

Pharmacy Manual



April 2019

NHS England INFORMATION READER BOX**Directorate**

Medical	Operations and Information	Specialised Commissioning
Nursing	Trans. & Corp. Ops.	Strategy & Innovation
Finance		

Publishing Approval Reference: 000464

Document Purpose	Guidance
Document Name	Pharmacy Manual - April 2019
Author	Pharmacy Team - NHS England
Publication Date	May 2019
Target Audience	NHS England Regional Directors, NHS England Directors of Commissioning Operations, NHS England Primary Care Teams
Additional Circulation List	CCG Accountable Officers
Description	A suite of policy booklets to guide NHS commissioning / contracting teams in commissioning high quality community pharmaceutical services.
Cross Reference	
Superseded Docs (if applicable)	NHS England Pharmacy Manual and Appendices April 2016
Action Required	N/A
Timing / Deadlines (if applicable)	1st May 2019
Contact Details for further information	ENGLAND.CommunityPharmacy@nhs.net Community Pharmacy Team NHS England Skipton House London SE1 6LH

Document Status

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Document Title: Pharmacy Manual 2019

Version number: 3

First published: 2013

Updated: April 2019

Prepared by: NHS England

Classification: OFFICIAL

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact the Pharmacy Team at England.CommunityPharmacy@nhs.net

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Executive summary

In 2016, the Pharmacy Manual was published (Gateway Ref 04161), providing NHS England and Primary Care Support England with a suite of procedures and template documents for the processing and determination of applications for inclusion in a pharmaceutical list, and the commissioning and management of the provision of pharmaceutical services.

Since then the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, have been amended and the way that provider assurance is undertaken has evolved, reflected in this new manual.

The manual has been divided into three parts.

Part 1 - Contains information that is relevant to both NHS England and Primary Care Support England.

- 1 Introduction and glossary
- 2 NHS England's decision-making structure
- 3 Delegated decision-making
- 4 Fitness and applicants

Part 2 - Contains procedures for the processing of routine and excepted applications, work that is undertaken on behalf of NHS England by Primary Care Support England. Minor amendments have been made to reflect the roles of Primary Care Support England as the processor of applications and NHS England as the body that makes all decisions relating to applications. In addition, steps have been added to the market entry procedures to set out the process to be followed where a successful applicant requests a timescale within which to submit a notice of commencement or consolidation. Annexes to this Part contain the template application forms, letters, reports and notices to be used in the processing of applications.

Part 3 - Contains procedures, guidance and template letters and documents for NHS England staff in the commissioning of pharmaceutical services.

The information specific to the function of NHS England commissioning teams has been drawn out into this section into the chapters described below:

28. New chapter which focuses on the decisions that NHS England will need to make as an application is processed.
29. New chapter which contains guidance for pharmaceutical services regulations committees on the determination of specific types of applications.
30. New chapter providing guidance to NHS England staff on the powers that may be exercised where concerns are raised regarding a contractor's fitness to practise.
31. Procedure for the determination of controlled localities.

32. New chapter which sets out the responsibilities on NHS England regarding the determination of applications from GPs who wish to either start dispensing or dispense to a new area. It also covers the determination of serious difficulty applications.
33. Advanced services.
34. New chapter providing guidance to NHS England staff on the commissioning of enhanced services.
35. Opening hours.
36. This chapter has been updated to reflect the role of NHS Prescription Services in provider assurance.
37. New chapter setting out the procedures to be followed where a contractor closes premises.
38. New chapter providing guidance to NHS England staff on matters relating to pharmaceutical services finance.

NHS England is committed to reviewing this manual regularly, to ensure it reflects changes in practice, legislation and regulation, and reflects the transformation of how applications for inclusion in a pharmaceutical list are submitted and processed.

CHAPTER 1

Introduction and Glossary

1 Introduction

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

Under the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended ("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 (DACs).

The above lists are referred to as pharmaceutical lists.

NHS England is also responsible for the following lists by Health and Wellbeing Board (HWB) area:

- 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.

Persons wishing to provide pharmaceutical services in England must be included in the relevant pharmaceutical list or lists held by NHS England. Pharmaceutical services are generally defined within the Regulations as the essential, advanced and enhanced services that are provided by pharmacy contractors and DACs and commissioned by NHS England.

1.1 The Pharmacy Manual

The Manual complements the Regulations and any Directions issued by the Secretary of State for Health and Social Care and should be read alongside them (and not in place of them).

If relevant, a chapter in the Manual will make reference to corresponding guidance issued by the Department of Health and Social Care ([the DHSC guidance](#)). The content of the DHSC Guidance is not repeated in the Manual and the DHSC guidance should therefore also be read alongside the Manual in order to ensure fair, proportionate and consistent decisions.

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

1.2 Fees, records and appeals

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 only reimburse the applicant's fee when a decision is made to defer their application in order to invite other routine applications under regulations 13, 15, 17, 18 or 20.

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.

Decisions made by NHS England can generally be appealed to the NHS Resolution's Primary Care Appeals service (PCAS), although most 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 PCAS or the First-tier Tribunal, any challenge would need to be made through the courts.

Glossary

AUR	Appliance Use Review
CCG	Clinical Commissioning Group
CDAO	Controlled Drug Accountable Officer
CPAF	Community Pharmacy Assurance Framework
DAC	Dispensing Appliance Contractor
Days	Calendar days unless working days is specifically stated
DBS	Disclosure and Barring Service
DHSC	Department of Health and Social Care
DHSC Guidance	Guidance issued by the DHSC to help NHS England in assessing applications to provide NHS pharmaceutical services
DoS	Directory of Services
DSP	Distance Selling Premises
EqA	Equality Act 2010
EEA	European Economic Area
EPS	Electronic Prescription Service
FPC	Family Practitioner Committee
GP	General Practitioner
GPhC	General Pharmaceutical Council
HOSC	Health Overview and Scrutiny Committee
HWB	Health and Wellbeing Board
IELTS	International English Language Testing System

LLP	Limited Liability Partnership
LPC	Local Pharmaceutical Committee
LPS	Local Pharmaceutical Services
MIS	Management Information Spreadsheet
MUR	Medicines Use Review and Prescription Intervention Service
NHS Act	National Health Service Act 2006
NHSBSA	NHS Business Services Authority
NHS England	NHS Commissioning Board (operating as NHS England)
NMS	New Medicine Service
OJEU	Official Journal of the European Union
OOH	Out of Hours
PCAS	NHS Resolution's Primary Care Appeals service
PCM	Pharmacy Contract Manager
PCT	Primary Care Trust
PhS	Pharmaceutical Services
PLDP	Performers Lists Decision Panel
PNA	Pharmaceutical Needs Assessment
PSED	Public Sector Equality Duty (section 149 EqA)
PSRC	Pharmaceutical Services Regulations Committee
SLA	Service Level Agreement
SOP	Standard Operating Procedures
SoS	Social and Other Specific services

The Directions	The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013
The 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 Regulations Committee Terms of Reference;
 - Pharmacy Contract Manager decision making;
 - The role of Performers Lists Decision 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 Regulations Committee meeting (if the decision has been made by that committee) or, otherwise, in a note made by the Pharmacy Contract Manager.
3. There may be occasions where applications take longer than the regulatory 30 days or four months to process and determine. An example of this would be where there is a delay in the receipt of references for applicants applying to be included in a pharmaceutical list for the first time.

Pharmaceutical Services Regulations Committee Terms of Reference

4. 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.
5. NHS England has delegated decision making to each PSRC in relation to matters under the Regulations listed in Chapter 3 where the decision maker is listed as the PSRC.

6. The voting membership of each PSRC shall be as follows:
 - Director of Commissioning (or their suitable, nominated deputy) who will chair the meeting in the absence of the Head of Primary Care;
 - Head of Primary Care (or their suitable, nominated deputy) who will chair the meeting; and
 - Up to two lay members (or equivalent).
7. Due to the knowledge and understanding of the Regulations that is required, PSRC lay members are considered to be 'expert volunteers' for the purposes of NHS England's volunteering policy and should receive the appropriate fee.
8. All members of the PSRC must have a good knowledge and understanding of the Regulations in order to reduce the likelihood of a successful appeal against decisions made. It is essential that members build up expertise in the Regulations and therefore consistency of attendance is expected.
9. Each member of a PSRC has a vote and the Chair has the casting vote, if necessary.
10. Each PSRC will be quorate if any two of the voting members are present one of which must be an NHS England officer.
11. 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.
12. The following persons will be co-opted to each PSRC:
 - Pharmacy Contract Manager (or equivalent); and
 - Pharmacy professional adviser (or equivalent) (if applicable).
13. 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 regulation or 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 voting or co-opted member or members.
14. 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).
15. 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.

16. Each PSRC shall secure such administrative support as is reasonably necessary to carry out its functions.
17. Each PSRC will meet monthly (or earlier if needed in order to discuss a case urgently) where there is a need. Where a meeting is not required the pharmacy contract manager will document this in line with local procedures.
18. Each PSRC will report at least every six months to an appropriate senior management committee (to be determined locally) on the decisions taken and the outcome of any appeals on those decisions.
19. HWBs are responsible for identifying current or future needs for, or improvements or better access to, a pharmaceutical service or pharmaceutical services in general via the pharmaceutical needs assessment (PNA). Each PSRC is required to review the PNAs in its area and to record the actions taken to address identified needs, improvements or better access whether this is via the market entry process or through local commissioning processes.

Pharmacy Contract Manager ("PCM") Decision Making

20. NHS England has established local Pharmacy Contract Managers ("PCM").
21. NHS England has delegated decision making through the PSRC to each PCM, or their suitable nominated deputy when the PCM is on leave, in relation to matters under the Regulations listed in Chapter 3 where the decision maker is listed as "PCM or PSRC".
22. Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations lists those persons who may take no part in determining or deferring an application. Before considering an application or making a decision which has been delegated to them, the PCM must document that they are not barred by virtue of the aforementioned regulation or paragraph.
23. The PCM may not make a decision if the circumstances set out in paragraph 26(2) of Schedule 2 to the Regulations apply (reasonable suspicion of bias).
24. 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.
25. 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 Lists Decision Panel

26. NHS England has established local Performers Lists Decision Panels ("PLDP").
27. NHS England may delegate decision making through the PSRC to each PLDP in relation to matters under the Regulations listed in Chapter 3 where the decision maker is listed as "PSRC or PLDP".
28. 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 or in paragraph 26 of Schedule 2 to the Regulations.
29. 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.
30. 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

31. NHS England will contract with a Primary Care Support Service Provider to provide administrative assistance for certain matters including pharmacy and DAC matters.
32. The Primary Care Support Service Provider is not authorised to make decisions on pharmacy or DAC matters.
33. Once an application is completed the Primary Care Support Service Provider will send a zipped folder of all the relevant documents and communications to the relevant NHS England regional team. This folder is to be securely filed and kept by the relevant regional team for future reference.
34. A service specification setting out the administrative tasks to be undertaken by the Primary Care Support Service Provider is provided [here](#). It should be noted that this is only a draft specification. It may be updated or amended from 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 versions of Pharmaceutical Needs Assessments

35. For some types of routine applications, the Regulations require NHS England to have regard to the relevant PNA which is defined as the PNA that is current at the time that the decision is made. It should however be noted that there will be occasions where the applicant has prepared their submission in accordance with a preceding PNA and will expect the application to be determined against that PNA. Where this doesn't happen, the applicant could claim that their application has not been dealt with justly.

36. 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 (regulation 22(2)).
37. Where a new PNA is published during the 45 day notification period, a letter will be prepared by the regional team and sent by the Primary Care Support Service Provider to the applicant and those persons who have made representations asking for their views on regulation 22(2), in particular whether the only way to determine the application justly is with regard to the earlier PNA.
38. The relevant PSRC will take into account any representations received on this matter and if it is satisfied that the application is to be determined against the new PNA then a second 45 day notification period will commence for all interested parties.
39. Where a new PNA is published after the 45 day notification period, but before the application is determined, a letter will be prepared by the regional team and sent by the Primary Care Support Service Provider to the applicant and those persons who have made representations asking for their views on regulation 22(2), in particular whether the only way to determine the application justly is with regard to the earlier PNA.
40. The relevant PSRC will take into account any representations received on this matter and if it is satisfied that the application is to be determined against the new PNA then a second 45 day notification period will commence for all interested parties.
41. Decisions are not to be made against draft versions of a PNA. Only final, published versions of PNAs

CHAPTER 3

Delegated Decision Making

Delegated Decision Making

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

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

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.

Where an applicant is applying to be included in the relevant pharmaceutical list for the first time and the checks on the fitness information reveal no adverse findings and the references are satisfactory the PSRC or PLDP may nominate an officer of NHS England who has the appropriate clinical experience to make decisions on whether the applicant is suitable to be included in the relevant pharmaceutical list on fitness grounds. Where the checks and/or references reveal adverse findings, which may lead the application to be refused or deferred on fitness grounds or for the applicant to be conditionally included, the PSRC or PLDP will be required to make the decision on the applicant's fitness.

Regulatory provision	Decision Maker	Chapter of Manual
Regulations 13 and 14 – determination of application (current need)	PSRC	Chapter 12 Chapter 22
Regulations 15 and 16 – determination of application (future need)	PSRC	Chapter 13 Chapter 22
Regulations 17 and 19 – determination of application (current improvement/better access)	PSRC	Chapter 14 Chapter 22
Regulations 18 and 19 – determination of application (unforeseen benefits)	PSRC	Chapter 15 Chapter 22
Regulations 20 and 21 – determination of application (future improvement / better access)	PSRC	Chapter 16 Chapter 22
Regulation 23 – determination of application (application from NHS chemist in respect of providing directed services)	PSRC	Chapter 24

Regulatory provision	Decision Maker	Chapter of Manual
Regulation 24 – determination of application (relocation involving no significant change)	PSRC	Chapter 17 Chapter 22
Regulation 25 – determination of application (distance selling pharmacies)	PSRC	Chapter 18
Regulation 26(1) – determination of application (change of ownership)	PCM or PSRC	Chapter 19
Regulation 26(2) – determination of application (relocation involving no significant change/change of ownership)	PSRC	Chapter 21 Chapter 22
Regulation 26A – determination of preliminary matters including refusal of application for reasons set out in Regulation 26A(5)(b)	PCM	Chapter 20
Regulation 26A – determination of application (consolidation onto an existing site)	PSRC	Chapter 20
Regulation 27 – determination of application (for temporary listing arising out of suspension)	PSRC	Chapter 25
Regulation 28 – determination of application (exercising right of return to the pharmaceutical list)	PCM or PSRC	Chapter 26
Regulation 29 – determination of application (temporary arrangements during emergencies / because of circumstances beyond the control of NHS chemists)	PCM or PSRC	Chapter 27
Regulation 30 – refusal on language requirement for some NHS pharmacists	PSRC or PLDP	Chapter 4
Regulation 31 - refusal: same or adjacent premises	PSRC	
Regulation 32 - deferrals arising out of LPS designations	PCM or PSRC	
Regulation 33 – determination of suitability of an applicant to be included in a pharmaceutical list on fitness grounds	PSRC or PLDP	Chapter 4

Regulatory provision	Decision Maker	Chapter of Manual
Regulation 34 – determination of deferral of application to be included in a pharmaceutical list on fitness grounds	PSRC or PLDP	Chapter 4
Regulation 35 – determination of conditional inclusion of an applicant to be included in a pharmaceutical list on fitness grounds	PSRC or PLDP	Chapter 4
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 NHS England 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 33
Regulation 40 – applications for new pharmacy premises in controlled localities: refusals because of preliminary matters	PSRC	
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 32
Regulation 44 - prejudice test in respect of routine applications for new pharmacy premises in a part of a controlled locality that is not a reserved location	PSRC	Chapter 32
Regulation 48(2) - determination of patient application ('serious difficulty' applications)	PCM or PSRC	Chapter 34
Regulation 50 – consideration of 'gradualisation' (i.e. the postponement of the discontinuation of services by dispensing doctors) for an application in relation to premises in, or within 1.6 kilometres of, a controlled locality	PSRC	Chapter 33
Regulations 51 to 60 – determination of doctor application (outline consent and premises approval) including the taking effect of decisions, relocations, gradual introduction of premises approval, temporary provisions in cases of relocations or additional premises where premises approval has not taken	PSRC	Chapter 34

Regulatory provision	Decision Maker	Chapter of Manual
effect, practice amalgamations, and lapse of outline consent and premises approval.		
Regulation 61 - temporary arrangements during emergencies or circumstances beyond the control of a dispensing doctor.	PCM or PSRC	Not discussed
Regulation 65(5) to (7) – direction to increase core opening hours	PCM or PSRC	Chapter 36
Regulation 67 – agreement of a shorter notice period for withdrawal from a pharmaceutical list	PSRC	
Regulation 69 – determination of whether there has been a breach of terms of service	PSRC	Chapter 38
Regulation 70 – determination of whether to issue a breach notice with or without an accompanying withholding of payments in connection with a breach of terms of service. Determination of whether to rescind a breach notice.	PSRC	Chapter 38
Regulation 71 – determination of whether to issue a remedial notice with or without an accompanying withholding of payments in connection with a breach of terms of service. Determination of whether to rescind a remedial notice.	PSRC	Chapter 38
Regulation 72 – determination of whether to withhold remuneration	PSRC	Chapter 38
Regulation 73 – determination of whether to remove premises or a chemist from the pharmaceutical list (following remedial or breach notice)	PSRC	Chapter 38
Regulation 74 – determination of whether to remove premises or a chemist from the pharmaceutical list (death, incapacity or cessation of service)	PSRC	Chapter 38
Regulation 79 – determination of review of fitness conditions originally imposed on the grant of an application	PSRC or PLDP	Chapter 32
Regulation 80 – determination of removal of a contractor for breach of fitness conditions	PSRC or PLDP	Chapter 31

Regulatory provision	Decision Maker	Chapter of Manual
Regulation 81 and 82 – determination of removal or contingent removal	PSRC or PLDP	Chapter 32
Regulation 83 – suspensions in fitness cases	PSRC or PLDP	Chapter 32
Regulation 84 – reviewing suspensions and contingent removal conditions	PSRC or PLDP	Chapter 32
Regulation 85 – general power to revoke suspensions in appropriate circumstances	PSRC or PLDP	Chapter 32
Regulation 94 – overpayments	PSRC	Chapter 39
Regulation 99 – designation of an LPS area	PSRC	Chapter 41
Regulation 100 – review of designation of an LPS area	PSRC	Chapter 41
Regulation 101 – cancellation of an LPS area	PSRC	Chapter 41
Regulation 104 – selection of an LPS proposal for development and decision to adopt proposal	PSRC	Chapter 41
Regulation 108 – right of return for LPS contractor	PSRC	Chapter 41
Schedule 2, paragraph 1(10) – whether best estimate is acceptable	PCM or PSRC	Chapter 29
Schedule 2, paragraph 11(1) – determination of whether there is missing information	PCM	Chapter 29
Schedule 2, paragraph 11(2)(b) – determination of review of reasonableness of request for missing information	PCM or PSRC	Chapter 29
Schedule 2, paragraph 14 – whether to defer consideration of application	PCM or PSRC	Chapter 29
Schedule 2, paragraph 19 – determination of who is to be provided with notice of a notifiable application	PCM	Chapter 29
Schedule 2, paragraph 21(4) – determination of whether the full disclosure principle applies to information contained within a notifiable application	PSRC	Chapter 29

Regulatory provision	Decision Maker	Chapter of Manual
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	Chapter 29
Schedule 2, paragraph 28 – determination of who is to be notified of decisions on routine and excepted applications	PCM or PSRC	Chapter 29
Schedule 3, paragraph 30 – determination of who is to have a third party right of appeal against decisions on routine and excepted applications	PCM or PSRC	Chapter 29
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 29
Schedule 2, paragraph 32 – determination of whether to accept a change to premises	PCM or PSRC	
Schedule 2, paragraph 33 – determination as to whether the future circumstances have arisen	PCM	
Schedule 2, paragraph 34(4)(c)(i) and 34A(4)(b)(i) – extension of latest date for receipt of notice of commencement	PCM or PSRC	Chapters 12 – 21, 24 - 27
Schedule 2, paragraph 35 – notice requiring the commencement of pharmaceutical services	PCM or PSRC	
Schedule 4, paragraph 23(1) / Schedule 5, paragraph 13(1) – consideration of a request to temporarily suspend the provision of services (fixed period)	PSRC	
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 into effect sooner than three months after receipt of notification of the change	PSRC	Chapter 37
Schedule 4, paragraph 23(7) / Schedule 5, paragraph 13(6) – consideration of a notification of a change of	PCM or PSRC	Chapter 37

Regulatory provision	Decision Maker	Chapter of Manual
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		
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 37
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 37
Schedule 4, paragraph 23 (10) / Schedule 5, paragraph 9 – review of reason for temporary suspension within the control of the contractor	PSRC	
Determination of applications to provide MURs at locations other than listed premises	PCM or PSRC	Chapter 35
Approval of responses to an appeal against, or challenge to, decisions of the PSRC	PCM or PSRC	
Approval of responses to an appeal against, or challenge to, decisions of the PCM	PCM or PSRC	
Determination of further action where CPAF identifies concerns	PCM or PSRC	Chapter 38
Determination of further action where the contractor fails or refuses to agree a date and time for a visit	PCM or PSRC	Chapter 38
Determination of action where any of the following are identified: <ul style="list-style-type: none"> • Patient safety issues; • NHS England is at risk of material financial loss; and/or • Possible fraudulent or criminal activity. 	PCM or PSRC	Chapter 38
Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report	PCM or PSRC	Chapter 38

Regulatory provision	Decision Maker	Chapter of Manual
Determination of action where the contractor exceeds the maximum number of AURs that may be done in any one year	PCM	Chapter 38

CHAPTER 4

Fitness and applicants

Chapter Aims and Objectives

1. This chapter provides information on how to manage fitness matters relating to applications for inclusion in a pharmaceutical list for the first time in accordance with the Regulations.
2. Procedures are set out in the following chapters for the different types of applicants:
 - Chapter 5 – Pharmacy – Individual
 - Chapter 6 – Pharmacy – Partnership
 - Chapter 7 – Pharmacy – Body Corporate
 - Chapter 8 – DAC – Individual
 - Chapter 9 – DAC – Partnership
 - Chapter 10 – DAC – 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 NHS England'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 for the first time. Those applying for inclusion in dispensing doctor lists are not subject to fitness / suitability checks (however these will be required for entry onto the performers list). Those who wish to provide local pharmaceutical services are subject to the fitness checks set out in Chapter 41.
7. Pharmaceutical list applicants must, unless already included in the 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 to NHS England or, prior to 1 April 2013, if the applicant is a body corporate to their home Primary Care Trust (PCT). This includes fitness information provided in support of an application relating to a different pharmaceutical list. 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, the Primary Care Support Service Provider will request the information is provided. Where the applicant fails or refuses to comply with the request the matter will be referred to NHS England.
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/business by unfounded or malicious allegations. When determining applications for inclusion in a pharmaceutical list, information provided, and the sources of it, must be assessed carefully.
10. Discrimination on the grounds of protected characteristics (age, disability, gender reassignment, marriage and civil partnership, race, religion or belief, sex or sexual orientation) must be prevented and utmost care must be taken to avoid imposing preferences or prejudices. Under the Public Sector Equality Duty, decision makers must have due regard to the need to eliminate discrimination, harassment, victimisation and other prohibited conduct; advance equality of

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

11. Applicants for inclusion in a pharmaceutical list of those undertaking to provide pharmaceutical services in particular by way of the provision of drugs i.e. pharmacy contractors, 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 (who may act for another body corporate only for the purposes of submitting an application and not operating any pharmacies).
12. Limited liability partnerships (LLPs) (who may have non-pharmacist partners) are bodies corporate and are therefore required to have a superintendent. For the purposes of the Regulations, the word 'director' includes a member of a limited liability partnership. Therefore, any requirement for a director to provide fitness information applies equally to a member of a limited liability partnership and the usual checks are to be undertaken on that information.
13. A company listed on the [Mutuals Public Register](#) (which is maintained by the Financial Conduct Authority) is a body corporate and is therefore required to have a superintendent. The Mutuals Public Register is the public record of registered mutual societies:
 - building societies
 - credit unions
 - friendly societies
 - registered societies
14. 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 via the [Companies House website](#).
15. Where a procedure in chapters 5 to 11 requires NHS England to contact an organisation for information, this can be done via email if deemed appropriate.

Determining an applicant's fitness to practise

16. Where the applicant is not already included in the pharmaceutical list for the area of the HWB in respect of other premises their fitness to practise must be assessed. This is irrespective of whether they are already included in another pharmaceutical list or lists.
17. The office of NHS England in whose area the applicant is seeking to open premises is responsible for determining the applicant's fitness to practise as well as the market entry element of the application.

Fitness information where the applicant has provided it in connection with another application

18. Where the fitness information has previously been provided by the applicant (sole trader, partnership or body corporate) this will be collated and checked by the Primary Care Support Service Provider to ensure it is correct and up-to-date, for example no new directors or superintendent have or has been appointed in the meantime. Where the information is up-to-date and complete it will be processed and passed to the relevant office of NHS England for a decision to be made.
19. It should be noted that where an individual has previously provided fitness information in relation to one legal entity, that information cannot be relied upon if they are party to an application made by another entity. For example, a sole trader successfully applies to be included in a particular pharmaceutical list. They subsequently form a company of which they are the only director and also the superintendent. The company submits a change of ownership application in relation to the pharmacy run by the sole trader. Although the director/superintendent is already included in the relevant pharmaceutical list as a sole trader they must provide the required fitness information on the company and themselves so that NHS England can assure itself that the company is a fit and proper person to be included in the relevant pharmaceutical list.
20. Decisions should be consistent across the offices of NHS England and it is not expected that offices will come to different decisions based upon the same information. Where new information is now available which would lead to a different decision this should be shared with the office who determined the previous application as it may need to take appropriate action if that application was granted.
21. Where there is missing information, or a change is identified this should be requested from the applicant.
22. If the information cannot be found the applicant is to be asked to provide the information again. Where the applicant fails or refuses to comply with the request

the matter will be referred to NHS England who will then consider what action is to be taken, for example treating it as missing information.

23. Where an applicant applies to two or more offices of NHS England at the same time the Primary Care Support Service Provider will highlight this to the relevant offices. It is expected that the offices will discuss the case and if an office is minded to come to a different decision to the other office or offices then it must robustly document its reasons and share them with the central office of NHS England as this could leave NHS England open to a successful challenge.
24. Where an applicant is already providing pharmaceutical services in another part of the country and an issue is identified when processing the fitness information in relation to the application this is to be shared with the other office of NHS England so that it can consider whether it needs to take action.
25. Fitness information provided in relation to applications for inclusion in a pharmaceutical list for the first time must be retained by the Primary Care Support Service Provider even if the application is subsequently refused or treated as withdrawn as the applicant can rely upon that information in relation to any future information. Similarly, if an application is granted but the applicant fails to open the premises the fitness information must be retained.

English Language Testing

26. 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).
27. NHS England requires such pharmacists to show that they have a recent pass of the academic version of International English Language Testing System (IELTS) test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test. 'Recent' means evidence relating to the IELTS test that is less than two years old at the point of making the application.

References

28. References must be provided for individual pharmacist (sole trader) applicants, pharmacists who are members of a partnership applicant, and the superintendent and each director who is a pharmacist of a body corporate applicant.
29. References are to 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.
30. The referee should be a pharmacist registered with the General Pharmaceutical Council (GPhC) and must be able to comment on the pharmacist's knowledge, skills and competence.
31. NHS England should not, without good reason, accept references from:
 - family members (and this includes family members of a partner, director or the superintendent giving references in relation to other partners, director or the superintendent);
 - business partners providing references for each other;
 - any person with a financial interest in the application;
 - pre-registration trainees; or
 - the applicant's (and this includes partners, directors and superintendents) pre-registration trainer.
32. Where NHS England accepts one of the above persons as a referee it must clearly document its reasons for doing.
33. The process for requesting references is set out in chapters 5 to 10, however there may be occasions where referees fail to respond, and no response is received from the applicant. There are three options available to NHS England in this situation.
34. Firstly, NHS England could treat the references as missing information. In this instance the missing information template letter should be sent to the applicant giving them ten working days to provide the references (note the requirement is to provide the names and addresses of two referees who are willing to provide references as opposed to just providing the name and addresses of two referees). It should be noted that the applicant could ask for an extension to this timescale and it is for the office of NHS England to make a decision as to whether

a longer period is to be allowed. If the applicant fails to respond to the letter, then the application is to be treated as withdrawn and the corresponding template letter should be sent to the applicant. There are no appeal rights for the applicant.

35. Where NHS England chooses to treat the references as missing information the 30 days / four month clock stops and only restarts when/if the references are provided.
36. Secondly, NHS England could decide to proceed without the references and refuse the application on fitness grounds as it cannot be assured that the applicant is a fit and proper person.
37. Thirdly, NHS England could decide to conditionally grant the application on fitness grounds. The applicant would have the right of appeal against both decisions to the First-tier Tribunal.
38. Whichever option NHS England chooses it must ensure that its reasoning is fully documented.

Mandatory Refusal of Applications on Fitness Grounds

39. Applications for inclusion in a pharmaceutical list must be refused if any of the grounds set out in regulation 33(1) are satisfied.
40. Where an application is refused on fitness grounds that is the end of the process unless they successfully appeal that decision. Should the applicant wish to re-apply then they are required to submit the fitness information and market entry application form again and pay the relevant fee.

Discretionary refusal of applications on fitness grounds

41. Applications for inclusion in a pharmaceutical list may be refused if any of the grounds set out in regulation 33(2) are satisfied.
42. When considering a refusal on discretionary grounds the decision-maker will take into account the matters set out in regulation 33(3).
43. When taking these matters into consideration, the decision-maker must consider the overall effect of all the matters considered (pursuant to regulation 33(4)).

44. Where an application is refused on fitness grounds that is the end of the process unless they successfully appeal the decision. Should the applicant wish to re-apply then they are required to submit the fitness information and market entry application form again and pay the relevant fee.

Deferral of applications on fitness grounds

45. 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 Regulations.
46. 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.
47. An application may only be deferred on fitness grounds in accordance with regulation 34(2).

Granting applications subject to conditions

48. 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.
49. Conditions must be specific and relevant to the particular concern or issue that has been identified.

Notification of Fitness Decisions

50. Where an application for inclusion in a pharmaceutical list is refused on fitness grounds or is granted subject to conditions, NHS England, via the Primary Care Support Service Provider, must notify the persons listed in regulation 88(2).

51. Notifications to the person/organisation shown in the left column of the table below should be sent to the address shown in the right column. This list is not exhaustive, and NHS England must therefore ensure that it confirms with the Primary Care Support Service Provider all of the persons who are to be notified having due regard to regulation 88(2). With regard to internal notifications, the Primary Care Support Service Provider will be aware of any other office of NHS England that is dealing with or subsequently receives an application from the applicant and therefore will be able to advise that other office accordingly should the applicant fail to declare the refusal or conditional inclusion.

Person / Organisation	Notifications sent to:
Secretary of State for Health and Social Care	Primary Care Appeals, NHS Resolution, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE appeals@resolution.nhs.uk
The Scottish Ministers	Chief Pharmaceutical Officer, Scottish Government, St Andrews House, Regent Road, Edinburgh, EH1 3DG
The Welsh Ministers	Notifications Clerk, Primary Care Division, Welsh Government, Cathays Park, Cardiff, CF10 3NQ gmscontract@gov.wales
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 Counter Fraud Authority	NHS Counter Fraud Authority, Skipton House 80 London Road, London. SE1 6LH generalenquiries@nhscfa.gsi.gov.uk
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)

CHAPTER 5

Procedure for Application to Join a Pharmaceutical List – Pharmacy – 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 pharmacy sole traders alongside their application for inclusion in a pharmaceutical list for the first time.
2. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. Fitness procedures must be completed, and a decision made 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 however NHS England may take longer where it has good cause. The decision-maker must therefore ensure that robust records are maintained to justify taking longer than the regulatory timescales.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application then this information is to be found. Where the applicant has completed the fitness information form check that the same sole trader is listed in that document against the previously provided fitness information.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 2). Include the completed fitness information form.</p>
3.	<p>Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 to the applicant. Go to step 13.</p> <p>If not all the information, documentation or undertakings have been provided, go to step 4.</p>

Action	
4.	<p>If information and/or documentation have not been provided, go to step 5.</p> <p>If undertakings have not been provided, go to step 10.</p>
5.	<p>Where there is missing information and/or documentation send Annex 4 (request for missing information).</p> <p>The amount of time to be given for submission is 10 working days.</p>
6.	<p>Diarise the date for the missing information and/or documentation to be submitted.</p>
7.	<p>If the applicant requests a review of the request, go to step 8.</p> <p>If the applicant does not request a review of the request, go to step 9.</p>
8.	<p>If the applicant requests a review of the request, forward this to the decision-maker for a decision.</p> <p>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 9.</p> <p>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 10.</p>
9.	<p>If the information and/or documentation are received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 10.</p> <p>If the information and/or documentation are not received by the due date send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
10.	<p>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 five working days.</p>
11.	<p>Diarise the date for the missing undertakings to be submitted.</p>
12.	<p>If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.</p> <p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received). Treat the application as withdrawn.</p>

Action	
	Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.
13.	<p>If the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 14.</p> <p>If the applicant qualified as a pharmacist in the United Kingdom, go to step 15.</p>
14.	<p>Where the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the decision-maker 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.</p> <p>Ensure the applicant has provided evidence of a recent pass of the academic version of IELTS test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.</p> <p>If the applicant has provided such evidence, go to step 15.</p> <p>If the applicant has not provided such evidence, refer the matter to the decision-maker.</p>
15.	Send Annex 12 to check the registration status of the applicant.
16.	<p>If registration of the applicant with the GPhC is confirmed, go to step 17.</p> <p>If registration of the applicant with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action.</p>
17.	<p>Send Annex 14 by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
18.	<p>Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://www.nhsla.com/fhsau/Pages/Home.aspx).</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>

Action	
19.	<p>Check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where the registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 15 (reference request) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 18).</p>
20.	<p>Diarise date for receipt of responses and follow-up action as below.</p>
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>If no response is received, send Annex 16 (letter to referee – chasing response) to that referee and if there is still no response send Annex 17 (non-receipt of reference) to the applicant.</p> <p>Diarise the date for receipt of responses.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
22.	<p>Once all the checks are completed, prepare the committee report (Annex 18) on the applicant and send to the relevant pharmacy contracts team. 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.</p>
23.	<p>If the applicant is suitable for inclusion, go to step 24.</p> <p>If the application is refused, go to step 25. If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	<p>If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (approval letter) to the applicant.</p>

Action	
	No other steps are necessary in relation to this element of the application.
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • Under regulation 30 (language requirement), send Annex 20 (refusal – language requirement); • Under regulation 33(1) (mandatory refusal), send Annex 21 (mandatory refusal) to the applicant; or • Under regulation 33(2) (discretionary refusal), send Annex 22 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 25 (deferral) to the applicant. 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.</p> <p>Once the outcome of the investigation is known send Annex 26 (no further grounds to defer) to the applicant.</p>
28.	<p>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 27 (application withdrawn) to the applicant. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p> <p>If the applicant updates the application and confirms that they wish to proceed send Annex 28 (application proceeding), refer to the decision-maker and return to step 22 above for a decision.</p>
29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>

Action

30. If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 29 to the interested parties. Send Annex 30 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.

