list accordingly and advise the relevant HWB.		

Action		Complete?	Notes
52.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 44).		
53.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 45) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Directory of Services • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 9

Procedure - Future Improvements or Better Access

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications offering to secure identified future improvements or better access are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations). It is to be used where either the address of the proposed premises is known or where a best estimate has been given.

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 9 of the DH Guidance.

4. A flowchart summarising the procedure where the address of the proposed premises is known is provided at Annex 1A.

5. A flowchart summarising the procedure where a best estimate has been given is provided at Annex 1B.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of an application to secure identified future improvements or better access check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, continue with this procedure. If they are, or could be, refer to Chapter 14 before continuing with this procedure. Check the application details have been		

Action		Complete?	Notes
	added to the applications database. Ensure the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided liaise with the officer responsible for fitness to practise checks (if applicable) to ensure that an acknowledgement of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant is offering to secure identified future improvements or better access to enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or		

Action		Complete?	Notes
	documentation in the application, liaise with the officer responsible for fitness to practise checks (if applicable).and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; • submission of the required fitness information – 10 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex		

Action		Complete?	Notes
	6). Go to step 12.		
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to secure identified future improvements or better access to enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if applicable) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to secure identified future improvements or better access to enhanced services, enclose with		

Action		Complete?	Notes
	the acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren't received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable) and send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Complete the deferral report (Annex 12) and send to the decision-maker (set out in Chapter 3) for a decision on whether the best estimate is acceptable (if relevant) and whether the application should be deferred under Regulation 21(1) to (4) or Regulation 32.		
17.	Refer to the DH guidance for further information on deciding whether the application should be deferred.		
18.	Where the best estimate of the location of the proposed premises is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, interested parties must be notified of the application. Annex 13 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
19.	Where the best estimate is acceptable (if relevant) and the application is not to be deferred on either non-fitness or fitness grounds, notify the interested parties of the application (Annex 14) enclosing a copy of the application.		

Action		Complete?	Notes
	Do not include any fitness to practise or personal information.		
20.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
21.	Once the outcome is known and the best estimate is acceptable (if relevant), notify interested parties of the application (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
22.	If the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 15) to the applicant.		
23.	Make a note of the reason for the deferral and diarise reminders so as to be able to recommence the processing of the application at the relevant time.		
24.	Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 16) to the applicant.		
25.	If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If they fail to respond their application is treated as withdrawn. Once the applicant has responded and		

Action		Complete?	Notes
	where they wish to proceed, notify interested parties of the application using the notification of application to interested parties (Annex 14) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
26.	If the decision-maker (set out in Chapter 3) confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 17) to the applicant.		
27.	Diarise the date for the second best estimate to be submitted.		
28.	On receipt of the second best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.		
29.	If the second best estimate is acceptable, send confirmation that the second best estimate is acceptable to the applicant (Annex 18) and notify interested parties as determined by the decision-maker (set out in Chapter 3) of the application using the notification of application to interested parties (Annex 14) If the second best estimate is not acceptable, write back to the applicant for a further best estimate.		
30.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 19) to the applicant.		
31.	During the 45-day notification period, ensure, if relevant, that a fitness to practise decision has been made (or will be made before the application is determined on		

Action		Complete?	Notes
	market entry grounds).		
32.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 20).		
33.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
34.	Chapter 8 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
35.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 21).		
36.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
37.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendation/decision.		

Action		Complete?	Notes
38.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
39.	Refer to Chapter 8 of the DH guidance for further information on the determination of applications.		
40.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 25 for information on third party rights of appeal. The granted decision letters for applications where the address of the premises is known are: • Granted – to the applicant (Annex 26); • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • Granted – to the applicant (Annex 29); • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). The refusal decision letters for applications where the address is known or a best estimate has been given are: • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed		

Action		Complete?	Notes
	distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
41.	Diarise the latest date for appeals to be made.		
42.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
43.	Where an address for the proposed premises was provided, if the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 34) to the applicant. Include a copy of the banking mandate.		
44.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 35 where the address of the proposed premises was provided or Annex 36 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate.		
45.	Where the application contains a best estimate of the location of the proposed premises, go to step 46. Where the application contains the address of the proposed premises, go to step 47.		
46.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address check that it was received within the relevant timescale. If it was, forward it to the		

Action		Complete?	Notes
	decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification. If the notification wasn't received in time send notification of receipt of premises not valid (Annex 37). If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 38) to the applicant and send notification of premises (Annex 39) to those parties notified of the decision on the original application. If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 40). Where the application provided a best estimate of the location of the proposed premises and the NHS Litigation Authority determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 41).		
47.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
48.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send an acknowledgement of receipt (Annex 42).		
49.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
50.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43) advising the applicant of their contractor number when received from NHS Prescription Services.		

Action		Complete?	Notes
51.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date update the list accordingly and advise the relevant HWB.		
52.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 44).		
53.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 45) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Directory of Services • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 10

Procedure – Application for No Significant Change Relocation

1.20.

Chapter aims and objectives

1. The purpose of this chapter is to ensure that no significant change relocation applications are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

2. This procedure covers applications from contractors to relocate to new premises within the same HWB's area or the area of a different HWB.

3. This chapter does not apply to contractors who hold LPS contracts.

4. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

5. This document must be read in conjunction with the Regulations and Chapter 10 of the DH Guidance.

6. A flowchart summarising the procedure to manage applications to relocate to new premises within the same HWB's area is provided at Annex 1A.

7. A flowchart summarising the procedure to manage applications to relocate to new premises within the area of a different HWB's is provided at Annex 1B.

8. Template applications forms are provided at Annex 2:

   - Annex 2A is for an application within the same HWB;
   - Annex 2B is for an application to a different HWB; and
   - The information in the template form at Annex 2C must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action		Complete?	Notes
1.	On receipt of a no significant change relocation application or an application for no significant change relocation in another HWB area, check the details have been added to the applications database. Ensure the database is updated as the application		

Action		Complete?	Notes
	progresses.		
2.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2).		
3.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided send an acknowledgement of receipt of the application (Annex 3) to the applicant. Where the applicant is offering to provide new enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
4.	Where the application is fully complete, move to step 15. Where there is missing information and/or documentation in the application, move to step 5. Where there are missing undertakings in the application, move to step 11.		
5.	Where there is missing information and/or documentation in the application, send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must		

Action		Complete?	Notes
	be within the timescales above provided that such timescales are reasonable.		
6.	Diarise the date for the missing information/documentation to be submitted.		
7.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
8.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 5 above. If the information is provided, go to step 9. If the information is not provided go to step 10. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 11.		
9.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to provide new enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
10.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (where the application relates to a relocation to another HWB area and the applicant is not already included in the		

Action		Complete?	Notes
	pharmaceutical list of that HWB) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
11.	Where there are missing undertakings in the application, complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
12.	Diarise the date for the missing undertakings to be submitted.		
13.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to provide new enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		
14.	If the missing undertakings aren't received by the due date, send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
15.	Where the application relates to a relocation within the same HWB area, once the application meets all requirements, interested parties must be notified of the application. Where the application relates to a relocation to another HWB area and the applicant is not already included in the		

Action		Complete?	Notes
	pharmaceutical list of that HWB, if the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known. Once the outcome is known or on receipt of confirmation that the application is not to be deferred on fitness grounds, notify interested parties of the application. Annex 12 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
16.	Notify the interested parties of the application (Annex 13) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
17.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 14) to the applicant. Where the application relates to a relocation to another HWB area and the applicant is not already included in the pharmaceutical list of that HWB, ensure a fitness to practise decision has been made (or will be made before the application is determined on market entry grounds).		
18.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 15).		
19.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so,		

Action		Complete?	Notes
	who it wishes to invite as additional presenters.		
20.	Chapter 10 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
21.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 16).		
22.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 17) and any additional presenters (Annex 18) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
23.	At the end of the 14-day period, prepare a report (Annex 19) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
24.	Refer to Chapter 8 of the DH guidance for further information on the determination of applications.		
25.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 20 for information on third party rights of appeal. The application granted decision letters are: • Granted – to the applicant (Annex 21);		

Action		Complete?	Notes
	• Granted – to a third party with no appeal rights (Annex 22); and • Granted – to a third party with appeal rights (Annex 23). The application refused decision letters are: • Refused – to the applicant (Annex 24); and • Refused – to a third party (Annex 25). When the letters are completed, send to the officer responsible for signing decision letters. Complete as far as possible the notice of commencement. Once the decision letters are signed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
26.	Diarise the latest date for appeals to be made.		
27.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
28.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 26) to the applicant.		
29.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 27).		
30.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		

Action		Complete?	Notes
31.	On receipt of a completed notice of commencement ensure that it was submitted in time. If it was, send an acknowledgement of receipt (Annex 28).		
32.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services.		
33.	Diarise the date that the applicant is to be included in the pharmaceutical list regarding the new premises. On that date update the list(s) accordingly and advise the relevant HWB(s).		
34.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 29).		
35.	Ensure the applications database has been kept up to date and enter the outcome of the application. Where the application related to a relocation to another HWB area and the applicant was not already included in the pharmaceutical list of that HWB, advise the officer responsible for fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 30) the usual parties which may include: • LPC; • HWB; • CCG; • commissioners of enhanced services; • Directory of Services • relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list;		

Action		Complete?	Notes
	• whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 11

Distance Selling

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications regarding distance selling are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

2. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This document must be read in conjunction with the Regulations and Chapter 11 of the DH Guidance.

4. A flowchart summarising the procedure below is provided at Annex 1.

5. A template application form is provided at Annex 2.

6. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

1.21.

Procedure

Action		Complete?	Notes
1.	On receipt of a distance selling application, check the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully		

Action		Complete?	Notes
	completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided, liaise with the officer responsible for fitness to practise checks (if relevant) and send an acknowledgement of receipt of the application (Annex 3) to the applicant. Where the applicant is offering to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with the officer responsible for fitness to practise checks (if relevant) and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but		

Action		Complete?	Notes
	not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 5 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 12.		
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		

Action		Complete?	Notes
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if relevant) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if relevant) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren’t received by the due date, send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Where the application is not to be deferred on fitness grounds, interested parties must		

Action		Complete?	Notes
	be notified of the application. Annex 12 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
17.	Where application is not to be deferred on fitness grounds, notify the interested parties as of the application (Annex 13) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
18.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
19.	Once the outcome is known, notify interested parties of the application (Annex 13) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
20.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 14) to the applicant. If relevant, ensure that a fitness to practise decision has been made (or will be made before the application is determined on market entry grounds).		
21.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 15).		

Action		Complete?	Notes
22.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
23.	Chapter 11 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
24.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 16).		
25.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 17) and any additional presenters (Annex 18) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
26.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendations / decisions (if relevant) and prepare a report (Annex 19) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
27.	Refer to Chapter 11 of the DH guidance for further information on the determination of applications.		
28.	After the meeting, prepare the relevant		

Action		Complete?	Notes
	decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 20 for information on third party rights of appeal. The application granted decision letters are: • Granted – to the applicant (Annex 21); • Granted – to a third party with no appeal rights (Annex 22); and • Granted – to a third party with appeal rights (Annex 23). The application refused decision letters are: • Refused – to the applicant (Annex 24); and • Refused – to a third party (Annex 25). When the letters are completed, send to the officer responsible for signing decision letters. Complete as far as possible the notice of commencement. Once the decision letters are signed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
29.	Diarise the latest date for appeals to be made.		
30.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
31.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 26) to the applicant. Include a copy of the banking mandate.		

Action		Complete?	Notes
32.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 27). Include a copy of the banking mandate.		
33.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
34.	On receipt of a completed notice of commencement ensure that it was submitted in time. If it was, send an acknowledgement of receipt (Annex 28).		
35.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services.		
36.	Send the notification of the NHS Pharmacy Contractor Code (Annex 29) advising the applicant of their contractor number when received from NHS Prescription Services.		
37.	Diarise the date that the applicant is to be included in the pharmaceutical list(s) regarding the new premises. On that date update the list(s) accordingly and advise the relevant HWB(s).		
38.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 30).		
39.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer responsible for fitness to practise checks of the outcome.		

Action		Complete?	Notes
	Update other databases as appropriate and inform (using Annex 31) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Directory of Services • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 12

Procedure - Change of Ownership

1.22.

Chapter aims and objectives

1. The purpose of this chapter is to ensure that change of ownership applications are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

2. Applications are to be determined within 30 days of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

3. This chapter must be read in conjunction with the Regulations and Chapter 12 of the DH Guidance.

4. This chapter does not apply to contractors who hold LPS contracts.

5. A flowchart summarising the procedure below is provided at Annex 1.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Procedure

Action		Complete?	Notes
1.	On receipt of a change of ownership application, check the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within 30 days.		
3.	Check that the application is fully		

Action		Complete?	Notes
	completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application forms (Annex 2 and 2A).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided, liaise with the officer responsible for fitness to practise checks (if relevant) and send an acknowledgement of receipt of the application (Annex 3) to the applicant. Where the applicant will be required to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with the officer responsible for fitness to practise checks (if relevant) and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but		

Action		Complete?	Notes
	not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 5 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 12.		
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		

Action		Complete?	Notes
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if relevant) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if relevant) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		
15.	If the missing undertakings aren’t received by the due date, send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	While the fitness to practise checks are being completed, where relevant, ensure that payment has cleared. If payment		

Action		Complete?	Notes
	hasn't cleared send a request for payment (Annex 12) to the applicant.		
17.	If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 13).		
18.	On receipt of the fitness to practise recommendation/decision, where relevant, prepare a report (Annex 14) on the application to the decision-maker (set out in Chapter 3).		
19.	Refer to Chapter 12 of the DH guidance for further information on the determination of applications.		
20.	After the meeting, prepare the relevant decision referring to Annex 15 for information on third party rights of appeal. The application granted decision letters are: • Granted – to the applicant (Annex 16); • Granted – to a third party with no appeal rights (Annex 17); and • Granted – to a third party with appeal rights (Annex 18). The application refused decision letters are: • Refused – to the applicant (Annex 19); and • Refused – to a third party (Annex 20). When the letters are completed, send to the officer responsible for signing decision letters. Complete as far as possible the notice of commencement. Once the decision letters are signed		

Action		Complete?	Notes
	distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
21.	Diarise the latest date for appeals to be made.		
22.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
23.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 21) to the applicant. Include a copy of the banking mandate.		
24.	If no appeal is made and the Commissioner granted the application, advise the decision-maker and send confirmation to the applicant (Annex 22). Include a copy of the banking mandate.		
25.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
26.	On receipt of a completed notice of commencement ensure that it was submitted in time. If it was, send an acknowledgement of receipt (Annex 23).		
27.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services.		
28.	Send the notification of the NHS Pharmacy Contractor Code (Annex 24) advising the applicant of their contractor number when received from NHS		

Action		Complete?	Notes
	Prescription Services.		
29.	Diarise the date that the applicant is to be included in the pharmaceutical list regarding the new premises. On that date update the list accordingly and advise the relevant HWB.		
30.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 25).		
31.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer responsible for fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 26) the usual parties which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Directory of Services • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 13

Procedure - Combined Change of Ownership and No Significant Change Relocation

1.23.

Chapter aims and objectives

1. The purpose of this chapter is to ensure that combined change of ownership and no significant change relocation applications are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the Regulations).

2. This procedure covers applications from persons wishing to take over the premises of another contractor that is included in a pharmaceutical list and relocate to a new address within the same HWB's area or the area of a different HWB.

3. Applications are to be determined within four months of receipt unless the Commissioner has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.

4. This document must be read in conjunction with the Regulations and Chapter 13 of the DH Guidance.

5. This chapter does not apply to contractors who hold LPS contracts.

6. A flowchart summarising the procedure below is provided at Annex 1.

7. Template applications forms are provided at Annex 2:

   - Annex 2A is for an application within the same HWB; and
   - Annex 2B is for an application to a different HWB.
   - The information in the template form at Annex 2C must be included in all routine and excepted applications for inclusion in a pharmaceutical list.
   -

Procedure

Action		Complete?	Notes
1.	On receipt of a combined change of ownership and no significant change relocation application either within the same		

Action		Complete?	Notes
	HWB or to another HWB's area, check the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within four months.		
3.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application form (Annex 2).		
4.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided, liaise with the officer responsible for fitness to practise checks (if relevant) and send an acknowledgement of receipt of the application (Annex 3) to the applicant. Where the applicant will be required to provide new enhanced services, enclose copies of the specifications for these services with the acknowledgement.		
5.	Where the application is fully complete, move to step 16. Where there is missing information and/or documentation in the application, move to step 6. Where there are missing undertakings in the application, move to step 12.		
6.	Where there is missing information and/or documentation in the application, liaise with		

Action		Complete?	Notes
	the officer responsible for fitness to practise checks (if relevant) and send to the applicant the acknowledgement of receipt of application and request for further information (Annex 4). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – 5 working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – 5 working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision to be made.		
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 5). The timescales for providing the information are as set out in step 5 above. If the information is provided, go to step 10. If the information is not provided go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 6). Go to step 12.		

Action		Complete?	Notes
10.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 7). Where the applicant is required to provide new enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided.		
11.	If the missing information/documentation isn't received by the due date, liaise with the officer responsible for fitness to practise checks (if relevant) and send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	Where there are missing undertakings in the application, liaise with the officer responsible for fitness to practise checks (if relevant) and complete then send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 9). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is 5 working days.		
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is required to provide new enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.		

Action		Complete?	Notes
15.	If the missing undertakings aren't received by the due date, send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Where the application is not to be deferred on fitness grounds, interested parties must be notified of the application. Annex 12 will assist to identify certain (but not all) parties to be notified – more particularly, those who would be significantly affected by the grant of the application / who might have a significant interest in the outcome of the application.		
17.	Where application is not to be deferred on fitness grounds, notify the interested parties as of the application (Annex 13) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
18.	If the application is to be deferred on fitness to practise grounds, do not progress any further until the outcome of the cause of the deferral is known.		
19.	Once the outcome is known, notify interested parties of the application (Annex 13) enclosing a copy of the application. Do not include any fitness to practise or personal information.		
20.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 14) to the applicant.		
21.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded		

Action		Complete?	Notes
	using the notification of circulation of comments (Annex 15).		
22.	Send copies of the representations to the decision-maker (set out in Chapter 3) and ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.		
23.	Chapter 13 of the DH guidance provides further information on deciding whether oral representations are to be heard.		
24.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 16).		
25.	If an oral hearing is to be held, confirm arrangements with the applicant (Annex 17) and any additional presenters (Annex 18) that the decision-maker (set out in Chapter 3) wishes to hear from. At least 14 days' notice must be given.		
26.	At the end of the 14-day period, contact the officer responsible for fitness to practise checks for the fitness to practise recommendations / decisions (if relevant) and prepare a report (Annex 19) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
27.	Refer to Chapter 13 of the DH guidance for further information on the determination of		

Action		Complete?	Notes
	applications.		
28.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 20 for information on third party rights of appeal. The application granted decision letters are: • Granted – to the applicant (Annex 21); • Granted – to a third party with no appeal rights (Annex 22); and • Granted – to a third party with appeal rights (Annex 23). The application refused decision letters are: • Refused – to the applicant (Annex 24); and • Refused – to a third party (Annex 25). When the letters are completed, send to the officer responsible for signing decision letters. Complete as far as possible the notice of commencement. Once the decision letters are signed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.		
29.	Diarise the latest date for appeals to be made.		
30.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
31.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 26) to the applicant.		

Action		Complete?	Notes
32.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 27).		
33.	Diarise the latest date by which the template notice of commencement can be submitted. Ensure this is updated if the Commissioner allows an extension.		
34.	On receipt of a completed notice of commencement ensure that it was submitted in time. If it was, send an acknowledgement of receipt (Annex 28).		
35.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services.		
36.	Send the notification of the NHS Pharmacy Contractor Code (Annex 29) advising the applicant of their contractor number when received from NHS Prescription Services.		
37.	Diarise the date that the applicant is to be included in the pharmaceutical list(s) regarding the new premises. On that date update the list(s) accordingly and advise the relevant HWB(s).		
38.	Where the notice of commencement was not submitted in time, i.e. it was submitted less than 14 days before the grant expired, send notification that the application has lapsed (Annex 30).		
39.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer responsible for fitness to practise checks of the outcome. Update other databases as appropriate and inform (using Annex 31) the usual parties		

Action		Complete?	Notes
	which may include: • LPC; • HWB; • CCG; • Commissioners of enhanced services; • Directory of Services • Relevant contracts manager and/or whomever is tasked with maintaining the pharmaceutical list; • Whomever is responsible for notification of payment of LPC levies; • the local PCS provider office; and • the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 14

Procedures - Controlled Localities

1.24.

Chapter aims and objectives

1. This chapter deals with issues relating to controlled localities, specifically:

    - The procedure for determining a controlled locality;
    - Additional steps for routine applications in a controlled locality; and
    - Additional steps for certain applications near a controlled locality.

2. This document must be read in conjunction with the Regulations and Chapter 14 of the DH Guidance.

Background

3. A controlled locality is an area determined by the Commissioner (or its predecessors or, on appeal, by the FHSAU) to be 'rural in character'. Areas that have not been determined as rural in character are not controlled localities unless and until formally determined to be so by the relevant decision-maker.

4. The Commissioner may find the Department for Environment, Food and Rural Affairs Rural Strategy's definition of rurality useful (see http://tinyurl.com/cgnetva).

5. In making a decision on controlled locality status, the Commissioner will need to consider a range of characteristics and features about a locality. It will have to consider all evidence and form a reasoned opinion but may be assisted in making that determination by considering the following factors:

    - environmental – the balance between different types of land use;
    - employment patterns (bearing in mind that those who live in rural areas may not work there);
    - community size and distance between settlements;
    - the overall population density;
    - transportation – the availability or otherwise of public transport and the frequency of such provision including access to services such as shopping facilities; and
    - the provision of other facilities, such as recreational and entertainment facilities.