If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 31 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.

Once the outcome of the appeal is known no further steps are necessary in relation to this element of the application.

CHAPTER 6

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

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 pharmacy partnerships alongside their application for inclusion in a pharmaceutical list for the first time.
2. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. 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.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application then this information is to be found. Where the applicant has completed the fitness information form check that the same partners are listed in that document against the previously provided fitness information.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 2). Include the fitness information form.</p>
3.	<p>Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 (confirmation of receipt of information) to the applicant. Go to step 13.</p>

Action	
	If any of the information, documentation or undertakings are missing, go to step 4.
4.	If information and/or documents have not been provided, go to step 5. If undertakings have not been provided, go to step 10.
5.	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.
6.	Diarise the date for the missing information and/or documentation to be submitted.
7.	If the applicant requests a review of the request, go to step 8. If the applicant does not request a review of the request, go to step 9.
8.	If the applicant requests a review of the request, forward this to the decision-maker 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 9. 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 10.
9.	If the information and/or documentation are received by the due date, send Annex 7 (confirmation of receipt of missing information) to the applicant. Go to step 10. If the information and/or documentation are not received by the due date send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.
10.	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 five working days.
11.	Diarise the date for the missing undertakings to be submitted.
12.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.

Action	
	<p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received). Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
13.	<p>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 14.</p> <p>If a partner of the applicant qualified as a pharmacist in the United Kingdom, go to step 15.</p>
14.	<p>Where a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, NHS England 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.</p> <p>Ensure the applicant has provided evidence of a recent pass of the academic version of IELTS test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.</p> <p>If the pharmacist has provided such evidence, go to step 15.</p> <p>If the pharmacist has not provided such evidence, refer the matter to the decision-maker.</p>
15.	<p>Send Annex 12 (email to the GPhC) to check the registration status of each partner.</p>
16.	<p>If registration of the partners with the GPhC is confirmed, go to step 17.</p> <p>If registration of a partner with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration).</p> <p>Diarise follow-up action.</p>
17.	<p>Send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>

Action	
18.	<p>Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant. (http://www.nhsla.com/fhsau/Pages/Home.aspx).</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
19.	<p>Check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where the registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 15 (request letter and pro forma) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 18).</p>
20.	<p>Diarise date for receipt of responses and follow-up action as below.</p>
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>If no response is received, send Annex 16 (letter to referee – chasing response) to that referee and if there is still no response send Annex 17 (non-receipt of reference) to the applicant.</p> <p>Diarise the date for receipt of responses.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
22.	<p>Once all the checks are completed, prepare the committee report (Annex 18) on the applicant for the decision-maker and send to the decision-maker. 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.</p>

Action	
	Advise the decision-maker that in the event of a refusal or conditional inclusion this applies collectively to the partnership as an entity and not to an individual.
23.	<p>If the applicant is suitable for inclusion, go to step 24.</p> <p>If the application is refused, go to step 25.</p> <p>If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	<p>If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (approval letter) to the applicant.</p> <p>No other steps are necessary in relation to this element of the application.</p>
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • Under regulation 30 (language requirement), send Annex 20 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 21 (mandatory refusal) to the applicant; or • under regulation 33(2) (discretionary refusal), send Annex 22 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 25 (deferral) to the applicant.</p> <p>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.</p>

Action	
	Once the outcome of the investigation is known send Annex 26 (no further grounds to defer) to the applicant.
28.	<p>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 27 (application withdrawn) to the applicant. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p> <p>If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding) refer to the decision-maker and return to step 22 above for a decision.</p>
29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>
30.	<p>If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 29 to the interested parties. Send Annex 30 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 31 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>Once the outcome of the appeal is known no further steps are necessary in relation to this element of the application.</p>

CHAPTER 7

Procedure for Application to Join a Pharmaceutical List – Pharmacy – 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 pharmacy bodies corporate alongside their application for inclusion in a pharmaceutical list for the first time.
2. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. 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.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>Check that the applicant has submitted all relevant fitness information required by paragraphs 2 to 4 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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application (which may have been a Primary Care Trust as the applicant is a body corporate) then this information is to be found. Where the applicant has completed the fitness information form check that the same directors and superintendent are listed in that document against the previously provided fitness information.</p> <p>Check to see who are listed as directors on Companies House. Check that the superintendent is registered as such for the body corporate on the GPhC register.</p>

Action	
2.	Send the 'first referral' to the decision-maker (Annex 2). Include the fitness information form.
3.	Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 (confirmation of receipt of information) to the applicant. Go to step 13. If any of the information, documentation or undertakings are missing, go to step 4.
4.	If information and/or documents have not been provided, go to step 5. If undertakings have not been provided, go to step 10.
5.	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.
6.	Diarise the date for the missing information and/or documentation to be submitted.
7.	If the applicant requests a review of the request, go to step 8. If the applicant does not request a review of the request, go to step 9.
8.	If the applicant requests a review of the request, forward this to the decision-maker 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 9. 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 10.
9.	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 10. If the information and/or documentation is not received by the due date send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.

Action	
10.	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 five working days.
11.	Diarise the date for the missing undertakings to be submitted.
12.	<p>If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.</p> <p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received). Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
13.	Check that the company is registered on the Companies House website 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.
14.	<p>If the company is not registered send Annex 12 (Companies House registration not confirmed) and diarise follow-up action.</p> <p>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.</p>
15.	Send Annex 14 (email to the GPhC) to check the registration status of the superintendent pharmacist and of any director of the company who is a registered pharmacist.
16.	<p>If registration of the applicant with the GPhC is confirmed, go to step 17.</p> <p>If registration of the superintendent with the GPhC is not confirmed, send Annex 15 (unable to confirm registration of superintendent).</p> <p>If registration of any director that states they are registered with the GPhC cannot be confirmed, send Annex 16 (unable to confirm registration of director).</p> <p>Diarise follow-up action.</p>
17.	<p>Send Annex 17 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the company, superintendent and any director.</p> <p>Checks on the superintendent and any director who is a registered pharmacist should include checks on other companies where they are or have been a superintendent or director.</p>

Action	
	Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.
18.	<p>Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the company, superintendent and any director (http://www.nhs.uk/ehrt/Pages/Home.aspx).</p> <p>Checks on the superintendent and any director should include checks on other companies where they are or have been a superintendent or director.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
19.	<p>Check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 18 (reference request) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 21).</p>
20.	Diarise date for receipt of responses and follow-up action as below.
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>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.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
22.	Once all the checks are completed, prepare the committee report (Annex 21) on the applicant for the decision-maker and send to the decision-maker.

Action	
	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.
23.	<p>If the applicant is suitable for inclusion, go to step 14.</p> <p>If the application is refused, go to step 25.</p> <p>If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	If the applicant is suitable for inclusion on fitness grounds, send Annex 22 (approval letter) to the applicant.
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • under regulation 33(1) (mandatory refusal), send Annex 23 (mandatory refusal) to the applicant; or • under regulation 33(2) (discretionary refusal), send Annex 24 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 25 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 26 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 27 (deferral) to the applicant.</p> <p>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.</p> <p>Once the outcome of the investigation is known send Annex 28 (no further grounds to defer) to the applicant.</p>
28.	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 29

Action	
	<p>(application withdrawn) to the applicant. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p> <p>If the applicant updates the application and confirms that they wish to proceed send Annex 30 (application proceeding) refer to the decision-maker and return to step 22 above for a decision.</p>
29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>
30.	<p>If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 31 to the interested parties. Send Annex 32 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 33 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p>

CHAPTER 8

Procedure for Application to Join a 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. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. 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.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application then this information is to be found. Where the applicant has completed the fitness information form check that the same sole trader is listed in that document against the previously provided fitness information.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 2). Include the fitness information form.</p>
3.	<p>Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 (confirmation of receipt of information) to the applicant. Go to step 13.</p>

Action	
	If not all the information, documentation or undertakings have been provided, go to step 4.
4.	If information and/or documents have not been provided, go to step 5. If undertakings have not been provided, go to step 10.
5.	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.
6.	Diarise the date for the missing information and/or documentation to be submitted.
7.	If the applicant requests a review of the request, go to step 8. If the applicant does not request a review of the request, go to step 9.
8.	If the applicant requests a review of the request, forward this to the decision-maker 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 9. 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 10.
9.	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 10. If the information and/or documentation is not received by the due date send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.
10.	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 five working days.
11.	Diarise the date for the missing undertakings to be submitted.

Action	
12.	<p>If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.</p> <p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received).</p> <p>Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
13.	<p>If the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, go to step 14.</p> <p>If the applicant qualified as a pharmacist in the United Kingdom, go to step 15.</p>
14.	<p>Where the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, NHS England 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.</p> <p>Ensure the applicant has provided evidence of a recent pass of the academic version of IELTS test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.</p> <p>If the applicant has provided such evidence, go to step 15.</p> <p>If the applicant has not provided such evidence, refer the matter to the decision-maker.</p>
15.	<p>Where the applicant is a pharmacist, send Annex 12 (email to the GPhC) to check the registration status of the applicant.</p>
16.	<p>If registration of the applicant with the GPhC is confirmed, go to step 17.</p> <p>If registration of the applicant with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration). Diarise follow-up action.</p>
17.	<p>Where the applicant is a pharmacist, GP, dentist or optometrist, send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker.</p>

Action	
18.	<p>Where the applicant is a pharmacist, GP, dentist or optometrist, initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://www.nhsla.com/fhsau/Pages/Home.aspx).</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
19.	<p>Where the applicant is a pharmacist, check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 15 (reference request) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 18).</p>
20.	<p>Diarise date for receipt of responses and follow-up action as below.</p>
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>If no response is received, send Annex 16 (letter to referee – chasing response) to that referee and if there is still no response send Annex 17 (non-receipt of reference) to the applicant.</p> <p>Diarise the date for receipt of responses.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
22.	<p>Once all the checks are completed, prepare the committee report (Annex 18) on the applicant for the decision-maker and send to the decision-maker.</p> <p>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.</p>

Action	
23.	<p>If the applicant is suitable for inclusion, go to step 24.</p> <p>If the application is refused, go to step 25.</p> <p>If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	<p>If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (approval letter) to the applicant.</p>
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • where the applicant is a pharmacist, under regulation 30 (language requirement), send Annex 20 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 21 (mandatory refusal) to the applicant; or • under regulation 33(2) (discretionary refusal), send Annex 22 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 25 (deferral) to the applicant. 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.</p> <p>Once the outcome of the investigation is known send Annex 26 (no further grounds to defer) to the applicant.</p>
28.	<p>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 27 (application withdrawn) to the applicant. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p>

Action

	<p>If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the decision-maker and return to step 22 above for a decision.</p>
29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>
30.	<p>If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 29 to the interested parties. Send Annex 30 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 31 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>Once the outcome of the appeal is known no further steps are necessary in relation to this element of the application.</p>

CHAPTER 9

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

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 partnerships alongside their application for inclusion in a pharmaceutical list for the first time.
2. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. 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.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application then this information is to be found. Where the applicant has completed fitness information form check that the same partners are listed in that document against the previously provided fitness information.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 2). Include a copy of the fitness information form.</p>
3.	<p>Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 (confirmation of receipt of information) can be sent to the applicant. Go to step 13.</p>

Action	
	If any of the information, documentation or undertakings are missing, go to step 4.
4.	If information and/or documents have not been provided, go to step 5. If undertakings have not been provided, go to step 10.
5.	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.
6.	Diarise the date for the missing information and/or documentation to be submitted.
7.	If the applicant requests a review of the request, go to step 8. If the applicant does not request a review of the request, go to step 9.
8.	If the applicant requests a review of the request, forward this to the decision-maker 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 9. 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 10.
9.	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 10. If the information and/or documentation is not received by the due date send Annex 8 (missing information not received) to the applicant. Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.
10.	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 five working days.
11.	Diarise the date for the missing undertakings to be submitted.
12.	If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.

Action	
	<p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received). Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
13.	<p>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 14.</p> <p>If a partner of the applicant qualified as a pharmacist in the United Kingdom, go to step 15.</p>
14.	<p>Where a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, NHS England 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.</p> <p>Ensure the applicant has provided evidence of a recent pass of the academic version of IELTS test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.</p> <p>If the pharmacist has provided such evidence, go to step 15.</p> <p>If the pharmacist has not provided such evidence, refer the matter to the decision-maker.</p>
15.	<p>Where a partner is a pharmacist, send Annex 12 (email to the GPhC) to check the registration status of each partner.</p>
16.	<p>If registration of the partners with the GPhC is confirmed, go to step 17.</p> <p>If registration of a partner with the GPhC is not confirmed, send Annex 13 (unable to confirm GPhC registration).</p> <p>Diarise follow-up action.</p>
17.	<p>Send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>

Action	
18.	<p>Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant. (http://www.nhs.uk/ehrt/Pages/Home.aspx)</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
19.	<p>Where a partner is a pharmacist, check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters, send Annex 15 (request letter and pro forma) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 18).</p>
20.	<p>Diarise date for receipt of responses and follow-up action as below.</p>
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>If no response is received, send Annex 16 (letter to referee – chasing response) to that referee and if there is still no response send Annex 17 (non-receipt of reference) to the applicant.</p> <p>Diarise the date for receipt of responses.</p>
22.	<p>Once all the checks are completed, prepare the committee report (Annex 18) on the applicant for the decision-maker and send to the decision-maker. 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.</p> <p>Advise the decision-maker that in the event of a refusal or conditional inclusion this applies collectively to the partnership as an entity and not to an individual.</p>

Action	
23.	<p>If the applicant is suitable for inclusion, go to step 24.</p> <p>If the application is refused, go to step 25.</p> <p>If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	<p>If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (approval letter) to the applicant.</p> <p>No other steps are necessary in relation to this element of the application.</p>
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • where the applicant is a pharmacist, under regulation 30 (language requirement), send Annex 20 (refusal – language requirement); • under regulation 33(1) (mandatory refusal), send Annex 21 (mandatory refusal) to the applicant; or • under regulation 33(2) (discretionary refusal), send Annex 22 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 23 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 25 (deferral) to the applicant. 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.</p> <p>Once the outcome of the investigation is known send Annex 26 (no further grounds to defer) to the applicant.</p>
28.	<p>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 27</p>

Action	
	<p>(application withdrawn) to the. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p> <p>If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the decision-maker and return to step 22 above for a decision.</p>
29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>
30.	<p>If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 29 to the interested parties. Send Annex 30 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 31 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>Once the outcome of the appeal is known no further steps are necessary in relation to this element of the application.</p>

CHAPTER 10

Procedure for Application to Join a Pharmaceutical List – Dispensing Appliance 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. Applications for inclusion in a pharmaceutical list are received and processed by the Primary Care Support Service Provider. All decisions relating to the applications are made by NHS England.
3. 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.
4. This document must be read in conjunction with the Regulations.
5. A fitness information form is provided at Annex 1.

Procedure

Action	
1.	<p>Check that the applicant has submitted all relevant fitness information required by paragraphs 2 to 4 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 1.</p> <p>Where the applicant is relying upon fitness information that has been provided in connection with a previous application (which may have been a Primary Care Trust) then this information is to be found. Where the applicant has completed the fitness information form check that the same directors are listed in that document against the previously provided fitness information.</p> <p>Where the applicant is a body corporate check to see who are listed as directors on Companies House.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 2). Include a copy of the fitness information form.</p>

Action	
3.	<p>Where the decision-maker confirms all relevant information, documentation and undertakings have been provided send Annex 3 (confirmation of receipt of information) to the applicant. Go to step 13.</p> <p>If any of the information, documentation or undertakings are missing, go to step 4.</p>
4.	<p>If information and/or documents have not been provided, go to step 5.</p> <p>If undertakings have not been provided, go to step 10.</p>
5.	<p>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.</p>
6.	<p>Diarise the date for the missing information and/or documentation to be submitted.</p>
7.	<p>If the applicant requests a review of the request, go to step 8.</p> <p>If the applicant does not request a review of the request, go to step 9.</p>
8.	<p>If the applicant requests a review of the request, forward this to the decision-maker for a decision.</p> <p>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 9.</p> <p>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 10.</p>
9.	<p>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 10.</p> <p>If the information and/or documentation is not received by the due date send Annex 8 (missing information not received) to the applicant.</p> <p>Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
10.	<p>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 five working days.</p>

Action	
11.	Diarise the date for the missing undertakings to be submitted.
12.	<p>If the missing undertakings are received by the due date, send Annex 10 (confirmation of receipt of missing undertakings). Go to step 13.</p> <p>If the missing undertakings are not received by the due date send Annex 11 (missing undertakings not received). Treat the application as withdrawn. Advise the decision-maker and relevant pharmacy contract manager. No further action is necessary.</p>
13.	Check that the company is registered on the Companies House website 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.
14.	If the company is not registered send Annex 12 (Companies House registration not confirmed) and diarise follow-up action. 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.
15.	Where a director is also a pharmacist, send Annex 14 (email to the GPhC) to check the registration status.
16.	<p>If registration of the director(s) with the GPhC is confirmed, go to step 17.</p> <p>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).</p> <p>Diarise follow-up action.</p>
17.	<p>Send Annex 16 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the company and the director(s).</p> <p>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. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
18.	<p>Where a director is also a pharmacist, initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the company and the directors (http://www.nhsla.com/fhsau/Pages/Home.aspx).</p> <p>Checks on the directors should include checks on other companies where they have been a director or, where they are a pharmacist, a superintendent.</p>

Action	
	Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.
19.	<p>Where a director is also a pharmacist, check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 17 (reference request) to each referee nominated by the applicant and go to step 20.</p> <p>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 (Annex 20)</p>
20.	Diarise date for receipt of responses and follow-up action as below.
21.	<p>If a reference is received, go to step 22.</p> <p>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 19.</p> <p>If no response is received, send Annex 18 (letter to referee – chasing response) to that referee and if there is still no response send Annex 19 (letter to applicant – non-receipt of reference) to the applicant.</p> <p>Diarise the date for receipt of responses.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
22.	<p>Once all the checks are completed, prepare the committee report (Annex 20) on the applicant for the decision-maker and send to the decision-maker.</p> <p>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.</p>
23.	<p>If the applicant is suitable for inclusion, go to step 24.</p> <p>If the application is refused, go to step 25.</p>

Action	
	<p>If the decision-maker is minded to conditionally include the applicant, go to step 26.</p> <p>If the application is deferred, go to step 27.</p>
24.	<p>If the applicant is suitable for inclusion on fitness grounds, send Annex 21 (approval letter) to the applicant.</p>
25.	<p>If the application is refused:</p> <ul style="list-style-type: none"> • under regulation 33(1) (mandatory refusal), send Annex 22 (mandatory refusal) to the applicant; or • under regulation 33(2) (discretionary refusal), send Annex 23 (discretionary refusal) to the applicant. <p>Go to step 29.</p>
26.	<p>If the decision-maker is minded to conditionally include the applicant, the decision-maker will arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 24 (minded to place conditions) to the applicant.</p> <p>Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 25 (conditions) to the applicant.</p> <p>Go to step 29.</p>
27.	<p>If the application is deferred send Annex 26 (deferral) to the applicant.</p> <p>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.</p> <p>Once the outcome of the investigation is known send Annex 27 (no further grounds to defer) to the applicant.</p>
28.	<p>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 28 (application withdrawn) to the applicant. Advise the relevant pharmacy contract manager and decision-maker. No further steps are necessary.</p> <p>If the applicant updates the application and confirms that they wish to proceed send Annex 29 (application proceedings), refer to the decision-maker and return to step 22 above for a decision.</p>

Action

29.	<p>If notice of an appeal against refusal or conditional inclusion is received, advise the decision-maker and assist in the production of a response. Once the outcome of the appeal is known move to step 30.</p> <p>If no appeal is made move to step 30.</p>
30.	<p>If the application is refused on fitness grounds (either by NHS England or on appeal by NHS Resolution) send Annex 30 to the interested parties. Send Annex 31 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted send Annex 32 to the relevant bodies set out in regulation 88 and as confirmed by NHS England.</p> <p>Once the outcome of the appeal is known no further steps are necessary in relation to this element of the application.</p>

CHAPTER 11

Fitness and Existing Contractors

Chapter Aims and Objectives

1. This chapter sets out the role of the Primary Care Support Service Provider in relation to the use of the fitness powers available to NHS England where concerns are identified in relation to a contractor who is included a pharmaceutical list in accordance with the Regulations. It does not apply to LPS contractors as they are not included in a pharmaceutical list.
2. This document should be read in conjunction with the Regulations.
3. The relevant PSRC will consider and determine fitness matters but may delegate a matter to the PLDP in recognition of the PLDP's expertise in fitness matters. Details of the constitution of the PLDP are set out in Chapter 2.

Changes of Director and/or Superintendent Pharmacist

4. Where a pharmacy body corporate appoints a new director or superintendent or a DAC body corporate appoints a new director, it must notify NHS England within 30 days (paragraph 32(4), Schedule 4 and paragraph 22(4), Schedule 5 of the Regulations). In practice they will notify the Primary Care Support Service Provider.
5. The fitness information form to use where a new director or superintendent is appointed is set out at Annex 1 for pharmacies and for a new director for DACs is at Annex 2.

Action	
1.	<p>Check that the contractor has submitted all relevant fitness information required by paragraphs 2 to 4 of Part 1 of Schedule 2 to the Regulations. This is particularly important if the contractor has not used the relevant fitness information form.</p> <p>Where the change relates to a director check that they are listed as a director on Companies House.</p> <p>Where the change relates to the superintendent check that they are registered as such for the body corporate on the GPhC register.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 3). Include copies of the fitness information form.</p> <p>The relevant NHS England regional team is:</p>

Action	
	<ul style="list-style-type: none"> • The one in whose area the body corporate's registered office is located, or • If the body corporate has no premises in that team's area, to the NHS England regional team in whose area its premises are located, or where the majority of its premises are located.
3.	Where the decision-maker confirms they are happy with the information provided send Annex 4 (confirmation of receipt of information) to the contractor. Go to step 6.
4.	<p>If the decision-maker requires further information, send Annex 5. The amount of time to be given for submission is 10 working days.</p> <p>Diarise the date for the information to be submitted.</p>
5.	<p>If the information and/or documentation is received by the due date, send Annex 6 (confirmation of receipt of missing information) to the contractor. Go to step 6.</p> <p>If the information and/or documentation is not received by the due date refer the matter to the decision-maker and relevant pharmacy contract manager.</p>
6.	Send Annex 7 (email to the GPhC) to check the registration status of the new superintendent and/or director if they are a registered pharmacist.
7.	<p>If registration of the new superintendent with the GPhC is confirmed, go to step 8.</p> <p>If registration of the new superintendent with the GPhC is not confirmed, send Annex 8 (unable to confirm registration of superintendent).</p> <p>If registration of the new director is not confirmed with the GPhC, send Annex 9 (unable to confirm registration of director).</p> <p>Diarise follow-up action.</p>
8.	<p>Send Annex 10 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the new superintendent and/or director.</p> <p>Checks on the superintendent and director who is a registered pharmacist should include checks on other companies where they are or have been a superintendent or director.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>

Action	
9.	<p>Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the superintendent and/or director (http://www.nhsla.com/fhsau/Pages/Home.aspx).</p> <p>Checks on the superintendent and/or director should include checks on other companies where they are or have been a superintendent or director.</p> <p>Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the decision-maker, particularly if it wasn't identified in the fitness form.</p>
10.	<p>Check that referees who are pharmacists are registered with the GPhC and whether there is any fitness to practise information recorded in relation to them on the GPhC register via the GPhC website.</p> <p>Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the decision-maker.</p> <p>Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 11 (reference request) to each referee nominated by the contractor and go to step 11.</p> <p>If alternative referees have been nominated because the contractor is unable to nominate two referees in respect of two recent posts, refer to this in the committee report (Annex 14).</p>
11.	<p>Diarise date for receipt of responses and follow-up action as below.</p>
12.	<p>If a reference is received, go to step 13.</p> <p>If a referee responds but declines to provide a reference, record the reasons for this (if provided) and ask the director/superintendent to nominate an alternative person. Go back to step 10.</p> <p>If no response is received, send Annex 12 (letter to referee – chasing response) to that referee and if there is still no response send Annex 13 (letter to director/superintendent – non-receipt of reference) to the relevant director/superintendent.</p> <p>Diarise the date for receipt of responses.</p> <p>If no responses are received refer the matter to the decision-maker.</p>
13.	<p>Once all the checks are completed, prepare the committee report (Annex 14) on the new superintendent and/or director and send to the decision-maker.</p>

Action	
14.	<p>If the decision-maker is satisfied that the contractor remains a fit and proper person, go to step 15.</p> <p>If the decision-maker is minded to remove the contractor on fitness grounds, go to step 16.</p> <p>If the decision-maker is minded to contingently remove the contractor, go to step 17.</p> <p>If the contractor is to be suspended, go to step 18.</p>
15.	Where the contractor remains a fit and proper person, send Annex 15 to them. There are no further actions to be undertaken with regard to this procedure.
16.	If the decision-maker is minded to remove the contractor on fitness grounds, they will arrange an oral hearing and liaise with the contractor. Go to step 19.
17.	If the decision-maker is minded to contingently remove the contractor on fitness grounds, they will arrange an oral hearing and liaise with the contractor. Go to step 20.
18.	If the decision-maker is minded to suspend the contractor, they will arrange an oral hearing and liaise with the contractor. Go to step 21.
19.	If the outcome is that the contractor is to be removed from the relevant pharmaceutical list or lists, send Annex 16 to all directors and the superintendent. Go to step 22.
20.	If the outcome is that the contractor is to be contingently removed from the relevant pharmaceutical list or lists, send Annex 17 to all directors and the superintendent. Go to step 23.
21.	If the outcome is that the contractor is to be suspended, send Annex 18 to all directors and the superintendent. Send Annex 19 as the regulation 88 notification. There are no further actions under this procedure.
22.	<p>If notice of an appeal against removal is received, advise the decision-maker and assist in the production of a response.</p> <p>Where NHS England's decision is upheld on appeal, i.e. the contractor is to be removed from the relevant pharmaceutical list or lists, or no appeal is made send Annex 20 as the regulation 88 notification. Send Annex 21 to:</p> <ul style="list-style-type: none"> • HWB, • CCG, • Public health team, • LMC

Action	
	<ul style="list-style-type: none"> • DoS lead, • Registration Authority, • Controlled Drugs Accountable Officer (CDAO), • OOHs provider, • Unwanted medicines collection and disposal contractor, • The organisation that cascades safety alerts, • Binley's, and • The Primary Care Support Service Provider's pharmacy payments team in relation to the LPC levy and the data manager. <p>NHS England will provide the required contact details for all but the last of the above listed persons.</p> <p>Where NHS England's decision is not upheld on appeal, i.e. the contractor is not to be removed from the relevant pharmaceutical list or lists there are no further actions to be undertaken with regard to this procedure.</p>
23.	<p>If notice of an appeal against contingent removal is received, advise the decision-maker and assist in the production of a response.</p> <p>Where NHS England's decision is upheld on appeal, i.e. the contractor is to be contingently removed from the relevant pharmaceutical list or lists, or no appeal is made send Annex 22 as the regulation 88 notification.</p> <p>Where NHS England's decision is not upheld on appeal, i.e. the contractor is not to be contingently removed from the relevant pharmaceutical list or lists there are no further actions to be undertaken with regard to this procedure.</p>

Changes of Director Name and Name or Address of the Superintendent

6. Where the name of a director of a body corporate or the name or address of the superintendent (pharmacy bodies corporate only) changes, it must notify NHS England within 30 days (paragraph 32(4), Schedule 4 and paragraph 22(4), Schedule 5 of the Regulations). In practice they will notify the Primary Care Support Service Provider.
7. On receipt of such information forward it to the NHS England regional team or teams where the contractor has premises.
8. There are no further actions in relation to this issue.

Provision of information on fitness matters as they arise

9. The Regulations require all contractors to provide information about fitness matters as they arise. This information is to be sent to the Primary Care Support Service Provider within seven days (paragraph 31, Schedule 4 and paragraph 21, Schedule 5 of the Regulations).
10. Where the contractor is a body corporate this information will be forwarded to:
 - The NHS England regional team in whose area the body corporate's registered office is located, or
 - If the body corporate has no premises in that team's area, to the NHS England regional team in whose area its premises are located, or where the majority of its premises are located.
11. For sole traders and partnerships this information will be sent to the NHS England regional team in whose area:
 - All the contractor's premises are located, or
 - The majority of its premises are located.
12. The PSRC (or PLDP) will determine whether or not the contractor remains suitable to be included in the relevant pharmaceutical list or lists. Options that are available to NHS England include:
 - Decision that the body corporate remains a fit and proper person to be included in a pharmaceutical list or lists,
 - Mandatory removal on the grounds of suitability – regulation 81 of the Regulations
 - Discretionary removal on fitness grounds – section 151(1)-(4) of the NHS Act 2006
 - Contingent removal on fitness grounds – section 152(1) of the NHS Act 2006
 - Suspension on fitness grounds – section 154(1) of the NHS Act
13. Notification of the decision to the contractor will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP will provide the required letters which include a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if notification under regulation 88 is required and whether the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
14. If the body corporate remains a fit and proper person to be included in a pharmaceutical list or lists, no regulation 88 notification is required.
15. If the body corporate is to be suspended the regulation 88 notification will be sent at the same time as the contractor is notified using Annex 23.
16. For removals (whether on mandatory or discretionary grounds) the regulation 88 notification is to be undertaken at the end of the 30-day appeal period if there are no appeals, or once any appeal has been heard and NHS England's

decision to remove has been upheld. Annex 24 is to be used for the regulation 88 notification. In addition, the following persons are to be notified by the Primary Care Support Service Provider using Annex 25:

- HWB,
- CCG,
- Public health team,
- DoS lead,
- CDAO,
- Unwanted medicines collection and disposal contractor,
- The organisation that cascades safety alerts, and
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager.

Contact details for the above, other than for the last bullet point, are to be provided by NHS England.

17. For contingent removals the regulation 88 notification is to be undertaken at the end of the 30-day appeal period if there are no appeals, or once any appeal has been heard and NHS England's decision to remove has been upheld. Annex 26 is to be used for the regulation 88 notification.
18. Regulation 88 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	Primary Care Appeals, NHS Resolution, 4th Floor, Arena Point, Merrion Way, Leeds, LS2 8PA appeals@resolution.nhs.uk
The Scottish Ministers	Chief Pharmaceutical Officer, Scottish Government, St Andrews House, Regent Road, Edinburgh, EH1 3DG
The Welsh Ministers	Notifications Clerk, Primary Care Division, Welsh Government, Cathays Park, Cardiff, CF10 3NQ gmscontract@gov.wales
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 Counter Fraud Authority	NHS Counter Fraud Authority, Skipton House 80 London Road, London. SE1 6LH generalenquiries@nhscfa.gsi.gov.uk

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)
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Use of the Fitness Powers

19. There may be occasion where NHS England identifies concerns relating to the fitness of a contractor. In this instance the PSRC (or PLDP) will need to consider use of the fitness powers set out in the NHS Act 2006 and Part 11 of the Regulations.
20. In general, the powers available to NHS England are set out in the NHS Act 2006 and the procedures to follow are set out in the Regulations. Where a PSRC (or PLDP) is considering use of the fitness powers it should first liaise with other regional teams in whose area the contractor has premises so that a consistent approach is taken across the country.
21. Options available to NHS England include:
 - Where there are no patient safety issues, monitoring the situation,
 - Mandatory removal on the grounds of suitability – regulation 81 of the Regulations
 - Discretionary removal on fitness grounds – section 151(1)-(4) of the NHS Act 2006
 - Contingent removal on fitness grounds – section 152(1) of the NHS Act 2006
 - Suspension on fitness grounds – section 154(1) of the NHS Act.
22. Where NHS England uses its fitness powers in relation to an existing contractor the role of the Primary Care Support Service Provider is to undertake the notification required by regulation 88 of the Regulations and notify other local organisations as requested by NHS England.
23. A notification under regulation 88 is to be made where NHS England:
 - Varies a condition that was placed upon a contractor when they were included in a pharmaceutical list for the first time – conditional inclusion
 - Removes a contractor from a pharmaceutical list on fitness grounds
 - Places a condition on a contractor's continued inclusion in a pharmaceutical list – contingent removal
 - Varies a contingent removal condition, or imposes a new condition
 - Suspends a contractor.

CHAPTER 12

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 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 NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 5 of the DHSC Guidance.
4. Where the application is for premises or a best estimate that is in a controlled locality, this chapter should be read with chapter 22.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of an application to meet an identified current need add the application details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application,</p>

Action	
	then Annex 2 should be completed so that it can be compared to the previously provided fitness information.
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application, the best estimate (if applicable) is acceptable and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) to the applicant.</p> <p>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 where these have been provided by the decision-maker.</p> <p>Move to step 22.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p> <p>Where the decision-maker confirms that the application is to be deferred move to step 17.</p> <p>Where the decision-maker confirms that the best estimate is not acceptable move to step 20.</p>
7.	<p>Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days.

Action	
	Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 7). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 8). Then go to step 22.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).</p> <p>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 these have not already been provided.</p> <p>Go to step 22.</p>
12.	<p>If the missing information/documentation isn't received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	Where there are missing undertakings in the application complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 11). The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.
14.	Diarise the date for the missing undertakings to be submitted.

Action	
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>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 not already provided.</p> <p>Go to step 22.</p>
16.	<p>If the missing undertakings aren't received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
18.	<p>If the decision-maker confirms that the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 14) to the applicant.</p> <p>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.</p>
19.	<p>Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant.</p> <p>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.</p> <p>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.</p> <p>If the applicant fails to respond, their application is treated as withdrawn.</p> <p>Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>

Action	
20.	<p>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 16) to the applicant.</p> <p>Diarise the date for the second-best estimate to be submitted.</p>
21.	<p>On receipt of the second-best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.</p> <p>If the second-best estimate is acceptable, and where the application is complete, send Annex 17 and move to step 22.</p> <p>If the second-best estimate is not acceptable, write back to the applicant for a further best estimate.</p>
22.	<p>Where the application is complete, it is not to be deferred or the reason for deferral no longer exists, and the best estimate is accepted where relevant notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 18) enclosing a copy of the application.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
23.	<p>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.</p>
24.	<p>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).</p>
25.	<p>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).</p>
26.	<p>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.</p>

Action	
27.	<p>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.</p> <p>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). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
28.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. Confirm these with the applicant (Annex 22) and any additional presenters (Annex 23) that the decision-maker wishes to hear from.</p> <p>At least 14 days' notice must be given.</p>
29.	<p>At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.</p>
30.	<p>Prepare a report (Annex 24) on the application for the decision-maker (as set out in Chapter 3) and send to the relevant pharmacy contracts team.</p>
31.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters for applications where the address of the premises is known are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 25) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). <p>The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). <p>The refusal decision letters for applications where the address is known or a best estimate has been given are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 32); and

Action	
	<ul style="list-style-type: none"> • Refused – to a third party (Annex 33). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
34.	<p>If NHS Resolution grants or confirms the grant of the application, and an address for the proposed premises was provided, complete and send a new notice of commencement and notification (Annex 34) to the applicant.</p> <p>Include a copy of the banking mandate.</p> <p>If NHS Resolution grants or confirms the grant of the application, and a best estimate of the location of the proposed premises was provided, send Annex 35 to the applicant.</p>
35.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36 where the address of the proposed premises was provided or Annex 37 where a best estimate of the location of the proposed premises was provided).</p> <p>Include a copy of the banking mandate where the applicant gave an address for the proposed premises.</p>
36.	<p>Where the application contains a best estimate of the location of the proposed premises, go to step 37.</p> <p>Where the application contains the address of the proposed premises, go to step 38.</p>
37.	<p>Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services.</p> <p>On receipt of the notification of the address forward it to the decision-maker (as set out in Chapter 3) to determine whether or not it is a valid notification.</p>

Action	
	<p>If the notification wasn't received in time send notification of receipt of premises not valid (Annex 38).</p> <p>If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 39) to the applicant and send notification of premises (Annex 40) to those parties notified of the decision on the original application.</p> <p>If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 41).</p> <p>Where the application provided a best estimate of the location of the proposed premises and NHS Resolution determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 42).</p>
38.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
39.	<p>If a request for an extension within which to open is received (Annex 43), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 44 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the request is refused send Annex 45 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 40.</p>
40.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 46 if it has not been received within this window.