6. Areas can, of course, change their character over time. For example:

- an area which was rural in character may cease to be a controlled locality if there has been substantial economic or social development;
- an area which was previously industrialised or had characteristics associated with more urban areas (e.g. high density housing) may become more rural in nature in the event of significant industry closures, population reduction or dispersal, or environmental initiatives. (They would not, however, be considered controlled localities unless and until determined to be so.).

7. The Commissioner may need to consider afresh whether an area is or is not a controlled locality as a result of receiving a routine application, at the request of a local pharmaceutical committee or local medical committee, or of its own volition.

8. Whenever a controlled locality determination is to be made, a site visit will be undertaken.

History of controlled localities and information available

9. The term ‘controlled locality’ did not exist in legislation until 1 April 1983 when it was introduced by the NHS (General Medical and Pharmaceutical Services) Amendment Regulations 1983.

10. Before 1 April 1983:

- Family practitioner committees (FPCs) had to form an opinion as to whether an area was rural in character;
- there was no requirement to delineate such areas on a map, although some FPCs may have chosen to do so.

11. From 1 April 1983:

- any areas that had been determined as rural in character before 1 April 1983 automatically became termed 'controlled localities';
- FPCs and successor organisations were required to delineate the boundaries of any controlled localities that they determined on a map (and with later regulations, maps were required to be published)

12. The Commissioner may therefore find itself with a variety of forms of information including:

- lists of villages that were determined to be rural in character before 1 April 1983;
- descriptions of areas that were determined to be rural in character before 1 April 1983;
- maps of controlled localities that were determined from 1 April 1983;
- a mixture of the above; or

- none of the above.

Gradualisation

13. Dispensing doctors may generally only provide pharmaceutical services to patients who live in a designated controlled locality, more than 1.6km (as the crow flies) from a pharmacy.

14. Gradualisation – that is, the postponement of any requirement for dispensing by doctors to cease – is to be considered alongside:

    - controlled locality determinations
    - determinations of routine applications

where these may have an impact on existing dispensing doctor services.

15. The aim of gradualisation is two-fold:

    - first, it allows patients a period of time within which to adjust to being given a prescription to take to a pharmacy rather than having their drugs and/or appliances dispensed at the surgery;
    - second, it allows the affected dispensing practice time to make whatever alterations to its working practices as may be necessary, such as reducing stock holdings and altering staff duties.

16. There is no separate procedure for making decisions on gradualisation, and consideration of the issue is therefore incorporated into the relevant market entry procedures. As well as considering any representations received, the following factors are to be taken into account when the Commissioner considers whether a period of gradualisation is to be given:

    - the number of patients affected;
    - the proportion of the GP practice's dispensing patient list that this represents;
    - where a new pharmacy application is granted where the pharmacy will serve previous dispensing patients, the opening date of the pharmacy and its ability to absorb former dispensing patients alongside others who choose to access its services.

Changes to controlled locality status

17. When the Commissioner considers that an area is no longer a controlled locality it must decide whether the provision of pharmaceutical services by a dispensing practice will be adversely affected.

18. If the Commissioner considers it will be, the Commissioner must inform those patients who are no longer eligible that they can no longer receive dispensing services, subject to any period of gradualisation.

Changes as a result of new pharmacy applications

19. If a new pharmacy application is granted and a dispensing patient now lives within 1.6km of that pharmacy, that patient must have their prescriptions dispensed at a pharmacy (either the new pharmacy or another one). The patient is no longer eligible to be treated as a dispensing patient unless:

- the new pharmacy is a distance selling pharmacy,
- a reserved location has been determined in connection with the pharmacy, or
- the Commissioner has granted a serious difficulty application in respect of the patient.

20. The new arrangements may, however, be phased in by means of a period of gradualisation.

21. Doctors may continue to dispense to their patients who live further than 1.6km from the new pharmacy who live in a controlled locality and for which the GP has outline consent (or historic rights).

Reserved locations

22. Reserved locations in controlled localities are areas where:

- the patient population (on the patient lists of primary medical service providers, excluding temporary residents) within 1.6km of the premises or the best estimate of the proposed location is less than 2,750; or
- the Commissioner is not satisfied that if pharmaceutical services were provided, the use of those services would be similar to, or greater than, the use that might be expected if the number of individuals residing in that area who are on a patient list were 2,750 or more.

23. If the Commissioner decides that an area is a reserved location, patients in the reserved location can continue to exercise a choice as to whether to receive dispensing services, i.e. from their doctor or use a pharmacy.

Period of gradualisation

24. The Commissioner may postpone the effect of its determination for up to six months but should bear in mind the words of Mr Justice Carnwath (in the 1996 case of R v North Yorkshire FHSA ex parte Dr Wilson and Partners:

"It is not part of the scheme of those regulations or indeed of the statute that pharmaceutical services should be relied upon to provide financial underpinning for medical services which are intended to be financed in other ways".

25. Periods of gradualisation should generally be no shorter than one month from the opening of the pharmacy and, other than in exceptional circumstances, should last no longer than three months. Exceptional circumstances may include:

- the loss by a dispensing practice of all their dispensing patients;
- where the reduction in number of dispensing patients would lead to staff changes or redundancy; or
- where there is only one pharmacy within a 1.6km radius of the practice premises and that is the pharmacy that is opening and its ability to absorb former dispensing patients effectively needs to be staged over time.

Procedure for Determining a Controlled Locality

Action		Complete?	Notes
1.	Where: • the Commissioner is considering making a determination as to whether or not an area is a controlled locality, or is part of one; or • If the LMC or LPC applies in writing for the Commissioner to determine whether or not an area is to be, or is to be part of, a controlled locality, refer to the controlled locality determinations database to determine whether the area has been determined in the last five years.		
2.	If the area has not been determined in the last five years, advise the decision-maker (set out in Chapter 3) that the process to make the determination may start. Record the intention to make a determination in the database and go to step 8. If the area has been determined in the last five years, advise the decision-maker (set out in Chapter 3) that it will first need to satisfy itself that there has been a		

Action		Complete?	Notes
	substantial change in circumstances in relation to that area since the determination was made. Record the intention to make a determination in the database and go to step 3.		
3.	If the decision-maker (set out in Chapter 3) is satisfied that there has been a substantial change in circumstances, gather relevant information on the area. This may involve a site visit. If a site visit is required, ensure sufficient information on the area is gathered to answer both this issue and also to assist if a determination is subsequently to be made (see step 10 below). Complete the report at Annex 1 and send to the relevant administrator/secretary.		
4.	If the LMC or LPC applied for the Commissioner to make a determination and the decision-maker (set out in Chapter 3) determines that there has been no substantial change in circumstances, send the notification of no substantial change (Annex 2) to the LMC or LPC that made the application.		
5.	Diarise the latest date for appeals to be made.		
6.	If notice of an appeal is received advise the decision-maker and assist in the production of a response.		
7.	If the FHSAU determines that there has been no substantial change in circumstances, update the “controlled localities determinations” database accordingly. There are no further actions to be undertaken. If the FHSAU determines that there has been a substantial change in		

Action		Complete?	Notes
	circumstances, move to the step 8.		
8.	If: • no determination has been made in the last five years; or • the decision-maker (set out in Chapter 3) or the FHSAU determines that there has been a substantial change in circumstances, move to step 9.		
9.	Send the notification to interested parties (Annex 3) notifying of the intention to make a controlled locality determination. Those who may be affected by the determination include: • Contractors included in a pharmaceutical list who have premises within the area that is to be determined, or have premises within 1.6km of the edge of that area (regulation 38(1)(b)) • Practices and dispensing doctors included in a dispensing doctors list who have dispensing patients living in the area to be determined, or have surgery premises within 1.6km of the edge of that area (regulation 38(1)(c)) • LPS contractors with premises within the area to be determined, or have premises within 1.6km of the edge of that area (regulation 38(1)(d)) • Providers of primary medical services with premises within the area that is to be determined, or have surgery premises within 1.6km of the edge of that area (regulation 38(1)(e))		
10.	During the 30-day notification period identify any dispensing patients living in the area that is to be determined. Arrange a site visit and gather information		

Action		Complete?	Notes
	on the area. Following the site visit prepare a report (Annex 4), which includes the findings of the site visit and any representations that have been received, for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
11.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made: • Notification of determination for those with appeal rights (Annex 5); • Notification of determination to dispensing practices (Annex 6); and/or • Notification of determination for those with no appeal rights (Annex 7). Send the letters to the officer responsible for signing decision letters for signing. Once the decision letters are signed distribute to the interested parties.		
12.	Diarise the latest date for appeals to be made.		
13.	If notice of an appeal is received advise the decision-maker and assist in producing a response.		
14.	If the decision-maker or, on appeal, the FHSAU, determines that the area is a controlled locality, or is part of a controlled locality, go to step 15. If the decision-maker or, on appeal, the FHSAU, determines that the area is no longer a controlled locality, or is no longer part of a controlled locality, go to step 16. If the decision-maker or, on appeal, the FHSAU determines that the area is not a controlled locality, or is not part of a		

Action		Complete?	Notes
	controlled locality, go to step 17.		
15.	If the decision-maker or, on appeal, the FHSAU, determines that the area is a controlled locality, or is part of a controlled locality, the boundary must be precisely delineated on a map and this map must then be published. Ensure that the map is of sufficient size to enable identification of a single dwelling as being either in a controlled or an uncontrolled, locality. Maps are to be produced and stored in an electronic format for ease of distribution, retrieval and editing. The map must be sent to the Health and Well-being Board (HWB) that has all or part of that controlled locality in its area within five working days. Update the controlled locality determinations database. There are no further actions regarding this procedure note.		
16.	If the decision-maker or, on appeal, the FHSAU, determines that the area is no longer a controlled locality, or is no longer part of a controlled locality, update and publish the relevant controlled locality map and update the controlled locality determinations database. Advise the HWB that has all or part of the area that is no longer a controlled locality in its area within 5 working days. Go to step 18		
17.	If the decision-maker or, on appeal, the FHSAU, determines that the area is not a controlled locality, or is not part of a controlled locality, update and publish the relevant controlled locality map if necessary and update the “controlled locality determinations” database.		

Action		Complete?	Notes
	Advise the HWB that has all or part of the area that is no longer a controlled locality in its area within five working days. Go to step 18.		
18.	If there are dispensing patients living in the area that has been determined not to be a controlled locality, record the date on which they must be removed from dispensing lists (having regard to the gradualisation decision, including any appeal relating to this). If gradualisation has been given, prepare lists of dispensing patients by practice within 1.6km of the pharmacy (i.e. those who will be removed from dispensing lists) and send a letter to the relevant practices (Annex 8) enclosing the list of patients and a copy of the letter to be sent to the affected patients (Annex 9). Resolve any queries raised by practices, carrying out site visits if necessary.		
19.	Note – the timescales may need to be altered to reflect the actual period of gradualisation or if no gradualisation has been given.		
20.	Diarise the date for responses from the practices		
21.	When the date for responses from the practices has passed or once any queries have been resolved, send the letter at Annex 9 to the affected patients.		
22.	Diarise the date of removal.		
23.	On the date of removal change the patients' dispensing status on Exeter. There are no further actions to be completed regarding this procedure.		

Additional steps for routine applications in a controlled locality

Action		Complete?	Notes
1.	On the day the application is received, check whether the premises or best estimate included in the application are in an area that has been determined to be, or could be, a controlled locality. If they definitely are not, follow the relevant market entry procedure and go no further with this procedure. If they are, or could be, move to step 2. Note that where it is not known whether the area is a controlled locality or not, this matter will need to be determined before a decision is made on the application.		
2.	On the day the application is received, calculate the total GP registered population within a 1.6 km radius of the proposed premises or best estimate. If the radius extends to an adjoining non-controlled locality, patients in this area should be included. Temporary residents should not be included. Identify any GP practices that have dispensing patients within 1.6 km of the proposed premises or best estimate and the number of such patients.		
3.	On completion of all the checks relating to the information, documentation and undertakings being included in the application, liaise with the officer dealing with the fitness to practise checks to ensure the application can be processed. If the application can be processed and the premises/best estimate may be in a controlled locality, move to step 4. If the application can be processed and the premises/best estimate are within a controlled locality, check the applications		

Action		Complete?	Notes
	database to see if regulation 40(2) is relevant. If regulation 40(2) is relevant, send the acknowledgement (Annex 10) to the applicant and move to step 13 below. If regulation 40(2) isn't relevant, send the acknowledgement letter (Annex 11) and continue with the relevant market entry procedure. When notifying the application under the relevant market entry procedure, use the text in Annex 19 in order that representations are sought on all the matters that are to be considered. Once the application is determined, come back to this procedure at step 16 below. If the application cannot be processed at this point, hold until it can be. If it is to be treated as withdrawn, there are no further actions to be taken regarding this procedure.		
4.	Pass the application to the decision-maker (set out in Chapter 3) for a decision as to whether a controlled locality determination is to be made, the area that is to be determined and whether the application should be deferred under regulation 38(4). If no determination of rurality is to be made, i.e. the decision-maker is satisfied the premises/best estimate are not in a controlled locality, follow the relevant market entry procedure and go no further with this one. If a determination of rurality is to be made, send notification of determination of controlled locality (Annex 12) to the interested parties and the applicant. If the decision-maker determines that the application is to be deferred include the additional wording in the letter to the applicant.		

Action		Complete?	Notes
5.	Arrange a site visit and gather information on the area. Following the site visit prepare a report (Annex 13), which includes the findings of the site visit and any representations that have been received, for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
6.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made: • Notification of decision to those with appeal rights (Annex 14); • Notification of decision and gradualisation to dispensing practices (Annex 15); and/or • Notification of decision to those with no appeal rights (Annex 16). Send to the officer responsible for signing decision letters for signing. Once the decision letters are signed distribute to the applicant and interested parties.		
7.	Diarise the latest date for appeals to be made. If no appeal is made, go to steps 8 and 9. If an appeal is made, go to step 10.		
8.	If no appeal is made and it was determined that the area is a controlled locality, delineate the boundary on a map and publish it. Ensure the map is of sufficient size to enable identification of a single dwelling as being either in a controlled or an uncontrolled, locality. Maps are to be produced and stored in an electronic format for ease of distribution, retrieval		

Action		Complete?	Notes
	and editing. Send a copy of the map to any HWB that has all or part of the controlled locality in its area. Check the applications database to see if regulation 40(2) is relevant. If it is, send the notification of no appeal – Regulation 40(2) applicable (Annex 17) to the applicant and move to step 13 below. If regulation 40(2) isn't relevant, send the notification of no appeal – Regulation 40(2) not applicable (Annex 18) to the applicant. Continue with the relevant market entry procedure. When notifying the application under the relevant market entry procedure, use the text at Annex 19 so that representations are sought on all the matters that are to be considered. Once the application is determined, come back to this procedure at step 16 below.		
9.	If no appeal is made and it was determined that the area is not a controlled locality, send notification to the applicant (Annex 20) and ensure the relevant map is updated to reflect any change in status. Advise any HWB that had all or part of that controlled locality in its area. If there are no dispensing patients living in the area, follow the relevant market entry procedure and go no further with this procedure. If there are dispensing patients living in the area and gradualisation was given, follow the relevant market entry procedure and complete the following actions. • Record the date on which they must be removed from dispensing lists having regard to the gradualisation decision, including any appeal relating		

Action		Complete?	Notes
	to this. • If gradualisation has been given, prepare lists of dispensing patients by practice within 1.6km of the pharmacy (i.e. those who will be removed from dispensing lists) and send the letters with the list of affected patients (Annex 21) and a copy of the letter to patients (Annex 22) to the relevant practices. • Resolve any queries raised by practices, carrying out site visits if necessary. • Send the letter (Annex 22) to the affected patients as soon as the date for responses from the practices has passed or once any queries have been resolved. • On the date of removal change the patients' dispensing status on Exeter. There are no further actions to be completed regarding this procedure.		
10.	If notice of an appeal is received advise the decision-maker and assist in producing a response. If the NHS Litigation Authority determines that the area is not a controlled locality, go to step 11. If the NHS Litigation Authority determines that the area is a controlled locality, go to step 12.		
11.	If the NHS Litigation Authority determines that the area is not a controlled locality, send notification of the outcome of the appeal to the applicant. If the area used to be a controlled locality, ensure the relevant map is updated to reflect the change in status. Advise any HWB that had all or part of that controlled locality in its area.		

Action		Complete?	Notes
	Follow the relevant market entry procedure and if no gradualisation has been given, go no further with this procedure. If gradualisation has been given prepare lists of dispensing patients by practice within 1.6 km of the pharmacy (i.e. those who will be removed from dispensing lists) and send notification of the outcome of the appeal (Annex 24) to the relevant practices. Resolve any queries raised by practices, carrying out site visits if necessary. Send the letter (Annex 22) to the affected patients as soon as the date for responses from the practices has passed or once any queries have been resolved. On the date of removal change the patients' dispensing status on Exeter. There are no further actions to be completed in respect of this procedure.		
12.	If the NHS Litigation Authority determines that the area is a controlled locality, delineate the boundary precisely on a map and publish it. Ensure that the map is of sufficient size to enable identification of a single dwelling as being either in a controlled or an uncontrolled, locality. Maps are to be produced and stored in an electronic format for ease of distribution, retrieval and editing. Send a copy of the map to any HWB that has all or part of the controlled locality in its area. Check the applications database and if regulation 40(2) is relevant, send notification of appeal – regulation 40(2) (Annex 25) to the applicant and move to step 17 below. If regulation 40(2) is not relevant, send notification of appeal – Regulation 40(2)		

Action		Complete?	Notes
	not applicable (Annex 26) to the applicant and continue with the relevant market entry procedure. When notifying the application under the relevant market entry procedure, use the text at Annex 19 in order that representations are sought on all the matters that are to be considered. Once the application is determined come back to this procedure at step 16 below.		
13.	Once the date for the applicant to submit any representations on regulation 40(2) has passed, send a copy of the application to the decision-maker (set out in Chapter 3) for a decision as to whether the application must be refused by virtue of that regulation.		
14.	If the decision-maker determines that the application is to be refused by virtue of regulation 40(2) send the refusal letter (Annex 27) to the applicant. Diarise the latest date for an appeal to be made. If notice of an appeal is received advise the decision-maker and assist in the production of a response. If there are no appeals, the application has been refused. Update the applications database to reflect the outcome. There are no further actions to be completed regarding this procedure. If the decision-maker's decision is overturned on appeal, send the letter relating to the outcome of the appeal (Annex 28) to the applicant and continue with the relevant market entry procedure. When notifying the application under the relevant market entry procedure, use the text at Annex 19 so that representations are sought on all the matters that are to be considered. Once the application is		

Action		Complete?	Notes
	determined come back to this procedure at step 16 below. If the decision-maker's decision is upheld on appeal, i.e. the application is refused, update the applications database. There are no further actions to be completed regarding this procedure.		
15.	If the decision-maker (set out in Chapter 3) determines that there are no grounds to refuse the application by virtue of regulation 40(2), send notification that regulation 40(2) is not applicable (Annex 29) to the applicant and continue with the relevant market entry procedure. When notifying the application under the relevant market entry procedure, use the text at Annex 19 in order that representations are sought on all the matters that are to be considered. Once the application is determined come back to this procedure at step 16 below.		
16.	If the application is refused, either by the Commissioner or on appeal, update the applications database. There are no further actions to be completed regarding this procedure.		
17.	If the application is granted, either by the Commissioner or on appeal, and a reserved location was determined, if the pharmacy subsequently opens, the boundary of that reserved location must be precisely delineated on the relevant controlled locality map. Ensure that the map is of sufficient size to enable identification of a single dwelling as being either within or outside the reserved location. Send a copy of that map to the relevant HWB. There are no further actions to be completed regarding this procedure.		

Action		Complete?	Notes
	If the pharmacy doesn't subsequently open, there are no further actions to be completed regarding this procedure.		
18.	If the application is granted, either by the Commissioner or on appeal, and a reserved location was not determined, record the date on which patients living within 1.6 km of the pharmacy must be removed from dispensing lists (having regard to the gradualisation decision, including any appeal relating to this) and carry out the following actions: • When the notice of commencement is received, prepare lists of dispensing patients by practice within 1.6 km of the pharmacy (i.e. those who will be removed from dispensing lists) and send the notification of opening hours (Annex 30) to GP practices with dispensing patients within 1.6km of the pharmacy. • Resolve any queries raised by practices on those lists. • Carry out site visits if necessary. • Send the letter (Annex 31) to the affected patients as soon as the date for responses from the practice has passed or once any queries have been resolved. • On the date of removal change the patients' dispensing status on Exeter. There are no further actions to be completed regarding this procedure.		

Additional steps for certain applications near a controlled locality

Action		Complete?	Notes
1.	If an application is: • made pursuant to Chapters 5 – 10 and 13; and • is for pharmacy premises where the address or best estimate is in a non-controlled locality but within 1.6km of a controlled locality, go to step 2. If the above does not apply, no further action is necessary pursuant to this procedure.		
2.	While the application is being checked to ensure all relevant information, documentation and undertakings have been included, ascertain which GP practices have dispensing patients in the adjoining controlled locality within 1.6 km of the proposed premises or best estimate and the number of such patients. If there are practices affected in this way, go to step 3. If there are no practices affected in this way, no further action is necessary pursuant to this procedure.		
3.	When notifying the application under the relevant market entry procedure, ensure the text at Annex 32 is used so that representations are sought on all the matters to be considered.		
4.	If the application is granted either by the Commissioner or on appeal, diarise the date on which patients living within 1.6 km of the pharmacy must be removed from dispensing lists (having regard to the gradualisation decision, including any appeal relating to this).		

Action		Complete?	Notes
5.	When the notice of commencement is received, prepare lists of dispensing patients by practice within 1.6km of the pharmacy (i.e. those who will be removed from dispensing lists) and send a letter to GP practices with dispensing patients (Annex 33) within 1.6km of the pharmacy.		
6.	Resolve any queries raised by practices on those lists. Carry out site visits if necessary.		
7.	Send a letter (Annex 34) to affected patients as soon as the date for responses from the practice has passed or once any queries have been resolved.		
8.	On the date of removal change the patients' dispensing status on Exeter.		

CHAPTER 15

Procedures - Dispensing Doctors

1.25.

Chapter aims and objectives

1. This chapter deals with issues relating to dispensing doctors, specifically:

   1.1 The procedure for ensuring that applications for outline consent and/or premises approval are dealt with in accordance with the Regulations which also includes:

      1.1.1 Relocations before the outline consent takes effect; and

      1.1.2 Relocations after the outline consent takes effect;

   1.2 The procedure for ensuring that the Commissioner makes decisions on 'serious difficulty' applications in a consistent manner that is fair to patients; and

   1.3 Dealing with requests from patients for the provision of pharmaceutical services from their GP practice, communication of dispensing patient list validation and discontinuation of provision of pharmaceutical services by doctors.

2. This chapter must be read in conjunction with Part 8 of the Regulations and Chapter 15 of the DH Guidance.

Background

3. Pharmacies may not always be viable in every part of the country, especially in more rural areas. That is where the services of dispensing doctors can, and do, play an important role ensuring patients receive their medicines promptly, efficiently and conveniently.

4. Whether a patient is eligible to receive NHS dispensing services from a GP or not depends on certain conditions being met. The first condition is whether or not they live in a designated "controlled" locality. A controlled locality is an area that has been determined, either by the Commissioner, a predecessor organisation or on appeal by the FHSAU, to be "rural in character".

5. Areas that have not been determined as rural in character are not controlled localities unless and until the Commissioner formally determines them to be so.

6. Dispensing doctors may generally only provide pharmaceutical services to patients who live in a designated controlled locality, more than 1.6km (as the crow flies) from a pharmacy.

7. Decisions made by the Commissioner can generally be appealed to the FHSAU, although some appeals on fitness issues go to the First-tier Tribunal. If

the Regulations make no provision for an appeal, or if someone is dissatisfied with a decision of the FHSAU, any challenge would need to be made via the courts. Robust audit trails will therefore be maintained for each application and all determinations will be fully reasoned.

Procedure for Determining Applications for Outline Consent and/or Premises Approval

8. In order to provide pharmaceutical services to eligible patients, doctors must apply to the Commissioner for outline consent and premises approval. The first table below deals with this.

9. If a doctor wishes to change the premises from which they provide pharmaceutical services, for example, a relocation to new premises, then they must apply for premises approval for the new premises. This may occur after the grant of the application but before the grant takes effect or after the grant has taken effect. The second and third tables below deal with these scenarios respectively.

Action		Complete?	Notes
1.	On receipt of an application for outline consent and premises approval, check the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Check that the following information has been provided: • The area to which the doctor wishes to provide services to is clearly specified; and • The doctor is requesting approval for the practice premises (premises approval) from which they wish to dispense. As all applications 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. If the information has been provided, send		

Action		Complete?	Notes
	the acknowledgement of receipt (Annex 1) and continue to the next step. If the information has not been provided, send the request for further information (Annex 2).		
3.	Check that the area for which the doctor is seeking outline consent is a controlled locality. If it is, continue to the next step. If it isn't, refer to the procedure for controlled locality determinations (Chapter 14) and advise the doctor that a controlled locality determination will need to be made before their application can be determined (Annex 3). The processing of the controlled locality determination will run in tandem with the processing of the application.		
4.	Notify interested parties of the application using Annex 4. Refer to regulation 52 for details on who must be notified.		
5.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 5.		
6.	Prepare a report (Annex 6) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
7.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted letters are: • Granted – to the applicant (Annex 7); • Granted – to an interested party with		

Action		Complete?	Notes
	no appeal rights (Annex 8); and • Granted – to an interested party with appeal rights (Annex 9). The refused letters are: • Refused – to the applicant (Annex 10); and • Refused – to an interested party (Annex 11), Refer to Annex 12 for third party rights of appeal. When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, send to the applicant and interested parties.		
8.	Diarise the latest date for appeals to be made.		
9.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
10.	If, at the end of the 30-day appeal period, or once notification of the appeal decision is received, the application is not approved, ensure the applications database has been kept up to date and enter the outcome of the application. File the application and related documentation in the practice's file. No other actions are required. If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is approved, go to the next step.		
11.	Check to see whether there are any outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises.		

Action		Complete?	Notes
	If there are none, go to step 12. If there are any outstanding applications, go to step 18.		
12.	Where there are no outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises, send Annex 13 to the doctor.		
13.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
14.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
15.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
16.	Ensure the Exeter system is updated where the practice did not previously provide pharmaceutical services. Advise the relevant person so that a contract variation notice is issued to vary the contractor's primary medical services contract to incorporate the dispensing clauses.		
17.	Inform the relevant HWB when outline consent takes effect in order that it may consider whether the PNA needs to be updated accordingly. No other actions are required.		
18.	Where there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises, send Annex 14.		

Action		Complete?	Notes
19.	Diarise the earliest date (the provisional date) that the applicant may request a determination as to when the outline consent is to take effect.		
20.	As soon as possible after the provisional date, send Annex 15 to the doctor.		
21.	On receipt of a request for a determination as to whether outline consent may take effect, check that it has been received within three months of Annex 15 having been sent. If it has, go to the next step. If it hasn't, go to step 39.		
22.	On receipt of a request for such a determination check: • that primary medical services are being provided at the premises, and • whether pharmaceutical services are being provided at the pharmacy premises to which the outstanding pharmacy application related. If primary medical services are being provided and pharmaceutical services are not being provided at the pharmacy premises to which the outstanding pharmacy application related, go to the next step. If primary medical services are not being provided or pharmaceutical services are being provided at the pharmacy premises to which the outstanding pharmacy application related, go to step 30.		
23.	Send Annex 16 to the applicant.		
24.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's		

Action		Complete?	Notes
	file.		
25.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
26.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
27.	Ensure the Exeter system is updated.		
28.	Where the practice did not previously provide pharmaceutical services: • ensure the Exeter system is updated; • advise NHS Prescription Services via form PPA305; and advise the relevant person so that a contract variation notice is issued in order to vary the contractor's primary medical services contract to incorporate the dispensing clauses.		
29.	Inform the relevant HWB when outline consent takes effect in order that it may consider whether the PNA needs to be updated accordingly. No other actions are required.		
30.	Where primary medical services are not being provided or pharmaceutical services are being provided at the pharmacy premises to which the outstanding pharmacy application related, send Annex 17.		
31.	Diarise the latest date for appeals to be made.		
32.	If notice of an appeal is received advise the decision-maker and assist in the		

Action		Complete?	Notes
	production of a response.		
33.	At the end of the 30-day appeal period or once notification of the appeal decision is received and outline consent is to take effect, update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
34.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
35.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
36.	Ensure the Exeter system is updated.		
37.	Where the practice did not previously provide pharmaceutical services: • ensure the Exeter system is updated; • advise NHS Prescription Services via form PPA305; and • advise the relevant person so that a contract variation notice is issued to vary the contractor's primary medical services contract to incorporate the dispensing clauses.		
38.	Inform the relevant HWB when outline consent takes effect so that it may consider whether the PNA needs to be updated accordingly. No other actions are required.		
39.	If outline consent is not to take effect, ensure the applications database has been kept up to date and enter the outcome of the application. File the application and related documentation in		

Action		Complete?	Notes
	the practice's file. No other actions are required.		

Relocations before outline consent takes effect

10. If an application for outline consent is granted but has not yet taken effect, the doctor may apply to change the premises from which they wish to provide pharmaceutical services to other premises in the area of the relevant HWB.

Action		Complete?	Notes
1.	On receipt of such an application ensure the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Check that the following information has been provided: • the address of the premises for which the doctor is seeking approval; and • whether the premises are listed in relation to another area for which the doctor has approval to dispense to.		
3.	Notify interested parties of the application using Annex 18. Refer to regulation 52 for details on who must be notified.		
4.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 19.		
5.	Prepare a report (Annex 20) on the application for the decision-maker (set out in Chapter 3) and send to the committee administrator/secretary.		

Action		Complete?	Notes
6.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted decisions letters are: • Granted – to the applicant (Annex 21); • Granted – to an interested party with no appeal rights (Annex 22); and • Granted – to an interested party with appeal rights (Annex 23). The refused decision letters are: • Refused – to the applicant (Annex 24); and • Refused – to an interested party (Annex 25). Refer to Annex 26 for details on third party rights of appeal. When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, distribute to the applicant and interested parties.		
7.	Diarise the latest date for appeals to be made.		
8.	If notice of an appeal is received advise the decision-maker and assist in the production of a response.		
9.	If, at the end of the 30-day appeal period or once notification of the appeal decision is received the application is approved, go to the next step. If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is not approved, ensure the applications database has been kept up to date and enter the outcome of the application. File		

Action		Complete?	Notes
	the application and related documentation in the practice's file. No further actions are required.		
10.	Check to see whether there are any outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises. If there are none, go to the next step. If there are any outstanding applications, go to step 17.		
11.	Send Annex 27 to the doctor.		
12.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
13.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
14.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
15.	Where the practice did not previously provide pharmaceutical services: • ensure the Exeter system is updated; • advise NHS Prescription Services via form PPA305; and • advise the relevant person so that a contract variation notice is issued in order to vary the contractor's primary medical services contract to incorporate the dispensing clauses.		
16.	Inform the relevant HWB when outline consent takes effect so it may consider whether the PNA needs to be updated		

Action		Complete?	Notes
	accordingly. No further actions are required.		
17.	If there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises send Annex 28.		
18.	Put a note in the outstanding pharmacy application file and send Annex 29 when it reaches its final outcome.		
19.	Diarise the date that premises approval will take effect should the pharmacy not open.		
20.	Put a note in the outstanding pharmacy application file to send Annex 30 to the doctor if the pharmacy opens. If the pharmacy does not open, send Annex 31 to the doctor one year after the outstanding pharmacy application reached its final outcome.		
21.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
22.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
23.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
24.	Ensure the Exeter system is updated.		
25.	Where the practice did not previously provide pharmaceutical services:		

Action		Complete?	Notes
	• ensure the Exeter system is updated; • advise NHS Prescription Services via form PPA305; and • advise the relevant person within the AT so that a contract variation notice is issued in order to vary the contractor's primary medical services contract to incorporate the dispensing clauses.		
26.	Inform the relevant HWB when outline consent takes effect so it may consider whether the PNA needs to be updated accordingly		

Relocations after outline consent takes effect

11. Once outline consent has taken effect the doctor may wish to relocate to new premises in relation to the area for which they have outline consent.

Action		Complete?	Notes
1.	On receipt of such an application ensure the details have been added to the applications database. Ensure the database is updated as the application progresses.		
2.	Check that the following information has been provided: • the address of the premises for which the doctor is seeking approval; and • whether the premises are listed in relation to another area for which the doctor has approval to dispense to.		
3.	Notify interested parties of the application using Annex 32. Refer to regulation 52 for details on who		

Action		Complete?	Notes
	must be notified.		
4.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 33.		
5.	Prepare a report (Annex 34) on the application for the decision-maker (set out in Chapter 3) and send to the committee administrator/secretary.		
6.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted decision letters are: • Granted – to the applicant (Annex 35); • Granted – to an interested party with no appeal rights (Annex 36); and • Granted – to an interested party with appeal rights (Annex 37). The refused decision letters are: • Refused – to the applicant (Annex 38); and • Refused – to an interested party (Annex 39). Refer to Annex 40 for details on third party rights of appeal. When completed, send to the officer responsible for signing decision letters. Once the decision letters are signed distribute to the applicant and interested parties.		
7.	Diarise the latest date for appeals to be made.		
8.	If notice of an appeal is received advise the decision-maker and assist in the		

Action		Complete?	Notes
	production of a response.		
9.	If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is approved, go to the next step. If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is not approved, ensure the applications database has been kept up to date and enter the outcome of the application. File the application and related documentation in the practice's file. No further actions are required.		
10.	Check to see whether there are any outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises. If there are none, go to the next step. If there are any outstanding applications, go to step 16.		
11.	Send Annex 41 to the doctor.		
12.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
13.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
14.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
15.	Inform the relevant HWB when premises approval takes effect in order that it may consider whether the PNA needs to be		

Action		Complete?	Notes
	updated accordingly. No further actions are required.		
	If there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises send Annex 42.		
16.	Put a note in the outstanding pharmacy application folder and send Annex 43 when it reaches its final outcome.		
17.	Diarise the date that premises approval will take effect should the pharmacy not open.		
18.	Put a note in the outstanding pharmacy application file to send Annex 44 to the doctor if the pharmacy opens. If the pharmacy does not open, send Annex 45 to the doctor one year after the outstanding pharmacy application reached its final outcome.		
19.	Update the dispensing doctors list accordingly and file the application and related documentation in the practice's file.		
20.	Ensure the applications database has been kept up to date and enter the outcome of the application.		
21.	Update other Commissioner databases as appropriate and inform the usual parties, for example, the relevant LMC and LPC.		
22.	Ensure the Exeter system is updated.		
23.	Inform the relevant HWB when outline consent takes effect in order that it may consider whether the PNA needs to be		

Action		Complete?	Notes
	updated accordingly. No further actions are required.		

Procedure for Determining 'Serious Difficulty' Applications

12. Provision has been in place for many decades to enable a patient who has 'serious difficulty' in accessing a pharmacy to receive NHS dispensing services from a doctor instead. This now appears in regulation 48(2).

13. Such instances are likely to be much rarer now than previously. Total pharmacy numbers have increased over the last few years, internet-based services are more common and accepted by patients, communities and populations may have grown to enable pharmacies to be viable in more remote areas, and many pharmacies now offer home delivery services. Nonetheless, it is possible that the Commissioner will have to deal with such applications.

    13.1 Such serious difficulty may arise either by reason of:

        13.1.1 distance, or

        13.1.2 inadequate means of communication.

14. Applications may be made whether or not the patient lives in a controlled locality. A patient may live within a short distance of a pharmacy as the crow flies but the layout or geographical features of the area means that the most practicable route to access a pharmacy presents considerable difficulties.

Action		Complete?	Notes
1.	Upon receipt of a serious difficulty application, add the details to the serious difficulty applications database. Ensure the database is updated as the application progresses.		
2.	Check that all information has been provided by the patient and that the patient's GP has completed the GP section. This is particularly important if the serious difficulty application form (Annex 46) has not been used. Where information is missing, inform either the patient or the GP.		

Action		Complete?	Notes
3.	Once all information is provided and it has been validated as much as possible, pass to the decision-maker (set out in Chapter 3) for a decision as to whether it is to be approved or not.		
4.	Refer to Annex 47 for factors that may be relevant to a serious difficulty application.		
5.	Ensure decisions are made and communicated to the patient and their GP practice within 30 days of receipt of a fully completed application.		
6.	Ensure decisions are fully reasoned and documented. There are no rights of appeal against the decision and therefore the only route for a patient to challenge such a decision is through the courts.		
7.	Where the application is approved, request that a patient note is added to the patient's Exeter file stating that the patient has been approved to be dispensed to under the serious difficulty rule and that approval is to be reviewed in five years' time unless there is a change to the patient's circumstances in the meantime, for example they change address.		
8.	Ensure that the application, decision and letter to the patient are stored electronically in the serious difficulty applications folder, ensuring documents are password protected as they will contain patient identifiable information.		

Dealing with Requests for the Provision of Pharmaceutical Services

15. Patients may at any time request in writing that their GP practice provides them with pharmaceutical services. The practice would then check that the patient meets one of the conditions set out in regulation 48. If the patient does meet a

condition, the practice must apply to the Commissioner enclosing the patient's request.

16. In reality, the practice would amend the patient's status on their clinical system from 'prescribing' to 'dispensing' – this is then transmitted to the Exeter system, which accepts the amendment without any validation (other than to check the practice is a dispensing practice). This has led to a considerable number of patients being accepted erroneously as dispensing patients.

Validating Dispensing Patient Lists

17. Validation of dispensing patient lists should be undertaken at two levels:

    - Does *the patient* meet one of the conditions set out in regulation 48?
    - Does *the practice* have (a) outline consent/historic rights to dispense to the patient's address and (b) premises approval for the premises at which they will provide pharmaceutical services to the patient?

18. The Commissioner will need to ensure that dispensing patient lists are accurate.

Patients: Monitoring the 1.6km Rule

19. Patients who live within 1.6km of a pharmacy (as the crow flies) must meet one of the exception to remain an eligible dispensing patient. Those exceptions are:

    - the patient lives within 1.6km of only a distance selling pharmacy;
    - the patient lives within a reserved location; or
    - the patient has successfully submitted a serious difficulty application.

20. The Commissioner should check once a year that all dispensing practices' dispensing patient lists are validated in respect of the 1.6km rule using the following steps.

Action		Complete?	Notes
1.	For each dispensing practice identify a list of dispensing patients who live within 1.6km of a pharmacy and check that: • They do not live within a reserved location that was defined in connection with that pharmacy, and • Have not had serious difficulty applications granted.		

Action		Complete?	Notes
2.	Send Annex 48 to the relevant GP practices enclosing a list of their patients who live within 1.6km of a pharmacy.		
3.	Review any comments that are received and resolve any disputes, carrying out site visits if necessary.		
4.	Once all outstanding issues are resolved, advise the decision-maker (set out in Chapter 3) of the numbers of patients involved for each practice both as a total number of patients and the percentage of the dispensing patient list this equates to. Request that a decision be made on the timescales for implementing the removal of patient from the dispensing patient list bearing in mind the time needed for the affected patients and the practice to adjust to the change.		
5.	Send Annex 49 to the affected practices. Any serious difficulty applications that are received are to be dealt with in accordance with the procedure for determining serious difficulty applications – see the relevant procedure in this Chapter.		
6.	On the date of removal from the practice's dispensing patient list, change the patients' dispensing status on Exeter to prescribing.		

1.26.

Patients: Ensuring Dispensing only Takes Place in Controlled Localities

21. Patients living outside of a controlled locality must have had a serious difficulty application granted or they will be unable to have drugs dispensed by their GP practice.

22. The Commissioner is required to publish its controlled locality maps. The Commissioner should check these maps against the addresses of dispensing

patients in its area to ensure that no patients living outside controlled localities are having drugs dispensed by their GP.

23. The Commissioner should check once a year that, unless they have successfully submitted a serious difficulty application, all dispensing patients live in a controlled locality using the following steps.

1.27.

Action		Complete?	Notes
1.	For each dispensing practice identify a list of dispensing patients who do not live in a controlled locality and check that none have had serious difficulty applications granted.		
2.	Send Annex 50 to the relevant GP practices enclosing a list of their patients who live outside of a controlled locality.		
3.	Review any comments that are received and resolve any disputes, carrying out site visits if necessary.		
4.	Once all outstanding issues are resolved, advise the decision-maker (set out in Chapter 3) of the numbers of patients involved for each practice both as a total number of patients and the percentage of the dispensing patient list this equates to. Request that a decision be made on the timescales for implementing the removal of patient from the dispensing patient list bearing in mind the time needed for the affected patients and the practice to adjust to the change.		
5.	Send Annex 51 to the affected practices. Any serious difficulty applications that are received are to be dealt with in accordance with the rurality and related determinations policy and the procedure for determining serious difficulty applications.		
6.	On the date of removal from the practice's		

Action		Complete?	Notes
	dispensing patient list change the patients' dispensing status on Exeter to prescribing.		

Practices: Historic Rights

24. Further validation will require accurate and up-to-date records of which areas practices have outline consent or historic rights to dispense to.

25. If a GP practice was authorised to dispense to patients in an area before 1 April 1983, they have accrued what have become known as historic rights. If a GP practice has been authorised to dispense to patients in an area on or after 1 April 1983, they have obtained outline consent.

26. In either case the practice must also have premises approval for the premises at which they provide pharmaceutical services. This information should be available in the dispensing doctors lists, which include the addresses of all GP practice premises that have premises approval.

27. The Commissioner must have in development a rolling programme to check once a year that dispensing patients, living in areas for which their GP practice has historic rights, meet one of the criteria set out in regulation 48(3)(b)(ii).

1.28.

Action		Complete?	Notes
1.	For each dispensing practice, identify a list of dispensing patients who appear not to meet one of the additional criteria and check that none has had serious difficulty applications granted.		
2.	Send Annex 52 to the relevant GP practices enclosing a list of their patients who do not appear to meet one of these criteria.		
3.	Review any comments received and resolve any disputes, carrying out site visits if necessary.		
4.	Once all outstanding issues are resolved, advise the decision-maker (set out in Chapter 3) of the numbers of patients involved for each practice, both as a total		

Action		Complete?	Notes
	number of patients and the percentage of the dispensing patient list this equates to.		
5.	Request that a decision be made on the timescales for implementing the removal of patient from the dispensing patient list bearing in mind the time needed for the affected patients and the practice to adjust to the change.		
6.	Send Annex 53 to the affected practices. Any serious difficulty applications that are received are to be dealt with in accordance with the rurality and related determinations policy and the procedure for determining serious difficulty applications.		
7.	On the date of removal from the practice's dispensing patient list change the patients' dispensing status on Exeter to prescribing.		