Action

	<ul style="list-style-type: none"> • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 47 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application, or (if there has been a subsequent notification of a different address) another address approved by NHS England, or (where the applicant gave a best estimate) the address approved by NHS England • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 48 to the applicant.</p> <p>Where no issues are identified forward the notice to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 49.</p> <p>Where it is not, send Annex 50.</p>
41.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
42.	Send the notification of the NHS Pharmacy Contractor Code (Annex 51) advising the applicant of their contractor number when received from NHS Prescription Services.

Action

43. Ensure the market entry tracker has been kept up to date and enter the outcome of the application.
- Update other databases as appropriate and inform (using Annex 52) the usual parties which includes the relevant:
- Local Pharmaceutical Committee (LPC),
 - Health and Wellbeing Board (HWB),
 - Clinical Commissioning Group (CCG),
 - Pharmacy contracts manager,
 - Public health team,
 - Directory of Services (DoS) lead,
 - Unwanted medicines collection and disposal contractor,
 - The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
 - Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 13

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 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 NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 6 of the DHSC Guidance.
4. Where the application is for premises or a best estimate that is in a controlled locality, this chapter should be read with chapter 22.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of an application to meet an identified future need add the application details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was</p>

Action	
	provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed and all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application, the best estimate (if applicable) is acceptable and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) to the applicant.</p> <p>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 where these have been provided by the decision-maker.</p> <p>Move to step 22.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that the application is to be deferred move to step 17.</p> <p>Where the decision-maker confirms that the best estimate is not acceptable move to step 20</p>
7.	<p>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 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days.

Action	
	Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 7). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 8). Go to step 22.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).</p> <p>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 these have not already been provided.</p>
12.	<p>If the missing information/documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application complete and send to the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 11).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.

Action	
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>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 not already provided.</p> <p>Go to step 22.</p>
16.	<p>If the missing undertakings aren't received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
18.	<p>If the decision-maker confirms that the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 14) to the applicant.</p> <p>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.</p>
19.	<p>Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant.</p> <p>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.</p> <p>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.</p> <p>If the applicant fails to respond, their application is treated as withdrawn.</p> <p>Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>

Action	
20.	<p>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 16) to the applicant.</p> <p>Diarise the date for the second-best estimate to be submitted.</p>
21.	<p>On receipt of the second-best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.</p> <p>If the second-best estimate is acceptable, and where the application is complete, send Annex 17 and move to step 22.</p> <p>If the second-best estimate is not acceptable, write back to the applicant for a further best estimate.</p>
22.	<p>Where the application is complete, it is not to be deferred or the reason for deferral no longer exists, and the best estimate is accepted where relevant notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 18) enclosing a copy of the application.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
23.	<p>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.</p>
24.	<p>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).</p>
25.	<p>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).</p>
26.	<p>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.</p>

Action	
27.	<p>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.</p> <p>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). Advise the relevant pharmacy contract manager.</p>
28.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. 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.</p> <p>At least 14 days' notice must be given.</p>
29.	<p>At the end of the 14-day period where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.</p>
30.	<p>Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.</p>
31.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters for applications where the address of the premises is known are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 25) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). <p>The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). <p>The refusal decision letters for applications where the address is known or a best estimate has been given are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33).

Action	
	<p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
34.	<p>If NHS Resolution grants or confirms the grant of the application, and an address for the proposed premises was provided, complete and send a new notice of commencement and notification (Annex 34) to the applicant.</p> <p>Include a copy of the banking mandate.</p> <p>If NHS Resolution grants or confirms the grant of the application, and a best estimate of the location of the proposed premises was provided, send Annex 35 to the applicant.</p>
35.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36 where the address of the proposed premises was provided or Annex 37 where a best estimate of the location of the proposed premises was provided).</p> <p>Include a copy of the banking mandate where the applicant gave an address for the proposed premises.</p>
36.	<p>Where the application contains a best estimate of the location of the proposed premises, go to step 37.</p> <p>Where the application contains the address of the proposed premises, go to step 38.</p>
37.	<p>Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services.</p> <p>On receipt of the notification of the address forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification.</p>

Action	
	<p>If the notification wasn't received in time send notification of receipt of premises not valid (Annex 38).</p> <p>If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 39) to the applicant and send notification of premises (Annex 40) to those parties notified of the decision on the original application.</p> <p>If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 41).</p> <p>Where the application provided a best estimate of the location of the proposed premises and NHS Resolution determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 42).</p>
38.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
39.	<p>If a request for an extension within which to open is received (Annex 43), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 44 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the request is refused send Annex 45 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 40.</p>
40.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 46 if it has not been received within this window.

Action

	<ul style="list-style-type: none"> • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 47 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application, or (if there has been a subsequent notification of a different address) another address approved by NHS England, or (where the applicant gave a best estimate) the address approved by NHS England • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 48 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 49.</p> <p>Where it is not, send Annex 50.</p>
41.	<p>Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.</p>
42.	<p>Send the notification of the NHS Pharmacy Contractor Code (Annex 51) advising the applicant of their contractor number when received from NHS Prescription Services.</p>
43.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 52) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead,

Action	
	<ul style="list-style-type: none"> • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 14

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 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 NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 7 of the DHSC Guidance.
4. Where the application is for premises or a best estimate that is in a controlled locality, this chapter should be read with chapter 22.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	<p>On receipt of an application to meet identified improvements or better access add the application details to the market entry tracker.</p> <p>Ensure the tracker is updated as the application progresses.</p>
2.	<p>Where the applicant is not already included in the pharmaceutical list in respect of other premises, fitness to practise checks will need to be</p>

Action	
	completed. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application, the best estimate (if applicable) is acceptable and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) can be sent to the applicant.</p> <p>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 where these have been provided by the decision-maker.</p> <p>Move to step 22.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that the application is to be deferred move to step 17.</p> <p>Where the decision-maker confirms that the best estimate is not acceptable move to step 20.</p>

Action	
7.	<p>Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 7). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 8). Go to step 22.</p>
11.	<p>On receipt of the information/ documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).</p> <p>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 these have not already been provided.</p> <p>Go to step 22.</p>
12.	If the missing information/documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.

Action	
	This is the end of the process.
13.	<p>Where there are missing undertakings in the application, complete send the acknowledgement of receipt of application and request for missing undertakings (Annex 11).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>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.</p> <p>Go to step 22.</p>
16.	<p>If the missing undertakings aren't received by the due date, send to confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
18.	<p>If decision-maker confirms that the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 14) to the applicant.</p> <p>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.</p>
19.	Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant.

Action

	<p>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.</p> <p>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.</p> <p>If the applicant fails to respond, their application is treated as withdrawn.</p> <p>Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
20.	<p>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 16) to the applicant.</p> <p>Diarise the date for the second-best estimate to be submitted.</p>
21.	<p>On receipt of the second-best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.</p> <p>If the second-best estimate is acceptable, and where the application is complete, send Annex 17 and move to step 22.</p> <p>If the second-best estimate is not acceptable, write back to the applicant for a further best estimate.</p>
22.	<p>Where the application is complete, it is not to be deferred or the reason for deferral no longer exists, and the best estimate is accepted where relevant notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 18) enclosing a copy of the application.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
23.	<p>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.</p>
24.	<p>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).</p>

Action	
25.	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).
26.	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.
27.	<p>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.</p> <p>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). Advise the relevant pharmacy contract manager.</p>
28.	If an oral hearing is to be held the decision-maker will make the arrangements. Confirm these 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.
29.	At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.
30.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
31.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters for applications where the address of the premises is known are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 25) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). <p>The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 26 where advised to do so by NHS England;

Action	
	<ul style="list-style-type: none"> • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). <p>The refusal decision letters for applications where the address is known or a best estimate has been given are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement. When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
34.	<p>If NHS Resolution grants or confirms the grant of the application, and an address for the proposed premises was provided, complete and send a new notice of commencement and notification (Annex 34) to the applicant.</p> <p>Include a copy of the banking mandate.</p> <p>If NHS Resolution grants or confirms the grant of the application, and a best estimate of the location of the proposed premises was provided, send Annex 35 to the applicant.</p>
35.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36 where the address of the proposed premises was provided or Annex 37 where a best estimate of the location of the proposed premises was provided).</p> <p>Include a copy of the banking mandate where the applicant gave an address for the proposed premises.</p>
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37.

Action

	<p>Where the application contains the address of the proposed premises, go to step 38.</p>
37.	<p>Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services.</p> <p>On receipt of the notification of the address forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification.</p> <p>If the notification wasn't received in time send notification of receipt of premises not valid (Annex 38).</p> <p>If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 39) to the applicant and send notification of premises (Annex 40) to those parties notified of the decision on the original application.</p> <p>If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 41).</p> <p>Where the application provided a best estimate of the location of the proposed premises and NHS Resolution determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 42).</p>
38.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
39.	<p>If a request for an extension within which to open is received (Annex 43), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 44 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the request is refused send Annex 45 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p>

Action	
	<p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 40.</p>
40.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 46 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 47 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application, or (if there has been a subsequent notification of a different address) another address approved by NHS England, or (where the applicant gave a best estimate) the address approved by NHS England • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 48 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it was valid send Annex 49</p> <p>Where it is not, send Annex 50.</p>
41.	<p>Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.</p>
42.	<p>Send the notification of the NHS Pharmacy Contractor Code (Annex 51) advising the applicant of their contractor number when received from NHS Prescription Services.</p>
43.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 52) the usual parties which includes the relevant:</p>

Action

- LPC,
- HWB,
- CCG,
- Pharmacy contracts manager,
- Public health team,
- DoS lead,
- Unwanted medicines collection and disposal contractor,
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 15

Procedure - Unforeseen Benefits

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 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 NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 8 of the DHSC Guidance.
4. Where the application is for premises or a best estimate that is in a controlled locality, this chapter should be read with chapter 22.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of an application offering unforeseen benefits check the application details have been added to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application, the best estimate (if applicable) is acceptable and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) can be sent to the applicant.</p> <p>Where the applicant is offering to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement where these have been provided by the decision-maker.</p> <p>Move to step 22.</p>
6.	Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.

Action	
	<p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p> <p>Where the decision-maker confirms that the application is to be deferred move to step 17.</p> <p>Where the decision-maker confirms that the best estimate is not acceptable move to step 20.</p>
7.	<p>Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 7). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 8). Go to step 22.</p>
11.	On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).

Action	
	<p>Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.</p> <p>Go to step 22.</p>
12.	<p>If the missing information/documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 11).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	<p>Diarise the date for the missing undertakings to be submitted.</p>
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 22.</p>
16.	<p>If the missing undertakings aren't received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>

Action	
18.	<p>If decision-maker confirms that the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 14) to the applicant.</p> <p>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.</p>
19.	<p>Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant.</p> <p>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.</p> <p>If the applicant fails to respond, their application is treated as withdrawn.</p> <p>Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
20.	<p>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 16) to the applicant.</p> <p>Diarise the date for the second-best estimate to be submitted.</p>
21.	<p>On receipt of the second-best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.</p> <p>If the second-best estimate is acceptable, and where the application is complete, send Annex 17 and move to step 22.</p> <p>If the second-best estimate is not acceptable, write back to the applicant for a further best estimate.</p>
22.	<p>Where the application is complete, it is not to be deferred or the reason for deferral no longer exists, and the best estimate is accepted where relevant notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 18) enclosing a copy of the application.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>

Action	
23.	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.
24.	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).
25.	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).
26.	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.
27.	<p>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.</p> <p>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). Advise the relevant pharmacy contract manager.</p>
28.	If an oral hearing is to be held the decision-maker will make the arrangements. 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.
29.	At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.
30.	Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
31.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters for applications where the address of the premises is known are:</p>

Action

	<ul style="list-style-type: none"> • Granted – to the applicant (Annex 25) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). <p>The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). <p>The refusal decision letters for applications where the address is known or a best estimate has been given are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 32); and • Refused – to a third party (Annex 33). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
34.	<p>If NHS Resolution grants or confirms the grant of the application, and an address for the proposed premises was provided, complete and send a new notice of commencement and notification (Annex 34) to the applicant.</p> <p>Include a copy of the banking mandate.</p> <p>If NHS Resolution grants or confirms the grant of the application, and a best estimate of the location of the proposed premises was provided, send Annex 35 to the applicant.</p>

Action	
35.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36 where the address of the proposed premises was provided or Annex 37 where a best estimate of the location of the proposed premises was provided).</p> <p>Include a copy of the banking mandate where the applicant gave an address for the proposed premises.</p>
36.	<p>Where the application contains a best estimate of the location of the proposed premises, go to step 37.</p> <p>Where the application contains the address of the proposed premises, go to step 38.</p>
37.	<p>Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services.</p> <p>On receipt of the notification of the address forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification.</p> <p>If the notification wasn't received in time send notification of receipt of premises not valid (Annex 38).</p> <p>If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 39) to the applicant and send notification of premises (Annex 40) to those parties notified of the decision on the original application.</p> <p>If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 41).</p> <p>Where the application provided a best estimate of the location of the proposed premises and NHS Resolution determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 42).</p>
38.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
39.	<p>If a request for an extension within which to open is received (Annex 43), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 44 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p>

Action

	<p>If the request is refused send Annex 45 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 40.</p>
40.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 46 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 47 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application, or (if there has been a subsequent notification of a different address) another address approved by NHS England, or (where the applicant gave a best estimate) the address approved by NHS England • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 48 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 49.</p> <p>Where it is not, send Annex 50.</p>
41.	<p>Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.</p>

Action	
42.	Send the notification of the NHS Pharmacy Contractor Code (Annex 51) advising the applicant of their contractor number when received from NHS Prescription Services.
43.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 52) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 16

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 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 NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 9 of the DHSC Guidance.
4. Where the application is for premises or a best estimate that is in a controlled locality, this chapter should be read with chapter 22.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of an application to secure identified improvements or better access add the application details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information</p>

Action	
	<p>in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application, the best estimate (if applicable) is acceptable and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) to the applicant.</p> <p>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.</p> <p>Move to step 22.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p> <p>Where the decision-maker confirms that the application is to be deferred move to step 17.</p> <p>Where the decision-maker confirms that the best estimate is not acceptable move to step 20.</p>
7.	<p>Where there is missing information and/or documentation in the application, send the acknowledgement of receipt of application and request for further information (Annex 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days.

Action	
	Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 7). The timescales for providing the information are as set out in step 6 above.</p> <p>If the information is provided, go to step 10.</p> <p>If the information is not provided go to step 11.</p> <p>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 8). Go to step 12.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).</p> <p>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.</p> <p>Go to step 22.</p>
12.	<p>If the missing information/documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application, complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 11).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.

Action	
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 22.</p>
16.	<p>If the missing undertakings aren't received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>
18.	<p>If decision-maker confirms that the application is to be deferred on non-fitness grounds complete and send the notification of deferral on non-fitness grounds (Annex 14) to the applicant.</p> <p>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.</p>
19.	<p>Once the reason for deferral ceases send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant.</p> <p>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.</p> <p>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.</p> <p>If the applicant fails to respond, their application is treated as withdrawn.</p> <p>Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 22.</p>

Action	
20.	<p>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 16) to the applicant.</p> <p>Diarise the date for the second-best estimate to be submitted.</p>
21.	<p>On receipt of the second-best estimate, send it to the decision-maker (set out in Chapter 3) for confirmation that it is acceptable.</p> <p>If the second-best estimate is acceptable, and where the application is complete, send Annex 17 and move to step 22.</p> <p>If the second-best estimate is not acceptable, write back to the applicant for a further best estimate.</p>
22.	<p>Where the application is complete, it is not to be deferred or the reason for deferral no longer exists, and the best estimate is accepted where relevant notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 18) enclosing a copy of the application.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
23.	<p>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.</p>
24.	<p>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).</p>
25.	<p>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).</p>
26.	<p>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.</p>

Action	
27.	<p>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.</p> <p>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). Advise the relevant pharmacy contract manager.</p>
28.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. 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.</p> <p>At least 14 days' notice must be given.</p>
29.	<p>At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.</p>
30.	<p>Prepare a report (Annex 24) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.</p>
31.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters for applications where the address of the premises is known are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 25) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 27); and • Granted – to a third party with appeal rights (Annex 28). <p>The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 26 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 30); and • Granted – to a third party with appeal rights (Annex 31). <p>The refusal decision letters for applications where the address is known or a best estimate has been given are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 32); and

Action	
	<ul style="list-style-type: none"> • Refused – to a third party (Annex 33). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
34.	<p>If NHS Resolution grants or confirms the grant of the application, and an address for the proposed premises was provided, complete and send a new notice of commencement and notification (Annex 34) to the applicant.</p> <p>Include a copy of the banking mandate.</p> <p>If NHS Resolution grants or confirms the grant of the application, and a best estimate of the location of the proposed premises was provided, send Annex 35 to the applicant.</p>
35.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36 where the address of the proposed premises was provided or Annex 37 where a best estimate of the location of the proposed premises was provided).</p> <p>Include a copy of the banking mandate where the applicant gave an address for the proposed premises.</p>
36.	<p>Where the application contains a best estimate of the location of the proposed premises, go to step 37.</p> <p>Where the application contains the address of the proposed premises, go to step 38.</p>
37.	<p>Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services.</p> <p>On receipt of the notification of the address forward it to the decision-maker (set out in Chapter 3) to determine whether or not it is a valid notification.</p>

Action	
	<p>If the notification wasn't received in time send notification of receipt of premises not valid (Annex 38).</p> <p>If the decision-maker is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 39) to the applicant and send notification of premises (Annex 40) to those parties notified of the decision on the original application.</p> <p>If the decision-maker is not satisfied that the notification is valid, send notification of non-valid premises (Annex 41).</p> <p>Where the application provided a best estimate of the location of the proposed premises and NHS Resolution determines that the applicant's notification of the premises was valid, send notification of valid appeal (Annex 42).</p>
38.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
39.	<p>If a request for an extension within which to open is received (Annex 43), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 44 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the request is refused send Annex 45 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 40.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 40.</p>
40.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 46 if it has not been received within this window.

Action	
	<ul style="list-style-type: none"> • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 47 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application, or (if there has been a subsequent notification of a different address) another address approved by NHS England, or (where the applicant gave a best estimate) the address approved by NHS England • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 48 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 49.</p> <p>Where it is not, send Annex 50.</p>
41.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
42.	Send the notification of the NHS Pharmacy Contractor Code (Annex 51) advising the applicant of their contractor number when received from NHS Prescription Services.
43.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 52) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead,

Action

- Unwanted medicines collection and disposal contractor,
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 17

Procedure – Application for No Significant Change Relocation

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 Regulations.
2. This chapter covers applications from contractors to relocate to new premises within the same HWB's area or the area of a neighbouring HWB. For the purposes of this type of application a 'neighbouring HWB' is defined within the Regulations as one which borders any part of the HWB area in which the premises is currently located.
3. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list.
4. Applications are to be determined within four months of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
5. This chapter must be read in conjunction with the Regulations and Chapter 10 of the DHSC Guidance.
6. As noted in Chapter 2 of the DHSC guidance, there are two different types of relocation application. The first type is a routine application that falls under Regulation 12(b)(ii). This is an application to relocate to new premises in order to meet a need, improvement or better access identified within the PNA, and which would result in a significant change to pharmaceutical services provision in the relevant HWB area. In this instance the applicant would submit the type of application that is relevant to the identified need, improvement or better access. For example, if the PNA identifies a current need for a pharmacy then the applicant should submit a current need application which would be processed in line with Chapter 12 and determined under regulation 13.
7. The second type is an excepted application that falls under Regulation 24. In order to meet the requirements of Regulation 24, the relocation must not result in a significant change to pharmaceutical services provision. In this instance the applicant would submit a no significant change relocation application which is processed in line with this chapter and determined under regulation 24.
8. Template applications forms are provided in the annexes to this chapter:
 - Annex 1 is for an application within the same HWB;
 - Annex 2 is for an application to a neighbouring HWB; and
 - The information in the template form at Annex 3 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of a no significant change relocation application or an application for no significant change relocation to a neighbouring HWB area, add the details to the market entry tracker. Ensure the tracker is updated as the application progresses.
2.	Where the applicant is applying to relocate to a neighbouring HWB area and they are not already included in the pharmaceutical list for that area in respect of other premises, fitness to practise checks will need to be completed. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 (Annexes 1 or 2 and 3).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 3 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 3 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	<p>Send the 'first referral' to the decision-maker (Annex 4).</p> <p>Annex 5 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 6) to the applicant.</p> <p>Where the applicant is offering to provide new enhanced services, enclose copies of the specifications for these services with the acknowledgement where these have been provided by the decision-maker.</p> <p>Go to step 17.</p>

Action	
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 12.</p>
7.	<p>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 7).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	<p>Diarise the date for the missing information/documentation to be submitted.</p>
9.	<p>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.</p>
10.	<p>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 8). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 9). Go to step 12.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 10).</p> <p>Where the applicant is offering to provide new enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.</p> <p>Go to step 17.</p>

Action	
12.	<p>If the missing information/documentation isn't received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 11). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>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 12).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	<p>Diarise the date for the missing undertakings to be submitted.</p>
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 13).</p> <p>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.</p> <p>Go to step 17.</p>
16.	<p>If the missing undertakings aren't received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 14). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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.</p> <p>Where the application relates to a relocation to a neighbouring HWB area and the applicant is not already included in the 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. Refer to the relevant chapter (5 to 10).</p> <p>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.</p>
18.	<p>Notify the interested parties of the application (Annex 15) enclosing a copy of the application.</p>

Action

	<p>Only include the market entry form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
19.	<p>During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 16) to the applicant.</p> <p>Where the application relates to a relocation to a neighbouring 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).</p>
20.	<p>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 17).</p>
21.	<p>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.</p>
22.	<p>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.</p> <p>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 18). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
23.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. Confirm these with the applicant (Annex 19) and any additional presenters (Annex 20) that the decision-maker (set out in Chapter 3) wishes to hear from.</p> <p>At least 14 days' notice must be given.</p>
24.	<p>At the end of the 14-day period, prepare a report (Annex 21) on the application for the decision-maker (set out in Chapter 3) and send to the relevant administrator/secretary.</p>

Action

25.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The application granted decision letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 22) and include Annex 23 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 24); and • Granted – to a third party with appeal rights (Annex 25). <p>The application refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 26); and • Refused – to a third party (Annex 27). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
26.	<p>Diarise the latest date for appeals to be made.</p>
27.	<p>If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p>
28.	<p>If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 28) to the applicant.</p>
29.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 29).</p>
30.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>

Action

31. If a request for an extension within which to open is received (Annex 30), pass it to the relevant decision-maker for a decision.

If the request is granted send Annex 31 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 32.

If the request is refused send Annex 32 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.

If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 32.

If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.

If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 32.

32. On receipt of a completed notice of commencement check the following points:

- It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 33 if it has not been received within this window.
- The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 34 where it has been submitted more than 14 days before the commencement date.
- The address is the same as the one in the original application,
- The superintendent pharmacist is the same as the one named in the original application
- The date of the grant of the application (which may have been on appeal by NHS Resolution)
- The GPhC premises registration number – this can be checked on the [GPhC website](#). Where it is not yet showing on the register email the GPhC for confirmation of registration.
- The notice is signed and dated.

If any information is missing or incorrect, send Annex 35 to the applicant.

Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.

Where it is valid send Annex 36.

Where it is not, send Annex 37.

Action

33.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
34.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 38) the usual parties which includes the relevant:</p> <ul style="list-style-type: none">• LPC,• HWB,• CCG,• Pharmacy contracts manager,• Public health team,• DoS lead,• Unwanted medicines collection and disposal contractor,• The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and• Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 18

Distance Selling Premises

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 Regulations.
2. Applications are to be determined within four months of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 11 of the DHSC Guidance.
4. A template application form is provided at Annex 1.
5. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of a distance selling premises application add the details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>

Action	
4.	<p>Send the 'first referral' to the decision-maker (Annex 3).</p> <p>Annex 4 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed all relevant information, documentation and undertakings have been provided, there are no grounds to defer the application and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 5) to the applicant.</p> <p>Where the applicant is offering to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement where these have been provided by the decision-maker.</p> <p>Move to step 18.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p>
7.	<p>Where there is missing information and/or documentation in the application, send the acknowledgement of receipt of application and request for further information (Annex 6).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	<p>Diarise the date for the missing information/documentation to be submitted.</p>
9.	<p>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.</p>
10.	<p>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</p>

Action	
	<p>request for information (Annex 7). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 8). Go to step 13.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 9).</p> <p>Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.</p> <p>Go to step 18.</p>
12.	<p>If the missing information/documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 11).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	<p>Diarise the date for the missing undertakings to be submitted.</p>
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12).</p> <p>Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 18.</p>
16.	<p>If the missing undertakings aren't received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 13). Advise the relevant pharmacy contract manager.</p>

Action	
	This is the end of the process.
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by NHS England, move to step 18.</p>
18.	<p>Where the application is complete and is not to be deferred on 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. Any standard operating procedures (SOP) that the applicant has provided are to be circulated unless NHS England confirms that the full disclosure principle doesn't apply.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
19.	<p>During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 15) to the applicant.</p> <p>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).</p>
20.	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 16).
21.	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.
22.	<p>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.</p> <p>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</p>

Action	
	treated as being withdrawn (Annex 17). Advise the relevant pharmacy contract manager.
23.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. Confirm these with the applicant (Annex 18) and any additional presenters (Annex 19) that the decision-maker (set out in Chapter 3) wishes to hear from.</p> <p>At least 14 days' notice must be given.</p>
24.	At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't hold the application until a decision is made. If it has, move to the next step.
25.	Prepare a report (Annex 20) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
26.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The application granted decision letters are:</p> <ul style="list-style-type: none"> • 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). <p>The application refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 24); and • Refused – to a third party (Annex 25). <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
27.	Diarise the latest date for appeals to be made.
28.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.

Action	
29.	If NHS Resolution 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.
30.	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.
31.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received advise the relevant pharmacy contract manager.
32.	If a request for an extension within which to open is received (Annex 28), pass it to the relevant decision-maker for a decision. If the request is granted send Annex 29 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 34. If the request is refused send Annex 30 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response. If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 34. If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process. If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 34.
33.	On receipt of a completed notice of commencement check the following points: <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 31 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 32 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application

Action	
	<ul style="list-style-type: none"> • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 33 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 34.</p> <p>Where it is not, send Annex 35.</p>
34.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
35.	Send the notification of the NHS Pharmacy Contractor Code (Annex 36) advising the applicant of their contractor number when received from NHS Prescription Services.
36.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 37) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 19

Procedure - Change of Ownership

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 Regulations.
2. Applications are to be determined within 30 days of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
3. This chapter must be read in conjunction with the Regulations and Chapter 12 of the DHSC Guidance.
4. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list.
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of a change of ownership application, add the details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	<p>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 1 and 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application,</p>

Action	
	then Annex 2 should be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the decision-maker (Annex 3).
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided and there are no grounds to defer the application send acknowledgement of receipt of the application (Annex 4) to the applicant.</p> <p>Where the applicant will be required to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement.</p> <p>Move to step 17.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p>
7.	<p>Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 5).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five 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 – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	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

Action	
	<p>request for information (Annex 6). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 7). Go to step 13.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 8).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.</p> <p>Go to step 17.</p>
12.	<p>If the missing information/documentation isn't received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 9). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application send the acknowledgement of receipt of application and request for missing undertakings (Annex 10).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	<p>Diarise the date for the missing undertakings to be submitted.</p>
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 17.</p>
16.	<p>If the missing undertakings aren't received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 12). Advise the relevant pharmacy contract manager.</p>

Action	
	This is the end of the process.
17.	<p>If the application is to be deferred on fitness grounds, do not progress any further until the outcome of the cause of the deferral is known. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known move to step 18.</p>
18.	<p>While the fitness to practise checks are being completed, where relevant, ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 13) to the applicant.</p>
19.	<p>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 14). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
20.	<p>On receipt of the fitness to practise recommendation/decision, where relevant, prepare a report (Annex 15) on the application to the decision-maker (set out in Chapter 3).</p>
21.	<p>After the meeting, prepare the relevant decision and enclose the decision report provided by the decision-maker.</p> <p>The application granted decision letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 16) and include Annex 17 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 18); and • Granted – to a third party with appeal rights (Annex 19). <p>The application refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 20); and • Refused – to a third party (Annex 21). <p>If granted, complete as far as possible the notice of commencement.</p> <p>Once the decision letters are prepared, distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>

Action	
22.	Diarise the latest date for appeals to be made.
23.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
24.	If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 22) to the applicant. Include a copy of the banking mandate.
25.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 23). Include a copy of the banking mandate.
26.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received advise the relevant pharmacy contract manager.
27.	If a request for an extension within which to open is received (Annex 24), pass it to the relevant decision-maker for a decision. If the request is granted send Annex 25 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 28. If the request is refused send Annex 26 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response. If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 28. If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process. If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 28.
28.	On receipt of a completed notice of commencement check the following points: <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 27 if it has not been received within this window.

Action	
	<ul style="list-style-type: none"> • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 28 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated <p>If any information is missing or incorrect, send Annex 29 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 30.</p> <p>Send Annex 31 to the old owner of the premises.</p> <p>Where it is not, send Annex 32.</p>
29.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
30.	Send the notification of the NHS Pharmacy Contractor Code (Annex 33) advising the applicant of their contractor number when received from NHS Prescription Services.
31.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 34) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor,

Action

- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 20

Consolidation onto an existing site

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications to consolidate onto an existing site are dealt with in line with the Regulations.
2. Applications are to be determined within four months of receipt unless NHS England has good cause to take longer.
3. This chapter must be read in conjunction with the Regulations. This chapter does not apply to contractors who hold LPS contracts as they are unable to submit this type of application.
4. A template application form is provided at Annex 1.
5. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1	On receipt of a consolidation onto an existing site application, add the application details to the market entry tracker. Ensure the tracker is updated as the application 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 form (Annex 1 and 2).
3.	Send the 'first referral' to the decision-maker (Annex 3). Annex 4 will assist in identifying certain parties to be notified – more particularly those who would be significantly affected by the grant of the application or who might have a significant interest in the outcome of the application.
4.	Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided and there are no grounds to refuse the application at this stage send an acknowledgement of receipt of the application (Annex 5) to the applicant. Where the applicant will be required to provide enhanced services, enclose copies of the specifications for these services where these have been provided by the decision-maker. Move to step 17.

Action	
5.	Where the decision-maker confirms that one or both of the premises listed in the application are distance selling premises or appliance contractor premises send Annex 6. This is the end of the process.
6.	Where the decision-maker confirms that there is missing information and/or documentation in the application move to step 7. Where the decision-maker confirms that there are missing undertakings in the application move to step 13.
7.	Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 7). The timescales to be set out in the request to provide the missing information are: <ul style="list-style-type: none"> • payment of the relevant fee – five working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – five working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	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 8). The timescales for providing the information are as set out in step 7 above. If the information is provided, go to step 11. If the information is not provided go to step 12. 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 9). Go to step 17.
11.	On receipt of the information/ documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 10). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.

Action	
	Go to step 17.
12.	<p>If the missing information/documentation isn't received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 11). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application, complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 12).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p> <p>Where there are further undertakings required following step 4 (provision of enhanced services) then send to the applicant the acknowledgement of receipt of application and request for undertakings under paragraph 9(2), Schedule 2 of the Regulations (Annex 13)</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9(2), Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 14).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 17.</p>
16.	<p>If the missing undertakings aren't received by the due date, send t confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 15). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	Where the application is complete notify the interested parties (except the HWB) as determined by the decision-maker (set out in Chapter 3) of the application (Annex 16) enclosing a copy of the application. Where the two sites are owned by different contractors include both as interested parties so that they are aware the application has been notified.

Action

	<p>Notify the HWB of the application (Annex 17) and enclose a copy of the application. Liaise with the decision-maker to see if a discussion is required with the HWB to confirm awareness and understanding of the requirement for the HWB to make representations for consolidation applications.</p> <p>Diarise a reminder letter to be sent to the HWB 10 days before the 45-day deadline for representations.</p> <p>Only include the market entry application form. Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
18.	<p>10 days before the 45-day deadline for representations check to see if the HWB has responded. If it hasn't, send Annex 18 and advise the relevant pharmacy contracts manager so that they can contact the HWB as appropriate.</p> <p>If the HWB has not provided representations by the deadline, send Annex 19 as soon as practicable. Follow this up with Annex 20 10 days later if no representations are received.</p> <p>If pursuant to sending Annexes 17 to 20, the HWB responds, the pharmacy contracts manager must review the HWB's representations. If it is reasonable to conclude that the HWB has not addressed the issue that it was required to address (as set out in the third paragraph of Annex 17), then send Annex 21 to the HWB.</p>
19.	<p>During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 22) to the applicant.</p>
20.	<p>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 23).</p> <p>Where the HWB's representations have been received after the 45-day notification period, such that they were not included in the representations circulated pursuant to the paragraph above, the HWB's representations should be circulated to all parties to which the other representations were circulated and 14 days should be given from the date the HWB's representations were sent for comments. Please see Annex 24.</p> <p>This may mean the original 14-day timescales for comments on the circulated representations is extended or, if the 14-day timescale has already passed, a new 14-day timescale will apply but only for comments on the HWB's representations.</p>

Action	
21.	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.
22.	<p>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.</p> <p>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 25).</p> <p>Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
23.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. Confirm arrangements with the applicant (Annex 26) and any additional presenters (Annex 27) that the decision-maker wishes to hear from.</p> <p>At least 14 days' notice must be given.</p>
24.	Prepare a report (Annex 28) on the application to the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
25.	<p>After the meeting, prepare the relevant decision and enclose the decision report provided by the decision-maker.</p> <p>The granted decision letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 29) and include Annex 30 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 31); and • Granted – to a third party with appeal rights (Annex 32). <p>The application refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 33); and • Refused – to a third party (Annex 34). <p>If granted, complete as far as possible the notice of consolidation.</p> <p>Once the decision letters are prepared, distribute to the applicant and interested parties enclosing the notice of consolidation where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>

Action	
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 NHS Resolution grants or confirms the grant of the application, complete and send a new notice of consolidation and notification (Annex 35) to the applicant. Include a copy of the banking mandate.
29.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 36).
30.	Diarise the latest date by which the template notice of consolidation can be submitted. If no notice of consolidation is received advise the relevant pharmacy contract manager.
31.	If a request for an extension within which to open is received (Annex 37), pass it to the relevant decision-maker for a decision. If the request is granted send Annex 38 to the applicant and diarise the latest date by which the notice of consolidation can be submitted. Move to step 32. If the request is refused send Annex 39 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response. If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of consolidation can be submitted. Move to step 32. If the outcome of the appeal is that the request is refused and the latest date by which the notice of consolidation can be submitted has passed, this is the end of the process. If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of consolidation move to step 32.
32.	On receipt of a completed notice of consolidation check the following points: <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 40 if it has not been received within this window. • The date that the consolidation will take effect – this must be within 14 days of the date on which the notice was received. Send Annex 41 where it has been submitted more than 14 days before the date the consolidation takes effect.