1.29.

Communications

28. Validation of dispensing patient lists began in 2013 and the Commissioner should continue to discuss the progress of this process with the relevant local medical committee (LMC) or committees and local pharmaceutical committee (LPC) or committees

29. Discussions should also take place with those dispensing practices whose dispensing patient lists are about to be validated so that they understand the basis of the exercise. Similarly discussions should be held with the relevant local Healthwatch organisation.

Discontinuation of the Provision of Pharmaceutical Services by Doctors

30. Changing patients' status from dispensing to prescribing will be a considerable change for patients and may require the GP practice to amend working practices and possibly result in staff changes or redundancy.

CHAPTER 16

Procedure - Advanced Services

N.B. This chapter does not yet cover the Seasonal Influenza Vaccination Advanced Service.

Chapter aims and objectives

1. The purpose of this chapter is to ensure that the provision of advanced services is dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended ("the Regulations").

2. This chapter must be read in conjunction with the Regulations and the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 ("the Directions").

3. This chapter does not apply to contractors who hold LPS contracts.

4. A pharmacy contractor or dispensing appliance contractor may provide one or more of the following advanced services, provided that it satisfies the conditions contained in the Directions in relation to those services:

    - medicines use review and prescription intervention services (MUR) - *pharmacy contractors only*;
    - new medicine service (NMS) - *pharmacy contractors only*;
    - stoma appliance customisation;
    - appliance use review services (AUR).

5. In particular:

    - if a pharmacy contractor or dispensing appliance contractor notifies the Commissioner that it wishes to provide one or more of the advanced services set out in the Directions, the Commissioner must ensure all the required information is received;
    - if a pharmacy contractor applies to the Commissioner seeking to provide MURs at premises other than its pharmacy premises, the Commissioner must determine that application in a fair and transparent manner.

Procedure

Action		Complete?	Notes
1.	On receipt of a notification of intention to provide an advanced service (or an application to provide MUR services at		

Action		Complete?	Notes
	premises other than the listed pharmacy premises), check the Directions to ensure that all the required information has been provided (as set out in the forms which appear at Annexes 1 to 8). In the case of an application to provide MURs at premises other than the listed pharmacy premises (i.e. not by telephone), the contractor must provide an enhanced Disclosure and Barring Service certificate in respect of each pharmacist providing MUR services. If the pharmacist already has an enhanced DBS certificate in connection with providing NHS services, a further certificate will not be required, although the Commissioner reserves the right to require a further certificate if it has reasonable cause to do so. Checks which are over and above the requirements of the Directions will not be paid for by the Commissioner.		
2.	If information is missing, ask the contractor to provide it within 10 working days, and advise it that it may not start to provide the service until the information is received.		
3.	If the contractor fails to provide the information within the required timescale write to advise it that it may not provide the service.		
4.	Monitor the NHS Prescription Services activity data to ensure that a contractor who has not provided the necessary information does not subsequently claim for the service. If there is evidence of claiming, refer to Chapter 19.		
5.	When all the required information is received, check the contractor's monitoring records to ensure that they are		

Action		Complete?	Notes
	compliant with their terms of service, as set out in Schedules 4 (*for pharmacy contractors*) or 5 (*for dispensing appliance contractors*) to the Regulations.		
6.	If the contractor is not compliant with its terms of service, write to advise that it may not provide the service until they are compliant and set out the actions required to demonstrate compliance with the terms of service.		
7.	Monitor the NHS Prescription Services activity data to ensure that a non-compliant contractor does not subsequently claim for the service. If there is evidence of claiming, refer to Chapter 19.		
8.	In relation to notifications, if the contractor is compliant: • write to the contractor to acknowledge receipt of all necessary information and inform them that the Commissioner's records have been updated to reflect the provision of the service; and • advise the relevant Health and Well-being Board that the service is being provided.		
9.	In relation to applications, if the contractor is compliant, follow the further steps set out below.		
10.	Where the Commissioner decides there is a need to ensure that the premises at which services will be provided are an "acceptable location" in accordance with Direction 4(5), the Commissioner should arrange a visit. Ideally this visit should take place before the contractor starts to provide the service.		

Action		Complete?	Notes
	If this is not possible and the contractor has provided all the required information and is in a position to start providing the service, then service provision may commence pending the visit. If the premises are found subsequently not to meet the requirements of Direction 4(5), refer to Chapter 19.		
11.	Following the premises visit, the Commissioner will decide whether the application should be approved in accordance with the steps set out below.		
12.	An application by a pharmacy contractor (in the Annex 2 form) to provide MUR services at alternative premises (involving an identified area for confidential consultations in premises other than their pharmacy premises (e.g. a local GP practice) will be approved if: • the conditions in Directions 4(3), 4(4) and 4(5)(b) are met; and • each pharmacist providing the service has a satisfactory enhanced Disclosure and Barring Service certificate.		
13.	An application by a pharmacy contractors (in the Annex 3 form) to provide MUR services at a particular patient's home on a particular occasion will be approved if: • the conditions in Directions 4(3) and 4(4) are met; • the patient is unable to attend the contractor's premises; and • each pharmacist providing the service has a satisfactory enhanced Disclosure and Barring Service certificate.		
14.	An application by a pharmacy contractors (in the Annex 4 form) to provide MUR		

Action		Complete?	Notes
	services at premises or a category of premises to a particular category of patients (e.g. for prisoners at a particular prison or residents of a care home) will be approved if: • the conditions in Directions 4(3) and 4(4) are met; • the area within which the service will be provided allows for adequate privacy for the consultation, and • each pharmacist providing the service has a satisfactory enhanced Disclosure and Barring Service certificate.		
15.	An application by a pharmacy contractors (in the Annex 5 form) to provide MUR services via the telephone for a particular patient on a particular occasion will be approved if: • the conditions in Directions 4(3) and 4(4) are met; • the contractor has put arrangements in place so that the telephone conversation cannot be overheard except by someone who the patient wants to hear the conversation (e.g. the call is made from the area for confidential consultation within the contractor's premises), and • the Commissioner is satisfied that the particular circumstances of the case mean that approval should be given e.g. a distance selling premises contractor identifies a patient living 100km away who would benefit from receiving the service, or a housebound patient requires MUR services (even though provision of the MUR service in this way is not considered ideal by the Commissioner because of the potential for misunderstanding and the inability to assess patient's current use).		

Action		Complete?	Notes
16.	Advise the contractor of the outcome of their application (no later than 15 working days from the date of the visit).		

CHAPTER 17

Procedure - Enhanced Services

Chapter aims and objectives

1. The purpose of this procedure is to ensure that applications to provide enhanced services are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended ("the Regulations").

2. Applications are to be determined within 30 days of receipt unless the Commissioner has good cause to take longer.

3. This document must be read in conjunction with the Regulations and the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 ("the Directions").

4. Applications may be submitted by contractors who are already included in a pharmaceutical list and wish to provide additional directed services (i.e. those in the Directions - advanced and enhanced services). It should be noted, however, that for advanced services it is not necessary for the contractor to apply and therefore any applications received under Regulation 23 will be for enhanced services.

5. The procedures for notification or approval of advanced services provision have been dealt with in Chapter 16 and this Chapter 17 deals only with applications for the provision of enhanced services commissioned by the Commissioner (and to which Regulation 23 therefore applies).

6. A flowchart summarising the procedure below is provided at Annex 1.

7. A template application form is provided at Annex 2.

Procedure

Action		Complete?	Notes
1.	On receipt of an application, add the details to the applications database (and ensure the database is updated as the application progresses).		
2.	Check that the application has been fully completed and that all relevant information, documentation and		

Action		Complete?	Notes
	undertakings have been provided, including the relevant cheque or proof of payment. This is particularly important if the applicant has not used the national application form set out at Annex 2.		
3.	If the application is fully completed and all relevant information, documentation and undertakings have been provided, send Annex 3. Include copies of the specifications for the services the applicant is applying to provide.		
4.	If information/documentation is missing, complete and send the request for missing information set out at Annex 4. The relevant timescale for information required by paragraph 1 of Schedule 2 to the Regulations is 5 working days.		
5.	Diarise the date for the missing information/documentation to be submitted.		
6.	If the applicant does not ask for a review of the request for missing information, go to step 11. If the applicant asks for a review of a request for missing information, forward this to the decision-maker (set out in Chapter 3) for a decision and go to step 7.		
7.	If the outcome of the review is that the information/documentation is not to be provided, send the applicant notification of the outcome of the review and withdrawal of the original request (Annex 5) then go to step 11. If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request		

Action		Complete?	Notes
	for information (Annex 6). The timescales for providing the information are as set out in step 4 above. Go to step 8.		
8.	Diarise the date for any missing information/documentation to be submitted.		
9.	If the missing information/documentation is received, send Annex 7 and include copies of the specifications for the services the applicant is applying to provide.		
10.	If the missing information and/or documentation is not received by the due date, send Annex 8 to the applicant which states that the application is being treated as withdrawn.		
11.	If undertakings are missing, complete and send Annex 9 (acknowledgement of receipt of application and request for missing undertakings). The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulation s is 5 working days.		
12.	Diarise the date for the missing undertakings to be submitted.		
13.	If the missing undertakings are received, send Annex 10 (acknowledgement of receipt of missing undertakings) and include copies of the specifications for the enhanced services the applicant is applying to provide.		
14.	If the missing undertakings are not received by the due date, send Annex 11 (which states that the application is being treated as withdrawn).		

Action		Complete?	Notes
15.	Check that payment has cleared. If it has cleared, go to step 16. If payment hasn't cleared, send Annex 12 to the applicant. Diarise the date for when payment is to be received and hold the application until payment has cleared. If payment does not clear send Annex 13 to the applicant and treat the application as withdrawn.		
16.	Once payment has cleared, prepare a report (Annex 14) for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
17.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The decision letter to the applicant where the application has been granted is provided at Annex 15. The decision letter to the applicant where the application has been refused is provided at Annex 16: When the letter is completed, send to the officer responsible for signing decision letters. Once the decision letter is signed, distribute to the applicant, enclosing the notice of commencement (where relevant).		
18.	Diarise the latest date for appeals to be made.		
19.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.		
20.	If the NHS Litigation Authority grants the application, complete and send a new		

Action		Complete?	Notes
	notice of commencement and Annex 17 to the applicant (including a copy of the banking mandate).		
21.	If the Commissioner granted the application, send Annex 18 to the applicant. Include a copy of the banking mandate.		
22.	Diarise the latest date by which the notice of commencement can be submitted.		
23.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send Annex 19.		
24.	On the date the applicant commences service provision update the relevant pharmaceutical list and advise the relevant HWB.		
25.	If a notice of commencement is submitted, but is submitted less than 14 days before the grant expires, send Annex 20.		
26.	Ensure the applications database has been kept up to date and enter the outcome of the application.		

CHAPTER 17A

Procedure - Temporary Listing Arising from Suspension

1.30.

Chapter aims and objectives

1. The purpose of this procedure is to ensure that applications for temporary listing in a pharmaceutical list (arising out of suspensions from that pharmaceutical list) are dealt with in line with the Regulations.

2. If a contractor is suspended from a pharmaceutical list on fitness grounds, the suspended contractor may nominate a person to provide services during the period of the suspension. That nominated person is required to apply for inclusion in the relevant pharmaceutical list regarding the suspended contractor's premises.

3. Applications are to be determined within 30 days of receipt unless the Commissioner has good cause to take longer.

4. This document must be read in conjunction with the Regulations (and, in particular Regulation 27).

5. A flowchart summarising the procedure below is provided at Annex 1.

6. A template application form is provided at Annex 2.

7. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

8. In accordance with direction 3(b)(i) of the Pharmaceutical Services (Fees for Applications) Directions 2013, no fee is payable in respect of an application under Regulation 28.

Procedure

Action		Complete?	Notes
1.	On receipt of an application for a temporary listing arising out of a suspension, add the details to the applications database (and ensure the database is updated as the application progresses).		
2.	Where the applicant is not already		

Action		Complete?	Notes
	included in the relevant pharmaceutical list in respect of other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks advising that the application is to be considered within 30 days.		
3.	Check that the application has been fully completed and that all relevant information, documentation and undertakings have been provided. This is particularly important if the applicant has not used the national application forms – Annex 2 and 2A.		
4.	If the application is fully completed and all relevant information, documentation and undertakings have been provided, liaise with the officer responsible for fitness to practise checks (if applicable) and send an acknowledgement of receipt of the application (Annex 3). Where the applicant is required to provide enhanced services, include copies of the specifications for these services.		
5.	If the application is fully complete, move to step 17. If there is missing information and/or documentation, move to step 6. If there are missing undertakings, move to step 13		
6.	If information/documentation is missing, liaise with the officer responsible for fitness to practise checks, then complete and send the request for missing information set out at Annex 4. The relevant timescales are as follows: • submission of the required fitness information – 10 working days; and		

Action		Complete?	Notes
	• information required by paragraph 1 of Schedule 2 to the Regulations – 5 working days.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant asks for a review of a request for missing information, forward this to the decision-maker (set out in Chapter 3) for a decision.		
9.	If the outcome of the review is that the information/documentation is not to be provided, send the applicant notification of the outcome of the review and withdrawal of the original request (Annex 5) then go to step 13. If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 6). The timescales for providing the information are as set out in step 6 above.		
10.	Diarise the date for any missing information/documentation to be submitted.		
11.	If the missing information/documentation is received, send an acknowledgement of receipt of the missing information/documentation (Annex 7). Where the applicant is required to provide enhanced services, include copies of the specifications for these services.		
12.	If the missing information and/or documentation is not received by the due date, liaise with the officer responsible for fitness to practise checks, then send to the		

Action		Complete?	Notes
	applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
13.	If undertakings are missing, liaise with the officer responsible for fitness to practise checks (if applicable), then complete and send to the applicant the acknowledgement of receipt of the application and request for missing undertakings (Annex 9) The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is 5 working days.		
14.	Diarise the date for the missing undertakings to be submitted.		
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is required to provide enhanced services, include copies of the specifications for these services.		
16.	If the missing undertakings are not received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable), then send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
17.	On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 12) for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		

Action		Complete?	Notes
18.	After the meeting, prepare the relevant decision letters based on the minutes of the meeting at which the decision was made and referring to Annex 18 for information on third party rights of appeal. The decision letters where the application has been granted are: • Granted – to the applicant (Annex 13); • Granted – to a third party with no appeal rights (Annex 14); and • Granted – to a third party with appeal rights (Annex 15). The decision letters where the application has been refused are: • Refused – to the applicant (Annex 16); and • Refused – to a third party (Annex 17). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, distribute to the applicant and interested parties, enclosing the notice of commencement (where relevant) with the applicant's letter.		
19.	Diarise the latest date for appeals to be made.		
20.	If notice of an appeal is received, advise the decision-maker and assist in producing a response.		
21.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 19 to the applicant (including a copy of the banking mandate).		

Action		Complete?	Notes
22.	If no appeal is made and the application was granted, advise the decision-maker and send Annex 20 to the applicant. Include a copy of the banking mandate.		
23.	Diarise the latest date by which the notice of commencement can be submitted.		
24.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send Annex 21.		
25.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
26.	Send the notification of NHS Pharmacy Contractor Code (Annex 22) advising the applicant of their contractor number when received from NHS Prescription Services.		
27.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date, update the list accordingly and advise the relevant HWB.		
28.	If a notice of commencement is submitted, but is submitted less than 14 days before the grant expires, send Annex 23.		
29.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform the usual parties including the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 17B

Procedure - Exercising a Right of Return

Chapter aims and objectives

1. The purpose of this procedure is to ensure that applications exercising a right of return are dealt with in line with the Regulations.

2. Applications are to be determined within 30 days of receipt unless the Commissioner has good cause to take longer.

3. This document must be read in conjunction with the Regulations (and, in particular, Regulation 28).

4. As an alternative to the national arrangements for the provision of pharmaceutical services, local pharmaceutical services (LPS) contracts allow pharmaceutical services to be commissioned that are tailored to specific local requirements. LPS complements the national contractual framework for pharmacy but is an important local commissioning tool in its own right. LPS provides flexibility to include within a single local contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements.

5. LPS contractors are not included in a pharmaceutical list (as they operate under Part 13 of the Regulations) but may have a right of return to a pharmaceutical list included in their LPS contract. If so, that right may be exercised by making an application under Regulation 28.

6. A flowchart summarising the procedure below is provided at Annex 1.

7. A template application form is provided at Annex 2

8. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

9. In accordance with direction 3(b)(ii) of the Pharmaceutical Services (Fees for Applications) Directions 2013, no fee is payable in respect of an application under Regulation 28.

Procedure

Action		Complete?	Notes
1.	On receipt of a right to return application, add the details to the applications		

Action		Complete?	Notes
	database (and ensure the database is updated as the application progresses).		
2.	If the applicant is not already included in the relevant pharmaceutical list regarding other premises, fitness to practise checks will need to be completed. Liaise with the officer responsible for fitness to practise checks, advising that the application is to be considered within 30 days.		
3.	Check that the application has been fully completed and that all relevant information, documentation and undertakings have been provided. This is particularly important if the applicant has not used the national application forms – Annex 2 and 2A.		
4.	If the application is fully completed and all relevant information, documentation and undertakings have been provided, liaise with the officer responsible for fitness to practise checks (where the applicant is not already included in the relevant pharmaceutical list) to ensure that an acknowledgment of receipt of the application (Annex 3) can be sent to the applicant. Where the applicant undertakes to provide enhanced services, include copies of the specifications for these services.		
5.	Where the application is complete, move to step 17. Where there is missing information and/or documentation, move to step 6. Where there are missing undertakings, move to step 13.		
6.	Where there missing information and/or		

Action		Complete?	Notes
	documentation, liaise with the officer responsible for fitness to practise checks (where the applicant is not already included in the relevant pharmaceutical list), then complete and send Annex 4. The relevant timescales are as follows: • submission of the required fitness information – 10 working days; and • information required by paragraph 1 of Schedule 2 to the Regulations – 5 working days.		
7.	Diarise the date for the missing information/documentation to be submitted.		
8.	If the applicant asks for a review of a request for missing information, forward this to the decision-maker (set out in Chapter 3) for a decision.		
9.	If the outcome of the review is that the information/documentation is not to be provided, send the applicant notification of the outcome of the review and withdrawal of the original request (Annex 5) then go to step 13. If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 6). The timescales for providing the information are as set out in step 6 above.		
10.	Diarise the date for any missing information/documentation to be submitted.		
11.	If the missing information/documentation is received, send an acknowledgement of receipt of the missing		

Action		Complete?	Notes
	information/documentation (Annex 7). Where the applicant is required to provide enhanced services, include copies of the specifications for these services.		
12.	If the missing information and/or documentation is not received by the due date, liaise with the officer responsible for fitness to practise checks, then send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
13.	If undertakings are missing, liaise with the officer responsible for fitness to practise checks (if applicable), then complete and send to the applicant the acknowledgement of receipt of the application and request for missing undertakings (Annex 9) The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is 5 working days.		
14.	Diarise the date for the missing undertakings to be submitted.		
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10). Where the applicant is required to provide enhanced services, include copies of the specifications for these services.		
16.	If the missing undertakings are not received by the due date, liaise with the officer responsible for fitness to practise checks (if applicable), then send to the applicant confirmation that the missing undertakings have not been received and		

Action		Complete?	Notes
	that the application is being treated as withdrawn (Annex 11).		
17.	On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 12) for the decision-maker (set out in Chapter 3).		
18.	After the meeting, prepare the relevant decision letters based on the decision-maker's reasoned decision and referring to Annex 18 for information on third party rights of appeal. The decision letters where the application has been granted are: • Granted – to the applicant (Annex 13); • Granted – to a third party with no appeal rights (Annex 14); and • Granted – to a third party with appeal rights (Annex 15). The decision letters where the application has been refused are: • Refused – to the applicant (Annex 16); and • Refused – to a third party (Annex 17). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, distribute to the applicant and interested parties, enclosing the notice of commencement (where relevant) with the applicant's letter.		
19.	Diarise the latest date for appeals to be made.		
20.	If notice of an appeal is received, advise the decision-maker and assist in producing a response.		

Action		Complete?	Notes
21.	If the NHS Litigation Authority grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 19 to the applicant (including a copy of the banking mandate).		
22.	If no appeal is made and the application was granted, advise the decision-maker and send Annex 20 to the applicant. Include a copy of the banking mandate.		
23.	Diarise the latest date by which the notice of commencement can be submitted.		
24.	On receipt of a completed notice of commencement ensure that it was submitted in time. Where it was, send Annex 21.		
25.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
26.	Send the notification of NHS Pharmacy Contractor Code (Annex 22) advising the applicant of their contractor number when received from NHS Prescription Services.		
27.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date, update the list accordingly and advise the relevant HWB.		
28.	If a notice of commencement is submitted, but is submitted less than 14 days before the grant expires, send Annex 23.		
29.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness		

Action		Complete?	Notes
	to practise checks of the outcome. Update other databases as appropriate and inform the usual parties including the company that collects and disposes of unwanted medicines where the new premises will open.		

CHAPTER 17C

Procedure - Temporary Arrangements

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications for temporary arrangements to be put in place (either during a declared emergency or for other reasons beyond the contractor's control) are dealt with in line with the Regulations.

2. Applications are to be determined within 30 days of receipt unless the Commissioner has good cause to take longer. Given the nature of the application, however, it should be determined as soon as possible.

3. This document must be read in conjunction with the Regulations - in particular regulation 29(1)(a) in relation to declared emergencies requiring flexible provision of services and regulation 29(1)(b) in relation to other circumstances where temporary arrangements may be put in place.

Declared emergencies

4. If an emergency is declared (through directions given by the Secretary of State under section 168A of the National Health Service Act 2006) – e.g. where there is a threat, or actual serious damage, to human welfare caused, or which may be caused, by the circumstances specified in the directions, for example pandemic influenza – the Commissioner must, for a specified period, exercise (or consider exercising) one or more or its functions under various provisions of the Regulations.

5. In the case of such an emergency, the Commissioner may make temporary amendments to the list entry of a contractor, e.g. enabling relocation or the use of additional premises, without needing to go through the normal application process. Such temporary amendments must only be for a specified period which can be no longer than the duration of the declared emergency.

6. A flowchart summarising the procedure for temporary arrangements due to an emergency is provided at Annex 1A.

7. A template application form is provided at Annex 2.

8. The information in the template form at Annex 2A must be included in all routine and excepted applications for inclusion in a pharmaceutical list

Suspension of services from listed premises for reasons beyond the control of the contractor

9. In the event of circumstances arising which require the temporary suspension of pharmaceutical services at the listed premises, the Commissioner may make

temporary amendments to the list so that the services will be provided at alternative premises nearby, if satisfied that the suspension is necessary for reasons that are beyond the control of the contractor.

10. The temporary suspension/relocation must be for no longer than 6 months (although this may be curtailed or extended for reasons set out in regulation 29(4) up to an overall maximum of 12 months). After this period, the contractor will revert to the overridden entry in the pharmaceutical list.

11. Reasons that are beyond the control of a contractor include fire or flooding (see regulation 29(1)(b)) but do not include:

    - planned refurbishment (see regulation 29(7));
    - difficulties with leases; or
    - planning laws.

12. The services provided, and the core and supplementary hours during which they are provided, must remain the same (including the provision of any advanced or enhanced services).

13. It should be noted that regulation 29 should not be used to apply for a temporary suspension of a contract where there is no emergency, it is not a matter that is beyond the control of the contractor and where the contractor has not provided three months' notice.

14. A flowchart summarising the procedure for temporary arrangements due to a suspension of services from the listed premises for reasons beyond the control of the contractor is provided at Annex 1B.

15. A template application form is provided at Annex 2.

Fees

16. In accordance with direction 3(b)(iii) of the Pharmaceutical Services (Fees for Applications) Directions 2013, no fee is payable in respect of an application under Regulation 29.

Procedure

Action		Complete?	Notes
1.	On receipt of an application, add the details to the applications database. Ensure the database is updated as the application progresses.		

Action		Complete?	Notes
2.	Check that the application is fully completed and all relevant information, documentation and undertakings have been provided. This is particularly important if the applicant has not used the national application forms – (Annex 2 and 2A).		
3.	Where the application is fully completed and all relevant information, documentation and undertakings have been provided, send an acknowledgement of receipt of application (Annex 3).		
4.	Where the application is complete, move to step 16. Where there is missing information and/or documentation, move to step 6. Where there are missing undertakings, move to step 12.		
5.	Where there missing information and/or documentation, liaise with the officer responsible for fitness to practise checks (where the applicant is not already included in the relevant pharmaceutical list), then complete and send Annex 4. The relevant timescales are as follows: • submission of the required fitness information – 10 working days; and • information required by paragraph 1 of Schedule 2 to the Regulations – 5 working days.		
6.	Diarise the date for the missing information/documentation to be submitted.		
7.	If the applicant asks for a review of a request for missing information, forward this to the decision-maker (set out in		

Action		Complete?	Notes
	Chapter 3) for a decision.		
8.	If the outcome of the review is that the information/documentation is not to be provided, send the applicant notification of the outcome of the review and withdrawal of the original request (Annex 5) then go to step 12. If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 6). The timescales for providing the information are as set out in step 6 above.		
9.	Diarise the date for any missing information/documentation to be submitted.		
10.	If the missing information/documentation is received, send an acknowledgement of receipt of the missing information/documentation (Annex 7).		
11.	If the missing information and/or documentation is not received by the due date, send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 8).		
12.	If undertakings are missing, complete and send to the applicant the acknowledgement of receipt of the application and request for missing undertakings (Annex 9) The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is 5 working days.		

Action		Complete?	Notes
13.	Diarise the date for the missing undertakings to be submitted.		
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 10).		
15.	If the missing undertakings are not received by the due date, send to the applicant confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 11).		
16.	Prepare a report (Annex 12 for declared emergencies and Annex 13 for the temporary suspension of pharmaceutical services) for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
17.	Refer to Annex 14 for further information on the determination of applications.		
18.	After the meeting, prepare the relevant decision letters. The decision letters where the application has been granted are: • Granted – to the applicant (Annex 15); • Granted – to a third party (Annex 16); The decision letters where the application has been refused are: • Refused – to the applicant (Annex 17); and • Refused – to a third party (Annex 18). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, distribute to the applicant and interested		

Action		Complete?	Notes
	parties, enclosing the notice of commencement (where relevant) with the applicant's letter.		
19.	Diarise the latest date by which the template notice of commencement can be submitted.		
20.	On receipt of a completed notice of commencement ensure it was submitted in time. Where it was, send Annex 19.		
21.	Complete the relevant NHS Prescription Services form (PPA305) and send to NHS Prescription Services with the applicant's completed mandate.		
22.	Send the notification of NHS Pharmacy Contractor Code (Annex 20) advising the applicant of their contractor number when received from NHS Prescription Services.		
23.	Diarise the date that the applicant is to be included in the pharmaceutical list. On that date, update the list accordingly and advise the relevant HWB.		
24.	If a notice of commencement is submitted, but is submitted less than 14 days before the grant expires, send Annex 21.		
25.	Ensure the applications database has been kept up to date and enter the outcome of the application. Advise the officer dealing with the fitness to practise checks of the outcome. Update other databases as appropriate and inform the usual parties including the company that collects and disposes of unwanted medicines where the new premises will open.		

Action		Complete?	Notes
26.	Where the application relates to temporary arrangements due to a declared emergency, the procedure ends here. Where the application relates to temporary arrangements due to the suspension of services from listed premises for reasons beyond the control of the contractor, follow the subsequent steps below.		
27.	Diarise the date on which the temporary arrangements are to end.		
28.	One month before, send Annex 22 to the applicant.		
29.	If the applicant requests an extension, prepare a report (Annex 23) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.		
30.	After the meeting, prepare the relevant decision letters. The decision letters where the application has been granted are: • Granted – to the applicant (Annex 24); • Granted – to a third party (Annex 25); The decision letters where the application has been refused are: • Refused – to the applicant (Annex 26); and • Refused – to a third party (Annex 27). When the letters are completed, send to the officer responsible for signing decision letters. Once the decision letters are signed, distribute to the applicant and interested parties.		
31.	If an extension is granted diarise the date		

Action		Complete?	Notes
	on which the temporary arrangements are to end. One month before, send Annex 28 to the applicant.		
32.	On the date the temporary arrangement comes to an end send Annex 29 to the applicant, update the relevant pharmaceutical list accordingly and advise the relevant HWB.		
33.	Update other databases as appropriate and inform the usual parties including the company that collects and disposes of unwanted medicines.		

CHAPTER 18

Procedures - Opening Hours

1.31.

Chapter aims and objectives

1. The purpose of this chapter is to describe the following procedures:

    - determining applications to change core opening hours;
    - dealing with notifications to change supplementary opening hours;
    - directing pharmacy and dispensing appliance contractors to open;
    - dealing with notifications of temporary suspension of services for reasons beyond the control of the contractor; and
    - determining requests for a temporary suspension of services that are within the contractor's control.

2. Procedures relating to:

    - dealing with notifications of failure to open; and
    - monitoring opening hours,
    - are contained in Chapter 19.

3. This document must be read in conjunction with the Regulations.

4. This chapter does not apply to contractors who hold LPS contracts.

5. For the avoidance of doubt, the week is defined as 00.00 on Monday to 23.59 on Sunday.

6. Contractors are not required to open on public (Christmas Day and Good Friday) or bank holidays (including any specially declared bank holidays). In addition, they are not required to open on Easter Sunday, which is neither a public nor bank holiday. They are encouraged to notify the Commissioner well in advance so that consideration can be given as to whether the provision of pharmaceutical services on these days will meet the reasonable needs of patients and members of the public. Annex 1 contains the document to be used by contractors for this purpose.

7. Twice a year, in January and August, the Commissioner will request that each pharmacy contractor in its area submits its intentions regarding the forthcoming holidays. The Regulations refer to assessments being made of access at a national level. For practical purposes the Commissioner will undertake assessments of adequacy of provision at HWB level. Once all the forms are received from the pharmacies in a HWB area an assessment will be made as to whether a contractor, or as appropriate contractors, is to be directed to open on a particular day or days.

8. Where a contractor is to be open on a bank or public holiday this information is to be entered onto their page on NHS Choices.

Procedure: determining applications to change core opening hours

9. In general DACs have core opening hours of not less than 30 hours a week and pharmacy contractors have core opening hours of 40 hours a week.

10. A contractor may apply to the Commissioner to change its core opening hours under their terms of service as set out in Schedules to the Regulations. A standard application form has been developed for this purpose (Annex 2).

11. Applications must be determined within 60 days of receipt unless the Commissioner has good cause to take longer, e.g. the contractor fails to provide the information requested under paragraph 26(2), Schedule 4 or paragraph 16(2), Schedule 5 of the Regulations, as appropriate.

12. It is particularly important that the contractor has provided the information required by paragraph 26(2) of Schedule 4 or paragraph 16(2) of Schedule 5 of the Regulations as appropriate, as the application cannot be determined without this. If information is requested the 60-day clock stops and only restarts at the point it is provided. The contractor is to be advised of this in the letter that is sent to them.

Action		Complete?	Notes
1.	On receipt of an application to change core opening-hours, check that all the required information has been provided and the declared current core opening hours match those included in the relevant pharmaceutical list. Request any missing information from the contractor or seek clarification on the hours that have been declared. Template wording is provided at Annex 3.		
2.	If, or once, the application is complete write to the contractor advising the latest date when a decision will be made. Template wording is provided at Annex 4.		
3.	Send a copy of the application to the LPC in whose area the contractor's premises are located seeking their views in the following circumstances: • Where the application seeks to		

Action		Complete?	Notes
	increase or reduce the number of core opening-hours (i.e. to be open for more or less than 30 or 40 hours a week) rather than keep the total number of hours the same but only change the days and times of opening; and/or • If there is an existing direction in place. Template wording is provided at Annex 5.		
4.	Prepare a report, which contains information on: • the advanced and enhanced services that the contractor provides at the premises; • whether the premises are subject to a condition set out in regulation 65 of the 2013 Regulations; • whether any previous directions have been issued about core opening hours, whether under the 2013 Regulations or earlier regulations; • other contractors in the area, in particular their opening hours, details of any advanced and enhanced services provided and distance from the contractor's premises; • any needs, improvements or better access that are included in the pharmaceutical needs assessment (PNA) for the area within which the contractor's premises are located; and • the opening hours of GP practices in the area.		
5.	Send the report to the decision-maker (set out in Chapter 3) for consideration.		
6.	Refer to Annex 6 for further information on determining applications.		

Action		Complete?	Notes
7.	Notify the contractor of the decision within the maximum 60-day period or within five working days of the decision being made, depending on which is the earlier. Issue a direction to the contractor if the contractor is seeking to increase or reduce its core opening hours to more than or less than 30 or 40 and the decision-maker agrees to this in full or in part. Annex 7 contains wording for the direction. Ensure that, where the contractor is seeking to increase its core opening hours to more than 30 or 40, the direction sets out the days on which, and the times at which, the contractor is required to provide pharmaceutical services for those hours that are in addition to the required 30 or 40. It should be noted that a direction could not simply require a contractor to be open for 30 or 40 core opening hours a week. It must have the effect of requiring a contractor to be open for either more or less than 30 or 40 hours a week.		
8.	If there are to be changes to the days on which, or times at which, the contractor is to provide services, they may not be introduced until: • (if the contractor does not appeal) not earlier than 30 days after the date it was notified of the decision; or • (if the contractor does appeal) not earlier than 30 days after the date it is notified of the FHSAU's decision.		
9.	Update the relevant pharmaceutical list once a change in core hours takes effect.		
10.	Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.		

Action		Complete?	Notes
11.	Ensure the contractor's entry on NHS Choices is updated for one-off and permanent changes.		
12.	File the application, decision and any direction that is issued in the contractor's premises file.		

Procedure: dealing with notifications to change supplementary opening hours

13. A contractor may notify the Commissioner of a change to its supplementary opening hours under its terms of service as set out in schedules 4 and 5 to the Regulations.

14. A standard notification form has been developed for this purpose (Annex 8).

Action		Complete?	Notes
1.	On receipt of a notification to change supplementary opening hours, check the declared current supplementary opening hours match those included in the relevant pharmaceutical list. Where they do not, seek clarification from the contractor. Wording is provided at Annex 9.		
2.	The notification will either: 1. not seek to implement the change sooner than the required three months; 2. seek to implement the change sooner than the required three months and increase the total number of hours open each week; or 3. seek to implement the change sooner than the required three months and reduce the total number of hours open each week, and the action for each is given below. 1. Where the contractor is not seeking		

Action		Complete?	Notes
	to implement the change sooner than the required three months, write to the contractor acknowledging the notification and confirm the date on which the changes are to take place. Wording is provided at Annex 10. 2. Where the contractor is seeking to implement the change sooner than the required three months and the change will increase the total number of hours it will be open each week, ask the decision-maker (set out in Chapter 3) to decide whether the change may take place sooner and write to advise the contractor accordingly. Wording is provided at Annex 11. 3. Where the contractor is seeking to implement the change sooner than the required three months and the change will reduce the total number of hours it will be open each week, prepare a report, which contains information on: • the advanced and enhanced services that the contractor provides at the premises; • other contractors in the area, in particular their opening hours, details of any advanced and enhanced services provided and distance from the contractor's premises; • any needs, improvements or better access that are included in the PNA for the area within which the contractor's premises are located; and • the opening hours of GP practices in the area. Send the report to the decision-maker (set out in Chapter 3), which will decide		

Action		Complete?	Notes
	whether the change can be implemented sooner than the confirmed date on which the change is to take effect. Advise the contractor of the decision accordingly. There are no rights of appeal where the decision-maker refuses to reduce the three-month notice period; however the decision should be fully reasoned and documented in case of legal challenge. Wording is provided at Annex 11.		
3.	Update the relevant pharmaceutical list once a change takes effect.		
4.	Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.		
5.	Ensure the contractor's entry on NHS Choices is updated for all changes.		

Procedure: directing pharmacy and dispensing appliance contractors to open

15. There may be occasion when the Commissioner needs to direct a particular contractor to open on certain days or at certain times e.g. on bank and public holidays.

Action		Complete?	Notes
1.	If the Commissioner identifies that the current opening hours of a particular contractor may not meet the needs of people living in its area or other likely users, consult the LPC in whose area the contractor's premises are located. Wording is provided at Annex 12. Following this consultation, the Commissioner must give notice to the contractor of the proposed changes to the days on which, or times at which, the		

Action		Complete?	Notes
	premises are to be open. As part of that notice the contractor is to be advised that it may make written representations about the proposed changes within 30 days. Wording is provided at Annex 13.		
2.	At the end of the 30 days produce a report and send it to the decision-maker (set out in Chapter 3), which will decide whether a direction is to be issued regarding the contractor's opening hours. Information on making the determination is provided at Annex 14.		
3.	Notify the contractor of the decision. Wording is provided at Annex 15. Any direction that is issued must meet the requirements of paragraph 25 of Schedule 4 or paragraph 15 of Schedule 5 of the Regulations. Annex 4 contains text for the direction. It should be noted that a direction could not simply require a contractor to be open for 30 or 40 core opening hours a week. It must have the effect of requiring a contractor to be open for either more or less than 30 or 40 hours per week. If the direction will increase a contractor's core opening hours to more than 30 or 40, then the direction must set out the total number of hours each week for which pharmaceutical services are to be provided and the days on which, and the times at which, the contractor is required to provide pharmaceutical services for those hours that are in addition to the required 30 or 40.		
4.	Update the relevant pharmaceutical list once a change takes effect.		
5.	Advise the HWB, LPC and LMC in whose area the contractor's premises are located		

Action		Complete?	Notes
	of the change.		
6.	Ensure the contractor's entry on NHS Choices is updated for all changes.		

Procedure: dealing with notifications of temporary suspension of services for reasons beyond the control of the contractor

16. There may be occasions when a contractor is unable to open its premises for a reason that is beyond its control. This includes:

- flooding of premises;
- lack of electricity;
- premises have been broken into; and
- pharmacist has not arrived.

17. It does not include planned refurbishment. It also does not include situations where the pharmacy occupies part of a larger building and the rest of the premises are closed as it is expected that contractors will have put in place arrangements to ensure they are able to fulfil their terms of service regarding their core and supplementary opening hours.

Action		Complete?	Notes
1.	Where there is a temporary closure outside of the contractor's control, the contractor is required to notify the Commissioner using the form at Annex 16.		
2.	Acknowledge receipt of a temporary suspension notification.		
3.	Review the reason for the temporary suspension. If it appears to be within the control of the contractor, refer the matter to the decision-maker (set out in Chapter 3) for a decision as to what, if any, further action to take in relation to performance management (Chapter 19).		

Action		Complete?	Notes
4.	Depending on how long the temporary suspension will or may last and the impact this will have on the provision of pharmaceutical services, it may be necessary to direct another contractor to open on different days or at different times. Refer to the procedure on directing pharmacy and dispensing appliance contractors to open in this Chapter 18		
5.	Where a temporary suspension is likely to last for more than one day, notify the LPC, LMC and HWB and ensure a note is put on the contractor's entry on NHS Choices advising of the period of time when the premises will be closed. Ensure the Directory of Services is also updated if appropriate.		
6.	If the temporary suspension is likely to last for a period of weeks, for example where the premises have burned down, the contractor may notify of a temporary closure and also apply under regulation 29 to temporarily relocate to alternative premises.		
7.	Enter all notifications into the electronic record of closures and file in the contractor's file.		

Procedure: determining requests for a temporary suspension of services that are within the contractor's control

18. Where a contractor knows in advance that it will not be able to open its premises it may request a temporary suspension of services for a set period.

19. Three months' notice must be given.

20. The form at Annex 17 should be used.

Action		Complete?	Notes
1.	On receipt of a request for a temporary closure that is within a contractor's control, check that three months' notice has been given. If less than three months' notice has been given, return the request to the contractor advising that it is refused. Wording is provided at Annex 18		
2.	Check that all relevant information has been provided. Where there is missing information, return the request to the contractor and ask them to provide all the required information. Wording is provided at Annex 19.		
3.	Where, or once, all the required information has been provided prepare a report which contains information on: • the advanced and enhanced services that the contractor provides at the premises; • other contractors in the area, in particular their opening hours, details of any advanced and enhanced services provided and distance from the contractor's premises; and • any needs, improvements or better access that are included in the PNA for the area within which the contractor's premises are located.		
4.	Send the report to the decision-maker (set out in Chapter 3) for a decision to be made as to whether the temporary suspension is to be approved.		
5.	Advise the contractor of the decision. Wording is provided at Annex 20. There are no rights of appeal against the decision; therefore the decision should be fully reasoned and documented in case of		

Action		Complete?	Notes
	legal challenge.		
6.	Notify the LPC, LMC and HWB if a temporary suspension is approved and will last for more than one day.		
7.	Ensure a note is put on the contractor's entry on NHS Choices advising of the period of time when the premises will be closed. Ensure the Directory of Service is updated , if appropriate.		

CHAPTER 19

Procedure - Monitoring Compliance and Managing Performance

Chapter aims and objectives

1. This chapter applies to the monitoring of Terms of Service compliance by contractors included in a pharmaceutical list maintained under the Regulations.

2. This chapter does not apply to contractors who hold a LPS contract unless reference is made in the terms of the contract or to the provision of pharmaceutical services by dispensing doctors.

3. This chapter must be read in conjunction with the Regulations, the Directions and the DH guidance on Market Exit.

4. The chapter sets out the approach to be taken to investigate compliance and, if non-compliance is identified, how it should be dealt with by the Commissioner.

5. The Commissioner does not hold separately documented contracts with those included in a pharmaceutical list. The Terms of Service for such contractors are set out in:

   - Schedule 4 to the Regulations (for pharmacy contractors);
   - Schedule 5 to the Regulations (for DACs); and
   - the Directions.

6. Paragraph 35(3) of Schedule 4 and paragraph 25(3) of Schedule 5 to the Regulations entitle the Commissioner have access to information from the contractor which is reasonably required for the purposes of monitoring the provision of pharmaceutical services.

7. This chapter describes how issues relating to the provision of pharmaceutical services by pharmacy contractors and DACs will be resolved, including

   - Procedures relating to monitoring compliance;
   - Contract monitoring visits;
   - Overpayments;
   - Procedure relating to managing performance;
   - Failures to open;
   - Monitoring opening hours; and
   - The stages of performance management.

8. Fitness to practise concerns are outside the remit of this chapter.

9. Most issues should be resolved without using the formal sanctions set out in the Regulations but there will be occasions when those formal sanctions, including removal of premises from the relevant pharmaceutical list, may be required.

10. All correspondence, file notes, reports, action plans and other documentation relating to each case will be maintained in chronological order, in files marked confidential and stored in a locked cabinet. Where files are kept electronically they will be password-protected and only a limited number of named personnel only will have access to both written and electronic files.

Procedures relating to monitoring compliance

11. Completion of the CPAF

- The Commissioner will monitor contractors against their Terms of Service based on the community pharmacy assurance framework (CPAF)..