Action	
	<ul style="list-style-type: none"> • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 42 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 43.</p> <p>Where it is not, send Annex 44.</p>
33.	Complete the relevant NHS Prescription Services form(s) and send to NHS Prescription Services with the applicant's completed mandate.
34.	Where the applicant doesn't own both sites send Annex 45 to the contractor whose premises are to be removed from the relevant pharmaceutical list.
35.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 46) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 21

Procedure - Combined Change of Ownership and No Significant Change Relocation

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 Regulations.
2. It 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 neighbouring HWB. For the purposes of this type of application a 'neighbouring HWB' is defined within the Regulations is one which borders any part of the HWB in which the premises is currently located.
3. Applications are to be determined within four months of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
4. This chapter must be read in conjunction with the Regulations and Chapter 13 of the DHSC Guidance.
5. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list.
6. Template applications forms are provided in the annexes to this chapter:
 - Annex 1 is for an application within the same HWB; and
 - Annex 2 is for an application to a different HWB.
7. The information in the template form at Annex 3 must be included in all routine and excepted applications for inclusion in a pharmaceutical list.

Procedure

Action	
1.	On receipt of a combined change of ownership and no significant change relocation application either within the same HWB or to another HWB's area, add the application details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together

Action	
3.	<p>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 relevant national application form (Annexes 1 or 2).</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 3 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 3 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	<p>Send the 'first referral' to the decision-maker (Annex 4).</p> <p>Annex 5 will assist in identifying certain 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.</p>
5.	<p>Where the decision-maker confirms the application is fully completed, all relevant information, documentation and undertakings have been provided, and the list of interested parties has been signed off send acknowledgement of receipt of the application (Annex 6) to the applicant.</p> <p>Where the applicant will be required to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement where these have been provided by the decision-maker.</p> <p>Move to step 17.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 13.</p>
7.	<p>Where there is missing information and/or documentation in the application send the acknowledgement of receipt of application and request for further information (Annex 7).</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • payment of the relevant fee – five working days; and • the information required by paragraph 1, Schedule 2 of the Regulations but not supplied – five working days.

Action	
	Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.
10.	<p>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 8). The timescales for providing the information are as set out in step 7 above.</p> <p>If the information is provided, go to step 11.</p> <p>If the information is not provided go to step 12.</p> <p>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 9). Go to step 17.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 10).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided.</p> <p>Go to step 17.</p>
12.	<p>If the missing information/documentation isn't received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 11). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings in the application complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 12).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9, Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.

Action	
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 13).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 17.</p>
16.	<p>If the missing undertakings aren't received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 14). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known, where the application is complete move to step 18.</p>
18.	<p>Where the application is complete and is not to be deferred on fitness grounds notify the interested parties as determined by the decision-maker (set out in Chapter 3) of the application (Annex 15) enclosing a copy of the application. Include both the applicant and the current owner as interested parties so that they are aware the application has been notified.</p> <p>Do not include any fitness to practise or personal information that may have been provided. Include a list of the interested parties so that all are aware of who has been notified. Blank out the information provided in section 1.5 of the application.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the application is notified by post advise the relevant pharmacy contract manager that it has been notified.</p>
19.	<p>During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 16) to the applicant.</p>
20.	<p>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 17).</p>

Action	
21.	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.
22.	<p>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.</p> <p>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 18). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
23.	<p>If an oral hearing is to be held the decision-maker will make the arrangements. Confirm arrangements with the applicant (Annex 19) and any additional presenters (Annex 20) that the decision-maker wishes to hear from.</p> <p>At least 14 days' notice must be given.</p>
24.	At the end of the 14-day period, where relevant, check that a decision has been made on the applicant's fitness to practise. If it hasn't, hold the application until a decision is made. If it has move to the next step.
25.	Prepare a report (Annex 21) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
26.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The application granted decision letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 22) and include Annex 23 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 24); and • Granted – to a third party with appeal rights (Annex 25). <p>The application refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 26); and • Refused – to a third party (Annex 27). <p>If the application is in or near a controlled locality please use the decision letters in Chapter 22.</p> <p>If granted, complete as far as possible the notice of commencement.</p>

Action	
	<p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
27.	Diarise the latest date for appeals to be made.
28.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response.
29.	If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and notification (Annex 28) to the applicant.
30.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 29).
31.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
32.	<p>If a request for an extension within which to open is received (Annex 30), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 31 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 33.</p> <p>If the request is refused send Annex 32 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 33.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 33.</p>

Action

33.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 33 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 34 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 35 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 36.</p> <p>Send Annex 37 to the old owner of the premises.</p> <p>Where it is not, send Annex 38 to the applicant.</p>
34.	<p>Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.</p>
35.	<p>Send the notification of the NHS Pharmacy Contractor Code (Annex 39) advising the applicant of their contractor number when received from NHS Prescription Services.</p>
36.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 40) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG,

Action

- Pharmacy contracts manager,
- Public health team,
- DoS lead,
- Unwanted medicines collection and disposal contractor,
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 22

Procedures - Controlled Localities and Rurality Matters

Chapter aims and objectives

6. This chapter deals with applications in controlled localities, specifically the additional steps for:
 - Pharmacy routine applications in a controlled locality; and
 - Certain pharmacy applications within 1.6km of a controlled locality.
7. This document must be read in conjunction with the relevant market entry chapter, the Regulations and Chapter 14 of the DHSC Guidance. Further information on the background to the current regulatory framework for rurality matters can be found in the Clothier Report¹ which was published in December 1977.

Background

7. A controlled locality is an area determined by NHS England (or its predecessors or, on appeal, by NHS Resolution) 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.
8. In making a decision on controlled locality status, NHS England 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.
9. 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;

¹ www.pcc-cic.org.uk/article/clothier-report

- 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.).
10. NHS England may need to consider afresh whether an area is or is not a controlled locality:
- as a result of receiving a routine application for pharmacy premises,
 - at the request of a local pharmaceutical committee or local medical committee, or
 - of its own volition, for example as a result of validating dispensing patient lists.

History of controlled localities and information available

11. 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.
12. 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.
13. 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)
14. NHS England 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.

15. The main reason why controlled localities need to be determined relates to the ability for GP practices to dispense to certain of their patients. Normally once someone has seen a GP and requires medication they are given a prescription to take or send to the pharmacy of their choice to be dispensed. However, in certain circumstances the prescription can be dispensed by the practice instead. Dispensing doctors may generally only provide pharmaceutical services (the dispensing service) to patients who live in a designated controlled locality, more than 1.6km (as the crow flies) from a pharmacy where the practice has premises approval and either outline consent or historic rights to dispense to that area.
16. NHS England 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 LPC or LMC, or of its own volition for example as a result of validating dispensing patient lists.

Gradualisation

17. Gradualisation – that is, the postponement of any requirement for dispensing by doctors to cease – is to be considered by NHS England:
 - Where it is determined that an area is no longer a controlled locality, or part of one,
 - Determinations of routine applications where the proposed premises or best estimate are in a controlled locality but not a reserved location,
 - Pharmacy applications (other than distance selling premises) involving a relocation where the proposed premises are in, or within 1.6km of, a controlled locality, or
 - Following a redetermination of a reserved location where it is determined that the pharmacy is no longer in a reserved location

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

18. 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.
19. There is no separate procedure for making decisions on gradualisation; instead it is a decision that will be made in the situations listed in paragraph 13 above. As well as considering any representations received, the following factors are to be taken into account when NHS England 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.

Reserved locations

8. The issue of reserved location status is to be considered by NHS England in relation to all pharmacy routine applications where the premises or best estimate are in a controlled locality.
9. Where the applicant identifies the premises from which they wish to provide pharmaceutical services, then that is the centre point to be used in undertaking the resident registered population count. The regulations refer to this as the 'relevant location'.
10. Where the applicant gives a best estimate then the decision-maker will need to have regard to that when estimating the likely location of the pharmacy. This location is then to be used as the centre point in undertaking the resident registered population count. The decision-maker should fully document how it determined this centre point.
11. Once the 'relevant location' has been determined this information is to be given to the primary care support service provider who will undertake the resident registered population count.
12. Representations on whether the 'relevant location' is within a reserved location or not will be sought when the application is notified to interested parties and will be taken into account by the decision-maker.
13. The reserved location determination is made based on the circumstances as they pertained on the day the application was received (regulation 41(2)).
14. The area within a 1.6km radius of the 'relevant location' is a reserved location if:
 - the number of individuals residing in the area which is within 1.6km of the 'relevant location' who are on a patient list (i.e. are registered with a GP practice, excluding temporary residents) is less than 2,750; and
 - NHS England is not satisfied that if pharmaceutical services were provided at the 'relevant location', 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.
15. Notice of the decision on the issue of reserved location status forms part of the notification of the decision to grant or refuse the application. The decision must be fully reasoned as the LPC, LMC, GP practices, LPS contractors or a person

on a pharmaceutical or dispensing doctor list who is notified of the decision can appeal it.

16. If the decision-maker determines that the 'relevant location' is within a reserved location this will only take effect if the application is granted and the pharmacy subsequently opens. If the application is refused or the pharmacy does not open then the reserved location determination falls.
17. Where a reserved location takes effect, then NHS England must:
 - delineate the boundary of the reserved location on a map,
 - publish that map, and
 - make that map available as soon as is practicable to the HWB that has all or part of that reserved location in its area.
18. At the point the reserved location takes effect, dispensing patients who live within it can remain as such with their dispensing practice but may also choose to have their prescriptions dispensed at a pharmacy, or both.

Additional steps for pharmacy applications in a controlled locality

19. This section of the chapter sets out the additional steps that are to be undertaken when processing a pharmacy application where the premises or best estimate is in, or within 1.6km of, a controlled locality.

Action	
1.	<p>Within the first referral questions for each type of routine application there are questions relating to controlled locality matters. Ensure they are included when you make the first referral.</p> <p>Where the decision-maker confirms that the premises/best estimate is not in a controlled locality, or near one, follow the relevant market entry procedure and go no further with this procedure.</p> <p>Where the decision-maker confirms the premises/best estimate is in a controlled locality move to step 2.</p> <p>Where the decision-maker confirms the premises/best estimate is near a controlled locality move to step 3.</p> <p>Where the decision-maker confirms that the application is to be deferred whilst a controlled locality determination is made move to step 4.</p>
2.	<p>Where the premises/best estimate is in a controlled locality, as soon as possible calculate the total GP registered population that resides within a 1.6 km radius of the proposed premises. Where the applicant has given a best estimate the decision-maker is to confirm the centre point to use for the 1.6km radius.</p>

Action

	<p>If the radius extends to an adjoining non-controlled locality, patients in this area should be included. Temporary residents should not be included.</p> <p>Identify each GP practice that has dispensing patients within 1.6 km of the proposed premises/best estimate and the number of such patients by practice.</p> <p>This information is to be included in the letter to interested parties and in the committee report that is prepared for the decision-maker and referred to in the market entry procedures.</p> <p>Update the interested party list to include the GP practices with dispensing patients within 1.6km of the proposed premises/best estimate and send it to the decision-maker for checking and sign-off. Move to step 5.</p>
3.	<p>Where the premises/best estimate is near a controlled locality, identify any GP practices that have dispensing patients within 1.6km of the premises/best estimate.</p> <p>Identify each GP practice that has dispensing patients within 1.6 km of the proposed premises/best estimate and the number of such patients by practice.</p> <p>This information is to be included in the committee report that is prepared for the decision-maker and referred to in the market entry procedures.</p> <p>Update the interested party list to include the GP practices with dispensing patients within 1.6km of the proposed premises/best estimate and send it to the decision-maker for checking and sign-off. Move to step 5.</p>
4.	<p>Where the decision-maker confirms the application is to be deferred pending a controlled locality determination, send Annex 1 to the applicant.</p> <p>Calculate the total GP registered population that resides within a 1.6 km radius of the proposed premises. Where the applicant has given a best estimate the decision-maker is to confirm the centre point to use for the 1.6km radius.</p> <p>If the radius extends to an adjoining non-controlled locality, patients in this area should be included. Temporary residents should not be included.</p> <p>Identify each GP practice that has dispensing patients within 1.6 km of the proposed premises/best estimate and the number of such patients by practice.</p> <p>No further action is required under this procedure until the determination has been made and the decision-maker advises the next steps. This may take a number of months, especially if there is an appeal.</p> <p>Where the outcome is that the premises/best estimate is not in a controlled locality send Annex 2. There are no further steps to take in relation to this procedure. Return to the relevant market entry procedure.</p>

Action	
	<p>Where the outcome is that the premises/best estimate is in a controlled locality send Annex 3.</p> <p>Identify the GP practices that have dispensing patients within 1.6km of the premises/best estimate. Update the list of interested parties, send to the decision-maker for checking and sign-off and move to step 5.</p>
5.	<p>Once it is known that the premises/best estimate is in a controlled locality, or is near one, but there is missing information, documentation or undertakings do not progress with this procedure until the application is complete. At that point move to step 6.</p>
6.	<p>Where the premises/best estimate is near a controlled locality move to step 12.</p> <p>Where the premises/best estimate is in a controlled locality move to step 7.</p>
7.	<p>Where the decision-maker has confirmed that regulation 40(2) does not apply move to step 11.</p> <p>Where the decision-maker has confirmed that regulation 40(2) does apply send Annex 4 to the applicant, diarise the date for their response and move to step 8.</p>
8.	<p>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) and any representations the applicant has made for a decision as to whether the application must be refused by virtue of that regulation.</p> <p>Move to step 9.</p>
9.	<p>If the decision-maker determines that the application is not to be refused by virtue of regulation 40(2) send Annex 5 to the applicant and move to step 11.</p> <p>If the decision-maker determines that the application is to be refused by virtue of regulation 40(2) send Annex 6 to the applicant.</p> <p>Diarise the latest date for an appeal to be made.</p> <p>If notice of an appeal is received advise the decision-maker and assist in the production of a response. Move to step 10.</p>
10.	<p>If there are no appeals, the application has been refused. Update the market entry tracker to reflect the outcome and advise the relevant pharmacy contracts manager. There are no further actions to be completed regarding this procedure.</p>

Action	
	<p>If the decision-maker's decision is upheld on appeal, i.e. the application is refused, update the market entry tracker. There are no further actions to be completed and this is the end of the process.</p> <p>If the decision-maker's decision is overturned on appeal, send Annex 7 to the applicant and move to step 11.</p>
11.	<p>When notifying the application under the relevant market entry procedure, use the text at Annex 8 so that representations are sought on all the matters that are to be considered. There are no further actions to be completed regarding this procedure.</p>

Additional steps for certain applications within 1.6km of a controlled locality

Action	
1.	<p>If an application is:</p> <ul style="list-style-type: none"> • made pursuant to Chapters 12 – 17 and 21; and • is for pharmacy premises where NHS England has confirmed that the address or best estimate is in a non-controlled locality but within 1.6km of a controlled locality, <p>go to step 2.</p>
2.	<p>Identify 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.</p> <p>If there are practices affected in this way, go to step 3.</p> <p>If there are no practices affected in this way, no further action is necessary pursuant to this procedure.</p>
3.	<p>Add the GP practices that have dispensing patients dispensing patients in the adjoining controlled locality within 1.6 km of the proposed premises or best estimate to the list of interested parties list and ask the relevant decision-maker to check and sign off the revised list.</p> <p>When notifying the application under the relevant market entry chapter, ensure the text at Annex 9 is used so that representations are sought on all the matters to be considered.</p>
4.	<p>If the application is granted either by NHS England and the notice of commencement is received, prepare lists of dispensing patients by practice</p>

Action

within 1.6km of the pharmacy (i.e. those who will be removed from dispensing lists) and send a letter to the pharmacy contract manager.

There are no further actions under this procedure.

CHAPTER 23

Procedures - Dispensing Doctors

Chapter aims and objectives

1. This chapter deals with issues relating to dispensing doctors, specifically the procedure for ensuring that applications for outline consent and/or premises approval are dealt with in accordance with the Regulations which also includes:
 - Relocations before outline consent takes effect; and
 - Relocations after outline consent takes effect;
2. This chapter must be read in conjunction with Part 8 of the Regulations and Chapter 15 of the DHSC 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. 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, where the practice has premises approval and either outline consent or historic rights to dispense to that area.

Procedure for Determining Applications for Outline Consent and Premises Approval

5. Where a doctor wishes to dispense to eligible patients in an area for which they do not already have premises approval and either historic rights or outline consent to dispense, they must first apply for outline consent and premises approval.

Action	
1.	On receipt of an application for outline consent and premises approval, check the details have been added to the market entry tracker. Ensure the tracker is updated as the application progresses.
2.	Annex 1 contains the template form for this type of application. 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. Send the 'first referral' to the decision-maker (Annex 2). Annex 3 will assist in identifying certain parties to be notified.

Action	
3.	<p>Where the decision-maker confirms the required information has been provided move to step 4.</p> <p>If the information has not been provided, send the request for further information (Annex 4). Allow five working days for receipt of the information.</p> <p>On receipt of the information move to step 4.</p> <p>If the information is not received by the due date advise the decision-maker.</p>
4.	<p>Where the decision-maker confirms that the area for which outline consent is sought is in a controlled locality or localities send Annex 5 and move to step 5.</p> <p>Where the decision-maker wishes to defer the application send Annex 6. No further action is required under this procedure until the determination has been made and the decision-maker advises the next steps. This may take a number of months, especially if there is an appeal. Once that matter is resolved return to this procedure, send Annex 7 and move to step 5.</p>
5.	<p>Notify interested parties of the application using Annex 8 copying in the relevant pharmacy contract manager. Do not circulate copies of patient requests to be dispensed that were submitted with the application.</p>
6.	<p>At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 9.</p>
7.	<p>Prepare a report (Annex 10) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contract manager.</p>
8.	<p>After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made.</p> <p>The granted letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 11); • Granted – to an interested party with no appeal rights (Annex 12); and • Granted – to an interested party with appeal rights (Annex 13). <p>The refused letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 14); and • Refused – to an interested party (Annex 15), <p>When the letters are completed send to the applicant and interested parties.</p>

Action	
	Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified and to whom.
9.	Diarise the latest date for appeals to be made.
10.	If notice of an appeal is received, advise the decision-maker and assist in the production of a response. If no notice of an appeal is received advise the relevant pharmacy contract manager.
11.	If, at the end of the 30-day appeal period, or once notification of the appeal decision is received, the application is not granted, ensure the market entry tracker has been kept up to date and enter the outcome of the application. 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 granted, go to the next step.
12.	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 step 13. If there are any outstanding applications, go to step 15.
13.	Where there are no outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises, advise the relevant pharmacy contract manager and send Annex 16 to the doctor.
14.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and inform (using Annex 17) the usual parties which includes the relevant: <ul style="list-style-type: none"> • LPC; • LMC; • HWB; • CCG; • NHSBSA; • The team that maintains the Exeter system; • Healthwatch; and

Action	
	<ul style="list-style-type: none"> • The CDAO.
15.	Where there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises advise the relevant pharmacy contract manager and send Annex 18.
16.	<p>Diarise the earliest date (the provisional date) that the doctor may request a determination as to when the outline consent is to take effect. This is the day after the end of the period of one year beginning on the day:</p> <ul style="list-style-type: none"> • NHS England determined the doctor's application, or • If that decision was appealed, the date on which NHS Resolution made its decision on the appeal.
17.	As soon as possible after the provisional date, send Annex 19 to the doctor.
18.	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 19 having been sent.
19.	<p>Check:</p> <ul style="list-style-type: none"> • With the relevant pharmacy contract manager 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. <p>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.</p> <p>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 22.</p>
20.	Send Annex 20 to the applicant.
21.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 17) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC; • LMC;

Action	
	<ul style="list-style-type: none"> • HWB; • CCG; • NHSBSA; • The team that maintains the Exeter system; • Healthwatch; and • The CDAO.
22.	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 21.
23.	Diarise the latest date for appeals to be made.
24.	If notice of an appeal is received advise the decision-maker and assist in the production of a response.
25.	<p>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, ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 17) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC; • LMC; • HWB; • CCG; • NHSBSA; • The team that maintains the Exeter system; • Healthwatch; and • The CDAO.
26.	If outline consent is not to take effect, ensure the market entry tracker has been kept up to date and enter the outcome of the application. No other actions are required.

Relocations before outline consent takes effect

6. 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	
1.	Annex 22 contains the template form for this type of application. On receipt of such an application ensure the details have been added to the market entry tracker. Ensure it is updated as the application progresses.
2.	Send the 'first referral' to the decision-maker (Annex 23). Annex 24 will assist in identifying certain parties to be notified.
3.	Notify interested parties of the application using Annex 25 copying in the relevant pharmacy contract manager.
4.	At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 26.
5.	Prepare a report (Annex 27) on the application for the decision-maker (set out in Chapter 3) and send to the pharmacy contract manager.
6.	<p>After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made.</p> <p>The granted decisions letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 28); • Granted – to an interested party with no appeal rights (Annex 29); and • Granted – to an interested party with appeal rights (Annex 30). <p>The refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 31); and • Refused – to an interested party (Annex 32). <p>When the letters are completed, send to the applicant and interested parties.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
7.	Diarise the latest date for appeals to be made.

Action	
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 granted, 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 granted, ensure the market entry tracker has been kept up to date and enter the outcome of the application. 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 13.
11.	Send Annex 33 to the doctor.
12.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and inform (using Annex 34) the usual parties which includes the relevant: <ul style="list-style-type: none"> • LPC; • LMC; • HWB; • CCG; • NHSBSA; • The team that maintains the Exeter system; • Healthwatch; and • The CDAO.
13.	If there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises send Annex 35.
14.	Put a note in the outstanding pharmacy application file and send Annex 36 when it reaches its final outcome.
15.	Diarise the date that premises approval will take effect should the pharmacy not open.

Action	
16.	<p>Put a note in the outstanding pharmacy application file to send Annex 37 to the doctor if the pharmacy opens.</p> <p>If the pharmacy does not open, send Annex 38 to the doctor one year after the outstanding pharmacy application reached its final outcome.</p>
17.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application. There are no further actions.</p>

Relocations after outline consent takes effect

7. 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	
1.	<p>Annex 39 contains the template form for this type of application.</p> <p>On receipt of such an application ensure the details have been added to the market entry tracker. Ensure the tracker is updated as the application progresses.</p>
2.	<p>Send the 'first referral' to the decision-maker (Annex 40).</p> <p>Annex 41 will assist in identifying certain parties to be notified.</p>
3.	<p>Notify interested parties of the application using Annex 42, copying in the relevant pharmacy contract manager.</p>
4.	<p>At the end of the 45-day notification period circulate representations to the applicant and those interested parties who responded using Annex 43.</p>
5.	<p>Prepare a report (Annex 44) on the application for the decision-maker (set out in Chapter 3) and send to the pharmacy contract manager.</p>
6.	<p>After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made.</p> <p>The granted decision letters are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 45); • Granted – to an interested party with no appeal rights (Annex 46); and • Granted – to an interested party with appeal rights (Annex 47).

Action	
	<p>The refused decision letters are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 48); and • Refused – to an interested party (Annex 49). <p>When completed, send to the applicant and interested parties.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified and to whom.</p>
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.	<p>If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is granted, go to the next step.</p> <p>If, at the end of the 30-day appeal period or once notification of the appeal decision is received, the application is not granted, ensure the market entry tracker has been kept up to date and enter the outcome of the application. No further actions are required.</p>
10.	<p>Check to see whether there are any outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises.</p> <p>If there are none, go to the next step.</p> <p>If there are any outstanding applications, go to step 13.</p>
11.	Send Annex 50 to the doctor.
12.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 51) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC; • LMC; • HWB; • CCG; • NHSBSA;

Action	
	<ul style="list-style-type: none"> • The team that maintains the Exeter system; • Healthwatch; and • The CDAO.
13.	If there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises send Annex 52.
14.	Put a note in the outstanding pharmacy application folder and send Annex 53 when it reaches its final outcome.
15.	Diarise the date that premises approval will take effect should the pharmacy not open.
16.	Put a note in the outstanding pharmacy application file to send Annex 54 to the doctor if the pharmacy opens. If the pharmacy does not open, send Annex 55 to the doctor one year after the outstanding pharmacy application reached its final outcome.
17.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application.

CHAPTER 24

Procedure - Directed Services

Chapter aims and objectives

1. The purpose of this procedure is to ensure that applications made under Regulation 23 to provide directed services (i.e. advanced and enhanced services) are dealt with in line with the Regulations.
2. Applications are to be determined within 30 days of receipt unless NHS England 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 as amended from time to time ("the Directions").
4. Applications may be submitted by contractors who are already included in a pharmaceutical list and wish to provide additional directed services. It should be noted, however, that requests to provide advanced services are more likely to be made under the Directions. Where that occurs, NHS England will follow the procedure in Chapter 35.
5. Template application form is provided at Annexes 1 and 2.
6. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list.

Procedure

Action	
1.	On receipt of a directed services application, add the details to the market entry tracker. Ensure the tracker is updated as the application progresses.
2.	Check that the application has been fully completed and that 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 set out at Annexes 1 and 2.
3.	Send the 'first referral' to the decision-maker (Annex 3)
4.	Where the decision-maker confirms the application is fully completed and all relevant information, documentation and undertakings have been provided, send Annex 4.

Action	
	<p>Include copies of the specifications for the enhanced services the applicant is applying to provide.</p> <p>Move to step 16.</p>
5.	<p>Where the decision-maker confirms that there is missing information and/or documentation in the application, move to step 6.</p> <p>Where the decision-maker confirms that there are missing undertakings in the application, move to step 12.</p>
6.	<p>Where there is missing information and/or documentation, send the request for missing information set out at Annex 5.</p> <p>The relevant timescale for information required by paragraph 1 of Schedule 2 to the Regulations is five working days.</p>
7.	<p>Diarise the date for the missing information/documentation to be submitted.</p>
8.	<p>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 and go to step 9.</p>
9.	<p>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 is five working days.</p> <p>If the information is provided, go to step 10.</p> <p>If the information is not provided, go to step 11.</p> <p>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 7) then go to step 16.</p>
10.	<p>On receipt of the missing information/documentation, send to the applicant an acknowledgement of receipt of missing information (Annex 8) and include copies of the specifications for the services the applicant is applying to provide if these have not already been provided.</p> <p>Go to step 16.</p>
11.	<p>If the missing information and/or documentation isn't received by the due date, send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 9). Advise the relevant pharmacy contract manager.</p>

Action	
	This is the end of the process.
12.	<p>Where there are missing undertakings in the application, send the acknowledgement of receipt of application and request for missing undertakings (Annex 10).</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is five working days.</p>
13.	Diarise the date for the missing undertakings to be submitted.
14.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11) and include copies of the specifications for the enhanced services the applicant is applying to provide if not already provided.</p> <p>Go to step 16.</p>
15.	<p>If the missing undertakings aren't received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 12). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
16.	<p>Check that payment has cleared. If it has cleared, go to step 18.</p> <p>If payment hasn't cleared, send a request for payment (Annex 13) to the applicant.</p>
17.	<p>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 withdrawn (Annex 14). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
18.	Once payment has cleared, prepare a report (Annex 15) for the decision-maker (set out in Chapter 3).
19.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The decision letter to the applicant where the application has been granted is provided at Annex 16.</p>

Action

	<p>The decision letter to the applicant where the application has been refused is provided at Annex 17.</p> <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
20.	<p>Diarise the latest date for appeals to be made where the application was refused.</p>
21.	<p>If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p>
22.	<p>If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 18 to the applicant.</p>
23.	<p>If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 19).</p>
24.	<p>Diarise the latest date by which the notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
25.	<p>If a request for an extension within which to open is received (Annex 20), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 21 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 26</p> <p>If the request is refused send Annex 22 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 26.</p>

Action	
	<p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 26.</p>
26.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 23 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 24 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send annex 25 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 26.</p> <p>Where it is not, send Annex 27.</p>
27.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 28) the usual parties which includes:</p> <ul style="list-style-type: none"> • The LPC • The HWB • Public health team, • DoS lead, and • The Primary Care Support Service provider’s pharmacy payments team and the data manager.

CHAPTER 25

Procedure - Temporary Listing Arising from Suspension

Chapter aims and objectives

1. The purpose of this chapter 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. Pharmacies which operate under a LPS contract are not included in a pharmaceutical list and therefore no temporary listing application may be made under Regulation 27.
3. Applications are to be determined within 30 days of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
4. This chapter must be read in conjunction with the Regulations (and, in particular Regulation 27).
5. A template application form is provided at Annex 1.
6. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list
7. 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 27.

Procedure

Action	
1.	On receipt of an application for a temporary listing arising out of a suspension, add the details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.
3.	Check that the application has been fully completed and that all relevant information, documentation and undertakings have been provided. This is

Action	
	<p>particularly important if the applicant has not used the national application forms – Annex 1 and 2.</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	Send the 'first referral' to the decision-maker (Annex 3).
5.	<p>Where the decision-maker confirms the application is fully completed and all relevant information, documentation and undertakings have been provided send an acknowledgement of receipt of the application (Annex 4).</p> <p>Where the applicant is required to provide enhanced services, include copies of the specifications for these services where these have been provided by the decision-maker.</p> <p>Move to step 18.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings, move to step 14.</p>
7.	<p>Where there is missing information and/or documentation complete and send the request for missing information set out at Annex 5.</p> <p>The timescales to be set out in the request to provide the missing information are:</p> <ul style="list-style-type: none"> • submission of the required fitness information – 10 working days; and • information required by paragraph 1 of Schedule 2 to the Regulations – five working days. <p>Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.</p>
8.	Diarise the date for the missing information/documentation to be submitted.

Action	
9.	If the applicant asks for a review of a request for missing information/documentation, forward this to the decision-maker (set out in Chapter 3) for a decision.
10.	<p>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 6) then go to step 14.</p> <p>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 7). The timescales for providing the information are as set out in step 7 above.</p>
11.	<p>On receipt of the information/documentation, send an acknowledgement of receipt of the missing information/documentation (Annex 8).</p> <p>Where the applicant is required to provide enhanced services, include copies of the specifications for these services if they have not already been provided.</p> <p>Go to step 17.</p>
12.	<p>If the missing information and/or documentation is not received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 9). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings complete and the acknowledgement of receipt of the application and request for missing undertakings (Annex 10)</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is five working days.</p>
14.	Diarise the date for the missing undertakings to be submitted.
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11).</p> <p>Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided.</p> <p>Go to step 17.</p>

Action	
16.	<p>If the missing undertakings are not received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 12). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known and where the application is complete move to step 18.</p>
18.	<p>On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 13) for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.</p>
19.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The decision letters where the application has been granted are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 14) and include Annex 15 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 16); and • Granted – to a third party with appeal rights (Annex 17). <p>The decision letters where the application has been refused are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 18); and • Refused – to a third party (Annex 19). <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
20.	<p>Diarise the latest date for appeals to be made.</p>
21.	<p>If notice of an appeal is received, advise the decision-maker and assist in producing a response.</p>

Action	
22.	<p>If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 20 to the applicant.</p> <p>Include a copy of the banking mandate.</p>
23.	<p>If no appeal is made and the application was granted, advise the decision-maker and send Annex 21 to the applicant. Include a copy of the banking mandate.</p>
24.	<p>Diarise the latest date by which the notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
25.	<p>If a request for an extension within which to open is received (Annex 22), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 23 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 26.</p> <p>If the request is refused send Annex 24 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 26.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 26.</p>
26.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 25 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 26 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application

Action	
	<ul style="list-style-type: none"> • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 27 to the applicant.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 28.</p> <p>Where it is not, send Annex 29.</p>
27.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
28.	Send the notification of NHS Pharmacy Contractor Code (Annex 30) advising the applicant of their contractor number when received from NHS Prescription Services.
29.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 31) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.
30.	NHS England will confirm as and when the suspension is lifted and the date that the applicant is to be removed from the relevant pharmaceutical list. At

Action

that point send Annex 32 to the applicant, complete the relevant NHS Prescription Services form and send to NHS Prescription Services

Update other databases as appropriate and inform (using Annex 33) the usual parties which includes the usual parties which includes the relevant:

- LPC,
- HWB,
- CCG,
- Public health team,
- DoS lead,
- Unwanted medicines collection and disposal contractor,
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 26

Procedure - Exercising a Right of Return

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications exercising a right of return to a pharmaceutical list are dealt with in line with the Regulations.
2. Applications are to be determined within 30 days of receipt unless NHS England has good cause to take longer.
3. This chapter 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 template application form is provided at Annex 1
7. The information in the template form at Annex 2 must be included in all routine and excepted applications for inclusion in a pharmaceutical list
8. In accordance with direction 3(b)(ii) of the Directions, no fee is payable in respect of an application under Regulation 28.

Procedure

Action	
1.	On receipt of a right to return application, add the details to the market entry tracker. Ensure the tracker 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. Refer to the relevant chapter of the manual relating to this and progress both elements of the application together.

Action	
3.	<p>Check that the application has been fully completed and that all relevant information, documentation and undertakings have been provided.</p> <p>This is particularly important if the applicant has not used the national application forms – Annexes 1 and 2.</p> <p>It should be noted that where the applicant is not already included in the pharmaceutical list in respect of other premises and so has provided the fitness information in connection with this application it is not necessary for them to complete Annex 2 as they will have already provided that information in the fitness form. However, if they are relying on fitness information that was provided in connection with a previous application, then Annex 2 should be completed so that it can be compared to the previously provided fitness information.</p>
4.	Send the 'first referral' to the decision-maker (Annex 3).
5.	<p>Where the decision-maker confirms the application is fully completed and all relevant information, documentation and undertakings have been provided send acknowledgment of receipt of the application (Annex 4) to the applicant.</p> <p>Where the applicant undertakes to provide enhanced services, include copies of the specifications for these services where these have been provided by the decision-maker. Move to step 17.</p>
6.	<p>Where the decision-maker confirms that there is missing information and/or documentation, move to step 7.</p> <p>Where the decision-maker confirms that there are missing undertakings, move to step 14.</p>
7.	<p>Where there is missing information and/or documentation complete and send Annex 5.</p> <p>The relevant timescales are as follows:</p> <ul style="list-style-type: none"> • submission of the required fitness information – 10 working days; and • information required by paragraph 1 of Schedule 2 to the Regulations – five working days.
8.	Diarise the date for the missing information/documentation to be submitted.
9.	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.