	Action	Complete?	Notes
1.	In June of each year, the NHS BSA, on behalf of the Commissioner will send a request to each pharmacy to complete a screening questionnaire which is a condensed version of the CPAF. Contractors will be given 4 weeks to complete the questionnaire which is facilitated by the NHSBSA..		
2.	Where the contractor is a large organisation, the NHS BSA will liaise with head offices to establish the most effective way of communicating the request within their organisations		
3.	The Commissioner Local Pharmaceutical Committees and Head Offices of major multiples will be provided with weekly updates throughout the 4 week period so that contractors can be encouraged on a local level to complete the questionnaire.		
4.	At the end of the 4 week period the answers to the screening questionnaire will be collated by the NHS BSA. The results and indicator set will be available for NHS England local teams via the NHSBSA information services portal within one month of the closure of the questionnaire.		

	Action	Complete?	Notes
5.	The data collected from this questionnaire along with other information held by the Commissioner will be used to shortlist pharmacies who will be considered for a contract monitoring visit. Only these pharmacies will be asked to complete a full CPAF questionnaire. Once NHS England has received the results of the full CPAF questionnaire they will then consider whether to follow up with a contract monitoring visit. The Commissioner will arrange visits to 1-2% of pharmacies that indicated they are compliant with the requirements referred to in the screening questionnaire to validate the answers and observe good practice. If concerns are identified or no CPAF return is submitted by a contractor, refer the case to the decision-maker (set out in Chapter 3) for further action to be taken.		
6.	The Commissioner will draw up a list of pharmacies that it considers may require a contract monitoring visit.		
7.	In September, the Commissioner will request that the pharmacies that may require a monitoring visit complete the full CPAF pre visit questionnaire. The questionnaire is facilitated by the NHSBSA on behalf of NHS England.		
8.	Reports will be provided to NHS England local teams by the NHSBSA		
9.	For some contractors, certain aspects of the Terms of Service may not be undertaken at the premises included in the pharmaceutical list (for instance, publicity material may be produced centrally and distributed to branches, patient complaints may be analysed centrally in order to produce the required annual report, and checking of qualifications and references for staff engaged in the provision of NHS services may be undertaken by a human resources service). Ensure that CPAF is completed in such a way as to reflect what happens at the premises named on it.		

	Action	Complete?	Notes
10.	If the completed CPAF questionnaire demonstrates that the contractor is compliant with the terms of service and it is decided that a visit will not be necessary, send Annex 1 to the contractor.		
11.	Ensure all subsequent communications are copied to the contractor's regional manager or superintendent pharmacists office (if relevant) so that they are aware of any action that the Commissioner is proposing to take (and therefore able to attend any visit should they so wish).		

Contract monitoring visits

12. Contractors are required by their Terms of Service to allow persons authorised by the Commissioner to enter and inspect the pharmacy premises at any reasonable time for the purposes of:

    - ascertaining whether the contractor is complying with the terms of service; and
    - auditing, monitoring and analysing the provision for patient care and treatment and the management of the pharmaceutical services provided.

13. Not all pharmacies will receive a visit each financial year (1 April to 31 March) as the Commissioner has adopted a risk-based approach to visits. Once the CPAF screening questionnaires have been submitted in June of each year, the following will be considered as part of the assessment of which contractors need to be prioritised for a contract monitoring visit:

    - new pharmacies which have been included in the pharmaceutical list since June of the previous financial year (excluding those that relocated during the intervening period);
    - pharmacies where there has been a change of ownership since June of the previous financial year;
    - pharmacies where issues or potential concern are identified in the completed CPAF documents or where a CPAF return was not submitted; and
    - pharmacies where issues of potential concern have been identified previously.

14. Contractors must maintain appropriate standard operating procedures (SOPs) for dispensing, repeat dispensing and support for self-care as part of complying with their Terms of Service.

15. The Commissioner need not carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for the Commissioner's representative to carry out any detailed examination because he or she will be unable to determine what is appropriate for the individual pharmacy concerned. Monitoring compliance requires only that the existence of an appropriate SOP be identified.

16. The most appropriate way to determine whether the pharmacy has an appropriate SOP is to ask to see it during a monitoring visit and to ask appropriate members of staff suitable questions about their procedures, thereby establishing the level of understanding and compliance with the SOP.

17. The Commissioner's representatives should not ask to see patient identifiable records unless a suitable confidentiality arrangement is in place. They may, however, observe the dispensing process during the visit (without intruding on patient confidentiality) in order to see that records are being made.

18. Pharmacies are required to maintain records of interventions that are deemed to be clinically significant. The Commissioner's representatives may ask to see evidence of these records or discuss the circumstances when records might be appropriate.

19. The Commissioner's representatives may request to see patient identifiable records for the purposes of monitoring compliance with the Terms of Service for medicine use reviews and the new medicines service. As the patient has given consent to the pharmacy to share information with the Commissioner, pharmacies will not be required to make any information anonymous before it is produced to the Commissioner. The Commissioner's representatives will however only ask to see medicine use review (MUR) and new medicines service records for consultations provided since 1 September 2010.

20. The following procedure should be followed:

	Action	**Complete?**	**Notes**
1.	If a contractor is to be visited, send Annex 2 and follow up the letter with a telephone call to arrange a date for the monitoring visit. The contractor may wish to invite a representative of the relevant LPC to attend.		
2.	If the contractor fails or refuses to agree a date and time for the visit, refer the matter to the decision-maker (set out in Chapter 3) for consideration as to what action is to be taken.		

	Action	Complete?	Notes
3.	Once the date for the visit is agreed, send Annex 3.		
4.	Ensure that the Commissioner's representatives who will undertake the visit have copies of the relevant CPAF documents and other information at least five working days before the visit.		
5.	At the visit, the Commissioner's representatives will identify themselves as attending on behalf of the Commissioner and show their identity badge. The Commissioner's representatives should carry the written authority by the Commissioner to inspect the premises to ensure there is no dispute about the right to inspect. The Commissioner's representatives must make every effort during the visit to ensure the provision of pharmaceutical services is not interrupted. The Commissioner's representatives must not enter any part of the pharmacy premises which is solely used as residential accommodation.		
6.	Ensure that accurate records are taken at the visit, particularly where actions and timescales are agreed with the contractor. Use the report generated following completion of the pre-visit questionnaire for this purpose. Advise the contractor that a copy of the visit report will be sent to them for review and signature.		
7.	If any of the following are identified, refer the matter immediately to the decision-maker (set out in Chapter 3): • Patient safety issues; • NHS England is at risk of material financial loss; and/or • Possible fraudulent or criminal activity. Where no such issues are identified, complete the visit report (Annex 4) within 15 working days of the visit and send two copies to the contractor.		
8.	Ensure that the contractor signs and returns one copy of the report and chase up where necessary.		

	Action	Complete?	Notes
9.	Ensure that the contractor completes the required actions within the agreed timescales, chasing up where necessary. If the contractor fails to complete the required actions or fails to respond, refer the matter to the decision-maker (set out in Chapter 3).		
10	If a contractor submits evidence that they have completed an agreed action, send Annex 5. Once a contractor has completed all the required actions, send Annex 6.		
11	Once all agreed actions are completed, file all related documentation in the contractor's file		

Overpayments

21. The Commissioner will monitor the number of MURs / AURs claimed and will recover overpayments in line with the procedures below.

22. As the Terms of Service require contractors to ensure that they do not claim more than the permitted number of MURs / AURs, the Commissioner must consider whether to deal with such overclaiming as a breach of the Terms of Service.

23. Activity data provided by NHS Prescription Services will be reviewed in order to identify those contractors who have begun to provide an advanced service to verify that all the required information has been provided.

24. The following procedure should be followed:

	Action	Complete?	Notes
1.	For MURs, go to step 2. For AURs, go to step 7.		
2.	Data on the number of MURs claimed by each pharmacy contractor is collated by the NHS Business Services Authority's (NHS BSA) NHS Prescription Services and provided to the Commissioner through the monthly MIS report. However there is a three-month delay between the numbers of MURs being reported to NHS Prescription Services and the data being sent to the Commissioner. On receipt of the monthly MIS report update the MUR		

	Action	Complete?	Notes
	activity database (Annex 7).		
3.	Monitor the overall number of MURs claimed. Contractors may not claim for more than 200 or 400 MURs in any one year. Where a contractor starts to provide the MUR service pursuant to arrangements entered into on or before 30 September, the contractor may provide 400 MURs in that first financial year Where a contractor starts to provide the MUR service pursuant to arrangements entered into on or after 1 October, the contractor may only provide 200 MURs in that first financial year. In subsequent financial years, the contractor may provide 400 MURs, unless it fails to demonstrate continuing compliance with the Terms of Service (in which case the provision of advanced services must cease).		
4.	If a contractor looks as though they may exceed the maximum number that may be done in a year, send Annex 8.		
5.	If a contractor exceeds the maximum number of MURs that may be done in any one year, send Annex 9. Once the deadline for the contractor's comments has passed, refer the matter to the Head of Commissioning in order that it may decide what further action is to be taken. The Head of Commissioning will escalate to the PSRC if the further action is likely to be controversial or if the matter involves large sums of money.		
6.	Enter the amount of the over-payment on the local payments application available through the NHS BSA website and send Annex 10 to the contractor.		
7.	Data on the number of appliance use reviews (AURs) claimed by each pharmacy contractor is collated by the NHS BSA NHS Prescription Services and provided to the Commissioner through the monthly MIS report. On receipt of the monthly MIS report, update the AUR activity database (Annex 11).		
8.	At the end of the financial year, identify the number of		

	Action	Complete?	Notes
	specified appliances that have been dispensed in that year. AURs must not amount to more than 1/35th of the aggregate number of specified appliances dispensed in that financial year. Specified appliances are defined in the Drug Tariff as: • any of the following appliances listed in Part IXA - ○ a catheter appliance (including a catheter accessory and maintenance solution), ○ a laryngectomy or tracheostomy appliance, ○ an anal irrigation system, ○ a vacuum pump or constrictor ring for erectile dysfunction, or ○ a wound drainage pouch; • an incontinence appliance listed in Part IXB; or • a stoma appliance listed in Part IXC.		
9.	Where a contractor exceeds the maximum number of AURs that may be done in any one year, send Annex 12.		
10	Once the deadline for the contractor's comments has passed, refer the matter to the decision-maker (set out in Chapter 3) in order that it may decide what further action is to be taken.		
11	Enter the amount of the over-payment on the local payments application available on the NHS BSA website and send Annex 13 to the contractor.		

25. The Commissioner will require pharmacy contractors providing MUR services to provide it with information from patient records on a quarterly basis. The Commissioner will request this information using the form of letter as set out at Annex 14A. The information must be provided to the same local office electronically, using the spreadsheet as set out at Annex 14B.

26. The Commissioner will require pharmacy contractors providing the NMS to provide it with information from patient records on a quarterly basis. Requests for this information will be sent to contractors from the local office of the Commissioner in the form of a letter as set out at Annex 14C. The information must be provided to the same local office electronically, using the spreadsheet as set out at Annex 14D

Procedure relating to managing performance

27. The Commissioner may become aware of potential breaches of Terms of Service in a number of ways other than the routine monitoring outlined above. These include:

- through analysis of data from the NHS Business Service Authority (NHSBSA) Prescription Services;
- via patient complaints;
- as a result of GPhC local inspection; and/or
- from a controlled drugs accountable officer.

28. All concerns in respect of each contractor's premises must be recorded so that the Commissioner can distinguish 'one-off' issues from those which are part of a wider pattern of non-compliance with the Terms of Service.

29. Concerns regarding the contractor's fitness to practise should be dealt with under the relevant policies and procedures.

30. The Regulations contain performance-related sanctions that may be used where a contractor is not complying with their Terms of Service. The PSRC may:

- engage in local dispute resolution;
- issue breach and/or remedial notices;
- withhold payments;
- remove the contractor from the pharmaceutical list.

31. The procedure leading to these sanctions is set out below and set out (in table form) at the end of this chapter.

32. Further information, examples and suggested approaches are set out in the DH Guidance document entitled "Regulations under the Health and Social Care Act 2012: performance sanctions including market exit for contractors providing pharmaceutical services" which can be accessed at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255964/nhs_pharm_servs_market_entry_performance_sancts.pdf.

33. The procedure relating to performance management follows a logical, stepped process for dealing with Terms of Service concerns as early as possible. A step or steps may be omitted (depending on the particular issue) if this is permitted by the Regulations, e.g. where there are patient safety issues.

Failures to Open

34. Once a contractor is included in the pharmaceutical list, there may be occasion where they are unable to open in line with their agreed opening hours for reasons beyond the control of the contractor.

35. In these circumstances the Terms of Service require that the contractor notifies the Commissioner of this temporary suspension and use all reasonable endeavours to resume service provision as soon as is practicable.

36. If a contractor does this, they are not in breach of their Terms of Service.

37. The following procedure should be used where a contractor fails to open:

	Action	Complete?	Notes
1.	When advised that premises are not open, check to see if any notification has been received from the contractor. Where notification has been received, go to step 2 Where the notification has not been received, go to step 5.		
2.	Where notification has been received, the temporary suspension of service provision should be recorded (refer to Annex 7 of the procedure for dealing with changes to pharmacy and dispensing appliance contractors opening hours).		
3.	Check to see if any previous notifications of temporary suspensions for the premises were recorded. If there were, see whether there is a pattern of failing to open. If none is found, no further action is required. Where there is a pattern, write to the contractor asking for their comments.		
4.	Review the comments and escalate the matter to Stage 1.		
5.	Where no notification has been received, send Annex 15 to the contractor.		
6.	On receipt of the response, where there is good cause for the temporary suspension, go to step 7. Where there is no good cause for the temporary suspension, go to step 8.		
7.	Where there is good cause, (e.g. the cause was outside the control of the contractor such as utilities interruption, minor flooding), send Annex 16. Record the failure to open (refer to Annex 7 of the		

	Action	Complete?	Notes
	procedure for dealing with changes to pharmacy and dispensing appliance contractors opening hours).		
8.	Where there is no good cause for the temporary suspension (e.g. the cause was not outside the control of the contractor such as failure to arrange locum cover where there was sufficient time to do so), record the failure to open, send Annex 17 to the contractor and refer the matter to the decision-maker (set out in Chapter 3) to decide what further action to take under Stage 2 of the performance management process.		

Monitoring Opening Hours

38. The Commissioner will monitor compliance with terms of service in relation to opening hours by requiring pharmacy contractors with core opening hours over 40 hours, and dispensing appliance contractors with core opening hours over 30 hours, to:

- complete a four weekly return (Annex 18) whether electronically or, if not possible, in paper copy; or
- in the case of a pharmacy, provide a copy of its pharmacy record covering the relevant time period that sets out the dates and times at which the responsible pharmacist became and ceased to be the responsible pharmacist.

39. The Commissioner will monitor whether the contractor is open during their contracted hours, and if relevant that the terms of accreditation for enhanced services are being met, by telephoning the pharmacy (in which case, the person telephoning will ask to speak to the responsible pharmacist who should confirm their name and General Pharmaceutical Council number) and the enhanced services available.

40. If a contractor appears to have failed to open without prior notification or authorisation, the Commissioner will write to the contractor seeking an explanation. The response will be considered by the Commissioner.

Stages of Performance Management

41. Where a potential breach of Terms of Service is identified or notified and there are concerns that there may be fraudulent behaviour, discuss the matter with NHS Protect.

42. Any further action to be taken under this procedure will be guided by their advice. If there are concerns about potentially criminal behaviour, refer the matter to the medical director. Any further action to be taken under this procedure will be guided by his or her advice.

43. The following procedure sets out the stages of the performance management process:

	Action	Complete?	Notes
1.	**Stage 1 – Identification or Notification of Potential Breaches** Where there is no evidence of fraud or criminal activity, contact the contractor and ask them to explain what has or, as the case may be, hasn't happened. It is important to establish whether or not there has been a breach of the Terms of Service and whether there was good cause for it.		
2.	On receipt of the contractor's response: • where there is no breach of Terms of Service, the matter is to be closed. Advise the contractor and update the relevant file. • where there is a breach of the Terms of Service, go to step 3.		
3.	Where there is a breach of the Terms of Service, NHS England is at risk of significant material financial loss. Where there are such risks escalate the matter to Stage 2 and refer it to the decision-maker (set out in Chapter 3). Where there are no such risks, go to step 4.		
4.	Where there are no such risks, the parties should engage in informal dispute resolution. This can be conducted through telephone communications, meetings or written communications including emails. There is no set process and the most appropriate means of engagement will depend on the nature of the dispute and the preferred ways of working of the Commissioner and contractor. One approach to resolving disputes informally is to develop and agree an action plan with the contractor to address the issue. Timescales for addressing the issue will depend on the nature of the issue but would normally be 30 days. Examples of situations in which it is appropriate to agree an action plan include: • failure to have an up-to-date practice leaflet; • failure to complete the required audits;		

	Action	Complete?	Notes
	• failure to submit the required paperwork in advance of commencing provision of an advanced service; • failure to complete the community pharmacy patient questionnaire. Monitor the contractor's actions and when all actions are complete, confirm to the contractor that the matter is now closed but will remain on file. Update the relevant file. No further action is to be taken.		
5.	If the contractor is unable to complete the action plan within the required timescale and has good cause for this, then one extension may be agreed with them. For example, an extension may be appropriate if an order for updated practice leaflets was placed in a timely manner but the printer was late delivering them At the end of the extended timescale, when the action plan is completed, write to the contractor confirming that the matter is now closed but will remain on file. Update the decision-maker (set out in Chapter 3) (for information only) and the relevant file. No further action is to be taken.		
6.	If the action plan is not completed within the extended timescale, escalate the matter to Stage 2 and refer it to the decision-maker (set out in Chapter 3).		
7.	If no action plan can be agreed with the contractor, escalate the matter to Stage 2 and refer it to the decision-maker (set out in Chapter 3).		
8.	**Stage 2 – Local Dispute Resolution** Where a matter is escalated to or reaches Stage 2 of the process, the decision-maker (set out in Chapter 3) will review the case and determine whether local dispute resolution should be undertaken and if so, by whom.		
9.	The aim of local dispute resolution is to reach agreement on whether or not the contractor is in breach of any Term of Service and to agree how the contractor will ensure the breach is either remedied or not repeated.		

	Action	Complete?	Notes
	When deciding whether local dispute resolution is to be undertaken, the decision-maker will have regard to the matters specified in regulation 69(3) of the Regulations. The matter should be escalated to Stage 3 if: • the matter has already been the subject of local dispute resolution and there are no new issues of substance that would delay escalation; • the premises are not, or have not been, open during core or supplementary hours without good cause; • it is necessary to protect the safety of persons who may receive services from the contractor; or • it is necessary to protect NHS England from material financial loss. Decisions will be fully minuted and reasoned.		
10	Where local dispute resolution is to be undertaken, write to advise the contractor of this and tell them who will represent the Commissioner. Local dispute resolution can be conducted through: • regular telephone communications; • face-to-face meetings at a mutually convenient location; or • written communications. Respond to the contractor's concerns and communications in a timely and reasonable manner. Ensure every reasonable effort to communicate and cooperate is made. Maintain accurate and complete written records of all discussions and correspondence on the contract file. If local dispute resolution is successful, write to the contractor confirming that the matter is now closed but will remain on their file. Update the relevant file and advise the outcome to the decision-maker. No further action is to be taken.		
11	If local dispute resolution is not successful, refer the matter back to the decision-maker (set out in Chapter 3) for escalation to Stage 3.		
12	**Stage 3 – Notices and Withholding Payments**		

	Action	Complete?	Notes
	Where a matter is escalated to or reaches Stage 3 of the process, the decision-maker (set out in Chapter 3) will review the case and decide whether a breach and/or remedial notice or notices are to be issued and whether any payments are to be withheld. When deciding what steps to take, the decision-maker may take into account previous relevant proven breaches of Terms of Service and action taken about them. Based on the contractor's history and previous use of performance-related sanctions by either the Commissioner or a PCT, the matter may be escalated straight to Stage 4.		
13	A notice or notices will be issued where the contractor is in breach of their Terms of Service and there is no good cause for the breach. Refer to Annex 19 for further information on: • what constitutes a breach; • examples of breaches that can or cannot be remedied; • what information should be contained within a notice; and • timescales.		
14	Where the decision-maker is considering whether or not to issue a breach or remedial notice, it will also consider whether or not to withhold payment of fees and allowances. It is not permissible to withhold payments in the absence of a breach or remedial notice. Payments can be withheld where: • the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that the contractor is required to provide; • the decision-maker is satisfied that the breach the withholding relates to is, or was, without good cause; and • the amount to be withheld is justifiable and proportionate having regard to the nature and seriousness of the breach and the reasons for it. All decisions to withhold payments will be fully minuted and reasoned.		

	Action	Complete?	Notes
15	Following the committee meeting, draft a letter based on the minutes of the meeting, complete Annex 20 or 21 or both where relevant and send to the contractor. If payments are to be withheld, complete that section of the relevant notice. If payments are not to be withheld, then this section can be deleted. A copy of any notice served should also be sent the contracts manager at the Commissioner which holds the contractors fitness to practise information.		
16	Where a remedial notice is issued, diarise the date for completion of the required action.		
17	Acknowledge receipt of confirmation from the contractor that the required steps were undertaken and ensure they have been completed by the required date or within the required timescale.		
18	Where all the required steps were satisfactorily completed write to the contractor to confirm that the matter is now closed but will remain on file. Update the relevant file and advise the outcome to the decision-maker. No further action is to be taken.		
19	Where the contractor fails to complete the action required by the remedial notice, write to the contractor at the end of the time period and ask for their views on why they failed to comply.		
20	Refer the matter back to the decision-maker for discussion about what further action is to be taken. Depending on the nature of the breach, this may include issuing further notices and withholding payments or the matter may be escalated to Stage 4.		
21	Where the breach relates to the provision of the services detailed in Schedule 4 or 5 of the Regulations and the contractor is providing advanced services, the decision-maker (set out in Chapter 3) will consider whether to issue a notice stopping the provision of those services and withholding payments for them.		
22	Where payments were withheld alongside a remedial notice, the contractor may submit a claim for the payments to be restored.		