Action	
10.	<p>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 6) then go to step 14.</p> <p>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 7). The timescales for providing the information are as set out in step 7 above.</p>
11.	<p>On receipt of the information/documentation, send to the applicant an acknowledgement of receipt of the missing information/documentation (Annex 8).</p> <p>Where the applicant is required to provide enhanced services, include copies of the specifications for these services if these have not already been provided. Go to step 17.</p>
12.	<p>If the missing information and/or documentation is not received by the due date send confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 9). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
13.	<p>Where there are missing undertakings complete and send the acknowledgement of receipt of the application and request for missing undertakings (Annex 10)</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is five working days.</p>
14.	<p>Diarise the date for the missing undertakings to be submitted.</p>
15.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11).</p> <p>Where the applicant is required to provide enhanced services, include copies of the specifications for these services if not already provided. Go to step 17.</p>
16.	<p>If the missing undertakings are not received by the due date send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 12). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>

Action	
17.	<p>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. Refer to the relevant chapter (5 to 10).</p> <p>Once the outcome of the deferral is known and where the application is complete move to step 18.</p>
18.	<p>On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 13) for the decision-maker (set out in Chapter 3).</p>
19.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The decision letters where the application has been granted are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 14) and include Annex 15 where advised to do so by NHS England; • Granted – to a third party with no appeal rights (Annex 16); and • Granted – to a third party with appeal rights (Annex 17). <p>The decision letters where the application has been refused are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 18); and • Refused – to a third party (Annex 19). <p>If granted, complete as far as possible the notice of commencement.</p> <p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
20.	<p>Diarise the latest date for appeals to be made.</p>
21.	<p>If notice of an appeal is received, advise the decision-maker and assist in producing a response.</p>
22.	<p>If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 20 to the applicant (including a copy of the banking mandate).</p>
23.	<p>If no appeal is made and the application was granted, advise the decision-maker and send Annex 21 to the applicant. Include a copy of the banking mandate.</p>

Action	
24.	<p>Diarise the latest date by which the notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
25.	<p>If a request for an extension within which to open is received (Annex 22), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 23 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 26.</p> <p>If the request is refused send Annex 24 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 26.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 26.</p>
26.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 25 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 26 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 27.</p>

Action	
	<p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 28.</p> <p>Where it is not, send Annex 29.</p>
27.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
28.	Send the notification of NHS Pharmacy Contractor Code (Annex 30) advising the applicant of their contractor number when received from NHS Prescription Services.
29.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 31) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 27

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 NHS England 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.
4. This chapter is not relevant to pharmacies operating under a LPS contract as they are not included in a pharmaceutical list.

Declared emergencies

5. 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 – NHS England must, for a specified period, exercise (or consider exercising) one or more of its functions under various provisions of the Regulations.
6. In the case of such an emergency, NHS England 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.
7. A template application form is provided at Annex 1.
8. The information in the template form at Annex 2 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, NHS England 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.

Fees

14. In accordance with direction 3(b)(iii) of the Directions, no fee is payable in respect of an application under Regulation 29.

Procedure

Action	
1.	On receipt of an application, add the details to the market entry tracker. Ensure the database is updated as the application progresses.
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 1 and 2).
3.	Send the 'first referral' to the decision-maker (Annex 3).

Action	
4.	<p>Where the decision-maker confirms the application is fully completed and all relevant information, documentation and undertakings have been provided, send an acknowledgement of receipt of application (Annex 4).</p> <p>Move to step 16.</p>
5.	<p>Where the decision-maker confirms that there is missing information and/or documentation, move to step 6.</p> <p>Where the decision-maker confirms that there are missing undertakings, move to step 13.</p>
6.	<p>Where there missing information and/or documentation complete and send Annex 5.</p> <p>The relevant timescales are as follows:</p> <ul style="list-style-type: none"> • submission of the required fitness information – 10 working days; and • information required by paragraph 1 of Schedule 2 to the Regulations – five working days.
7.	<p>Diarise the date for the missing information/documentation to be submitted.</p>
8.	<p>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.</p>
9.	<p>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).</p> <p>The timescales for providing the information are as set out in step 6 above.</p> <p>If the information is provided, go to step 16. If the information is not provided go to step 11.</p> <p>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 7) then go to step 16.</p>
10.	<p>On receipt of the information/documentation send to the applicant an acknowledgement of receipt of the missing information/documentation (Annex 8).</p> <p>Go to step 16.</p>
11.	<p>If the missing information and/or documentation is not received by the due date, send to the applicant confirmation that the information/documentation</p>

Action	
	<p>has not been received and the application is therefore being treated as withdrawn (Annex 9). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
12.	<p>Where there are missing undertakings complete and send the acknowledgement of receipt of the application and request for missing undertakings (Annex 10)</p> <p>The timescale to be set out in the request to provide the undertakings required by paragraph 9 of Schedule 2 of the Regulations is five working days.</p>
13.	<p>Diarise the date for the missing undertakings to be submitted.</p>
14.	<p>On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11).</p> <p>Go to step 16.</p>
15.	<p>If the missing undertakings are not received by the due date, send confirmation that the missing undertakings have not been received and that the application is being treated as withdrawn (Annex 12). Advise the relevant pharmacy contract manager.</p> <p>This is the end of the process.</p>
16.	<p>Prepare a report (Annex 13 for declared emergencies and Annex 14 for the temporary suspension of pharmaceutical services) for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.</p>
17.	<p>After the meeting, prepare the relevant decision letters and enclose the decision report provided by the decision-maker.</p> <p>The decision letters where the application has been granted are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 15) and include Annex 16 where advised to do so by NHS England; • Granted – to a third party (Annex 17); <p>The decision letters where the application has been refused are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 18); and • Refused – to a third party (Annex 19). <p>If granted, complete as far as possible the notice of commencement.</p>

Action

	<p>When the letters are completed distribute to the applicant and interested parties enclosing the notice of commencement where relevant with the applicant's letter.</p> <p>Copy the relevant pharmacy contract manager into the emails or where the decision is notified by post advise the relevant pharmacy contract manager that the decision has been notified.</p>
18.	<p>Diarise the latest date by which the template notice of commencement can be submitted.</p> <p>If no notice of commencement is received advise the relevant pharmacy contract manager.</p>
19.	<p>If a request for an extension within which to make the change is received (Annex 20), pass it to the relevant decision-maker for a decision.</p> <p>If the request is granted send Annex 21 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Move to step 20.</p> <p>If the request is refused send Annex 22 to the applicant. If notice of an appeal is received, advise the decision-maker and assist in the production of a response.</p> <p>If the outcome of the appeal is that the extension is granted, diarise the latest date by which the notice of commencement can be submitted. Move to step 21.</p> <p>If the outcome of the appeal is that the request is refused and the latest date by which the notice of commencement can be submitted has passed, this is the end of the process.</p> <p>If the outcome of the appeal is that the request is refused, but the applicant still has time to submit a notice of commencement move to step 21.</p>
20.	<p>On receipt of a completed notice of commencement check the following points:</p> <ul style="list-style-type: none"> • It has been received within the six-month grant period or such longer time as NHS England or NHS Resolution has allowed. Send Annex 23 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be within 14 days of the date on which the notice was received. Send Annex 24 where it has been submitted more than 14 days before the commencement date. • The address is the same as the one in the original application • The superintendent pharmacist is the same as the one named in the original application

Action	
	<ul style="list-style-type: none"> • The date of the grant of the application (which may have been on appeal by NHS Resolution) • The GPhC premises registration number – this can be checked on the GPhC website. Where it is not yet showing on the register email the GPhC for confirmation of registration. • The notice is signed and dated. <p>If any information is missing or incorrect, send Annex 25.</p> <p>Where no issues are identified forward it to the relevant decision-maker for confirmation it is valid.</p> <p>Where it is valid send Annex 26.</p> <p>Where it is not, send Annex 27.</p>
21.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
22.	<p>Ensure the market entry tracker has been kept up to date and enter the outcome of the application.</p> <p>Update other databases as appropriate and inform (using Annex 28) the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.
23.	<p>Where the application relates to temporary arrangements due to a declared emergency, the procedure ends here.</p> <p>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.</p>
24.	Diarise the date on which the temporary arrangements are to end.

Action	
25.	One month before, send Annex 29 to the applicant.
26.	If the applicant requests an extension, prepare a report (Annex 30) on the application for the decision-maker (set out in Chapter 3) and send to the relevant pharmacy contracts team.
27.	<p>After the meeting, prepare the relevant decision letters.</p> <p>The decision letters where the application has been granted are:</p> <ul style="list-style-type: none"> • Granted – to the applicant (Annex 31) and include Annex 16 where advised to do so by NHS England; • Granted – to a third party (Annex 32); <p>The decision letters where the application has been refused are:</p> <ul style="list-style-type: none"> • Refused – to the applicant (Annex 33); and • Refused – to a third party (Annex 34). <p>When the letters are completed distribute to the applicant and interested parties.</p>
28.	If an extension is granted diarise the date on which the temporary arrangements are to end. One month before, send Annex 35 to the applicant.
29.	<p>On the date the temporary arrangement comes to an end send Annex 36 to the applicant, and inform the usual parties (using Annex 37) which includes the relevant:</p> <ul style="list-style-type: none"> • LPC, • HWB, • CCG, • Pharmacy contracts manager, • Public health team, • DoS lead, • Unwanted medicines collection and disposal contractor, • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and • Any other organisation for which the relevant pharmacy contract manager has provided contact details for.

CHAPTER 28

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 the end of the chapter. The guidance goes on to look at each of the duties in more detail

Equality duties

- A key concept of the Equality Act 2010 is the protection of certain personal characteristics, namely: age; disability; gender reassignment; marriage and civil partnership; pregnancy and maternity; race; religion or belief; sex; and sexual orientation. These are known as “the protected characteristics”.
- The Equality Act 2010 prohibits unlawful discrimination in the provision of services and the exercise of public functions.
- The Equality Act 2010 also 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).

- Not every protected characteristic is “relevant” to discrimination in the provision of services/exercise of public functions or to the PSED. This is explained further in the detailed guidance below.

The "Regard Duties"

- The "Regard Duties" are the duty to have regard to the:
 - 1..4 need to reduce health inequalities (see section 13G of the NHS Act 2006)
 - 1..5 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 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 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 the duty to act with a view to:
 - 1..8 delivering services in a way that promotes the NHS constitution (see section 13C(1)(a) of the NHS Act 2006)
 - 1..9 securing continuous improvement in the quality of services in health and public health services (see section 13E of the NHS Act 2006)
 - 1..10 enabling patients to make choices about their care (see section 13I of the NHS Act 2006)
 - 1..11 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 the duty to promote:
 - 1..12 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 involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)
- 1..14 innovation in the health service (see section 13K of the NHS Act 2006)
- 1..15 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

- NHS England must, in the exercise of its functions, have regard to the need to reduce inequalities between patients with respect to:
 - 19..1 their ability to access health services, and

- 19..2 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

- A key concept of the Equality Act 2010 is the protection of certain personal characteristics, namely:
 - 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
- Not every protected characteristic is “relevant” to discrimination in the provision of services/exercise of public functions or to the PSED.

Unlawful discrimination

- The Equality Act 2010 prohibits unlawful discrimination in the provision of services and the exercise of public functions on the grounds of a protected characteristic. However, this does not apply to the protected characteristics of age (in relation to people who are under 18 years old) or marriage and civil partnership.
- There are broadly four types of discrimination in the provision of services and exercise of public functions that are unlawful under the Equality Act 2010:
 - 2..10 Direct discrimination - services are not available to someone because they are, for example, over 35 or 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 applies 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, for example, 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.

Marriage and civil partnership is not a "relevant protected characteristic" for the purposes of the PSED; however, the PSED applies to all other protected characteristics.

- 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 cost 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, for example, a year's time.

- There are a few themes arising from the cases that have been 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 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 available to how a court would interpret NHS England's Regard Duties. From these it can be learned 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:

- 19..1 reduce inequalities between patients with respect to their ability to access health services, and
 - 19..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 making 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 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 the duty to promote:

- 4..1 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 involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)
 - 4..3 innovation in the health service (see section 13K of the NHS Act 2006)
 - 4..4 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, for example, 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.
 - NHS England has published guidance on involving people in their own health and care (<https://www.england.nhs.uk/publication/involving-people-in-their-own-health-and-care-statutory-guidance-for-clinical-commissioning-groups-and-nhs-england/>)

5. The view to duties

- The "View To Duties" are the duty to:
 - 5..1 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 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 act with a view to enabling patients to make choices about their care (see section 13I of the NHS Act 2006)
 - 5..4 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 that 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 primary medical, dental, ophthalmic and pharmaceutical services (which include Local 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's Patient and Public Participation Policy](#) sets out its ambition to put patients and the public at the heart of everything it does
- NHS England has published a set of documents, known as 'frameworks' to strengthen patient and public participation in the services that it is responsible for commissioning. For pharmaceutical services, the relevant document is the [Framework for patient and public participation in primary care commissioning](#).
- NHS England has published detailed [guidance](#) on patient and public participation in commissioning health and care, which includes NHS England process for assessing whether the involvement duty applies and how to document plans for public involvement.

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 and 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 ceasing to commission a particular service from pharmacies. It is sometimes (but not always) possible to 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 departing 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.

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.

CHAPTER 29

Decision Making

Chapter aims and objectives

1. The purpose of this chapter is to ensure that routine and excepted applications are dealt with in line with the Regulations.
2. In general routine and excepted applications will be received and processed by the Primary Care Support Service Provider. Any applications received directly by NHS England should be forwarded on. Whilst applications are processed there will be times when a decision or decisions need to be made by NHS England in line with chapter 3. This chapter identifies those times and provides additional information for NHS England to consider. It also identifies when NHS England will be notified of progress.
3. Applications are to be determined within 30 days (applications which are not notified to interested parties) or four months (applications which are notified) unless NHS England has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.
4. This chapter must be read in conjunction the Regulations and the relevant chapter of the DHSC guidance.

Receipt and first referral

5. Routine and excepted applications are to be received by the Primary Care Support Service Provider who will process them on behalf of NHS England.
6. On receipt, an initial check will be undertaken to ensure that all the required forms have been submitted and that all relevant sections are completed. This will be undertaken by the Primary Care Support Service Provider who will then send a 'first referral' to the relevant NHS England pharmacy contracts team i.e. the team in whose area the proposed premises or best estimate is located.
7. The decision-maker (see Chapter 3) will need to consider the questions asked in the first referral and respond to the Primary Care Support Service Provider within five working days. The questions will cover topics such as:
 - Issues relating to rurality
 - Whether the best estimate is acceptable
 - Whether there is any missing information, documentation or undertakings (the Primary Care Support Service Provider will have provided a preliminary view on this but it is for NHS England to confirm if anything is missing),
 - Whether there are any grounds for deferring the application as set out in the pertinent regulations
 - Confirmation of any enhanced services that are commissioned, and
 - Sign-off of the list of interested parties (notifiable applications only).

8. When considering whether the application should be deferred the decision-maker should refer to the relevant DHSC guidance chapter.
9. The decision-maker should ensure that all decisions are robustly documented in case of a subject appeal or challenge.
10. Where the application is for a no significant change relocation the decision-maker will need to check whether the pharmacy is one that previously applied under the 'out of town retail area' exemption (pre September 2012). The list of retail areas approved by the Secretary of State for Health can be found [here](#) (select 'Control of entry' on the left-hand side of the screen).
11. It should be noted that contractors who hold a LPS contract may not submit a change of ownership, a significant change relocation, a combined change of ownership application or a significant change relocation application as they and the premises are not included in the relevant pharmaceutical list. One of the first referral questions for these types of application will ask whether the applicant holds a LPS contract.

Interested parties

12. Determining the parties who must be notified of applications pursuant to paragraph 19 of Schedule 2 to the Regulations is the responsibility of the decision-maker set out in Chapter 3.
13. The following paragraphs will help the decision-maker to identify 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.
14. The following paragraphs will not cover every potential scenario and therefore ultimate responsibility to determine who is to be notified of an application rests with the decision-maker.
15. Where the decision-maker is reasonably satisfied that the distances shown in the paragraphs below will include persons who would not be significantly affected or who would not have a significant interest, the distances can be reduced to an appropriate level. Conversely, if the distances do not identify any persons then they may be increased accordingly. When identifying contractors who may be significantly affected by the grant of the application, NHS England may wish to look at practice prescribing dispensing data which is published by the [NHSBSA](#) on a monthly basis as this shows where prescriptions written by GP practices are dispensed.

Contractors included in a pharmaceutical list (paragraph 19(1)(c)(i))

16. Contractors included in one of the pharmaceutical lists should be considered to be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises or best estimate lie in a locality that is not controlled, the contractor's premises are within 2km in a direct line from the applicant's proposed premises or best estimate, or
 - where the applicant's proposed premises or best estimate lie in a controlled locality, the contractor's premises are located within 8km in a direct line from the applicant's proposed premises or best estimate.

Head offices of bodies corporate are also to be notified where this information is known.

Currently, the NHS website is used to identify these contractors. The decision-maker should be aware that this search will not identify distance-selling premises as these are listed separately on the NHS website. The decision-maker will therefore need to identify any distance-selling premises that fall within the above distances or are considered to be significantly affected.

Persons entitled to be included in a pharmaceutical list (paragraph 19(1)(c)(ii))

17. Persons whose applications for inclusion have been granted (but who are yet to be included) should be considered to be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises or best estimate lie in a locality that is not controlled, the person's proposed premises are located within 2km in a direct line from the applicant's proposed premises or best estimate, or
 - where the applicant's proposed premises or best estimate lie in a controlled locality, the person's proposed premises are located within 8km in a direct line from the applicant's proposed premises or best estimate.

Local pharmaceutical services (LPS) contractors (paragraph 19(1)(d))

18. LPS contractors should be considered to be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises or best estimate lie in a locality that is not controlled, the LPS contractor's premises are located within 2km in a direct line from the applicant's proposed premises or best estimate, or
 - where the applicant's proposed premises or best estimate lie in a controlled locality, the LPS contractor's premises are located within 8km in a direct line from the applicant's proposed premises or best estimate.

Patient, consumer or community groups in the HWB area (paragraph 19(1)(e))

19. The following groups should be considered to have a significant interest in the outcome of the application and be notified:
- where the applicant's proposed premises are in a controlled locality, the relevant Parish Council;

- where the application offers to provide unforeseen benefits for a specific patient group, any group that is representative of that group of patients.

GP practices (paragraph 19(1)(f)(i))

20. For routine pharmacy applications, dispensing practices that have dispensing patients within 1.6km of the applicant's proposed premises or best estimate should be considered to have a significant interest in the outcome of the application and should be notified of it.
21. For excepted pharmacy applications that include a relocation that does not result in significant change and distance selling premises applications, dispensing practices that have dispensing patients within 1.6km of the applicant's proposed premises or best estimate should be considered to have a significant interest in the outcome of the application and should be notified of it.
22. It is not envisaged that dispensing practices will have a significant interest in the outcome of other types of notifiable applications and therefore need not routinely be notified of them. Ultimately though it is for the decision-maker to decide on a case by case basis.

GP performers included in the dispensing doctor list (paragraph 19(1)(f)(ii))

23. GP performers included in the dispensing doctors list that have dispensing patients within 1.6km of the proposed premises or best estimate should be considered to have a significant interest in the outcome of the application and should be notified of it (if the practice has not already been notified under paragraph 19(1)(f)(i)).

Any other person (paragraph 19(2))

24. Any other person who NHS England believes has a significant interest in the outcome of the application may be notified of it. This may include other applicants who have also submitted the same type of application for the same location but who do not fall within any of the above paragraphs.

Explanatory note for patient, consumer or community groups

25. In order to help these groups understand why they are being notified of the application, the PCM will need to complete the relevant explanatory note and send it to the Primary Care Support Service Provider for inclusion with the notification letter. The cover letter for the explanatory note is already part of the notification letter and therefore doesn't need to be sent with the explanatory note.
26. The explanatory notes can be found in Annexes 1 to 11 of this chapter. Supplementary questions relating to pharmacy applications in controlled localities can be found in annex 12.

Best estimates

27. NHS England must be satisfied that the applicant has given their best estimate of the proposed location of their premises. In coming to this decision NHS England must be satisfied that:
- It is the best estimate that the applicant can reasonably make at that time and,
 - That the reasons for granting or refusing the application would essentially be the same if the applicant located at any location within the range of possible locations covered by the estimate, if the application was granted.
28. Statements such as “in the vicinity of” and “within 100m of the junction of the High Street and Church Lane” are likely to cause issues if the application is granted and the applicant subsequently notifies the address at which they intend to open. They may also cause difficulties if they mean that it is not possible to identify if the best estimate is in a controlled locality or not, or if it straddles the boundary between two HWB areas. Best estimates that are worded in these ways are therefore unlikely to be acceptable.
29. NHS England must fully document its reasons for not accepting a best estimate and this reasoning must be provided to the applicant in order that an acceptable best estimate may be provided. Where NHS England is not satisfied that it is the best estimate that the applicant can give this will be treated as ‘missing information’ under paragraph 11, Schedule 2 of the Regulations.

More than 40 core opening hours

30. Where a pharmacy applicant undertakes to provide pharmaceutical services for more than 40 core opening hours as part of their application a conversation will need to take place with them in order to agree which are the 40 core opening hours and which are the additional opening hours. Agreement is to be reached with the applicant as to the times and days of the additional directed opening hours.

Review of missing information

31. Where missing information is identified the Primary Care Support Service Provider will request this from the applicant. On occasion the applicant may ask for a review of this request and this will be passed to the decision-maker for consideration. The Primary Care Support Service Provider will advise the applicant of the decision.

Failure to provide missing information and/or undertakings

32. Where an applicant fails to provide information and/or undertakings that have been identified as missing by the specified timescale the application is treated as withdrawn in line with the Regulations. The Primary Care Support Service Provider will advise the decision-maker of this.

Notification to interested parties

33. The Primary Care Support Service Provider will advise the decision-maker when the application is notified to interested parties.

When should applications be heard together?

34. Where NHS England is presented with more than one application offering to meet the same current or future need, or to secure the same current or future improvements or better access, it may consider that it is reasonable to hear the applications together.
35. The Regulations do not set out when in the application process a decision should be made to hear applications together. NHS England has to exercise case management judgement without full knowledge of what applications may or may not be made in the future, or how long in the future they will be made and, once made, will be ready for determination.
36. If applications are not received together, hearing applications together could lead to a delay in the determination of the first application (given the need to notify interested parties of the second application) and detrimentally affect the first application if the applications are refused on the basis of the cumulative effect.
37. NHS England considers that it is usually reasonable and fair to adopt a cut off time after which a received application will not be considered together with a previously received application. If a second application is received after 30 days of the date that the first application was notified to interested parties, then NHS England will usually consider that it is not appropriate to hear the applications together. There may be circumstances in which a different approach is to be taken and it is for each decision maker to consider whether it is reasonable to determine the applications together and fully document the reasons why.

Oral hearings

38. At the end of the 45-day notification period the Primary Care Support Service Provider will send copies of the representations that have been received to the decision-maker who will then decide whether an oral hearing is to be arranged or whether the application can be determined on the papers.
39. When an oral hearing is to be held the decision-maker is responsible for setting the date and time and sourcing a venue. This information is then to be passed to the Primary Care Support Service Provider who will advise the applicant and any additional presenters who the decision-maker wishes to invite.
40. The following is an extract from paragraphs 63 to 67 of Chapter 13 of the DHSC Guidance (with references to the provisions of the Regulations removed).
41. Oral hearings are not required to be held for every application decision and NHS England should make a judgement on when it is necessary to do so. This is likely to be based on the complexity of the application, previous applications in the area

and any appeals, particularly upheld appeals, to NHS Resolution regarding those applications, and the number and type of representations made in respect of the application from those notified of it.

42. If NHS England decides to hear oral representations prior to determining an excepted application it must:
 - Give the applicant and any additional presenters not less than 14 days' notice of the time and place for the oral hearing; and
 - Advise the applicant who else has been invited to make representations at the hearing. This may include other applicants where NHS England has decided to determine two or more applications together.
43. The Regulations define a person as an additional presenter if:
 - The application to which the hearing relates is a notifiable application;
 - They were given notice of the application and made representations. As part of the representations, the person must have indicated that they would wish to make oral representations if an oral hearing took place, and they must have identified a matter about which NHS England considers it would be desirable to hear further evidence about from the person at the oral hearing; and
 - NHS England is satisfied that the person made a reasonable attempt to express their views on the application in their written representation.
44. The decision-maker must therefore take a view, based on written representations on whether the application should be refused or granted, and the reasoning for that view. It is for NHS England to then decide whether they wish to hear further evidence on those reasons at the oral hearing. It should be noted that where an interested party simply says they would wish to attend an oral hearing without giving a view on the application this is not sufficient. If a person notified of an application does not state in their written representations that they would wish to make oral representations, NHS England is not required to invite them to an oral hearing if it decides to hold one.
45. If NHS England decides at or after the oral hearing that an application is to be deferred, it may hold a further oral hearing once the period of deferral has expired if it so wishes. This is a matter for NHS England to make a decision on and it is not obliged to hold a further hearing.

Non-payment of fee

46. The Primary Care Support Service Provider will ensure that payment is received and cleared before a decision is made on the application. Should the first payment fail then the Primary Care Support Service Provider will request a second payment. If this fails then the application will be treated as withdrawn and the decision-maker notified accordingly.

Application report

47. The Primary Care Support Service Provider will partially complete the template report and will pass it to NHS England for completion. Due regard should be given

to the relevant regulations and DHSC guidance chapter in the completion of the report.

Determination

48. The decision-maker is responsible for ensuring that all relevant regulations are considered and that decisions are fully documented and minuted. It is not good enough to simply say that an application has been granted or refused.
49. Where an application is considered that is not in a controlled locality then the order that the regulations are to be considered in is as follows:
 - Regulation 31 – same or adjacent premises
 - Regulation 32 – LPS designation (routine applications only)
 - Application-specific regulations
50. For applications that are in a controlled locality:
 - Regulation 40 – 5 year bar (routine applications for pharmacies only)
 - Regulation 31 – same or adjacent premises
 - Regulation 32 – LPS designations (routine applications only)
 - Regulation 41 – reserved location (routine applications for pharmacies only)
 - Regulation 44 – prejudice test if the premises/best estimate not in a reserved location (routine applications for pharmacies only)
 - Application-specific regulations
 - Regulation 50 – gradualisation (only if a routine application for a pharmacy is granted and no reserved location is determined)
51. For applications that are within 1.6km of a controlled locality:
 - Regulation 31 – same or adjacent premises
 - Regulation 32 – LPS designations (routine applications only)
 - Application-specific regulations
 - Regulation 50 – gradualisation (only if the application is granted)
52. Where a regulation is not relevant this must be fully documented.
53. A decision report is to be prepared, in a PDF format, in respect of each application that is determined and sent to the Primary Care Support Service Provider who will include it with the decision letters.

Core opening hours conditions – granted applications

54. Pharmacy applicants may undertake to provide pharmaceutical services for more than 40 core opening hours as part of their application. The wording below is to be added to the decision report:
 - “The applicant undertakes to provide pharmaceutical services at the proposed pharmacy premises for more than 40 core opening hours per week,
 - The applicant and NHS England have agreed that pharmaceutical services are to be provided at the proposed pharmacy premises during those

additional opening hours that exceed the 40 core opening hours at set times and on set days, and

- The application was granted having regard to that undertaking and that agreement.
- The applicant has confirmed that the 40 core opening hours are [*insert times and days*].
- The applicant and NHS England have agreed that the additional opening hours are [*insert times and days*].

55. As and when the applicant is included in the relevant pharmaceutical list a direction will need to be issued in respect of the additional opening hours. See paragraph 79 below.

Conditions relating to providing directed services

56. Pharmacy applicants may undertake to provide specified directed services as part of their routine or excepted application where commissioned by NHS England in the circumstances set out in regulation 66(4) to (5). Where an application is granted, inclusion of the applicant is subject to the condition set out in regulation 66(5) and the wording in the paragraph below is to be added to the decision report.

57. “By virtue of Regulation 66(5) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended you must:

- Provide the following directed service[s], and
- Not unreasonably withhold agreement to the service specification[s] for [*that/those*] service[s],

where they are commissioned within 3 years of the date the premises are included in the pharmaceutical list for the area of [*insert name*] Health and Wellbeing Board.

- [*list services and date from which they are to be provided where/if this is known*]

58. Where an application is subject to this condition the Primary Care Support Service provider is to be advised that the “Acceptance of Regulation 66(5) condition” annex is to be included with the decision letter that is sent to the applicant. The Primary Care Support Service Provider is to be advised of which services are to be included in the services section of the notice of commencement/consolidation.

Distance selling premises: specific conditions

59. The wording in the paragraph below is to be added to the decision report relating to the grant of a distance selling premises application.

60. “As the application is in respect of distance selling premises, by virtue of regulation 64(3) of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, if the applicant is subsequently included in the pharmaceutical list for the area of *[insert name]* Health and Wellbeing board in respect of the premises included in the application that inclusion will be subject to the following conditions:
- The applicant must not offer to provide pharmaceutical services to persons who are present at (which includes in the vicinity of) the proposed premises;
 - the means by which the applicant provides pharmaceutical services must be such that any person receiving those services does so otherwise than at the proposed premises;
 - the proposed premises must not be on the same site or in the same building as the premises of a provider of primary medical services with a patient list;
 - the pharmacy procedures for the premises must be such as to secure:
 - the uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
 - the safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else’s behalf, and the applicant or the applicant’s staff; and
 - nothing in the applicant’s practice leaflet, in the applicant’s publicity material in respect of the proposed premises, in material published on behalf of the applicant publicising services provided at or from the proposed premises or in any communication (written or oral) from the applicant or the applicant’s staff to any person seeking the provision of essential services from the applicant must represent, either expressly or impliedly, that:
 - the essential services provided at or from the premises are only available to persons in particular areas of England, or
 - the applicant is likely to refuse, for reasons other than those provided for in the applicant’s terms of service, to provide drugs or appliances ordered on prescription forms or repeatable prescription forms which are presented by particular categories of patients (for example, because the availability of essential services from the applicant is limited to other categories of patients).”

Granting of applications subject to fitness conditions

61. Where it has been determined (by the PSRC or PLDP) that the applicant is, if the market entry element of the application is granted, to be included in the relevant pharmaceutical list subject to specified fitness conditions the wording in the following paragraph is to be added to the decision report.
62. “Should a valid notice of commencement be received in relation to this application, inclusion of the applicant in the pharmaceutical list for the area of *[insert name]* Health and Wellbeing Board is subject to the following fitness condition[s]:
- *[insert details of condition or conditions]*.

Rights of appeal

63. After determining the application, the decision-maker must then determine whether the applicant has a right of appeal and whether anyone has a third party right of appeal in line with the Regulations.
64. Rights of appeal for the applicant are set out in:
- Paragraph 36, Schedule 2 of the Regulations,
 - Regulations 33 and 35 (refusal or conditional inclusion on fitness grounds)
 - Regulation 45(1)(c) (determinations in connection with reserved locations), and
 - Regulation 63(1)(b) (gradualisation).

Rights of appeal for applicants – paragraph 36, Schedule 2 of the Regulations

A right of appeal should be given to the applicant where:

- Their application is refused on grounds set out in Parts 3 to 5 or 7 of the Regulations
- That a notification pursuant to a condition imposed by paragraph 31, Schedule 2 is invalid (conditional grant of applications where the address of the premises is unknown)
- To refuse to accept that a notification under paragraph 32(2), Schedule 2 is a valid notification (changes to the premises specified in an application after its grant but before the listing of the premises)
- To impose or vary a condition imposed pursuant to paragraph 33, Schedule 2 (conditional grant in cases relating to future needs or future improvements or better access)
- To refuse to allow an extension period under paragraph 34(4)(c)(i) or 34A(4)(b)(i), Schedule 2 (taking effect of listing decisions: general and taking effect of decisions relating to business consolidations)
- To give notice under paragraph 35, Schedule 2 (notice requiring the commencement of pharmaceutical services).

65. Where an application is granted, third party rights of appeal are to be given under paragraph 30, Schedule 2 and for rurality matters regulation 63.

Third party rights of appeal – notifiable applications

In order to determine whether a particular third party should be given a third party right of appeal against a decision to grant a notifiable application, the following questions should all be answered with a 'yes'.

- Is the third party a pharmacy or DAC whose interests might, in the opinion of NHS England, be significantly affected by the decision?
- Are they either included in the relevant pharmaceutical list, or are entitled to be because they have had an application granted but haven't yet submitted their notice of commencement, or are an LPS contractor?
- Did they make representations on the application within the 45-day notification period?
- Is the PSRC satisfied that they made a reasonable attempt to express their grounds for opposing the application adequately in their representations?

In relation to the final bullet point, a third party right of appeal should not be given if the grounds for opposing the application:

- Amount to a challenge to the legality or reasonableness of a PNA, or to the fairness of the process by which the HWB undertook that assessment, and
- Are vexatious or frivolous.

Third party rights of appeal – non-notifiable applications

In order to determine whether a particular third party should be given a third party right of appeal against a decision to grant a non-notifiable application, the following questions should all be answered with a 'yes'.

- Is the third party a pharmacy or DAC whose interests might, in the opinion of NHS England, be significantly affected by the decision?
- Are they either included in the relevant pharmaceutical list, or are entitled to be because they have had an application granted but haven't yet submitted their notice of commencement, or are an LPS contractor?

66. Persons in any of the following categories should not be considered to satisfy paragraph 30(3)(c) or regulation 63(3)(c) and they should not therefore be given a third party right of appeal:
- A notified person who responds with these or similar words: "Thank you for notifying us of this application. We have no specific comments to make at this time but reserve the right to comment later."
 - A notified person who does not explicitly state that they oppose the application.
 - A notified person who gives no grounds for opposing the application.
67. The decision-maker must fully document the reasons for giving (or not giving) third party rights of appeal to a particular party.
68. In addition, consideration will need to be given to rights of appeal in relation to controlled locality determinations (regulation 45(1)(a) and (b), reserved location determinations (regulation 45(1)(c)) and gradualisation determinations (regulation 63(1)(b)).

Notification of decision and appeals

69. The Primary Care Support Service Provider will advise the decision-maker when the determination is notified to interested parties.
70. If an appeal to NHS Resolution or the First-tier Tribunal is notified to the Primary Care Support Service Provider this will be passed to the decision-maker for a response.

Waiving the 30-day appeal period

71. Even if no third party right of appeal is given it is not possible to waive the 30-day appeal period. Should an applicant choose to submit their notice of commencement/consolidation within the 30-day appeal period it should be processed as normal and the applicant included in the relevant pharmaceutical

list. However, should a valid notice of appeal be received by NHS Resolution the notice of commencement/consolidation will cease to have effect (paragraph 34(5), Schedule 2).

72. Examples of what this means are as follows:
- A new pharmacy/dispensing appliance contractor premises would need to cease providing pharmaceutical services with immediate effect.
 - Where a pharmacy/dispensing appliance contractor has relocated it will need to return to the previous premises.
 - In relation to changes of ownership, the previous owner is to be included in the relevant pharmaceutical list and the new owner is to be removed.

Best estimate applications

73. If an applicant gave a best estimate in their routine application then, if granted, they are required to notify the address at which they intend to provide pharmaceutical services within a specified time.
74. On receipt of such an address this will be forwarded to the decision-maker by the Primary Care Support Service Provider for consideration in line with paragraph 31, Schedule 2. It should be noted that the decision-maker will have 14 days from the date the address was received by the Primary Care Support Service Provider within which to make a decision.

Receipt of notice of commencement

75. Where an application is granted the applicant must submit their notice of commencement to the Primary Care Support Service Provider within a specified time. On receipt it will be sent to the decision-maker for consideration as to whether it is valid or not in line with paragraph 34, Schedule 2. The decision will be communicated to the applicant by the Primary Care Support Service Provider.
76. It should be noted that the applicant will be included in the relevant pharmaceutical list with effect from the date on the notice of commencement unless the decision-maker advises the Primary Care Support Service Provider otherwise. Reasons for not including the applicant should be fully documented as the only recourse if the applicant is not happy is via a legal challenge.
77. The Primary Care Support Service Provider will send a memo to certain persons advising of the inclusion in the pharmaceutical list. These persons include the relevant:
- LPC,
 - HWB,
 - CCG,
 - Pharmacy contracts manager,
 - Public health team,
 - DoS lead,
 - Unwanted medicines collection and disposal contractor,

- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
- Any other organisation for which the relevant pharmacy contract manager has provided contact details for, for example the Registration Authority and the organisation that cascades safety alerts.

Inclusion in the relevant pharmaceutical list

78. It is the responsibility of NHS England to include the applicant and their premises in the relevant pharmaceutical list.
79. Where an applicant:
- Undertook to provide pharmaceutical services at the proposed pharmacy premises for more than 40 core opening hours per week,
 - The applicant and NHS England agreed that pharmaceutical services are to be provided during the additional core opening hours at set times and on set days, and
 - The application is granted having regard to that undertaking and that agreement,
- a direction (Annex 13) is to be issued when the applicant is included in the relevant pharmaceutical list.

CHAPTER 30

Information on Determination of Applications

Introduction

1. The purpose of this chapter is to provide guidance to NHS England when determining applications.

NHS Resolution publications

2. NHS England should ensure that it is familiar with [appeal decisions](#) and [guidance notes](#) issued by NHS Resolution. Consideration should be given to [signing up](#) to receive an email whenever documents are updated or added to the website.

Consolidations

Preliminary Matters

3. In accordance with the procedure set out in Chapter 20 of the Pharmacy Manual, a number of initial matters will already have been decided. This approach is intended to filter out applications that do not comply with the requirements for a consolidation application (as set out in Regulation 26A of the Regulations). Applications are to be determined within four months of receipt unless NHS England has good cause to take longer, e.g. a delay in receiving references.
4. The preliminary decisions include:
 - Rejecting the application where the application relates to distance selling premises or appliance contractor premises;
 - Rejecting the application where the application relates to premises that are in more than one single HWB; and
 - Whether NHS England intends to commission enhanced services.

Who can make a consolidation application?

5. A consolidation application may be made by:
 - A person who is listed in the relevant pharmaceutical list in relation to both the continuing premises and the closing premises – Regulation 26A(3)(a);
 - A person who is listed in the relevant pharmaceutical list in relation to the continuing premises (site 1) and seeks a change of ownership of the closing premises (site 2) – Regulation 26A(3)(b);
 - A person who is listed in the relevant pharmaceutical list in relation to the closing premises (site 2) and seeks a change of ownership of the continuing premises (site 1) – Regulation 26A(4).
6. The decision maker should be aware of which application type applies to ensure that the correct regulatory test is applied. Please refer to the section below (Refusing a consolidation application) for more information.

Is fitness to practise relevant?

7. As set out paragraph 5 above, a consolidation application must be made by a person who is either already listed in the pharmaceutical list in relation to the continuing premises (site 1) or the closing premises (site 2) or both. Regardless of who is making the application, the applicant will already be included in the relevant pharmaceutical list and will not need to provide full fitness information.

Representations from relevant parties

8. The application will have been circulated to interested parties including the relevant HWB. A consolidation application differs from other types of pharmacy applications in that the HWB is required to provide representations that, at a minimum, cover a specific point – whether, if the application were granted, in the opinion of the HWB the proposed removal of premises from the relevant pharmaceutical list would or would not create a gap in pharmaceutical services that could be met by a routine application to:
 - a) Meet a current or future need for pharmaceutical services; or
 - b) Secure improvements, or better access, to pharmaceutical services.
9. Regardless of whether the HWB makes other comments on the application, it must provide a view on this.
10. The procedure set out in Chapter 20 of the Pharmacy Manual contains template letters to the HWB making clear that the HWB needs to provide this information.
11. The Regulations do not set out the consequence of the HWB not providing this information and NHS England has no legal power to force the HWB to provide the required information.
12. NHS England has considered whether it is able to determine the application where a HWB does not provide the information despite multiple requests. If the HWB does not provide the required information after the 45-day deadline has passed and after further requests are made, NHS England will proceed to determine the application on the information before it. NHS England considers it would be unfair on an applicant, who may well have submitted a consolidation application for pressing financial reasons, to delay determination of the application any further.

Refusing a consolidation application

13. Regulations 26A(5) to (7) set out matters which NHS England must consider in order to determine whether or not it must refuse the application.
14. Regulations 26A(6) and (7) are dependent on who has made the application and only the relevant provision should be applied to the relevant application.
 - Regulation 26(a)(6) applies where either of the first two bullet points in paragraph 4 above apply; and
 - Regulation 26A(7) applies where the third bullet point in paragraph 4 above applies.

15. Regulation 26A(5) applies to all applications and should be considered first. If the application is not refused by virtue of Regulation 26A(5) then Regulation 26A(6) or (7) should be considered.

Regulation 26A(5)

16. Regulation 26A(5) states that a consolidation application must be refused if:
 - Either of the premises are distance selling premises (“DSPs”) or DAC premises; or
 - NHS England is satisfied that granting the application would create a gap in pharmaceutical services provision that could be met by a routine application to meet a current or future need for pharmaceutical services or to secure improvements, or better access, to pharmaceutical services.
17. Whether either of the premises are DSP or DAC premises should have been determined as a preliminary matter. Nevertheless, the decision maker should ensure that this has not been missed and that the application is not required to be refused for this reason.
18. NHS England considers that it is reasonable to infer that the reference to “gap in pharmaceutical services provision” in the second bullet point above is to be interpreted in a similar way to references to gaps in provision as set out in Paragraphs 2 and 4, Schedule 1 of the Regulations.
19. In other words, if granting a consolidation application results in the creation of a need for pharmaceutical services, or a situation where if pharmaceutical services were provided they would secure improvements or better access to pharmaceutical services, then there would be a gap in service provision.
20. This second criterion for refusal is the issue on which the HWB is required to give a view. The decision maker should note that Regulation 26A(5) requires NHS England to refuse the application if it (NHS England) is satisfied that a gap would be created that could be met by a routine application. Where the HWB has provided its view the decision maker should not simply take the HWB’s view and adopt it without first putting its mind to the matter. NHS England is likely to have received representations on this issue from the application and interested parties other than the HWB. The decision maker must consider all representations before it when considering this issue.
21. There will likely be a large number of factors that need to be taken into account when considering whether granting an application would create a gap that can be met by a routine application. The factors are likely to be similar to the factors taken into account by the HWB in assessing whether there are gaps for the purposes of the PNA.
22. Factors that may be relevant include (but are not limited to) whether the opening hours offered at the continuing premises (site 1) are sufficient to ensure that the consolidation does not leave a gap in service provision or whether the applicant is undertaking to provide the same pharmaceutical services in the continuing premises as were provided in the closing premises (site 2) or the continuing premises previously.

23. A further factor that may be relevant is the extent to which the closing premises (site 2) leads to a loss of facilities, e.g. access for wheelchairs, disabled parking etc. If a party argues that the consolidation would lead to a loss of facilities, then the decision maker will likely need to consider points including, but not limited to:
- The extent to which there is evidence that such loss of facilities would occur;
 - The extent that other pharmacies in the area provide such facilities and the geographical spread of those pharmacies;
 - The effect of the loss of facilities on persons accessing pharmaceutical services in the area; and
 - Whether such a loss amounts to a gap in service provision.
24. Ultimately, the decision maker will need to consider the extent to which representations are supported by evidence. NHS England may determine that less weight is attributed to representations not supported by evidence.

Statutory duties of NHS England

25. There are a number of statutory duties which NHS England must take into account when considering a consolidation application. These duties are set out in legislation and it is important that the decision maker is familiar with all of these duties.
26. Decision makers are referred to Chapter 28 which sets out a comprehensive explanation of the duties and how to comply with them.

When should applications be heard together

27. Where NHS England is presented with more than one consolidation application of a specific area it may consider that it is reasonable to hear the applications together.
28. Regulation 26A(8) provides that if applications are being considered together, as regards the issue of gaps in provision, each application may be refused on the basis of the cumulative effect on provision of all the applications being considered together.
29. The Regulations do not set out when in the application process a decision should be made to hear applications together. If applications are not received together, hearing applications together could lead to a delay in the determination of the first application (given the need to notify interested parties of the second application) and detrimentally affect the first application if the applications are refused on the basis of the cumulative effect.
30. NHS England considers that it is reasonable and fair to adopt a cut off time after which a received application will not usually be considered together with a previously received application. If a second application is received after 30 days of the date that the first application was notified to interested parties, then NHS England will usually consider that it is not appropriate to hear the applications together. There may be exceptional reasons why this approach is not complied with and it is for each decision maker to consider whether any exceptional factors apply and to fully document the reasons why it is appropriate to determine the applications together.

Distance selling premises

31. Within their application the applicant is required to provide sufficient information to satisfy the PSRC that the pharmacy procedures for the pharmacy premises are likely to secure:
 - The uninterrupted provision of essential services, during the opening hours of the premises, to persons anywhere in England who request those services, and
 - The safe and effective provision of essential services without face to face contact between any person receiving the services, whether on their own or on someone else's behalf, and the applicant or their staff.
32. Applicants are not required to provide their SOPs but may choose to do so in order to satisfy the PSRC in relation to the above.
33. It is not the role of the PSRC, or NHS England in general, to approve the SOPs or otherwise determine them to be fit for purpose. However, they should be read as they will assist the PSRC in coming to a decision with regards regulation 25(2)(b). In reading them the PSRC will therefore wish to consider how the applicant proposes to undertake those requirements of essential services which would normally be done face to face with the patient, for example receiving prescriptions, collecting prescription charges or asking for evidence that a patient is not required to pay prescription charges.

Temporary arrangements during emergencies or for circumstances beyond the control of the contractor

34. 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 – NHS England must, for a specified period, exercise (or consider exercising) one or more of its functions under various provisions of the Regulations.
35. In the case of such an emergency, NHS England 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.
36. In the event of circumstances arising which require the temporary suspension of pharmaceutical services at the listed premises, NHS England 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.
37. 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.

38. 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.
39. 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).
40. 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.
41. When considering whether to grant an application under regulation 29 the decision maker will take the following criteria into account:
 - The provision of pharmaceutical services by other contractors.
 - If the application was refused what impact would it have on the provision of pharmaceutical services to the patient groups who use the closed premises and other likely users?
 - How long are the premises likely to remain closed?
 - Will the contractor be able to move back into them?
42. Depending on the provision of pharmaceutical services by other contractors it may not always be necessary to grant such applications and they are not to be granted merely for business convenience. It is expected that contractors will have appropriate insurance to protect their income. For example, if a contractor's premises were flooded and had to temporarily close but there were other contractors in the area where patients and members of the public could easily access pharmaceutical services, it would not be necessary to grant the application.
43. The overall aim of this type of application is to ensure that patients and members of the public continue to be able to access pharmaceutical services.

CHAPTER 31

Fitness and Existing Contractors

Chapter Aims and Objectives

1. This chapter provides information on how to manage fitness matters relating to contractors who are already included a pharmaceutical list in accordance with the Regulations. It does not apply to LPS contractors as they are not included in a pharmaceutical list.
2. This document should be read in conjunction with the Regulations and the NHS Act 2006 (the “Act”).
3. The PSRC will consider and determine fitness matters but may delegate a matter to the PLDP in recognition of the PLDP's expertise in fitness matters. Details of the constitution of the PLDP are set out in Chapter 2.

Grounds for action

4. The Regulations and the Act provide a framework within which NHS England can take action if a pharmacy or dispensing appliance contractor's conduct, competence or performance gives cause for concern. Protection of patients and members of the public must be the overriding consideration when considering the powers that are available.
5. Action can be taken on the three grounds that are set out in the Act, namely:
 - Efficiency – the continued inclusion of the contractor in a pharmaceutical list would be prejudicial to the efficiency of the services which those included in a list undertake to provide.
 - Fraud – the contractor has (whether on their own or together with another) by an act or omission caused, or risked causing, detriment to any health scheme by securing or trying to secure for themselves or another any financial or other benefit, and knew that they or the other was not entitled to the benefit.
 - Suitability – the contractor is unsuitable to be included in a pharmaceutical list.

Use of the powers

6. There may be occasion where NHS England identifies concerns relating to the fitness of a contractor. In this instance the PSRC (or PLDP) will need to consider use of the fitness powers set out in the Act and Part 11 of the Regulations.
7. Whilst the powers that are available to NHS England are set out in the Act, further details and the process to be followed are set out in the Regulations. Where a PSRC (or PLDP) is considering use of the fitness powers it should first liaise with

other regional teams in whose area the contractor has premises so that a consistent approach is taken across the country.

8. Options available to NHS England include, where there are no patient safety issues, monitoring the situation.
9. Section 151 of the Act sets out the grounds when NHS England may (or must, in prescribed circumstances) remove a contractor from the pharmaceutical list or lists that they are included in, and these relate to efficiency, fraud and suitability grounds.
10. Regulation 81 sets out instances where NHS England must remove a contractor (“mandatory removal”), having first followed the process set out in regulation 82. These include where the contractor (and where the contractor is a body corporate, any director or superintendent of that body corporate) has been convicted in the UK of murder, or is the subject of a national disqualification.
11. Section 152(1) of the Act makes provision for NHS England to contingently remove a contractor from the pharmaceutical list or lists that they are included on efficiency or fraud grounds. Effectively this means that the contractor’s continued inclusion is subject to conditions that aim to address the concerns that have been identified. It should be noted that this is not an option where NHS England is satisfied that the contractor is not suitable to be included in a pharmaceutical list or lists.
12. Section 154(1) of the Act makes provision for NHS England to suspend a contractor from the pharmaceutical list or lists that they are included in whilst:
 - It decides whether to remove or contingently remove the contractor, or
 - Whilst it waits for a decision affecting the contractor of a court or regulatory body.
13. It must be noted that suspension is a neutral act, not a disciplinary sanction. NHS England must be satisfied that suspension is necessary for the protection of members of the public or otherwise in the public interest and it should therefore be a rare event. Misuse of the suspension power can result in injustice, in damage to the contractor’s reputation, career and personal life, and in waste of NHS resources.

Changes of Director and/or Superintendent Pharmacist

14. Where a pharmacy body corporate appoints a new director or superintendent or a DAC body corporate appoints a new director, it must send the relevant form to the Primary Care Support Service Provider within 30 days (paragraph 32(4), Schedule 4 and paragraph 22(4), Schedule 5 of the Regulations). The required checks will be undertaken and a report prepared and submitted to:
 - The NHS England regional team in whose area the body corporate’s registered office is located, or

- If the body corporate has no premises in that team's area, to the NHS England regional team in whose area its premises are located, or where the majority of its premises are located.
15. The PSRC will consider the fitness information (and may delegate to the PLDP) to determine whether the body corporate remains a fit and proper person.
 16. Options that are available to the PSRC/PLDP include:
 - Decision that the body corporate remains a fit and proper person to be included in a pharmaceutical list or lists,
 - Mandatory removal on the grounds of suitability – regulation 81 of the Regulations
 - Discretionary removal on fitness grounds – section 151 of the Act
 - Contingent removal on fitness grounds – section 152(1) of the Act
 - Suspension on fitness grounds – section 154(1) of the Act
 17. The decision, the outcomes of the checks and the information provided by the contractor is to be communicated to other regional teams in whose area the body corporate has premises that are included in a pharmaceutical list.
 18. Notification of the decision to the contractor and notification under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision. The regulation 88 notification will take place either at the end of the 30-day appeal period or, if there is an appeal, once any appeal has been heard.
 19. Where a contractor is removed (but not contingently removed) on fitness grounds the following persons are also to be notified by the Primary Care Support Service Provider:
 - HWB,
 - CCG,
 - Public health team,
 - LMC
 - DoS lead,
 - Registration Authority,
 - Controlled Drugs Accountable Officer (CDAO),
 - OOHs provider,
 - Unwanted medicines collection and disposal contractor,
 - The organisation that cascades safety alerts,
 - Binley's, and
 - The Primary Care Support Service Provider's pharmacy payments team in relation to the LPC levy and the data manager.
 20. This notification will take place at the end of the 30 day appeal period, or once any appeal has been heard and NHS England's decision has not been

overturned. Contact details for the above, other than for the last bullet point, are to be provided to the Primary Care Support Service Provider.

21. There may be occasions where referees fail to respond and no response is received from the body corporate. In this instance NHS England will need to consider whether the body corporate remains a fit and proper person to be included in the relevant pharmaceutical list or lists. Where NHS England is not satisfied that this is the case it will need to consider use of the fitness sanctions set out above (removal, contingent removal or suspension).

Changes of Director Name and Name or Address of the Superintendent

22. Where the name of a director of a body corporate or the name or address of the superintendent (pharmacy bodies corporate only) changes it must send the relevant form to the Primary Care Support Service Provider within 30 days or as soon as is practicable thereafter (paragraph 32(3), Schedule 4 and paragraph 22(3), Schedule 5 of the Regulations). This form will be sent to the regional teams in whose area the contractor has premises.
23. Unless the change of name is related to a new person being appointed the only actions that are required is to:
 - Update relevant databases, and
 - Notify other regional teams in whose area the body corporate has premises that are included in a pharmaceutical list

Provision of information on fitness matters as they arise

24. The Regulations require all contractors to provide information about fitness matters as they arise. This information is to be sent to the Primary Care Support Service Provider within seven days (paragraph 31, Schedule 4 and paragraph 15, Schedule 5 of the Regulations).
25. Where the contractor is a body corporate this information will be sent to:
 - The NHS England regional team in whose area the body corporate's registered office is located, or
 - If the body corporate has no premises in that team's area, to the NHS England regional team in whose area its premises are located, or where the majority of its premises are located.
26. For sole traders and partnerships this information will be sent to the NHS England regional team in whose area:
 - All the contractor's premises are located, or
 - The majority of its premises are located.

27. The PSRC (or PLDP) will determine whether or not the contractor remains suitable to be included in the relevant pharmaceutical list or lists. Options that are available to NHS England include:
- Decision that the body corporate remains a fit and proper person to be included in a pharmaceutical list or lists,
 - Mandatory removal on the grounds of suitability – regulation 81 of the Regulations
 - Discretionary removal on fitness grounds – section 151 of the Act
 - Contingent removal on fitness grounds – section 152(1) of the Act
 - Suspension on fitness grounds – section 154(1) of the Act
28. The decision and the information provided by the contractor is to be communicated to other regional teams in whose area the body corporate has premises that are included in a pharmaceutical list.
29. Notification of the decision to the contractor and notification under regulation 88 will be undertaken by the Primary Care Support Service Provider. It should be noted that notification under regulation 88 is not required where NHS England is satisfied that the body corporate remains a fit and proper person. The PSRC/PLDP is to provide the required letters which include a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if notification under regulation 88 is required and whether the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
30. Notifications required by regulation 88 will be made by the Primary Care Support Service Provider at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned.
31. Where a contractor is removed (but not contingently removed) on fitness grounds the following persons are also to be notified by the Primary Care Support Service Provider:
- HWB,
 - CCG,
 - public health team,
 - LMC
 - DoS lead,
 - Registration Authority,
 - CDAO,
 - OOHs provider,
 - Unwanted medicines collection and disposal contractor,
 - The organisation that cascades safety alerts,
 - Binley's, and
 - The Primary Care Support Service Provider's pharmacy payments team in relation to the LPC levy and the data manager.

32. This notification will take place at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned. Contact details for the above, other than for the last bullet point, are to be provided to the Primary Care Support Service Provider.

Procedure for Removal

33. Regulation 82 of the Regulations sets out the procedure to follow where NHS England is considering:
- Discretionary removal of a contractor under section 151(2) to (4) of the Act – efficiency, fraud and unsuitability cases
 - Mandatory removal of a contractor under section 151(5) of the Act and regulation 81 of the Regulations
 - Removal of a contractor under section 152(3)(b) of the Act – removal for failure to comply with a contingent removal condition
 - Removal of a contractor under regulation 80 of the Regulations – removal for failure to comply with a conditional inclusion condition
34. Although regulation 81 directs NHS England to remove a contractor in certain circumstances, the procedure set out in regulation 82 must first be followed.
35. Where it is considering removal of a contractor, before reaching its decision the PSRC (or PLDP) must send Annex 1 to the contractor. It is recommended that the date of the hearing is arranged approximately 5 to 7 days after the end of the 30-day period within which the contractor may submit their written representations or advise that they will attend the hearing to make oral hearings.
36. Where the PSRC (or PLDP) is considering the removal of a contractor it should also consider whether it should suspend the contractor whilst the above procedure is followed and until either the end of the appeal period or until the outcome of the appeal is known, whichever is the later.
37. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made. Annex 2 is then to be sent to the contractor. The contractor may appeal the decision to the First-Tier Tribunal.
38. Where the decision is made to remove the contractor, this decision will not take effect until:
- Where the contractor does not appeal the decision, the end of the 30-day appeal period.
 - Where the contractor appeals the decision, the appeal has been heard and the First-tier Tribunal confirms the decision of NHS England. If the First-tier Tribunal comes to a different decision to NHS England, that decision will over-ride NHS England's decision.
39. Notification of the decision under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned

statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).

40. Where a contractor is removed on fitness grounds the following persons are also to be notified by the Primary Care Support Service Provider:
 - HWB,
 - CCG,
 - public health team,
 - DoS lead,
 - Controlled Drugs Accountable Officer (CDAO),
 - Unwanted medicines collection and disposal contractor,
 - The organisation that cascades safety alerts, and
 - The Primary Care Support Service Provider's pharmacy payments team in relation to the LPC levy and the data manager.
41. This notification will take place at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned. Contact details for the above, other than for the last bullet point, are to be provided to the Primary Care Support Service Provider.

Procedure for Contingent Removal

42. Regulation 82 of the Regulations sets out the procedure to follow where NHS England is considering contingently removing a contractor under section 152(1) of the Act.
43. Where it is considering contingent removal of a contractor, before reaching its decision the PSRC (or PLDP) must send Annex 3 to the contractor. It is recommended that the date of the hearing is arranged approximately 5 to 7 days after the end of the 30-day period within which the contractor may submit their written representations or advise that they will attend the hearing to make oral hearings.
44. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made. Annex 4 is then to be sent to the contractor. The contractor may appeal the decision to the First-Tier Tribunal.
45. Where the decision is made to contingently remove the contractor, this decision will not take effect until:
 - Where the contractor does not appeal the decision, the end of the 30-day appeal period.
 - Where the contractor appeals the decision, the appeal has been heard and the First-tier Tribunal confirms the decision of NHS England. If the First-tier

Tribunal comes to a different decision to NHS England, that decision will over-ride NHS England's decision.

46. Notification of the decision under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
47. Notifications required by regulation 88 will be made by the Primary Care Support Service Provider at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned.

Procedure for Suspension

48. Regulation 83 of the Regulations sets out the procedure to follow where NHS England is considering suspending a contractor from a pharmaceutical list under:
 - Section 154(1) of the Act - necessary to do so for the protection of members of the public or is otherwise in the public interest while it decides whether or not to remove or contingently remove a contractor or while it awaits a decision of a court or regulatory body, or
 - Section 155(2) of the Act – suspension pending an appeal against a decision to remove a contractor.
49. Where it is considering suspending a contractor, before reaching its decision the PSRC (or PLDP) must send Annex 5 to the contractor.
50. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made. Annex 6 is then to be sent to the contractor.
51. Notification of the decision under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
52. Where a contractor is suspended, payments to them will need to be made in line with the requirements of the Part XIX of the Drug Tariff.
53. While a contractor is suspended they must be treated as not being included in a pharmaceutical list or lists from which they have been suspended even though their name appears in it or them.
54. Sections 154 and 155 of the Act sets out the length of time that a contractor may be suspended:

- Where the contractor is suspended while NHS England decides whether or not to remove or contingently remove them – maximum of six months
- Where the contractor is suspended while a decision of a court or regulatory body is awaited – no maximum time period, however NHS England must specify the period of time during which the contractor is to remain suspended once the decision is known, and this may not exceed six months.
- Where the contractor is suspended pending an appeal – until the expiry of the 28-day period for appealing to the First-tier Tribunal and, if such an appeal is made, until disposal of the appeal

55. The PSRC (or PLDP) may terminate a suspension at any time. Where it does it must send Annex 7.

Procedure for Review of Some Suspensions

56. Section 157(1) of the Act makes provision for the PSRC (or PLDP) to review a suspension where requested to do so by the contractor, and for the PSRC (or PLDP) to review a suspension of its own volition. This does not apply to a suspension imposed by, or continuing pursuant to, and order of the First-tier Tribunal, or a suspension pending an appeal.

57. It should be noted that the contractor may not request a review before the end of the period of:

- Three months beginning on the date of the decision of NHS England to suspend them, or
- Six months beginning with the date of NHS England's decision on the previous review.

58. On receipt of a request to review a suspension send Annex 8 to the contractor.

59. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made.

60. The options available to the PSRC (or PLDP) are:

- Confirm the suspension, or
- Terminate the suspension.

61. Depending on which decision is made send either Annex 9 (suspension confirmed) or 10 (suspension terminated).

62. If the suspension is terminated then the contractor will be able to re-commence the provision of pharmaceutical services. Notification of the decision under regulation 88(8) will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h). Advise the

Primary Care Support Service Provider so that a memo may also be sent to interested parties.

63. Where a suspension is terminated the following persons are also to be notified by the Primary Care Support Service Provider:
- HWB,
 - CCG,
 - pharmacy contracts manager,
 - public health team,
 - DoS lead,
 - CDAO,
 - Unwanted medicines collection and disposal contractor
 - The organisation that cascades safety alerts, and
 - The Primary Care Support Service Provider's pharmacy payments team in relation to the LPC levy and the data manager.
64. If, as a result of their suspension, an application had been granted under 27 of the Regulations (Applications for temporary listings arising out of suspensions) at the point the suspension is lifted advise the Primary Care Support Service Provider.

Procedure for Review of Contingent Removal

65. Section 157(1) of the Act makes provision for the PSRC (or PLDP) to review a contingent removal where requested to do so by the contractor, and for the PSRC (or PLDP) to review a contingent removal of its own volition. This does not apply to a contingent removal imposed by the First-tier Tribunal.
66. It should be noted that the contractor may not request a review before the end of the period of:
- Three months beginning on the date of the decision of NHS England to contingently remove them, or
 - Six months beginning with the date of NHS England's decision on the previous review.
67. On receipt of a request to review a contingent removal send Annex 11 to the contractor. Where the PSRC (or PLDP) decides to review a contingent removal of its own volition, send Annex 12.
68. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made.
69. The options available to the PSRC (or PLDP) are:
- Confirm the contingent removal,
 - Vary the conditions,
 - Impose different conditions,

- Revoke the contingent removal, or
 - Remove the contractor from the relevant pharmaceutical list or lists.
70. Notification of the decision under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
71. Notifications required by regulation 88 will be made by the Primary Care Support Service Provider at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned.

Procedure for Review of Conditional Inclusion

72. Regulation 79 of the Regulations makes provision for the PSRC (or PLDP) to review a conditional inclusion where requested to do so by the contractor, and for the PSRC (or PLDP) to review a contingent removal of its own volition.
73. It should be noted that the contractor may not request a review:
- In the case of the first request, until at least three months have elapsed since they were included in the relevant pharmaceutical list, or
 - Thereafter, until six months have elapsed since the PSRC (or PLDP) determined the outcome of the previous review.
74. On receipt of a request to review a conditional inclusion send Annex 13 to the contractor. Where the PSRC (or PLDP) decides to review a contingent removal of its own volition, send Annex 14.
75. An oral hearing, which the contractor may or may not choose to attend, will then be held by the PSRC (or PLDP) and a decision made.
76. The options available to the PSRC (or PLDP) are:
- Remove the condition or conditions,
 - Leave the condition or conditions unchanged,
 - Vary the condition or conditions, or
 - Impose different conditions.
77. Any varied or different condition must be a condition with a view to preventing any:
- Prejudice to the efficiency of the services, or any of the services, which the contractor has undertaken to provide, or
 - Act or omission within section 151(3)(a) of the Act (fraud).

78. If, in the course of this review, the PSRC (or PLDP) determines that the contractor has failed to comply with a condition it may remove the contractor from the relevant pharmaceutical list or lists following the procedure in paragraphs 21 to 27 above.
79. Notification of the decision under regulation 88 will be undertaken by the Primary Care Support Service Provider. The PSRC/PLDP is to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
80. Notifications required by regulation 88 will be made by the Primary Care Support Service Provider at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned.

National Disqualification

81. If the First-tier Tribunal removes a contractor from a pharmaceutical list, it may also decide to disqualify them from inclusion in the pharmaceutical lists prepared by NHS England (section 159 of the Act). This is referred to as national disqualification.
82. It may also impose a national disqualification on a contractor if it dismisses an appeal against a refusal by NHS England to include them in a pharmaceutical list.
83. NHS England may apply to the First-tier Tribunal for a national disqualification to be imposed on a contractor after it has:
 - Removed the contractor from a pharmaceutical list, or
 - Refused to include an applicant in a pharmaceutical list on fitness grounds.
84. Where a PSRC (or PLDP) removes a contractor on fitness grounds or refuses an application on fitness grounds, consideration is to be given as to whether an application for national disqualification should be made. It must be noted though that any such application must be made before the end of the period of three months beginning with the date of the removal or refusal.
85. The effect of a national disqualification is that the contractor may not be included in a pharmaceutical list and if they are already so included NHS England must remove them.
86. The contractor may ask the First-tier Tribunal to review a national disqualification, and on review the First-tier Tribunal may confirm or revoke it.

External notifications of Fitness Decisions

87. Regulation 88 of the Regulations requires certain fitness decisions to be notified to a prescribed list of persons. This will be undertaken by the Primary Care Support Service Provider, however it is for the PSRC (or PLDP) to provide a fully reasoned statement of its decision and provide contact details for those persons who are to be notified under regulation 88(2)(b), (g) and (i) of the Regulations. It is also to confirm if the NHS Counter Fraud Authority is to be notified under regulation 88(2)(h).
88. Notifications required by regulation 88 will be made by the Primary Care Support Service Provider at the end of the 30-day appeal period, or once any appeal has been heard and NHS England's decision has not been overturned.

Limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing

89. Regulation 76 of the Regulation applies where a contractor would otherwise be removed from a pharmaceutical list as a result of:
- A change of ownership,
 - The end of a temporary listing arising from a suspension,
 - A consolidation, or
 - A notice of withdrawal from a pharmaceutical list.
90. If the contractor is to be removed in any of the above circumstances but the PSRC (or PLDP):
- Is investigating them with a view to removing, suspending or contingently removing them on fitness grounds,
 - Has decided to remove or contingently remove the contractor on fitness grounds but has not yet done so, or
 - Has suspended the contractor,

it must not, without the consent of NHS Resolution, remove the contractor under regulation 75 until the relevant investigation or proceedings have been concluded.

CHAPTER 32

Procedures - Controlled Localities and Rurality Matters

Chapter aims and objectives

1. This chapter deals with issues relating to controlled localities, specifically:
 - The procedure for determining a controlled locality;
 - Decisions relating to gradualisation;
 - The procedure for re-determining a reserved location; and
 - Appeal rights.
2. This document must be read in conjunction with the Regulations and Chapter 14 of the DHSC Guidance. Further information on the background to the current regulatory framework for rurality matters can be found in the Clothier Report² which was published in December 1977.

Background

3. A controlled locality is an area determined by NHS England (or its predecessors or, on appeal, by NHS Resolution) 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. NHS England may find the Department for Environment, Food and Rural Affairs definition of rurality useful but may come to a different decision in relation to any particular area.³
5. In making a decision on controlled locality status, NHS England 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 character over time. For example:

² www.pcc-cic.org.uk/article/clothier-report

³ <https://www.gov.uk/government/collections/rural-urban-classification>

- 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. NHS England 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 for example as a result of validating dispensing patient lists.
 8. Whenever a controlled locality determination is to be made, a site visit may need to 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 1983⁴.
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. NHS England 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;

⁴ <http://www.legislation.gov.uk/ukxi/1983/313/contents/made>

- a mixture of the above; or
- none of the above.

Prejudice

13. Where a routine application to open new or additional pharmacy premises is received for a controlled locality and the decision-maker (set out in chapter 3) determines that it is not in a reserved location, the test of “prejudice” must be applied.
14. If the decision-maker (set out in Chapter 3) is satisfied that granting the routine application would, in its opinion, prejudice the proper provision of relevant NHS services, either in the relevant HWB area or in the area of a neighbouring HWB, then it must refuse the application. The decision-maker must be satisfied that granting the routine application would prejudice the proper provision of relevant NHS services, not that it may or could do so.
15. The onus is on the person/organisation alleging prejudice to provide evidence of this. The decision-maker (set out in Chapter 3) will therefore need to take into account all representations it receives with regards to the issue of prejudice.
16. The Regulations do not provide any definition of the concept of prejudice. In general, it means that nothing must be done which would compromise the ability of people in any controlled locality to access pharmaceutical services, LPS, dispensing services or primary medical services. In the 1996 case *R –v- North Yorkshire FHSA ex parte Dr Wilson and Partners Justice Carnwath* said *"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"*.
17. A mere reduction in the total level of service provided by a particular pharmacy or GP practice is not of itself prejudice. Prejudice arises where the service that people can rightly expect to be provided by the NHS has in some respect to cease or otherwise be curtailed or withdrawn without proper substitution in the area. In practice, the existence of prejudice involves, to a greater or lesser extent, making a judgment about events that will occur in the future. Inevitably, therefore, it can often be extremely difficult to judge whether or not there will be prejudice.
18. The burden of proof is on the party alleging that prejudice will occur. Each case will, therefore, turn very much on its own particular facts. In considering questions of prejudice, it is important that the decision-maker focus only on those services which have to be provided within the terms of service of NHS primary medical and pharmaceutical services provision. The fact that non-NHS services or NHS services provided above the standard level set by the terms of service may be curtailed should not be regarded as relevant.

Gradualisation

19. 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 where the practice has premises approval and either outline consent or historic rights to dispense to that area.
20. When NHS England 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.
21. If a new pharmacy routine 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 only pharmacy they live within 1.6km of is a distance selling pharmacy, or
 - a reserved location has been determined in connection with the pharmacy and has taken effect, or
 - NHS England has granted a serious difficulty application in respect of the patient.
22. The new arrangements may, however, be phased in by means of a period of gradualisation.
23. Gradualisation – that is, the postponement of any requirement for dispensing by doctors to cease – is to be considered:
 - Where it is determined that an area is no longer a controlled locality, or part of one,
 - Determinations of routine applications where the proposed premises or best estimate are in a controlled locality but not a reserved location,
 - Pharmacy applications (other than distance selling premises) involving a relocation where the proposed premises are in, or within 1.6km of, a controlled locality, and
 - Following a redetermination of a reserved location where it is determined that the pharmacy is no longer in a reserved location

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

24. 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 or send 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.