	Action	Complete?	Notes
	Where such a claim is made, check that all the required actions were satisfactorily completed. Where they were satisfactorily completed, advise the contractor that payments are to be restored from the date all the required actions were completed. Update the relevant file and advise the outcome to the decision-maker.		
23	Where they have are not been satisfactorily completed, refuse the claim and send Annex 22 to the contractor.		
24	If notice of an appeal against the decision not to restore payments is received, respond accordingly. Where the FHSAU determines that payments are to be restored, action this accordingly.		
25	**Stage 4 – Removal from the Pharmaceutical List** Where a matter is escalated to or reaches Stage 4 of the process, the decision-maker (set out in Chapter 3) will review the case and decide whether removal is justifiable and proportionate having regard to the nature and seriousness of the breach or breaches and the reason (if known) for it or them. The relevant officer who holds the contractors fitness to practise information should be informed.		
26	If the decision-maker determines that removal is not justifiable or proportionate, then the matter is to be referred back to Stage 3.		
27	If the decision-maker determines that removal may be justifiable and proportionate, arrange an oral hearing to give the contractor the opportunity to make oral representations should they so wish and write to them advising of the proposed action and offering the opportunity to make written or oral representations. At least 30 days' notice is to be given. Consult with the LPC in whose area the contractor's premises are located.		
28	Following consideration of the written and/or oral representations by the decision-maker, send Annex 23 or 24 to the contractor as relevant.		

	Action	Complete?	Notes
29	If notice of an appeal against removal is received, advise the decision-maker and assist in producing a response.		
30	Once the outcome of the appeal is known and it is confirmed that the decision to remove is upheld: • send Annex 25 to the contractor; • advise the NHS BSA's NHS Prescription Services of the closure using form PPD305; • update the pharmaceutical list; and • advise the HWB in whose area the premises were located.		
31	Update other databases as appropriate and inform the usual parties including the company that collects and disposes of unwanted medicines.		
32	If the decision to remove is not upheld, refer the matter back to the decision-maker to decide what further action is to be taken, if any.		

Table of Performance Management Procedure

The table on the next page shows the stages of the Performance Management Procedure.

Stage	Intervention likely to occur	Escalation to another stage
Stage 1: Concern(s) identified by, or reported to, the Sub-Regional Team	Informal resolution between the Head of Commissioning and the contractor. An action plan will be agreed where non-compliance is identified along with a timescale for completion.	• There are patient safety concerns. • The Commissioner is at risk of material financial loss. • The contractor fails to complete the action plan. • The contractor fails to engage with the Sub-Regional Team.
Stage 2: Informal resolution is unsuccessful or it is necessary to omit stage 1 to protect: • The safety of persons who may receive services from the contractor, or • NHS England from material financial loss.	Matter referred to the decision-maker for discussion on what action to take. Options include: • agreeing a further action plan; or • undertaking local dispute resolution in line with regulation 69 of the 2013 Regulations.	• Where the matter has already been the subject of local dispute resolution and there are no new issues of substance that would justify a delay in escalation. • The premises are not, or have not been, open during core or supplementary hours without good cause. • It is necessary to protect the safety of persons who may receive services from the contractor. • It is necessary to protect NHS England from material financial loss.

Stage	Intervention likely to occur	Escalation to another stage
Stage 3: Local dispute resolution has either failed to resolve the issue or is not appropriate due to patient safety or material financial loss grounds	Matter referred to the decision-maker for discussion as to what further action may be taken. Options available include: • issuing breach or remedial notice / notices and withholding payments; and • stopping the provision of advanced services where the contractor is failing to comply with their Terms of Service as set out in the 2013 regulations.	• The contractor has failed to comply with a previously issued remedial notice. • The contractor has been issued with repeated remedial and/or breach notices in relation to the same Term of Service. • The contractor has previously been issued with a remedial or breach notice in relation to the same Term of Service and the decision-maker is satisfied that the contractor is likely to persist in breaching the Term of Service without good cause. • The contractor has been issued with repeated remedial and/or breach notices in relation to different Terms of Service and the decision-maker is satisfied the contractor is likely to persist in breaching the Terms of Service without good cause.

Stage	Intervention likely to occur	Escalation to another stage
Stage 4: Removal from the pharmaceutical list	Removal of the premises to which the breach or breaches related from the pharmaceutical list. Removal must be justifiable and proportionate having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them.	• Not applicable.

CHAPTER 20

Background and Procedure – Local Pharmaceutical Services

Chapter aims and objectives

1. The purpose of this chapter is to ensure that local pharmaceutical services ("LPS") are dealt with in line with the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended (the "Regulations").

2. This chapter provides information on:

   - the background to LPS,
   - the differences between LPS and national pharmaceutical services arrangements;
   - benefits of LPS;
   - examples of using LPS;
   - making LPS arrangements; and
   - the procedure for managing LPS proposals.

Background to LPS

3. LPS allows the Commissioner to commission pharmaceutical services tailored to meet specific local requirements. LPS complements the national contractual framework for community pharmacy but is an important local commissioning tool in its own right. LPS provides flexibility to include within a single local contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements.

4. All services currently eligible to be provided through national pharmacy arrangements may be provided through LPS schemes in addition to services not traditionally associated with pharmacy. Training and education may also be provided through LPS contracts associated with particular LPS schemes, including training and education for those who are or may become involved in the provision of LPS.

5. LPS is likely to be immediately useful where national arrangements do not permit a specific configuration of services which may be required by the Commissioner or where the current providers are unable or unwilling to provide certain services. However, this does not preclude a variety of other circumstances in which LPS may be used.

6. LPS schemes may also be co-located in premises with national arrangements, for instance, to address the needs of a particular patient group.

Differences between LPS and national pharmaceutical services arrangements

7. It is for the Commissioner to decide when and in what circumstances it wishes to enter into a LPS contract. LPS provides the Commissioner with the flexibility to decide not just where it might wish to locate LPS schemes but also to determine the mix of services within any given scheme.

8. A LPS contract may provide for any such combination of services as the parties agree between them.

9. The level of remuneration for services provided under LPS contracts is decided locally between parties to the contract and is not dictated nationally.

10. LPS is not subject to 'market entry' conditions.

11. The Commissioner has the power to "designate" areas, premises or descriptions of premises when deciding whether to develop and/or implement LPS arrangements. This has the effect of allowing the Commissioner to choose to defer consideration of routine applications to the pharmaceutical list under the Regulations in the area under designation. Refer to Annex 1 for further information on designations.

12. The Commissioner must determine, before entering into an LPS contract, whether the person is to be given a right of return to the pharmaceutical list after ceasing to provide services. The principles (which may be amended from time to time) by which the Commissioner will make right of return determinations must be published and are set out at Annex 2.

Benefits of LPS

13. LPS is an important local commissioning tool that provides flexibility to build local contracts, which support the local delivery of improved health services through:

    - the use of local contracts designed to address local healthcare priorities, in specific or unique situations and without restriction on location;
    - the better use of pharmacies to increase access to a broader range of health services;
    - the provision or reconfiguration of services designed around patients or specific groups of patients;
    - the better use of pharmacists' skills especially in extending clinical services in local areas;

- providing opportunities for LPS contractors to work within contracts that they have had input into;
- pharmacists working more closely with other health professionals (e.g. by leading integrated teams of health professionals or working as part of such a team); and
- providing the Commissioner with the flexibility to participate in health promotion schemes in a wider context (e.g. local regeneration projects).

14. Benefits of LPS to patients include:

- access to services that have been designed with their needs in mind;
- the opportunity to benefit from the pharmacist's expertise;
- access to a broader range of care, facilitated by the local pharmacy; and
- locally based services that offer easy access, especially for those with reduced mobility.

Examples of scenarios using LPS to address pharmaceutical services needs

15. Examples where LPS contracts may be useful include:

- The Commissioner identifies a geographic area where it wishes to improve access to primary care services available through pharmacy. For example, it wishes to make better use of the pharmacist's knowledge and skills to provide services to specific patient groups, for example, patients over 75 years of age. It also wishes to include services such as testing and monitoring of certain conditions, for example, blood pressure, glucose levels and weight measurement. In addition, it wishes to put in place access to broader services, for example, podiatry and a referral pathway to services such as occupational therapy, social care services and local authority services.
- The Commissioner considers there is an area with a rising population of individuals with long-term conditions resident in the community. It wishes to have the pharmacy to provide a domiciliary service for provision of medicines and to act as an access point for advice and support on medicines and signposting for other agencies such as social care and other health professionals, for example, community nurses, working within the local community. As part of an LPS contract, it wishes to have the pharmacist provide training to support carers in helping patients with medicine taking.
- The Commissioner wishes to commission the provision of access to pharmaceutical services in specified out-of-hours periods covering certain geographic areas. It also wishes to include the provision of a pharmaceutical service to a residential care home within the LPS contract.

- The Commissioner wishes to provide a care pathway for certain categories of patients through an LPS contract; e.g.
    - those who may be exhibiting symptoms of depression and have otherwise not been identified. The Commissioner wishes to have a system whereby such patients, if identified by the pharmacist, are referred to the local community mental healthcare team.
    - those patients who have been prescribed medication for certain mental health conditions. In such cases, the contract will require the provision of support by the pharmacist to help such patients to take their medicines, especially in the case of those who are newly diagnosed with such conditions.
- The Commissioner wishes to set up a network of health promoting pharmacies through an LPS contract. It envisages that such service will extend to those suffering certain ill-health conditions that are ameliorated through sustained healthy lifestyle choices as well as a service for those who wish to maximise their health and well-being. Pharmacies providing this service will act as 'centres of excellence' and referrals to the service will be made by a broad range of health professionals.
- An area's pharmaceutical needs are currently met by existing contractors through a mix of national contractual framework arrangements and LPS contracts but notes that amongst the national contractual framework contractors are some 'low volume' providers. The Commissioner, in considering the impact of the ending of the fixed professional allowance for such providers may wish to consider the use of LPS as a contracting tool to assure itself that the pharmaceutical needs of its population continue to be met.

Making LPS arrangements

16. LPS arrangements can be made in two ways:
    - by a person putting forward a proposal for LPS arrangements without the Commissioner advertising, inviting or initiating the process; or
    - by the Commissioner specifying the services and/or location and any other details of an LPS arrangement that it wishes to commission and inviting prospective providers to come forward.

LPS proposals submitted without invitation

17. The Regulations allow any potential provider to make a proposal at any time to the Commissioner for LPS arrangements. If the proposal is not vexatious or frivolous then the Commissioner must consider whether or not to select that proposal for development. As this is a right which is clearly set out in the Regulations, all providers can be said to be aware that this right exists and the Commissioner may consider there is no need to advertise this right or for it to

enter into a set procurement process as its process to award LPS contracts is set in the Regulations.

18. When the Commissioner receives a proposal for LPS arrangements in this way, the procedure below should be followed. The Commissioner should ensure that all persons submitting LPS proposals are treated equally.

Inviting LPS proposals

19. Where the Commissioner specifies the services and/or location and any other details of an LPS arrangement, it should comply with the Public Contracts Regulations 2015 (the "Procurement Regulations"). Pharmacy services are categorised as "social and other specific services" ("SOS") under the Procurement Regulations.

20. Where SOS are over the relevant threshold which is £625,050, the Commissioner would be obliged to:

    - issue a contract notice in the Official Journal of the European Union ("OJEU") describing the process it will follow for the procurement;
    - at the same time as publication of the notice all "procurement documents" (including contract, specification, terms etc) must be available via an internet address;
    - within 24 hours publish the OJEU notice on Contracts Finder (the UK website to encourage SMEs); and
    - within 30 days of the award of the contract, publish a contract award notice in OJEU and on Contracts Finder.

21. Throughout the procurement process, the Commissioner is obliged to be transparent, and treat bidders equally and without discrimination.

22. Where SOS is under the relevant threshold but over £25,000, the Commissioner would be obliged to:

    - publish information about the contract opportunity on Contracts Finder. If the information is advertised elsewhere (e.g. the Commissioner's website), the information must be published on Contracts Finder within 24 hours of it being publishing elsewhere;
    - at the same time as publication of the notice, the relevant contract documents must be available via an internet address. Relevant contract documents include any documents that contain more information than in the published Contracts Finder advertisement and that is intended by the Commissioner to be taken into account by those responding to the advertisement; and
    - publish a contract award notice on Contracts Finder within a reasonable time.

23. The Commissioner should ensure that any procurement is conducted in accordance with the Commissioner's standing orders and standing financial instructions.

24. The Commissioner should adopt a procurement process that will ensure compliance with the Procurement Regulations and the provisions of the Regulations that apply to LPS arrangements. This process may be based on the procedure below but with the procedure amended to fit the needs of the procurement exercise and the requirements of the Procurement Regulations.

25. It is strongly advised that the Commissioner seeks legal advice to ensure that the process adopted satisfies all the legal requirements that apply to the Commissioner.

Procedure for managing LPS proposals

Action		Complete?	Notes
1.	On receipt of an LPS proposal, check that the proposal contains the appropriate information including fitness information required by Regulation 106. This is particularly important if the applicant has not used the fitness information form set out at Annex 3. Ensure details have been added to any appropriate database. Ensure the database is updated as the proposal progresses.		
2.	Forward the LPS proposal to the Pharmacy Contracts Manager to consider whether the LPS proposal is vexatious or frivolous. If it is determined that the proposal is vexatious or frivolous (i.e. no serious intent to deliver services), send Annex 4 (rejection of proposal) to the proposer. No further action is required. If it is determined that the proposal is not vexatious or frivolous, send Annex 5 to the proposer and go to step 3.		
3.	Consider whether to select the proposal		

Action		Complete?	Notes
	for development. Refer to Annex 6 for guidance. If required: • send Annex 7 to the local authority and those bodies set out in Regulation 107; and/or • carry out service user involvement exercise – Annex 1		
4.	Prepare a report (Annex 8) for the PSRC on whether to select the proposal for development and send to the committee administrator/secretary.		
5.	After the meeting, prepare the relevant decision letters: • Selected – to the proposer (Annex 9); • Selected – to a third party (Annex 10); • Not selected – to the proposer (Annex 11). If the LPS proposal is selected for development, go to step 6. If the LPS proposal is not selected for development, no further actions are necessary.		
6.	Develop the proposal. Refer to Annex 12 for further information.		
7.	Determine whether any funding should be provided to the proposer. Refer to Annex 13 for further information.		
8.	Ensure an assessment of equality impact of the proposal is carried out and recorded with reference to the protected characteristics and it documents how feedback from service user involvement has been taken into account.		

Action		Complete?	Notes
9.	Prepare a report (Annex 14) for the PSRC on whether the proposal should be adopted and if so whether a right of return should be given. Send to the committee administrator/secretary.		
10.	After the meeting, prepare the relevant decision letters: • Adopted – to the proposer (Annex 15); or • Not adopted – to the proposer (Annex 16). It would be good practice to inform the bodies that were notified of the decision to select the proposal for development of the outcome of the matter. If the LPS proposal is selected, go to step 11. If the LPS proposal is not selected, no further actions are necessary.		
11.	Prepare the template LPS contract (Annex 17) with information taken from the agreed proposal, development stage and adoption determination (if relevant) Refer to the guidance at Annex 18 for completing the template LPS contract. N.B. Be aware of Public Contract Regulations 2015 which were not in place when the guidance was issued. Clarify any final matters and arrange for the LPS contract to be signed.		

CHAPTER 21

General Duties of NHS England

1. INTRODUCTION

- This chapter outlines the general duties that NHS England must comply with that are likely to affect the decisions it takes regarding the provision of primary care.
- There are many general duties on NHS England. It is important that decision-makers are familiar with all of these because if a duty has not been complied with when a decision is taken, that decision can be challenged in the courts on the grounds that it is unlawful.
- This guidance looks at the general duties that NHS England is required to comply that are most applicable to primary care, providing examples to illustrate how they might affect decision making.
- Below is a summary of the duties that are covered by this guidance. The full wording from the legislation is provided at Annex 1. The guidance goes on to look at each of the duties in more detail

Equality duties

- The Equality Act 2010 prohibits unlawful discrimination in the provision of services on the grounds of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation. These are the "protected characteristics".
- As well as these prohibitions against unlawful discrimination the Equality Act 2010 requires NHS England to have "due regard" to the need to:

  1..1 eliminate discrimination that is unlawful under the Equality Act;

  1..2 advance equality of opportunity between people who share a relevant protected characteristic and people who do not share it; and

  1..3 foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

This can require NHS England to take positive steps to reduce inequalities. The duty is known as the public sector equality duty or PSED (see section 149 of the Equality Act).

The "Regard Duties"

- The "Regard Duties" are:

1..4 the duty to have regard to the need to reduce health inequalities (see section 13G of the NHS Act 2006)

1..5 the duty to have regard to the desirability of allowing others in the healthcare system to act with autonomy and avoid imposing unnecessary burdens upon them, so far as this is consistent with the interests of the health service (see section 13F of the NHS Act 2006)

1..6 the duty to have regard to the need to promote education and training of those working within (or intending to work within) the health service (see section 13M of the NHS Act 2006)

1..7 the duty to have regard to the likely impact of commissioning decisions on healthcare delivered in areas of Wales or Scotland close to the border with England (see section 13O of the NHS Act 2006)

The "View To Duties"

- The "View To Duties" are:

1..8 the duty to act with a view to delivering services in a way that promotes the NHS constitution (see section 13C(1)(a) of the NHS Act 2006)

1..9 the duty to act with a view to securing continuous improvement in the quality of services in health and public health services (see section 13E of the NHS Act 2006)

1..10 the duty to act with a view to enabling patients to make choices about their care (see section 13I of the NHS Act 2006)

1..11 the duty to act with a view to securing integration, including between health and other public services that impact on health, where this would improve health services (see section 13N of the NHS Act 2006)

The "Promote Duties"

- The "Promote Duties" are:

  1..12 the duty to promote awareness of the NHS Constitution among patients, staff and members of the public (see section 13C(1)(b) of the NHS Act 2006)

  1..13 the duty to promote the involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)

  1..14 the duty to promote innovation in the health service (see section 13K of the NHS Act 2006)

  1..15 the duty to promote research and the use of research on matters relevant to the health service (see section 13L of the NHS Act 2006)

The "Involvement Duty"

- NHS England has a duty to make arrangements to secure that service users and potential service users are involved in:

  1..16 the planning of commissioning arrangements by NHS England;

  1..17 NHS England's development and consideration of proposals for changes to commissioning arrangements, if the implementation of the proposals would impact on the range of health services available to service users or the manner in which they are delivered; and

  1..18 NHS England decisions affecting the operation of commissioning arrangements, if those decisions would have such an impact.

Duty to act fairly & reasonably

- NHS England has a duty to act fairly and reasonably when making its decisions. These duties come from case law that applies to all public bodies.

Duty to obtain advice

- NHS England has a duty to "obtain appropriate advice" from persons with a broad range of professional expertise (see section 13J of the NHS Act 2006)

Duty to exercise functions effectively

- NHS England has a duty to exercise its functions effectively, efficiently and economically (see section 13D of the NHS Act 2006)

Duty as to reducing inequalities

- The Board must, in the exercise of its functions, have regard to the need to:-

  25..1 reduce inequalities between patients with respect to their ability to access health services, and

  25..2 reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.

Duty not to prefer one type of provider

- NHS England must not try to vary the proportion of services delivered by providers according to whether the provider is in the public or private sector, or some other aspect of their status.

2. Equality duties

The protected characteristics

- The Equality Act 2010 prohibits unlawful discrimination in the provision of services (including healthcare services) on the basis of "protected characteristics". The protected characteristics are:

  2..1 age

  2..2 disability

  2..3 gender reassignment

  2..4 marriage and civil partnership

  2..5 pregnancy and maternity

  2..6 race

2..7 religion or belief (which can include an absence of belief)

2..8 sex

2..9 sexual orientation

Unlawful discrimination can also occur if a person is put at a disadvantage because of a combination of these factors.

Unlawful discrimination

- There are broadly four types of discrimination in the provision of services that are unlawful under the Equality Act:

2..10 Direct discrimination services are not available to someone because they are e.g. not married, over 35, a woman. Apart from a few limited exceptions, direct discrimination will always be unlawful, unless it is on the grounds of age and the discrimination is a proportionate means of achieving a legitimate aim.

2..11 Indirect discrimination occurs when NHS England apply a policy, criterion or practice equally to everybody but which has a disproportionate negative impact on one of the groups of people sharing a protected characteristic, and where the complainant cannot themselves comply. The classic example is a height requirement, which is likely to exclude a much greater proportion of women than men because women are on average significantly shorter. Requirements that require people to behave in a certain way will amount to indirect discrimination if compliance is not consistent with reasonable expectations of behaviour. For example, a requirement not to wear a head covering would be indirectly discriminatory on the grounds of religion, even though followers of religions which require a head covering are physically able to remove it.) Indirect discrimination is not unlawful if it is a proportionate means of achieving a legitimate aim.

2..12 Disability discrimination occurs if a person is treated unfavourably because of something "arising in consequence of their disability". This captures discrimination that occurs not because of a person's disability per se (e.g. a person has multiple sclerosis) but because of the behaviour caused by the disability (e.g. use of a wheelchair). So an inability of someone with multiple sclerosis to access services when using their wheelchair could be an instance of disability discrimination. Disability discrimination is not unlawful if it is a proportionate means of achieving a legitimate end.