25. There is no separate procedure for making decisions on gradualisation, instead it is a decision that will be made in the situations listed in paragraph 23 above. As well as considering any representations received, the following factors are to be taken into account when NHS England 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.

26. NHS England may postpone the effect of its:

- determination that an area is no longer a controlled locality or part of a controlled locality, or
- decision to grant a routine application for pharmacy premises, or
- decision to grant a no significant change relocation within or into a controlled locality

for a period of time 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 these 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."

27. Periods of gradualisation should generally be no shorter than one month 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 its dispensing patients,
- where the reduction in the number of dispensing patients would lead to staff changes or redundancies, or
- where there is only one pharmacy within a 1.6km 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.

28. If NHS England determines that there will be a period of gradualisation it is for NHS England to inform those patients who are no longer eligible that they can no longer receive dispensing services and to provide support to those patients in finding a pharmacy.

29. Whilst gradualisation is most often thought of in connection with the loss of dispensing patients by a dispensing practice, it may also be given to a pharmacy where a dispensing practice successfully applies for outline consent and premises approval for a new area (regulation 57).

Procedure for Determining a Controlled Locality

- 30. NHS England may at any time consider and determine whether or not any locality, because it is rural in character, is to be a controlled locality or is to be part of a controlled locality.
- 31. In addition, a LMC or LPC may apply in writing to NHS England requesting that it determine whether or not a specified area is to be a controlled locality or is to be part of a controlled locality.
- 32. It is important that accurate records are maintained of all controlled locality determinations due to the five year bar set out in regulation 36(3). Ideally a searchable database will be maintained.

Action	
1.	<p>Where:</p> <ul style="list-style-type: none"> • The decision-maker (Chapter 3) 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 NHS England to determine whether or not an area is to be, or is to be part of, a controlled locality, <p>refer to controlled locality records to determine whether the area has been determined in the last five years.</p>
2.	<p>If the area has not been determined in the last five years, record the intention to make a determination and go to step 8.</p> <p>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 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.</p>
3.	<p>Where the decision-maker (set out in Chapter 3) must first satisfy itself that there has been a substantial change in circumstances, gather relevant information on the area. This may involve a site visit.</p> <p>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 paragraph 10 below).</p> <p>Complete the report at Annex 1.</p>
4.	<p>If the decision-maker (set out in Chapter 3) determines that there has been no substantial change in circumstances send Annex 2 to the LMC or LPC that made the application and move to step 5 below.</p>

Action	
	Where the decision to make a determination was not instigated by a request from the LMC or LPC there are no further actions in relation to this procedure.
5.	Diarise the latest date for appeals to be made.
6.	If notice of an appeal is received advise the decision-maker (set out in Chapter 3) and assist in the production of a response.
7.	<p>If NHS Resolution determines that there has been no substantial change in circumstances, update the controlled localities database accordingly. There are no further actions to be undertaken.</p> <p>If NHS Resolution determines that there has been a substantial change in circumstances, move to the step 8.</p>
8.	<p>If:</p> <ul style="list-style-type: none"> • no determination has been made in the last five years; or • the decision-maker (set out in Chapter 3) or NHS Resolution determines that there has been a substantial change in circumstances, <p>move to step 9.</p>
9.	<p>Send Annex 3 to interested parties notifying of the intention to make a controlled locality determination. Those who may be affected by the determination include:</p> <ul style="list-style-type: none"> • The LPC whose area includes all or part of the area to be determined (regulation 38(1)(a)); • The LMC whose area includes all or part of the area to be determined (regulation 38(1)(b)); • 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)(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)); • Practices and dispensing doctors included in a dispensing doctors list who have dispensing patients living in the area to be determined (regulation 38(1)(e)); • Where the determination is as a consequence of a routine application, the person making that application; and • Any HWB whose area includes all or part of the area to be determined

Action	
	<p>Consideration should be given as to whether there are any providers of primary medical services who are not dispensing practices but who may be affected by the determination. If there are then they should be notified (regulation 38(1)(e)).</p> <p>Under regulation 38(2) notice of the proposed determination may be given to such other persons as the decision-maker (set out in Chapter 3) considers it appropriate to do so. This may include Parish Councils and patient participation groups.</p>
10.	<p>During the 30-day notification period identify any dispensing patients living in the area that is to be determined.</p> <p>Arrange a site visit, if required, and gather information on the area.</p> <p>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).</p>
11.	<p>After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made:</p> <ul style="list-style-type: none"> • 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). <p>Distribute to the interested parties.</p>
12.	<p>Diarise the latest date for appeals to be made.</p>
13.	<p>If notice of an appeal is received advise the decision-maker (set out in Chapter 3) and assist in producing a response.</p>
14.	<p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area is a controlled locality, or is part of a controlled locality, go to step 15.</p> <p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area is no longer a controlled locality, or is no longer part of a controlled locality, go to step 16.</p> <p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution determines that the area is not a controlled locality, or is not part of a controlled locality, go to step 17.</p>

Action	
15.	<p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area is a controlled locality, or is part of a controlled locality, the boundary must be precisely delineated on a map.</p> <p>Ensure that the map is of sufficient size to enable identification of a single dwelling as being in a controlled locality or not. Maps are to be produced and stored in an electronic format for ease of distribution, retrieval and editing.</p> <p>The map must be sent to the HWB that has all or part of that controlled locality in its area.</p> <p>Update the controlled locality database.</p> <p>There are no further actions.</p>
16.	<p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, 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 database.</p> <p>Advise the HWB that has all or part of the area that is no longer a controlled locality in its area.</p> <p>Go to step 18</p>
17.	<p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, 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 database.</p> <p>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.</p> <p>Go to step 18.</p>
18.	<p>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 practice dispensing lists (having regard to the gradualisation decision, including any appeal relating to this).</p> <p>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).</p> <p>Resolve any queries raised by practices, carrying out site visits if necessary.</p>

Action	
19.	Diarise the date for responses from the practices
20.	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.
21.	Diarise the date of removal.
22.	On the date of removal ask the Primary Care Support Service Provider to change the patients' dispensing status on Exeter. There are no further actions to be completed.

Redeterminations of Controlled Localities

33. Where the question of whether or not an area is to be a controlled locality, or is to be part of a controlled locality, has been determined that question must not be considered again in relation to that area:
- For five years, beginning with the date of the determination of NHS England, or if that determination was appealed, the date of the decision on appeal;
 - Unless NHS England is satisfied (within that five years) that there has been a substantial change in circumstances in relation that area since the question was last determined.
34. It is therefore important that accurate records are maintained of all controlled locality determinations.

Reserved locations

35. The issue of reserved location status is to be considered in relation to all pharmacy routine applications where the premises or best estimate are in a controlled locality.
36. Where the applicant identifies the premises from which they wish to provide pharmaceutical services, then that is the centre point to be used in undertaking the resident registered population count. The Regulations refer to this as the 'relevant location'.
37. Where the applicant gives a best estimate then the decision-maker (set out in Chapter 3) will need to have regard to that when estimating the likely location of the pharmacy. This location is then to be used as the centre point in undertaking the resident registered population count. The decision-maker (set out in Chapter 3) should fully document how it determined this centre point. Where the applicant

has given a poorly defined best estimate, or one which straddles the boundary of a controlled locality, then it will be necessary to ask the applicant to provide a better best estimate. This will be necessary in order to determine the centre point for the resident registered population count, and also to determine whether the best estimate falls within a controlled locality or not.

38. Once the 'relevant location' has been determined this information is to be given to the Primary Care Support Service Provider who will undertake the resident registered population count.
39. Representations on whether the 'relevant location' is within a reserved location or not will be sought when the application is notified to interested parties and will be taken into account by the decision-maker (set out in Chapter 3).
40. The decision-maker (set out in Chapter 3) should note that the reserved location determination is made based on the circumstances as they pertained on the day the application was received (regulation 41(2)).
41. The area within a 1.6km radius of the 'relevant location' is a reserved location if:
 - the number of individuals residing in the area which is within 1.6km of the 'relevant location' who are on a patient list (i.e. are registered with a GP practice, excluding temporary residents) is less than 2,750; and
 - NHS England is not satisfied that if pharmaceutical services were provided at the 'relevant location', 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.
42. The second bullet point in essence means that where the decision-maker (set out in Chapter 3) is satisfied that the use of pharmaceutical 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 then it would not determine that the 'relevant location' is in a reserved location. Decision-makers should be aware of a change in the way that NHS Resolution has approached the issue of reserved locations, in particular in relation to regulation 41(3)(b) and should read appeal decision [SHA/18698](#) which was issued in September 2017.
43. Notice of the decision on the issue of reserved location status forms part of the notification of the decision to grant or refuse the application. The decision must be fully reasoned as the LPC, LMC, GP practices, LPS contractors or a person on a pharmaceutical or dispensing doctor list who is notified of the decision can appeal it.
44. If the decision-maker (set out in Chapter 3) determines that the 'relevant location' is within a reserved location this will only take effect if the application is granted and the pharmacy subsequently opens. If the application is refused or the pharmacy does not open then the reserved location determination falls
45. Where a reserved location takes effect, then NHS England must:
 - delineate the boundary of the reserved location precisely on a 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,
 - publish that map, and
 - make that map available as soon as is practicable to the HWB that has all or part of that reserved location in its area.
46. At the point the reserved location takes effect, dispensing patients who live within it can remain as such with their dispensing practice but may also choose to have their prescriptions dispensed at a pharmacy, or both.
47. If the applicant fails to submit a valid notice of commencement and the pharmacy is not included in the relevant pharmaceutical list, then the reserved location determination does not take effect.

Re-determinations of a reserved location

48. The applicant, or any future owner of the pharmacy, may request that NHS England undertakes a further determination or determinations. Where this occurs, the following procedure should be followed.
49. It should be noted that NHS England cannot revisit a reserved location determination of its own accord.

Action	
1.	On the day the request is received, ask for a resident registered patient count to be undertaken by the Primary Care Support Service Provider using either the identified premises or the 'relevant location'.
2.	Send Annex 10 to those interested parties listed in paragraph 19, Schedule 2 of the Regulations referring to Annex 11.
3.	During the 30-day notification period identify any dispensing patients living in the area that is to be determined.
4.	Prepare a report (Annex 12), which includes the resident registered population count and any representations that have been received, for the decision-maker (set out in Chapter 3). Include information on the number of dispensing patients by practice who may be affected if the area is no longer a reserved location.
5.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made: <ul style="list-style-type: none"> • Notification of determination for those with appeal rights (Annex 13);

Action	
	<ul style="list-style-type: none"> • Notification of determination to dispensing practices (Annex 14); and/or • Notification of determination for those with no appeal rights (Annex 15). <p>Once the decision letters are signed distribute to the interested parties.</p>
6.	Diarise the latest date for appeals to be made.
7.	If notice of an appeal is received advise the decision-maker (set out in Chapter 3) and assist in producing a response.
8.	<p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area within 1.6km of the 'relevant location' is still a reserved location go to step 9.</p> <p>If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area within 1.6km of the 'relevant location' is no longer a reserved location go to step 10.</p>
9.	If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area within 1.6km of the 'relevant location' is still a reserved location there are no further actions to take.
10.	If the decision-maker (set out in Chapter 3) or, on appeal, NHS Resolution, determines that the area within 1.6km of the 'relevant location' is no longer a reserved location, the map should no longer be published and the HWB advised accordingly.
11.	<p>If there are dispensing patients living in the area that has been determined to no longer be a reserved location, record the date on which they must be removed from practice dispensing lists (having regard to the gradualisation decision, including any appeal relating to this).</p> <p>If gradualisation has been given, prepare lists of dispensing patients by practice (i.e. those who will be removed from dispensing lists) and send a letter to the relevant practices (Annex 16) enclosing the list of patients and a copy of the letter to be sent to the affected patients (Annex 17).</p> <p>Resolve any queries raised by practices, carrying out site visits if necessary.</p> <p>Note – the timescales may need to be altered to reflect the actual period of gradualisation or if no gradualisation has been given.</p>
12.	Diarise the date for responses from the practices

Action	
13.	When the date for responses from the practices has passed or once any queries have been resolved send the letter at Annex 17 to the affected patients.
14.	Diarise the date of removal.
15.	On the date of removal ask that the patients' dispensing status be amended on Exeter. There are no further actions to be completed.

Additional steps for pharmacy routine applications in a controlled locality

50. This section of the chapter is relevant where a pharmacy routine application in a controlled locality is granted, a period of gradualisation was given as a result of the grant of the application, and a valid notice of commencement is received.

1.	When the notice of commencement is received, request the Primary Care Support Service Provider for a list of the dispensing patients who live within 1.6km of the pharmacy by practice. On receipt send Annex 18 to each practice that has dispensing patients who live within 1.6km of the pharmacy, enclosing the list of patients and a copy of the letter to be sent to the affected patients (Annex 19). Resolve any queries that may be raised by the practices, carrying out site visits if necessary.
2.	Send Annex 19 to the affected patients as soon as the date for responses by the practices has passed or once any queries have been resolved.
3.	Advise the Primary Care Support Service Provider of the date on which each patient's dispensing status is to be amended on the Exeter system.
4.	There are no further actions to be completed regarding this procedure.

Additional steps for pharmacy routine applications near a controlled locality

51. This section of the chapter is relevant where a pharmacy routine application in or within 1.6km of a controlled locality is granted, a period of gradualisation was given as a result of the grant of the application, and a valid notice of commencement is received.

1.	<p>When the notice of commencement is received, request the Primary Care Support Service Provider for a list of the dispensing patients who live within 1.6km of the pharmacy by practice.</p> <p>On receipt send Annex 20 to each practice that has dispensing patients who live within 1.6km of the pharmacy, enclosing the list of patients and a copy of the letter to be sent to the affected patients (Annex 21).</p> <p>Resolve any queries that may be raised by the practices, carrying out site visits if necessary.</p>
2.	<p>Send Annex 21 to the affected patients as soon as the date for responses by the practices has passed or once any queries have been resolved.</p>
3.	<p>Advise the Primary Care Support Service Provider of the date on which each patient's dispensing status is to be amended on the Exeter system.</p>
4.	<p>There are no further actions to be completed regarding this procedure.</p>

Appeal rights

52. Regulation 45 of the Regulations sets out when a right of appeal is to be given in relation to decisions made under Part 7 of the Regulations. It should be noted that appeal rights in relation to rurality matters are wider than for those in relation to the overall decision on a routine or excepted application and care must be taken to ensure that appeal rights are given correctly.
53. It is for NHS England to determine who is to be given a right of appeal and against which decision. The decision-maker should ensure that this is clearly articulated within the decision report on each application or determination.

Giving appeal rights

An unforeseen benefits application is received and the applicant gives a best estimate in a village which is part of a controlled locality. In determining the application NHS England:

- Is satisfied that there are no grounds to refuse the application by virtue of regulation 40(2).
- Notes that there is no other pharmacy in the village and therefore it is not required to refuse the application by virtue of regulation 31.

- Notes that there is no LPS designation in place in, or for, the village and therefore it is not required to refuse the application by virtue of regulation 32.
- Notes that there are 1,500 people living within 1.6km of the 'relevant location' and is satisfied that it is within a reserved location.
- Notes that as a reserved location determination has been made it is not necessary to consider the prejudice test in regulation 44.
- Having considered regulations 18 and 19 is satisfied that granting the application would confer significant benefits on persons in the area of the relevant HWB which were not foreseen when the PNA was published.

The application is therefore granted and the decision-maker (set out in Chapter 3) decides that a period of one month's gradualisation should be given to the dispensing practice that will lose 100 dispensing patients which equates to 5% of its dispensing patient list.

Appeal rights are given as follows:

- The applicant may appeal the reserved location decision.
- The GP practice may appeal the reserved location and gradualisation decisions.
- The LMC and LPC may appeal the reserved location decision.
- The four pharmacies who were notified of the application as NHS England was of the opinion that their interests may be significantly affected if the application were granted were notified of the decision and given a right of appeal against the reserved location decision and the decision to grant the application.

54. A right of appeal against a decision that an area is or is not a controlled locality or part of one should be given to:
- The person whose routine application led to the decision to make the controlled locality determination,
 - The LPC who is given notice of the decision,
 - The LMC who is given notice of the decision, and
 - GP practices, LPS contractors, and a person on a pharmaceutical or dispensing doctors list who, in the opinion of NHS England, may be affected by the determination and who are given notice of the decision.
55. Where a LMC or LPC asks NHS England to determine whether or not an area is, or is part of, a controlled locality but NHS England is satisfied that it cannot under regulation 36(3), then that committee is given a right of appeal but only that committee.
56. Appeal rights in relation to a determination as to whether or not a 'relevant location' is in a reserved location are to be given to:
- The person whose routine application led to the reserved location determination,
 - The LPC who is given notice of the decision,
 - The LMC who is given notice of the decision, and
 - GP practices, LPS contractors, and a person on a pharmaceutical or dispensing doctors list who, in the opinion of NHS England, may be affected by the determination and who are given notice of the decision.

57. Appeal rights in relation to the re-determination of a reserved location are to be given to:
- The person whose routine application (and any future owner of the pharmacy) led to the reserved location determination,
 - The LPC who is given notice of the decision,
 - The LMC who is given notice of the decision, and
 - GP practices, LPS contractors, and a person on a pharmaceutical or dispensing doctors list who, in the opinion of NHS England, may be affected by the determination and who are given notice of the decision.
58. Where an application is granted partly on the basis that in the opinion of NHS England to do so would not prejudice the proper provision of relevant NHS services in the area of the relevant HWB or of a neighbouring HWB, then appeal rights against the prejudice test in regulation 44 are to be given to:
- A GP practice, or another person on the dispensing doctor list of the area of the relevant HWB, who made representations in writing within the 45-day period, and
 - The decision-maker (set out in Chapter 3) is satisfied that having regard to those representations that the practice/person made a reasonable attempt to adequately express their grounds for opposing the application and those grounds do not amount to a challenge to the legality or reasonableness of a PNA or to the fairness of the process by which the assessment was undertaken, and the grounds are not vexatious or frivolous.
59. In the case of a GP practice care should be taken that a right of appeal is only given in relation to elements of the decision rather than the overall decision to grant an application.

CHAPTER 33

Procedures - Dispensing by Doctors

Chapter aims and objectives

8. The purpose of this chapter is to ensure that applications from doctors to provide pharmaceutical services and serious difficulty applications are dealt with in line with the Regulations.
9. In general applications from doctors will be received and processed by the Primary Care Support Service Provider. Any applications received directly by NHS England should be forwarded on. Whilst applications are processed there will be times when a decision or decisions need to be made by NHS England in line with chapter 3. This chapter identifies those times and provides additional information for NHS England to consider. It also identifies when NHS England will be notified of progress.
10. Applications are to be determined within 30 days (applications which are not notified to interested parties) or four months (applications which are notified) unless NHS England has good cause to take longer, e.g. a delay in completing the required fitness to practise checks.
11. The chapter also deals with serious difficulty applications from patients and validating dispensing patient lists.
12. This chapter must be read in conjunction with Part 8 of the Regulations and Chapter 15 of the DHSC Guidance.

Background

13. 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.
14. 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, where the practice has premises approval and either outline consent or historic rights to dispense to that area.
15. Decisions made by NHS England can generally be appealed to NHS Resolution. If the Regulations make no provision for an appeal for example decisions on serious difficulty applications, or if someone is dissatisfied with a decision of NHS Resolution, any challenge would need to be made via the courts. Robust audit trails must therefore be maintained for each application and all determinations and decisions made under this chapter must be fully reasoned.

Outline consent and/or premises approval applications

Receipt and first referral

16. Outline consent and/or premises approval applications are to be received by the Primary Care Support Service Provider who will process them on behalf of NHS England.
17. On receipt, the Primary Care Support Service Provider will send a 'first referral' to the relevant NHS England pharmacy contracts team i.e. the team in whose area the dispensing doctor's premises are located.
18. The decision-maker (see Chapter 3) will need to consider the questions asked in the first referral and respond to the Primary Care Support Service Provider within five working days.
19. In relation to applications for outline consent and premises approval, depending on the availability of controlled locality maps it may be necessary to defer the application in order that a controlled locality determination can be made. Where this is the case advise the Primary Care Support Service Provider who will advise the applicant. The controlled locality determination will be undertaken by NHS England, following the process set out in Chapter 9. Once the controlled location determination has been made, advise the Primary Care Support Service Provider so that they can continue to process the application.
20. It is for NHS England to check the information that has been provided by the applicant is sufficient.

Identifying interested parties

21. Determining the parties who must be notified of applications pursuant to regulation 52 of the Regulations is the responsibility of the decision-maker set out in Chapter 3.
22. The following paragraphs will help the decision-maker to identify 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.
23. The following paragraphs will not cover every potential scenario and therefore ultimate responsibility to determine who is to be notified of an application rests with the decision-maker.
24. Where the decision-maker is reasonably satisfied that the distances shown in the paragraphs below will include persons who would not be significantly affected or who would not have a significant interest, the distances can be reduced to an appropriate level. Conversely, if the distances do not identify any persons then they may be increased accordingly. When identifying contractors who may be significantly affected by the grant of the application, NHS England may wish to look at practice prescribing dispensing data which is published by the [NHSBSA](#) on a monthly basis as this shows where prescriptions written by GP practices are dispensed.

Contractors included in a pharmaceutical list (regulation 52(1)(c)(i))

25. The interests of contractors included in one of the pharmaceutical lists might be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises lie in a locality that is not controlled, the contractor's premises are within 2km in a direct line from the applicant's proposed premises, or
 - where the applicant's proposed premises lie in a controlled locality, the contractor's premises are located within 8km in a direct line from the applicant's proposed premises.

Head offices of bodies corporate are also to be notified where this information is known.

Persons entitled to be included in a pharmaceutical list (regulation 52(1)(c)(ii))

26. The interests of persons whose applications for inclusion have been granted (but who are yet to be included) might be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises lie in a locality that is not controlled, the person's proposed premises are located within 2km in a direct line from the applicant's proposed premises, or
 - where the applicant's proposed premises lie in a controlled locality, the person's proposed premises are located within 8km in a direct line from the applicant's proposed premises.

Local pharmaceutical services (LPS) contractors (regulation 52(1)(d))

27. The interests of LPS contractors might be significantly affected by the grant of the application (and notified of it) if:
- where the applicant's proposed premises lie in locality that is not controlled, the LPS contractor's premises are located within 2km in a direct line from the applicant's proposed premises, or
 - where the applicant's proposed premises lie in a controlled locality, the LPS contractor's premises are located within 8km in a direct line from the applicant's proposed premises.

Patient, consumer or community groups in the HWB area (regulation 52(1)(e))

28. The following groups should be considered to have a significant interest in the outcome of the application and be notified:
- where the applicant's proposed premises are in a controlled locality, the relevant Parish Council.

GP practices (regulation 52(1)(f))

29. Dispensing practices that have dispensing patients within the area identified in the application should be considered to have a significant interest in the outcome of the application and should be notified of it.

GP performers included in the dispensing doctor list (regulation 52(1)(f))

30. GP performers included in the dispensing doctors list that have dispensing patients within the area identified in the application should be considered to have a significant interest in the outcome of the application and should be notified of it (if the practice is not already being notified).

Explanatory note for patient, consumer or community groups

31. In order to help these groups, understand why they are being notified of the application, the PCM will need to complete the relevant explanatory note and send it to the Primary Care Support Service Provider for inclusion with the notification letter. The cover letter and explanatory note are already part of the notification letter.

Notification to interested parties

32. The Primary Care Support Service Provider will advise the decision-maker when the application is notified to interested parties. Patient requests to be dispensed to which accompanied the application will not be circulated.

Application report

33. The Primary Care Support Service Provider will partially complete the template report and will pass it to NHS England for completion. Due regard should be given to the relevant regulations in Part 8 of the Regulations and DHSC guidance chapter in the completion of the report.

Determination

34. The decision-maker is responsible for ensuring that all relevant regulations are considered and that decisions are fully documented in the minutes. It is not good enough to simply say that an application has been granted or refused.
35. Regulation 51 sets out the matters to be considered when determining an application for outline consent and premises approval. Regulation 55(2) sets out the matters for premises approval applications (either before or after outline consent takes effect).

Rights of appeal

36. After determining the application, the decision-maker must then determine whether the applicant has a right of appeal and whether anyone has a third party right of appeal in line with the Regulations.
37. Rights of appeal for the applicant and third parties are set out in regulation 63 of the Regulations.
38. The decision-maker must fully document the reasons for giving (or not giving) third party rights of appeal to a particular party.

Notification of decision and appeals

39. The Primary Care Support Service Provider will advise the decision-maker when the determination is notified to interested parties.
40. If an appeal to NHS Resolution is notified to the Primary Care Support Service Provider this will be passed to the decision-maker for a response.

Taking effect

41. Where an application for outline consent and premises approval is granted, NHS England will need to determine when outline consent takes effect in line with regulation 53(3) to (14) of the Regulations. Where a doctor only applies for premises approval, taking effect is to be determined in line with regulation 56 of the Regulations.
42. The Primary Care Support Service Provider will check for outstanding applications at the end of the 30-day appeal period and advise the relevant pharmacy contract manager accordingly.
43. Where there is an outstanding pharmacy application which affects the taking effect of outline consent the Primary Care Support Service Provider will advise the applicant. Where a request for a determination as to whether outline consent may take effect is received it will be forwarded to the relevant pharmacy contract manager so a determination can be made. Such determinations are to be made in line with the Regulations and the Primary Care Support Service Provider will advise the applicant of the outcome.
44. Whilst the Regulations set out when outline consent and premises approval may take effect, in reality there may be a delay in the practice actually starting to dispense to patients who live in the area it now has outline consent for. NHS England will need to liaise with the practice and the relevant CCG so that NHS BSA and the Exeter system can be updated where a practice starts dispensing for the first time. In this instance the primary medical services contract will need to be varied to include the dispensing terms of service, however where a practice is already dispensing no variation to the primary medical services contract is required.
45. The relevant dispensing doctors list will need to be updated once the practice starts dispensing to the new area and at this point the relevant LMC, LPC and HWB will also need to be notified.

Procedure for Determining 'Serious Difficulty' Applications

46. 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).
47. 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 NHS England will have to deal with such applications.

48. The test is whether a patient would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of:
 - distance, or
 - inadequacy of means of communication.
49. Applications may be made whether or not the patient lives in a controlled locality.
50. Each case is to be considered on its merits although the following factors are not generally deemed to warrant the grant of a serious difficulty application as they do not meet the requirements of regulation 48(2):
 - Lack of access to a car
 - Working away from home regularly
 - Claims that a pharmacy is inaccessible, however the person is able to access their GP surgery and/or other healthcare services and/or other facilities required for everyday living
 - Lack of internet access
 - Convenience.

Action	
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 1) has not been used. Where information is missing, inform either the patient or the GP.
3.	Once all information is provided and it has been validated as much as possible, pass to the PSRC for a decision as to whether it is to be granted or not.
4.	Ensure decisions are made and communicated to the patient and their GP practice within 30 days of receipt of a fully completed application. Annex 2 is to be used where the application is refused.

Action	
5.	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.
6.	Where the application is granted, ask the Primary Care Support Service Provider to update the patient's entry on the Exeter system and to add a patient note to the patient's Exeter file stating that the patient may 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.
7.	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

51. 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 NHS England enclosing the patient's request.
52. 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

53. 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 or 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?
54. NHS England will need to ensure that dispensing patient lists are accurate.
55. Where a dispensing practice is considering merging with another practice the regional team will need to discuss and agree with them which areas they have

premises approval and either historic rights or outline consent to where this is not already documented.

56. Validation of dispensing patient lists began in 2013 and NHS England should continue to discuss the progress of this process with the relevant LMC(s) and LPC(s).
57. 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.

Patients: Monitoring the 1.6km Rule

58. 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.
59. NHS England 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	
1.	For each dispensing practice identify a list of dispensing patients who live within 1.6km of a pharmacy and check that: <ul style="list-style-type: none"> • They do not live within a reserved location that was defined in connection with that pharmacy, and • Have not had serious difficulty applications granted.
2.	Send Annex 3 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 Pharmaceutical Services Regulations Committee 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. Although these patients should not have been dispensed to by their practice, a period of gradualisation may be given to allow patients to adjust

Action	
	to losing their dispensing status and for practices to adjust their working practices accordingly.
5.	Send Annex 4 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, ask the Primary Care Support Service Provider to change the patients' dispensing status on Exeter to prescribing.

Patients: Ensuring Dispensing only Takes Place in Controlled Localities

60. Patients who do not live within a controlled locality must have had a serious difficulty application granted or they will be unable to have drugs dispensed by their GP practice.
61. NHS England is required to publish its controlled locality maps. NHS England 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.
62. NHS England 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.

Action	
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 5 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 Pharmaceutical Services Regulations Committee of the numbers of patients involved for

Action

	<p>each practice both as a total number of patients and the percentage of the dispensing patient list this equates to.</p> <p>Although these patients should not have been dispensed to by their practice, a period of gradualisation may be given to allow patients to adjust to losing their dispensing status and for practices to adjust their working practices accordingly.</p>
5.	<p>Send Annex 6 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.</p>
6.	<p>On the date of removal from the practice's dispensing patient list, ask the Primary Care Support Service Provider to change the patients' dispensing status on Exeter to prescribing.</p>

CHAPTER 34

Procedure - Advanced Services

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 Regulations and the Directions.
2. This chapter does not apply to contractors who hold LPS contracts. It also doesn't apply where a contractor applies to provide one or more advanced services under regulation 23 of the Regulations – for those applications please refer to chapter 24.
3. A pharmacy contractor or DAC 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);
 - community pharmacy seasonal influenza vaccination - *pharmacy contractors only*; and
 - NHS urgent medicine supply pilot scheme– *pharmacy contractors only*
4. In particular if a:
 - Pharmacy contractor or DAC notifies NHS England that it wishes to provide one or more of the advanced services set out in the Directions, NHS England must ensure all the required information is received;
 - Pharmacy contractor applies to NHS England seeking to provide MURs at premises other than its pharmacy premises, NHS England must determine that application in a fair and transparent manner.
5. As at January 2018, sign-up to provide the influenza vaccination and NHS urgent medicine supply services is managed by NHS Business Services Authority (NHSBSA) NHS Prescription Services and is therefore not included within this chapter. NHS England has agreed the arrangements for managing this process with NHS Prescription Services and they are not incorporated within the Pharmacy Manual.
6. Where a pharmacy wishes to provide the influenza vaccination service to people living in long-stay residential care homes or other long-stay care facilities, NHS England should follow the process set out in the service specification.

Procedure

7. For the avoidance of doubt this procedure covers the provision of MURs, NMS, AURs and the stoma appliance customisation service.
8. On receipt of a notification of intention to provide one or more of the above listed advanced services (or an application to provide MUR services at premises other than the listed pharmacy premises or via the telephone), check the Directions to ensure that all the required information has been provided as set out in the following forms:
 - MUR notification form (PSNC's PREM1) - <http://psnc.org.uk/services-commissioning/advanced-services/murs/mur-premises-requirements/>
 - MUR provision at alternative premises (PSNC's PREM2A, PREM2B or PREM2C) - <http://psnc.org.uk/services-commissioning/advanced-services/murs/conducting-murs-off-the-pharmacy-premises/>
 - MUR provision via the telephone for a particular patient on a particular occasion (PREM2D) - <http://psnc.org.uk/services-commissioning/advanced-services/murs/conducting-murs-off-the-pharmacy-premises/>
 - NMS notification form - <http://psnc.org.uk/services-commissioning/advanced-services/nms/notifying-nhs-england-prior-to-providing-the-nms/>
 - Stoma appliance customisation and AUR notification form - <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff/drug-tariff-part-ix>
9. 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 (DBS) certificate in respect of each pharmacist providing MUR services.
10. If the pharmacist already has an enhanced DBS certificate in connection with providing NHS services, a further certificate will not be required, although NHS England reserves the right to require a further certificate if it has reasonable cause to do so. Where an enhanced DBS certificate is required, NHS England will not pay for, or reimburse the cost of, it.
11. If any 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.
12. If the contractor fails to provide the information within the required timescale write to advise it that it may not provide the service.
13. 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 37.
14. When all the required information is received, check the contractor's monitoring records to ensure it is satisfactorily complying with its obligations under Schedule 4 (for pharmacy contractors) or 5 (for DACs) to the Regulations.

15. 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.
16. In relation to notifications, if the contractor is compliant:
 - write to the contractor to acknowledge receipt of all necessary information and inform them that NHS England's records have been updated to reflect the provision of the service; and
 - advise the relevant HWB that the service is being provided.
17. In relation to applications, if the contractor is compliant, and where NHS England 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),⁵ NHS England should arrange a visit.
18. Ideally this visit should take place before the contractor starts to provide the service. 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),⁵ refer to Chapter 37.
19. Following the premises visit, NHS England will decide whether the application should be granted in accordance with the steps set out below.
20. An application by a pharmacy contractor (PREM2A) 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 DBS certificate.
21. An application by a pharmacy contractor (PREM2B) 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 DBS certificate.
22. An application by a pharmacy contractor (PREM2C) to provide MUR 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 DBS certificate.

⁵ For MUR services. See Direction 6(9) for NMS and Direction 9(5) for the stoma appliance customisation service.

23. In relation to an application to provide MURs services via the telephone the following is to be noted:
- Applications are to be made individually in advance;
 - The contractor must provide a rationale for requesting a 'telephone MUR'. Applications on the basis of business convenience are not to be granted;
 - MURs should only be conducted via telephone in exceptional circumstances for the benefit of the patient; and
 - Patient consent should be obtained before the request is made.
24. Requests to conduct more than 5% of MURs via telephone are considered unusual.
25. An application by a pharmacy contractor 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
 - NHS England 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 NHS England because of the potential for misunderstanding and the inability to assess patient's current use).
26. Advise the contractor of the outcome of their application no later than 15 working days from the date of the visit.
27. File copies of all forms relating to the provision of advanced services in the contractor's premises file.

CHAPTER 35

Enhanced Services

Chapter aims and objectives

1. This chapter deals with the commissioning of enhanced services by NHS England. It is not to be used where a contractor applies under regulation 23 to provide an enhanced service (see chapter 24).