2..13 A failure to make "reasonable adjustments" for people with disabilities who are put at a substantial disadvantage by a practice or physical feature. The duty also requires bodies to put an "auxiliary aid" in place where this would remove a substantial disadvantage e.g. a hearing aid induction loop The duty to make reasonable adjustments might e.g. require NHS England to make consultation materials available in braille. However some care is needed here. People with disabilities have a right to access services in broadly the same way as people without disabilities, so far as is reasonable. Offering a telephone consultation to a wheelchair using patient who is prevented from accessing a clinic by steps may in fact be unlawful discrimination rather than a reasonable adjustment. The wheelchair user should be able to access services in broadly the same way as others i.e. by attending practice premises for a consultation.

(Unlawful discrimination is also prohibited in the field of employment and other areas but these are not covered in this guidance.)

Public sector equality duty

- As well as these prohibitions against unlawful discrimination the Equality Act 2010 requires NHS England to have "due regard" to the need to:

  2..14 eliminate discrimination that is unlawful under the Act;

  2..15 advance equality of opportunity between people who share a relevant protected characteristic and people who do not share it; and

  2..16 foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

  This can require NHS England to take positive steps to reduce inequalities. In this regard the Act permits treating some people more favourably than others but not if this amounts to unlawful discrimination. The duty is known as the public sector equality duty or PSED (see section 149 of the Act). The PSED has been used successfully on many occasions to challenge changes to services.

- This means that NHS England has a duty to help eliminate any unlawful discrimination practised by the providers of primary care e.g. through requiring premises to be accessible. Failing to use its negotiating power to secure such changes could be seen as a breach by NHS England of the

PSED, as well as a breach of the non-discrimination rules by the service provider.

- Carrying out appropriate equality impact assessments is usually critical to proving discharge of the PSED, although they are not as such a legal requirement. This is because if there is no assessment of the impact of a possible change on groups with protected characteristics, it is very difficult to argue that NHS England had the impact properly in mind when it made its decision. This is the case even if the impact on protected groups is minimal.

- It is not always easy to assess equality impact. A robust service user involvement exercise will help NHS England identify any issues. It is advisable to ask question(s) directly aimed at equalities issues. In many cases it is advisable to take special steps to reach hard to reach groups affected by the decisions (e.g. by making involvement materials available in languages other than English). The more likely a decision is to disproportionately affect a protected group, the more important it is to get feedback from that group about the decision.

- The PSED means that NHS England must consider equalities issues when making decisions. In some cases there may be a solution that causes less disadvantage to a protected group but for other reasons is undesirable. In these situations it is important to acknowledge the disadvantage caused and be clear about why the decision was taken. This may include outlining costs concerns. It also makes sense to monitor the situation e.g. does the demographic of service users change as a result of the decision and timetable a formal review in e.g. a year's time.

- There are a few themes arising from the cases we have seen so far on the application of the PSED (and similar duties in previous legislation).

  2..17 A need to explicitly recognise that the PSED applies and equalities issues need to be considered

  2..18 The duty is an ongoing one – to be considered at all stages of decision-making not just at the end.

  2..19 A need to be clear about the factors driving a decision, even if these are unpalatable e.g. budgetary pressures.

  2..20 A need to analyse in some detail the impact of a proposed policy or decision so that the public authority has a clear idea of who is affected and how. Statements of impact need to be supported by evidence where possible.

2..21 If a decision is made that will impact negatively on a protected group, that should be acknowledged and the rationale explained.

2..22 There should be a detailed consideration as to how any negative impact of the decision could be mitigated. If the steps identified are not practicable, this should be explained.

2..23 The duty must be complied with at the time of the decision. After the event reasoning is rarely allowed.

3. The regard duties

Introduction

- The **"Have regard"**, **"act with a view to"** or **"promote"** duties. These form a loose hierarchy of duties:

  3..1 The duty to have regard means that when taking actions, a certain thing must be considered

  3..2 The duty to promote means action must be taken that actually achieves an outcome. Additionally, it is possible to promote something by encouraging others to do it.

  3..3 The duty to act with a view to means that action must be taken with a purpose in mind.

- In contrast to the Promotion Duties and the View To Duties, the Regard Duties apply to every action of NHS England where it is carrying out its primary care functions. (Pausing there, the duty will not normally apply to "private law" decisions that would be taken by any private sector organisation – making HR decisions, leasing estate etc.)

- The PSED cases are the best guide that we have to how a court would interpret NHS England's Regard Duties. We can learn from these that:

  3..4 Those in NHS England who have to take decisions must be made aware of their duty to have regard to the various issues outlined in the duties. Failure to do so will render the decision unlawful.

  3..5 The Regard Duties must be fulfilled before and at the time that a particular decision is being considered. If they are not, any attempts to retrospectively justify a decision as consistent with the Regard Duties will not be enough to discharge them.

3..6 Officers need to engage with the Regard Duties with rigour and with an open mind.

3..7 It is good practice for the decision maker to make reference to the Regard Duties.

3..8 It is not possible for NHS England to delegate the duties down to another organisation to comply with. They will always remain with NHS England. If NHS England acts through contractors it must ensure as necessary that they act consistently with the duties.

3..9 The Regard Duties are continuing ones that apply throughout decision-making. It is not enough to only "rubber stamp" a decision by reference to the Regard Duties at the end of a decision-making process. The Regard Duties need to be borne in mind throughout.

3..10 It is crucial to keep an adequate record of how the Regard Duties are considered. If records are not kept it will make it more difficult, evidentially, for NHS England to persuade a court that it has fulfilled the duties imposed.

- One key point to understand is that there is no obligation to achieve the object of the Regard Duties e.g. it is not unlawful not to eliminate health inequalities (although equally, if health inequalities persist and widen, that fact would need to inform consideration of the regard duty.). Nor does NHS England have the luxury of "pausing" the health service while it investigates health inequality or any other matter. The duties are to have regard, not to achieve perfection, and this is a practical rather than an academic exercise.

Reduce health inequalities

- Of the Regard Duties, the requirement to have regard to the need to:-

  25..1 Reduce inequalities between patients with respect to their ability to access health services, and

  25..2 reduce health inequalities between patients with respect to the outcomes achieved for them by the provision of health services

- When making decisions about primary care – particularly about service changes – decision-makers will need to bear in mind the impact on health inequalities. To do this NHS England will need some data around existing

health inequalities, and to consider whether its decision can be used to diminish these.

- The detail and causes of health inequalities is a highly complex area, ranging from the highest level of generality (male vs female life expectancy, say) down to very granular data taking into account a patients place of residence, age, smoking status etc. NHS England must try to obtain the data needed to understand and address health inequality, but there is a trade off between making further enquiries and taking decisions and moving the health service on.
- The key point is that NHS England can show (through documentation) that the impact a decision will have on health inequalities has been taken into account, and that its decision is based on some relevant data.

Act with autonomy

- NHS England has a duty to have regard to the desirability of allowing others in the healthcare system to act with autonomy and avoid imposing unnecessary burdens upon them, so far as this is consistent with the interests of the health service.

Promote education and training

- NHS England has a duty to have regard to the need to promote education and training of those working within (or intending to work within) the health service.

Impact in areas of Wales or Scotland

- NHS England has a the duty to have regard to the likely impact of commissioning decisions on healthcare delivered in areas of Wales or Scotland close to the border with England. This will clearly be relevant for those working in regional teams that border Wales or Scotland. NHS England will also need to comply with the duty when making national strategic decisions about the delivery of primary care – that affect bordering areas as well as others.

4. The promote duties

- It is helpful to look next at the Promote Duties. These are:

4..1 the duty to promote awareness of the NHS Constitution among patients, staff and members of the public (see section 13C(1)(b) of the NHS Act 2006)

4..2 the duty to promote the involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)

4..3 the duty to promote innovation in the health service (see section 13K of the NHS Act 2006)

4..4 the duty to promote research and the use of research on matters relevant to the health service (see section 13L of the NHS Act 2006)

- However a decision which is positively contrary to achieving the relevant outcome might breach a promote duty unless there was some compelling reason to adopt it. In this situation please contact the NHS England Legal Team for further guidance.
- Additionally, some decisions will be obvious opportunities where e.g. patient involvement could easily be promoted. In such cases the safest course of action is to ensure that this is done.
- To meet the duty NHS England does not have to do everything itself – be more innovative, improve its use of research data etc. It can meet the duty by encouraging other people to do things.

5. The view to duties

- The **"View To Duties"** are:

5..1 the duty to act with a view to delivering services in a way that promotes the NHS constitution (see section 13C(1)(a) of the NHS Act 2006)

5..2 the duty to act with a view to securing continuous improvement in the quality of services in health and public health services (see section 13E of the NHS Act 2006)

5..3 the duty to act with a view to enabling patients to make choices about their care (see section 13I of the NHS Act 2006)

5..4 the duty to exercise its functions with a view to securing that health services are provided in an integrated way where it considers that this would:-

(a) improve the quality of those services (including the outcomes that are achieved from their provision)

(b) reduce inequalities between persons with respect to their ability to access those services, or

(c) reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services.

- In many ways the considerations for these duties and the Promote Duties are the same. One difference is that while a Promote Duty can be met by encouraging others to achieve it (e.g. encouraging GP practices to make better use of telehealth devices), with the View To Duties the actions have to be carried out by NHS England.
- The View To duties are less onerous than the Promote Duties because they do not require NHS England to achieve a particular outcome (although that would be desirable)– only to do something that aims to achieve it. This is in contrast to the Promote Duties, which require an outcome to be achieved.
- Again, the View To duties are most likely to affect strategic decisions taken at directorate level. Provided NHS England can show that within the totality of its activities there has been significant action taken with the intention of achieving the outcomes that NHS England is required to have a view to, the duty is discharged.
- As with the Promote Duties, decision-makers on the ground should be wary of doing something actively goes against one of the goals set out in the View To duties. In this situation please contact the NHS England Legal Team for further guidance. Also, if there is a clear opportunity to help deliver one of the View To objectives, it is best to take it.

6. The involvement duty

Overview

- Under section 13Q of the NHS Act 2006, NHS England has a statutory duty to 'make arrangements' to involve the public in the commissioning services for NHS patients.
- Section 13Q applies to:

6..1 the planning of commissioning arrangements

6..2 the development and consideration of any proposals that would impact on the manner in which services are delivered to individuals or the range of services available to them

6..3 decisions that would impact on the manner in which services are delivered to individuals or the range of services available to them

- The section 13Q duty only applies to plans, proposals and decisions about services that are directly commissioned by NHS England. This includes GP, dental, ophthalmic and pharmaceutical services.

NHS England's arrangements for public involvement

- The statutory duty to 'make arrangements' under section 13Q of the NHS Act 2006 is essentially a requirement to make plans and preparations for public involvement.
- NHS England has set out its plans as to how it intends to involve the public in its 'Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning'. The document sets out and explains the arrangements NHS England has in place:

6..4 Corporate infrastructure – how public involvement is embedded in the way that NHS England is constituted and carries out its business

6..5 Involvement initiatives – initiatives designed to involve the public in strategic planning and the development of policy or other aspects of NHS England's activities

6..6 Monitoring arrangements – a step-by-step process to help commissioners identify whether the section 13Q applies and decide whether sufficient public involvement activity is already in place or whether additional public involvement is required

6..7 Responsive arrangements – guidance to commissioners on how to make arrangements for public involvement where monitoring has indicated that such arrangements are required.

- As well as setting out the above arrangements, which NHS England commissioners should follow, the document is regularly reviewed and updated and contains useful resources for commissioners, including:

6..1 Details of existing corporate infrastructure and involvement initiatives which could be drawn upon by commissioners to involve the public in their commissioning activities.

6..2 Reference to NHS England's framework for involving patients and the public in primary care commissioning, which includes resources developed especially for primary care.

6..3 Resources to help commissioners identify whether the section 13Q applies, put in place appropriate arrangements for public involvement and avoid legal challenge.

6..4 Guidance on a variety of topics that often arise, such as what 'public involvement' means, how to involve the public, who to involve, when involvement should take place, urgent decisions and joint involvement exercises

6..5 Case studies based upon primary care scenarios

6..6 Summaries of related legal duties

6..7 Details of how to seek further advice if needed.

- The document is intended to be used by both NHS England staff (who need to understand and comply with the arrangements when commissioning services) and the public (to understand how NHS England involves the public in its commissioning of services). It is not intended for CCGs, who are required to make their own arrangements for public involvement under section 14Z2 of the NHS Act 2006.

7. Duty to act fairly & reasonably

- NHS England has a duty to act fairly and reasonably when making its decisions. These duties come from case law that applies to all public bodies.

Acting fairly

- Normally, to act fairly NHS England will need to act in accordance with its own policies. It can depart from guidance if there is good reason to do so. In this scenario NHS England will need to explain the situation fully to the people & organisations affected and give them a chance to provide their views on the procedure to be followed. This will include why it wants to depart from the usual policy and what it will do instead.

- NHS England also needs to be careful about keeping to promises made to contractors or the public e.g. that there will be a public consultation before any final decision is made on closing a particular pharmacy. It is sometimes (but not always) possible depart from such promises.

Therefore care should be taken about giving any clear commitments to a particular course of action until NHS England is sure that it is what it wants to do. If NHS England is considering depart from a commitment it has given to do a particular thing or follow a particular type of process, please contact the NHS England Legal Team for further guidance.

- It is also important to act proportionately, taking into account any adverse impact on patients and/or contractors.

Acting reasonably

- NHS England has to take all relevant factors into account when making its decisions and exclude irrelevant factors. It is up to NHS England how much weight it gives competing considerations and may give a factor no weight at all. The key point is that all the relevant factors are identified and documented.

- The reasons for NHS England's decisions also need to "stack up". It is important for NHS England to document its reasons for a decision as NHS England needs not only to act reasonably but be able to show that it has acted reasonably by reference to contemporaneous documents. This means that particularly where a controversial decision is being made the thinking behind the decision needs to be carefully documented.

8. The duty to obtain advice

- NHS England has a duty to "obtain appropriate advice" from persons with a broad range of professional expertise (see section 13J of the NHS Act 2006).

- This means that decision-makers need to collect appropriate information before making decisions. If NHS England does not have the information it needs then it should seek out appropriate advice. In many cases it will not be necessary to do this as all the necessary information is to hand. The duty is most relevant to strategic decisions taken at directorate level, where decision-makers will need to document how they obtain advice from those with professional expertise (some of whom may be NHS England employees or secondees).

9. The duty to exercise functions effectively

- NHS England has a duty to exercise its functions effectively, efficiently and economically (see section 13D of the NHS Act 2006).

- This is a statutory reformulation of a duty that has been contained for many years in Managing Public Money and its predecessors. If NHS England has complied with the other duties in this guidance – in particular the duty to act reasonably – it is highly unlikely that it will breach this duty.

10. The duty not to prefer one type of provider

- NHS England must not try and vary the proportion of services delivered by providers according to whether the provider is in the public or private sector, or some other aspect of their status.
- This means that NHS England must focus on the services delivered by an organisation and its sustainability. It should not make choices about contractors based solely on their status as e.g. company, partnership, public sector, private sector, charity or not for profit organisation.

Annex 1

Extracts from Legislation

The NHS Act 2006 – sections 13C – 13Q

General duties of the Board

[References to "the Board" are to NHS England]

13C Duty to promote NHS Constitution

(1) The Board must, in the exercise of its functions--

(a) act with a view to securing that health services are provided in a way which promotes the NHS Constitution, and

(b) promote awareness of the NHS Constitution among patients, staff and members of the public.

(2) In this section, "patients" and "staff" have the same meaning as in Chapter 1 of Part 1 of the Health Act 2009 (see section 3(7) of that Act).

13D Duty as to effectiveness, efficiency etc

The Board must exercise its functions effectively, efficiently and economically.

13E Duty as to improvement in quality of services

(1) The Board must exercise its functions with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with--

(a) the prevention, diagnosis or treatment of illness, or

(b) the protection or improvement of public health.

(2) In discharging its duty under subsection (1), the Board must, in particular, act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services.

(3) The outcomes relevant for the purposes of subsection (2) include, in particular, outcomes which show--

(a) the effectiveness of the services,

(b) the safety of the services, and

(c) the quality of the experience undergone by patients.

(4) In discharging its duty under subsection (1), the Board must have regard to--

(a) any document published by the Secretary of State for the purposes of this section, and

(b) the quality standards prepared by NICE under section 234 of the Health and Social Care Act 2012.

13F Duty as to promoting autonomy

(1) In exercising its functions, the Board must have regard to the desirability of securing, so far as consistent with the interests of the health service--

(a) that any other person exercising functions in relation to the health service or providing services for its purposes is free to exercise those functions or provide those services in the manner it considers most appropriate, and

(b) that unnecessary burdens are not imposed on any such person.

(2) If, in the case of any exercise of functions, the Board considers that there is a conflict between the matters mentioned in subsection (1) and the discharge by the Board of its duties under sections 1(1) and 1H(3)(b), the Board must give priority to those duties.

13G Duty as to reducing inequalities

The Board must, in the exercise of its functions, have regard to the need to--

(a) reduce inequalities between patients with respect to their ability to access health services, and

(b) reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services.

13H Duty to promote involvement of each patient

The Board must, in the exercise of its functions, promote the involvement of patients, and their carers and representatives (if any), in decisions which relate to--

(a) the prevention or diagnosis of illness in the patients, or

(b) their care or treatment.

13I Duty as to patient choice

The Board must, in the exercise of its functions, act with a view to enabling patients to make choices with respect to aspects of health services provided to them.

13J Duty to obtain appropriate advice

The Board must obtain advice appropriate for enabling it effectively to discharge its functions from persons who (taken together) have a broad range of professional expertise in--

(a) the prevention, diagnosis or treatment of illness, and

(b) the protection or improvement of public health.

13K Duty to promote innovation

(1) The Board must, in the exercise of its functions, promote innovation in the provision of health services (including innovation in the arrangements made for their provision).

(2) The Board may make payments as prizes to promote innovation in the provision of health services.

(3) A prize may relate to--

(a) work at any stage of innovation (including research);

(b) work done at any time (including work before the commencement of section 23 of the Health and Social Care Act 2012).

13L Duty in respect of research

The Board must, in the exercise of its functions, promote--

(a) research on matters relevant to the health service, and

(b) the use in the health service of evidence obtained from research.

13M Duty as to promoting education and training

The Board must, in exercising its functions, have regard to the need to promote education and training for the persons mentioned in section 1F(1) so as to assist the Secretary of State in the discharge of the duty under that section.

13N Duty as to promoting integration

(1) The Board must exercise its functions with a view to securing that health services are provided in an integrated way where it considers that this would--

(a) improve the quality of those services (including the outcomes that are achieved from their provision),

(b) reduce inequalities between persons with respect to their ability to access those services, or

(c) reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services.

(2) The Board must exercise its functions with a view to securing that the provision of health services is integrated with the provision of health-related services or social care services where it considers that this would--

(a) improve the quality of the health services (including the outcomes that are achieved from the provision of those services),

(b) reduce inequalities between persons with respect to their ability to access those services, or

(c) reduce inequalities between persons with respect to the outcomes achieved for them by the provision of those services.

(3) The Board must encourage clinical commissioning groups to enter into arrangements with local authorities in pursuance of regulations under section 75 where it considers that this would secure--

(a) that health services are provided in an integrated way and that this would have any of the effects mentioned in subsection (1)(a) to (c), or

(b) that the provision of health services is integrated with the provision of health-related services or social care services and that this would have any of the effects mentioned in subsection (2)(a) to (c).

(4) In this section--

"health-related services" means services that may have an effect on the health of individuals but are not health services or social care services;

"social care services" means services that are provided in pursuance of the social services functions of local authorities (within the meaning of the Local Authority Social Services Act 1970).

130 Duty to have regard to impact on services in certain areas

(1) In making commissioning decisions, the Board must have regard to the likely impact of those decisions on the provision of health services to persons who reside in an area of Wales or Scotland that is close to the border with England.

(2) In this section, "commissioning decisions", in relation to the Board, means decisions about the carrying out of its functions in arranging for the provision of health services.

13P Duty as respects variation in provision of health services

The Board must not exercise its functions for the purpose of causing a variation in the proportion of services provided as part of the health service that is provided by persons of a particular description if that description is by reference to—

(a) whether the persons in question are in the public or (as the case may be) private sector, or

(b) some other aspect of their status.

13Q Public involvement and consultation by the Board

(1) This section applies in relation to any health services which are, or are to be, provided pursuant to arrangements made by the Board in the exercise of its functions ("commissioning arrangements").

(2) The Board must make arrangements to secure that individuals to whom the services are being or may be provided are involved (whether by being consulted or provided with information or in other ways) –

(a) in the planning of the commissioning arrangements by the Board,

(b) in the development and consideration of proposals by the Board for changes in the commissioning arrangements where the implementation of the proposals would have an impact on the manner in which the services are delivered to the individuals or the range of health services available to them, and

(c) in decisions of the Board affecting the operation of the commissioning arrangements where the implementation of the decisions would (if made) have such an impact.

(3) The reference in subsection (2)(b) to the delivery of services is a reference to their delivery at the point when they are received by users.

(4) This section does not require the Board to make arrangements in relation to matters to which a trust special administrator's report or draft report under section 65F or 65I relates before the Secretary of State makes a decision under section 65K(1), is satisfied as mentioned in section 65KB(1) or 65KD(1) or makes a decision under section 65KD(9) (as the case may be).

THE EQUALITY ACT 2010 - SECTION 149

Advancement of equality

149 Public sector equality duty

(1) A public authority must, in the exercise of its functions, have due regard to the need to—

(a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;

(b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;

(c) foster good relations between persons who share a relevant protected characteristic and persons who do not share it.