Background

2. Pharmaceutical services are defined as those services that NHS England may commission from pharmacies and dispensing appliance contractors namely:
 - Essential services in Part 2, Schedule 4 and the terms of service set out in Schedule 5 of the Regulations,
 - Advanced services for example MURs and the NMS, and
 - Enhanced services
3. The Directions list the advanced and enhanced services that NHS England may commission. These services are referred to as 'directed services' in the regulations and 'additional pharmaceutical services' in the NHS Act 2006.
4. The enhanced services that NHS England may currently (April 2019) commission from pharmacies are listed in Direction 14:
 - An anticoagulant monitoring service
 - An antiviral collection service
 - A care home service
 - A disease specific medicines management service
 - A gluten free food supply service
 - An independent prescribing service
 - A home delivery service
 - A language access service
 - A medication review service
 - A medicines assessment and compliance support service
 - A minor ailment scheme
 - A needle and syringe exchange service
 - An on demand availability of specialist drugs service
 - Out of hours services
 - A patient group direction service
 - A prescriber support service
 - A schools service
 - A screening service
 - A stop smoking service
 - A supervised administration service

- A supplementary prescribing service
 - An emergency supply service
5. The purpose of each service is briefly outlined in the Directions, but NHS England is free to develop its own specifications for each service that it wishes to commission in conjunction with the relevant LPC or LPCs. There are no national prices or pricing structure for enhanced services and these will be agreed with the relevant LPC or LPCs. Service Level Agreements (SLA) may be used for the commissioning of enhanced services from pharmacies.
 6. Where NHS England chooses to commission a service that is not listed in Direction 14 then it is not an enhanced service and consideration will need to be given as to how it is to be commissioned as a service level agreement will not be sufficient.
 7. Other organisations such as CCGs and local authorities may choose to commission services from pharmacies. Where they do, for example the public health services of smoking cessation and needle exchange, these are not enhanced services and do not fall within the definition of pharmaceutical services. They should be termed locally commissioned services.
 8. Where a CCG commissions services from a pharmacy or pharmacies it should use the NHS Standard Contract.

Minimum requirements for service specifications and SLAs

9. Where a pharmacy enhanced service is commissioned the service specification and SLA must:
 - State that the service is being commissioned as an enhanced service, and
 - Reference the relevant part of Direction 14, for example a minor ailment service is being commissioned under Direction 14(1)(f).
10. In addition, it is suggested that the following requirements are included:
 - That the contractor must be fully compliant with the essential services and clinical governance requirements,
 - The premises at which the service is to be provided,
 - The times at which and days on which the service is to be provided,
 - Any specific training, experience, knowledge or qualifications that the staff providing the service must have,
 - How claims for payment are to be made and to whom,
 - How assurance and potential breaches of the requirements will be managed,
 - The circumstances when payment may be withheld,
 - The duration of the SLA,
 - Any notice period should a contractor wish to withdraw from a service,
 - Any reviews of the service provision,
 - Any review of the service specification and how to contribute to the review,
 - Any reporting requirements for service providers, and
 - How complaints about the service will be managed.

Commissioning services against pharmaceutical needs assessments

11. Pharmacy teams should review any needs for, or improvements or better access to, pharmaceutical services that have been identified in the PNAs. This could include the need for a new pharmacy or pharmacies or for a specified service or services.
12. Where a PNA identifies the need for a new pharmacy or pharmacies consideration should be given to whether this should be procured via a LPS contract or left to the usual market entry route.
13. In coming to a decision as to whether or not to commission a specific service, pharmacy teams will wish to discuss this with the relevant CCG and/or local authority.
14. The HWB is to be advised when NHS England begins to commission an enhanced service, or where it ceases to do so, or where there is a change in provider or providers as this will or may have implications for the PNA.
15. Where a CCG or local authority asks NHS England to commission a service from a pharmacy or pharmacies on its behalf, NHS England should first check that it is a service that is listed in the Directions. Where it isn't then the request is to be declined.
16. If the service does fall within the Directions then a discussion will take place as to the benefits and risks of commissioning such a service as an enhanced service by NHS England rather than directly as a locally commissioned service by the CCG or local authority. In the majority of cases it is expected that commissioning a service directly would be the more suitable.
17. The administration fee that will be charged to the CCG or local authority for undertaking the commissioning will need to be considered. This fee is to include staff time and any other administration costs.

Payments

18. Payments for enhanced services are to be made via the NHS BSA local payment application. Pharmacy teams must ensure they accurately enter payments against the relevant service name. Where a commissioned service doesn't fall within one of the listed names it is unlikely to be an enhanced service.

Review and decommissioning

19. The continued commissioning of enhanced services should be reviewed against the relevant PNA to ensure they remain fit for purpose and are meeting the identified needs of the population. Regional teams should bear in mind the duration of the SLA and ensure that reviews are undertaken sufficiently in advance of the termination date so as to allow enough time to continue to commission or decommission the services as appropriate.

20. Should decommissioning of enhanced services be considered by NHS England, it should ensure that it complies with the agreed terms of the SLA regarding termination, and its general duties (see Chapter 28).
21. In particular, regional teams will need to work closely with HWBs in the development of new PNAs so that where services are to be decommissioned as a result of the new PNA sufficient time can be identified to allow for consultation with service users.

CHAPTER 36

Procedures - Opening Hours

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 37.
3. This document must be read in conjunction with the Regulations.
4. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list. Requests by an LPS contractor to change their opening hours should be dealt with in line with their contract.
5. For the avoidance of doubt, the week is defined as 00.00 on Monday to 23.59 on Sunday.
6. It is NHS England's responsibility to ensure that the DoS is updated in line with notified changes to supplementary opening hours and successful applications to change core opening hours. It is for the contractor to ensure that their NHS website profile (where available) is updated in line with notified changes to supplementary opening hours and successful applications to change core opening hours.

Bank and public holidays

7. 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 NHS England 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.

8. Twice a year NHS England will ask each pharmacy contractor in its area to submit its intentions regarding the forthcoming holidays. The Regulations refer to assessments being made of access at a national level. For practical purposes NHS England will undertake assessments of adequacy of provision at HWB level. Once the information is received from the pharmacies in a HWB area an assessment will be made as to whether a contractor is or, as appropriate, contractors are to be directed to open on a particular day or days (see below for the process to issue a direction).
9. Where a contractor is to be open on a bank or public holiday or Easter Sunday this information is to be entered onto their page on the NHS website by the contractor. Ensure that the relevant DoS lead is informed accordingly.

Procedure: determining applications to change core opening hours

10. 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 although some will have 100 core opening hours ("100 hour pharmacies"). It must be noted that there is no ability for 100 hour pharmacies to apply to reduce their core opening hours to less than 100 hours per week. References to 30 hours and to 40 hours, below, are to DACs and pharmacy contractors respectively.
11. A contractor may apply to NHS England 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).
12. Applications must be determined within 60 days of receipt unless NHS England 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.
13. 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.
14. 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.
15. Request any missing information from the contractor or seek clarification on the hours that have been declared. Template wording is provided at Annex 3.
16. If, or once, the application is complete write to the contractor advising the latest date by when a decision will be made. Template wording is provided at Annex 4.

17. Where the application relates to a pharmacy 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 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.

18. 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 PNA for the area within which the contractor's premises are located; and
 - the opening hours of GP practices in the area.
19. When determining the application, the decision-maker must bear in mind that applications to change core opening hours should only be approved where they reflect a change in the needs of people in the area, or other likely users of the premises, for pharmaceutical services.
20. Applications are to be refused in the following circumstances:
- Where they are based simply on business convenience;
 - The premises are subject to the 100 hours condition set out in regulation 65(1) of the Regulations, and the contractor is seeking to reduce their core opening hours to less than 100 per week; and/or
 - The premises are subject to the condition set out in regulation 65(4) or (5) of the Regulations or the NHS (Pharmaceutical Services) Regulations 2012, as amended, unless at least three years have passed since that condition was imposed.
21. The decision-maker's decision on the application is to be recorded in the minutes of the meeting. The minutes must also include the facts relied upon and the duly justified reasons for the decision.
22. 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.

23. 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 6 contains wording for the direction.
24. 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.
25. It should be noted that a direction cannot 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.
26. 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 NHS Resolution's decision.
27. Update the relevant pharmaceutical list once a change in core hours takes effect.
28. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.
29. Ensure the contractor's entry on the DoS is updated for one-off and permanent changes. Remind the contractor to update their NHS website profile.
30. 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

31. A contractor may notify NHS England of a change to its supplementary opening hours under its terms of service as set out in schedules 4 and 5 to the Regulations.
32. A standard notification form has been developed for this purpose (Annex 7).
33. 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 8.
34. The notification will either:
 - not seek to implement the change sooner than the required three months;
 - seek to implement the change sooner than the required three months and increase the total number of hours open each week; or
 - seek to implement the change sooner than the required three months and reduce the total number of hours open each week.

35. Where the contractor is not seeking 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 9.
36. 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 10.
37. 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 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.

38. Update the relevant pharmaceutical list once a change in supplementary opening hours takes effect.
39. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.
40. Ensure the contractor's entry on the DoS is updated for one-off and permanent changes. Remind the contractor to update their NHS website profile.
41. File the notification in the contractor's premises file.

Procedure: directing pharmacy and dispensing appliance contractors to open

42. There may be occasion when NHS England needs to direct a particular contractor to open on certain days or at certain times e.g. on bank and public holidays.
43. If NHS England 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 11.
44. Following this consultation, NHS England must give notice to the contractor of the proposed changes to the days on which, or times at which, the 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 12.
45. 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.
46. Where NHS England directs a contractor to be open for more than 30 or 40 core opening hours in any week it must be satisfied that the contractor will receive reasonable remuneration regarding those additional hours. Such remuneration will be agreed locally between NHS England and the contractor
47. Notify the contractor of the decision. Wording is provided at Annex 13.
48. 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.
49. 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.
50. 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.
51. Update the relevant pharmaceutical list if the direction is for permanent or long-term changes in opening hours.
52. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of permanent or long-term changes.
53. Ensure the contractor's entry on the DoS is updated for long term or permanent changes. Remind the contractor to update their NHS website profile.
54. File the direction in the contractor's premises file.

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

55. 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; and
 - premises have been broken into.
56. 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.
57. Where there is a temporary closure outside of the contractor's control, the contractor is required to notify NHS England using the form at Annex 14.
58. Acknowledge receipt of a temporary suspension notification and review the reason for it. 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 37).
59. 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.
60. 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 the NHS website advising of the period of time when the premises will be closed. Ensure the DoS is also updated.
61. 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.
62. 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

63. 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. Three months' notice must be given.
64. The form at Annex 15 should be used.
65. On receipt of a request for a temporary closure that is within a contractor's control, check that three months' notice has been given.

66. 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 16.
67. 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 17.
68. 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.
69. 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.
70. Advise the contractor of the decision using the wording provided at Annex 18. There are no rights of appeal against the decision; therefore, the decision should be fully reasoned and documented in case of legal challenge.
71. Notify the LPC, LMC and HWB if a temporary suspension is approved and will last for more than one day.
72. Remind the contractor to update their entry on the NHS website advising of the period of time when the premises will be closed. Update the DoS.

CHAPTER 37

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 to it is made in the terms of the contract. Neither does it apply to the provision of pharmaceutical services by dispensing doctors.
3. This chapter must be read in conjunction with the Regulations, the Directions and the DHSC 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 NHS England or its representative.
5. NHS England 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 NHS England to 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;
 - 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. Concerns regarding a contractor's fitness should be dealt with in line with chapter 31.

9. Most issues should be resolved in discussion with the contractor 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 will have access to both written and electronic files.

Pre-screening Questionnaire and Completion of the community pharmacy assurance framework

11. NHS England will monitor contractors against their Terms of Service based on the community pharmacy assurance framework (CPAF).
12. Each year the NHSBSA, on behalf of NHS England will send a request to each pharmacy to complete a screening questionnaire which is a condensed version of the CPAF. Once the date has been agreed Annex 1 is to be tailored and sent by regional teams to the pharmacy contractors in their area. Where wording needs to be tailored this will be provided by the central team.
13. Contractors will be given four weeks to complete the questionnaire which is facilitated by the NHSBSA.
14. Where the contractor is a large organisation, the NHSBSA will liaise with head offices to establish the most effective way of communicating the request within their organisations.
15. NHS England, LPCs and head offices of major multiples will be provided with weekly updates throughout the four week period so that contractors can be encouraged on a local level to complete the questionnaire.
16. At the end of the four week period the answers to the screening questionnaire will be collated by the NHSBSA. The results and indicator set will be available for NHS England via the NHSBSA information services portal within one month of the closure of the questionnaire.
17. The data collected from this questionnaire along with other information held by NHS England will be used to shortlist pharmacies that 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.
18. NHS England 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.
19. 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.

20. NHS England will draw up a list of pharmacies that it considers may require a contract monitoring visit using the criteria in paragraph 27 below. The list of pharmacies who require a visit and the reasons why they have been selected will be documented on the spreadsheet sent from the NHSBSA. This spreadsheet is to be returned to the NHSBSA in the timescales set out. The NHSBSA will then notify each of these pharmacies that they could receive a contract monitoring visit and request that the full CPAF is completed. For Corporate Bodies, the superintendent pharmacist's office is to be informed if any of their branches have been asked to complete the full CPAF. In addition, LPCs should be informed if any of their pharmacies have been selected, although they are not to be told which pharmacies have been selected.
21. NHS England will advise each pharmacy that has been selected to complete the full CPAF pre visit questionnaire using the text in Annex 2. Contractors will be given four weeks to complete the questionnaire which is facilitated by the NHSBSA.
22. At the end of the four week period the answers to the full CPAF questionnaire will be collated by the NHSBSA. The results and indicator set will be made available to NHS England via the NHSBSA information services portal within one month of the closure of the questionnaire. They will be reviewed by the regional team to determine the lists of pharmacies that will receive a visit. Again, the reasons for selecting a pharmacy for a visit will need to be documented and shared with the NHSBSA when requested at the end of the CPAF process.
23. For some contractors, certain aspects of the Terms of Service might not be undertaken at the premises included in the relevant 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).
24. 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 3 to the contractor.
25. Ensure all subsequent communications are copied to the contractor's regional manager or superintendent pharmacist's office (if relevant) so that they are aware of any action that NHS England is proposing to take (and therefore able to attend any visit should they so wish).

Contract monitoring visits

26. Contractors are required by their Terms of Service to allow persons authorised by NHS England 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 of patient care and treatment and the management of the pharmaceutical services provided.
27. Not all pharmacies will receive a visit each financial year (1 April to 31 March) as NHS England has adopted a risk-based approach to visits. Once the CPAF screening questionnaires have been submitted each year, the criteria set out below will be considered as part of the assessment of which contractors need to be prioritised for a contract monitoring visit. The reasoning for the pharmacies selected to complete the full CAPF must be recorded on the NHSBSA spreadsheet (see paragraph 20 above).
 - Non-completion of CPAF screening questionnaire (mandatory selection factor)
 - CPAF screening questionnaire response – overall score less than 2 or where a contractor has scored Level 1 or below for more than three questions
 - Pharmacies identified through the part 1 verification process above as not having the evidence to support their CPAF screening returns
 - New pharmacies which have been included in the relevant pharmaceutical list since June of the previous financial year (excluding those that relocated during the intervening period or those already visited);
 - Pharmacies where there has been a change of ownership since June of the previous financial year unless already visited;
 - Pharmacies where issues or potential concerns are identified in the completed CPAF documents or where a CPAF return was not submitted;
 - Pharmacies where issues of potential concern have been identified previously by regional teams, the Provider Assurance team or from other NHSBSA data; or
 - Concerns relating to patient safety, complaints, adverse NHS website comments and other miscellaneous concerns (irrespective of the score for the screening questionnaire).
 28. 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.
 29. NHS England need not carry out a detailed analysis of the content of the SOPs. Indeed, it would be unwise for NHS England'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.
 30. 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.
 31. NHS England's representatives should not ask to see patient identifiable records. They may, however, observe the dispensing process during the visit (without intruding on patient confidentiality) in order to see that records are being made.

32. Pharmacies are required to maintain records of interventions that are deemed to be clinically significant. NHS England's representatives may ask to see evidence of these records or discuss the circumstances when records might be appropriate.
33. NHS England's representatives may ask to see patient identifiable records for the purposes of monitoring compliance with the Terms of Service for those advanced services which require patient consent to be gained. In this instance as the patient has given consent to the pharmacy to share information with NHS England, pharmacies will not be required to make any information anonymous before it is produced to NHS England. Only those records for which the pharmacy can produce the patient's written consent can be viewed.
34. The following procedure should be followed for contract monitoring visits.

	Action
1.	<p>If a contractor is to be visited, send Annex 4 and follow up the letter with a telephone call to arrange a date for the monitoring visit.</p> <p>The contractor may wish to invite a representative of the relevant LPC to attend.</p>
2.	<p>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.</p>
3.	<p>Once the date for the visit is agreed, send Annex 5.</p>
4.	<p>Ensure that NHS England'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.</p>
5.	<p>At the visit, NHS England's representatives will identify themselves as attending on behalf of NHS England and show their identity badge.</p> <p>NHS England's representatives must make every effort during the visit to ensure the provision of pharmaceutical services is not interrupted.</p> <p>NHS England's representatives must not enter any part of the pharmacy premises which is solely used as residential accommodation.</p>
6.	<p>Ensure that accurate records are taken at the visit, particularly where actions and timescales are agreed with the contractor.</p> <p>Advise the contractor that a copy of the visit report will be sent to them for review and signature.</p>
7.	<p>If any of the following are identified, refer the matter immediately to the decision-maker (set out in Chapter 3):</p>

Action	
	<ul style="list-style-type: none"> • Patient safety issues; • NHS England is at risk of material financial loss; and/or • Possible fraudulent or criminal activity. <p>Where no such issues are identified, complete the visit report (Annex 6) within 15 working days of the visit and send a copy to the contractor giving them ten working days to confirm their agreement to the report, actions and timescales. Advise the NHSBSA of the date the visit took place and the date the report was sent to the contractor.</p>
8.	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).
9.	<p>If a contractor submits evidence that they have completed an agreed action, send Annex 7.</p> <p>Once a contractor has completed all the required actions, send Annex 8.</p>
10.	Once all agreed actions are completed, file all related documentation in the contractor's file. Advise the NHSBSA that all agreed actions have been completed.

MUR service – number of claims

35. The NHSBSA, on behalf of NHS England, will monitor the number of MURs provided each financial year by each contractor. Where a contractor claims more than the maximum number this will be drawn to the attention of the contractor and a recovery made.
36. No action is required by NHS England regional teams.

MUR and NMS quarterly data

37. MUR and NMS are advanced services within the community pharmacy contractual framework. Pharmacy contractors providing the MUR and the NMS services are required by the Directions to maintain records of the consultations. When requested, pharmacy contractors must provide information on the MUR and NMS interventions undertaken in the previous quarter to NHS England.
38. NHS England has requested that this data is provided on an on-going basis and pharmacies must therefore complete the nationally agreed electronic reporting template with details of the MUR/NMS conducted in that quarter, using data collated from pharmacy records.

39. The NHSBSA now administers the collection of MUR and NMS information from pharmacy contractors on behalf of NHS England. Pharmacy contractors therefore need to submit their quarterly MUR and NMS data to the NHSBSA rather than emailing the report to NHS England. If a contractor normally provides MURs or NMS, but does not do so in a specific quarter, there is no requirement for the contractor to submit a 'nil-return' submission of data to the NHSBSA.
40. Pharmacy contractors must submit their MUR and NMS quarterly information to the NHSBSA within 10 working days from the last day of the quarter the data refers to (last day of June, September, December and March). For clarification a 'working day' excludes Saturday, Sunday and public and bank holidays.
41. NHSBSA will send reminders to contractors and will advise NHS England which have not submitted a return for that quarter.

Failures to Open

42. Once a contractor is included in a 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.
43. In these circumstances the Terms of Service require that the contractor notifies NHS England of this temporary suspension and uses all reasonable endeavours to resume service provision as soon as is practicable.
44. If a contractor does this, they are not in breach of their Terms of Service unless NHS England determines that the reason for the temporary suspension was within the control of the contractor.
45. The following procedure should be used where a contractor fails to open.

Action	
1.	<p>When advised that premises are not open, check to see if any notification has been received from the contractor.</p> <p>Where notification has been received, go to step 2</p> <p>Where the notification has not been received, go to step 5.</p>
2.	<p>Where notification has been received, the temporary suspension of service provision should be recorded.</p>
3.	<p>Check to see if any previous notifications of temporary suspensions for the premises were recorded.</p> <p>If there were, see whether there is a pattern of failing to open. If none is found, no further action is required.</p> <p>Where there is a pattern, write to the contractor asking for their comments.</p>

	Action
4.	Review the comments and escalate the matter to Stage 1 of the procedure relating to managing performance.
5.	Where no notification has been received, send Annex 9 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 10. Record the failure to open.
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 11 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 procedure relating to managing performance.

Monitoring Opening Hours

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

Procedure relating to managing performance

47. NHS England 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 NHSBSA;
 - NHSBSA Provider Assurance activity;
 - via patient complaints;
 - information from other pharmacy contractors;
 - as a result of GPhC local inspection; and/or
 - from a controlled drugs accountable officer.

48. All concerns in respect of each contractor's premises must be recorded so that NHS England can distinguish 'one-off' issues from those which are part of a wider pattern of non-compliance with the Terms of Service.
49. Concerns regarding the contractor's fitness to practise should be dealt with in line with chapter 31.
50. 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 alongside issuing a notice;
 - remove the contractor in respect of specific premises from the relevant pharmaceutical list.
51. The procedure leading to these sanctions is set out below and set out (in table form) at the end of this chapter.
52. Further information, examples and suggested approaches are set out in the DHSC Guidance document⁶ entitled "Regulations under the Health and Social Care Act 2012: performance sanctions including market exit for contractors providing pharmaceutical services".
53. 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.

What Constitutes a Contractual Breach?

54. A contractual breach occurs when one or more parties, who have entered into a contractual agreement, fail or refuse to perform their obligations under the agreement. NHS England does not hold a separate written contract with pharmacy contractors or DACs but a contractual relationship exists from the point at the contractor is included in the relevant pharmaceutical list. The terms of that relationship are set out in the Terms of Service.

Examples of Contractual Breaches Which Can Be Remedied

⁶

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/255964/nhs_pharm_servs_market_entry_performance_sancts.pdf

55. Where a contractor breaches a Term of Service and the breach is capable of remedy, NHS England will issue a remedial notice requiring the contractor to remedy the breach. Examples of breaches that are capable of remedy include:
- lack of standard operating procedures which are required by the terms of service;
 - failure to undertake the pharmacy-based audit within the required timescale; and
 - failure to appoint a clinical governance lead.
56. The remedial notice will include:
- the nature of the breach, including the relevant regulatory reference;
 - the steps the contractor must take, to NHS England's satisfaction, to remedy the breach;
 - the timescale during which the required steps are to be completed; and
 - an explanation of how the contractor may exercise their right of appeal to NHS Resolution.
57. The timescale for completion of the required action or actions will be at least 30 days after sending the notice (unless NHS England is satisfied that a shorter period is appropriate on patient safety grounds or to protect NHS England from material financial loss).

Examples of Contractual Breaches Which Cannot be Remedied

58. Where a contractor breaches a term of service and the breach is not capable of remedy, NHS England will issue a breach notice requiring the contractor not to repeat the breach. Examples of breaches that are not capable of remedy include:
- failure to open on a specific day or days, or at specific times of a day or days, in line with agreed core and supplementary opening hours;
 - failure to offer to deliver specified appliances to patients;
 - failure to offer a reasonable supply of disposable bags and wipes to patients using specified appliances;
 - failure to deal with past complaints;
 - failure to provide updated fitness to practise information in the prescribed time.
59. The breach notice will include:
- the nature of the breach, including reference to any relevant regulation; and
 - an explanation of how the contractor may exercise their right of appeal to NHS Resolution.

Rescinding Breach and Remedial notices

- 60. Since 26 November 2018 NHS England has the ability to rescind a breach or remedial notice after it has been issued. It should however be noted that if NHS Resolution confirms, on appeal, that the notice was correctly issued then NHS England cannot rescind it.
- 61. Where the PSRC decides that it is appropriate to rescind a breach or remedial notice the reasoning for this must be fully documented.

Stages of Performance Management

- 62. 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 the NHS Counter Fraud Authority. Any further action to be taken under this procedure will be guided by their advice.
- 63. If there are concerns about potentially criminal behaviour, refer the matter to the regional medical director. Any further action to be taken under this procedure will be guided by his or her advice.
- 64. Throughout the process remind the contractor that they may involve their LPC if they so wish.
- 65. The following procedure sets out the stages of the performance management process.

	Action
1.	<p>Stage 1 – Identification or Notification of Potential Breaches</p> <p>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.</p> <p>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.</p>
2.	<p>On receipt of the contractor's response:</p> <ul style="list-style-type: none"> • 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.	<p>Where there is a breach of the Terms of Service assess whether there is any risk to patient safety or whether NHS England is at risk of significant material financial loss.</p> <p>Where there are such risks escalate the matter to Stage 2 and refer it to the decision-maker (set out in Chapter 3).</p> <p>Where there are no such risks, go to step 4.</p>

	Action
4.	<p>Where there are no such risks the parties should seek to deal with the breach informally. 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 NHS England and contractor.</p> <p>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:</p> <ul style="list-style-type: none"> • failure to have an up-to-date practice leaflet; • failure to complete the required audits; • failure to submit the required paperwork in advance of commencing provision of an advanced service; • failure to complete the community pharmacy patient questionnaire. <p>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.</p> <p>Update the relevant file. No further action is to be taken.</p>
5.	<p>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.</p> <p>At the end of the extended timescale, if the action plan is completed, write to the contractor confirming that the matter is now closed but will remain on file.</p> <p>Update the decision-maker (set out in Chapter 3) (for information only) and the relevant file. No further action is to be taken.</p>
6.	<p>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).</p>
7.	<p>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).</p>
8.	<p>Stage 2 – Local Dispute Resolution</p> <p>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.</p> <p>At this stage, the breach is considered to be disputed and regulation 69 applies. The steps set out here are intended to comply with that regulation.</p>

	Action
9.	<p>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.</p> <p>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.</p> <p>The matter should be escalated directly to Stage 3 if:</p> <ul style="list-style-type: none"> • 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. <p>Decisions will be fully minuted and reasoned.</p>
10.	<p>Write to advise the contractor that local dispute resolution under regulation 69 is taking place, and tell them who will represent NHS England.</p> <p>Local dispute resolution can be conducted through:</p> <ul style="list-style-type: none"> • regular telephone communications; • face-to-face meetings at a mutually convenient location; and/or • written communications. <p>Respond to the contractor's concerns and communications in a timely and reasonable manner.</p> <p>Ensure every reasonable effort to communicate and cooperate is made. Letters that are sent via the post are to be sent 'signed for' and 'deliver' and 'read' receipts are to be requested for emails. Proof that communications have been received is to be kept on file.</p> <p>Maintain accurate and complete written records of all discussions and correspondence on the contract file.</p> <p>If local dispute resolution is successful, write to the contractor confirming that the matter is now closed but will remain on their file.</p> <p>Update the relevant file and advise the outcome to the decision-maker. No further action is to be taken.</p>
11.	<p>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.</p>
12.	<p>Stage 3 – Notices and Withholding Payments</p>

	Action
	<p>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.</p> <p>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.</p> <p>Based on the contractor's history and previous use of performance-related sanctions by either NHS England or a PCT, the matter may be escalated straight to Stage 4.</p>
13.	<p>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.</p> <p>If the matter was escalated straight to this stage for one of the reasons set out in paragraph 9 above, the breach or remedial notice should explain why this was done and confirm that this is why no stage 2 dispute resolution took place.</p>
14.	<p>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.</p> <p>Payments can be withheld where:</p> <ul style="list-style-type: none"> • 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. <p>All decisions to withhold payments will be fully minuted and reasoned.</p>
15.	<p>Following the PSRC meeting, draft a letter based on the minutes of the meeting. Complete Annex 12 or 13 or both where relevant and send to the contractor.</p> <p>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.</p> <p>A copy of any notice served should also be sent to the pharmacy contract manager at other regional teams where the contractor has premises (where this information is known).</p>
16.	<p>Where a remedial notice is issued, diarise the date for completion of the required action.</p>

	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 in respect of a breach of the Directions and withholding payments for the advanced services.
22.	Where payments were withheld alongside a remedial notice, the contractor may submit a claim for the payments to be restored. 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 14 to the contractor.
24.	If notice of an appeal against the decision not to restore payments is received, respond accordingly. Where NHS Resolution 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

	Action
	<p>justifiable and proportionate having regard to the nature and seriousness of the breach or breaches and the reason (if known) for it or them.</p> <p>The pharmacy contract manager at other regional teams where the contractor has premises (where this information is known) should be informed of the removal.</p>
26.	<p>If the decision-maker determines that removal is not justifiable or proportionate, then the matter is to be referred back to Stage 3.</p>
27.	<p>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.</p> <p>At least 30 days' notice is to be given.</p> <p>Consult with the LPC in whose area the contractor's premises are located.</p>
28.	<p>Following consideration of the written and/or oral representations by the decision-maker, send Annex 15 or 16 to the contractor as relevant.</p>
29.	<p>If notice of an appeal against removal is received, advise the decision-maker and assist in producing a response.</p>
30.	<p>Once the outcome of the appeal is known and it is confirmed that the decision to remove is upheld:</p> <ul style="list-style-type: none"> • send Annex 17 to the contractor; • advise the NHSBSA of the closure using the relevant form; and • update the relevant pharmaceutical list.
31.	<p>Update other databases as appropriate and inform the usual parties which includes the relevant:</p> <ul style="list-style-type: none"> • LPC • HWB • CCG • The GPhC • The DoS lead • The Registration Authority • The public health team at the relevant local authority • Local GP practices (possibly using data published by NHSBSA to identify where prescriptions dispensed at the premises come from) • Controlled Drugs Accountable Officer (CDAO) • Out of Hours (OOHs) provider • The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, • Binleys

	Action
	<ul style="list-style-type: none"> • The organisation that cascades safety alerts, and • The company that collects and disposes of unwanted medicines where the pharmacy was located.
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 below shows the stages of the Performance Management Procedure.

Stage	Intervention likely to occur	Escalation to another stage
<p>Stage 1: Concern(s) identified by, or reported to, NHS England.</p>	<p>Informal resolution with the contractor.</p> <p>An action plan will be agreed where non-compliance is identified along with a timescale for completion.</p>	<ul style="list-style-type: none"> • There are patient safety concerns. • NHS England is at risk of material financial loss. • The contractor fails to complete the action plan. • The contractor fails to engage with NHS England.
<p>Stage 2: Informal resolution is unsuccessful or it is necessary to omit stage 1 to protect:</p> <ul style="list-style-type: none"> • The safety of persons who may receive services from the contractor, or • NHS England from material financial loss. 	<p>Matter referred to the decision-maker for discussion on what action to take.</p> <p>Options include:</p> <ul style="list-style-type: none"> • agreeing a further action plan; or • undertaking local dispute resolution in line with regulation 69 of the 2013 Regulations. 	<ul style="list-style-type: none"> • 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
<p>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</p>	<p>Matter referred to the decision-maker for discussion as to what further action may be taken.</p> <p>Options available include:</p> <ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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.
<p>Stage 4: Removal from the relevant pharmaceutical list</p>	<p>Removal of the premises to which the breach or breaches related from the pharmaceutical list.</p> <p>Removal must be justifiable and proportionate having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them.</p>	<ul style="list-style-type: none"> • Not applicable.

CHAPTER 38

Market Exit

Chapter aims and objectives

1. This chapter deals with the closing of premises whether that be as a result of:
 - A contractor giving notice of their wish to withdraw from a pharmaceutical list in respect of their listed premises and the premises will close,
 - A contractor closes premises without first giving notice,
 - NHS England removes a contractor and a specified premises following use of the performance related sanctions or fitness powers, or
 - A consolidation application.
2. NHS England staff should read it in conjunction with chapters 32 and 38 of the Manual (use of fitness powers in relation to contractors and monitoring compliance and managing performance).

Background

3. Where a contractor wishes to withdraw from a pharmaceutical list they are required to give notice:
 - Pharmacies with 40 core opening hours - at least three months,
 - Pharmacies with 100 core opening hours - at least six months,
 - Pharmacies with more than 40 core opening hours where a direction is in place – at least three months, and
 - Dispensing appliance contractors – at least three months
4. However, regulation 67 of the Regulations states that where it is impracticable for the contractor to give the required notice period they must notify NHS England as soon as it is practicable to do so. In addition, NHS England can agree to a shorter notice period.
5. Annex 1 is the form that contractors should use where they wish to withdraw from a pharmaceutical list. Completed forms are to be sent to the Primary Care Support Service Provider who will forward it to the NHS England regional team in whose area the premises are located.

Limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing

6. Regulation 76 of the Regulation applies where a contractor would otherwise be removed from a pharmaceutical list as a result of a notice of withdrawal from a pharmaceutical list.

7. Where a contractor is to be removed following a notice of withdrawal but the PSRC (or PLDP):

- Is investigating them with a view to removing, suspending or contingently removing them on fitness grounds,
- Has decided to remove or contingently remove the contractor on fitness grounds but has not yet done so, or
- Has suspended the contractor,

it must not, without the consent of NHS Resolution, remove the contractor under regulation 75 until the relevant investigation or proceedings have been concluded.

Closure where the required notice period has been given

8. Where NHS England receives a notice from a contractor who wishes to withdraw specified premises from a pharmaceutical list check that the required notice period has been given. Where it hasn't move to the next section of this chapter.
9. Send Annex 2 to the contractor and brief the NHS England communications team.
10. Add the closure to the agenda of the next PSRC meeting.
11. Ask the Primary Care Support Service Provider to send Annex 3 to the following persons and provide the required contact details:
- The relevant CCG
 - The public health team at the relevant local authority
 - The relevant HWB
 - The relevant LPC and LMC
 - The relevant DoS lead
 - The relevant RA
 - Local GP practices (possibly using data published by NHSBSA to identify where prescriptions dispensed at the premises come from)
 - The relevant CDAO
 - The relevant OOHs provider
 - The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager,
 - Binleys, and
 - The organisation that cascades safety alerts.
12. The above must be notified. Regional teams are free to notify other relevant persons and where they choose to do so must provide the required contact details. Such persons may include:
- The relevant Healthwatch
 - The relevant Health Overview and Scrutiny Committee (HOSC)
 - The local GPhC inspector,

- Parish councils if applicable, and/or local city/district/county councillors
 - The local MP.
13. Contact the company which collects and disposes of unwanted medicines and ask them to liaise with the contractor to arrange a final collection.
 14. Ensure the contractor provides confirmation that the actions set out in Annex 2. Where these aren't received follow this up with the contractor.
 15. One week before the closure date, the Primary Care Support Service Provider will:
 - Complete and submit the relevant NHSBSA form⁷
 - Notify the relevant DoS lead of the closure date.
 16. If the contractor withdraws their notice of closure at any point before the pharmaceutical list is amended the Primary Care Support Service Provider will send a further memo to the above persons.
 17. The regional team needs to be mindful of regulation 76 (limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing). Where there are ongoing fitness investigations or proceedings in relation to the contractor and NHS England is considering removing them and their premises from a pharmaceutical list on fitness grounds it must not remove the contractor under regulation 75 (voluntary and automatic removal of listings: change of ownership, relocation, temporary provision and voluntary closure) until the relevant fitness investigation or proceedings have been concluded.
 18. On the day after the closure date update the relevant pharmaceutical list, any other local databases, any other teams within the regional who may need to know, and ask the Primary Care Support Service Provider to send Annex 4 to those persons listed in paragraph 9 above and any other persons who were notified under paragraph 10 above. Send Annex 5 to the contractor.

Closure where the required notice period has not been given

19. Where a contractor fails to give the required notice period pass this to the PSRC for a decision as to what, if any, action is to be taken or whether a shorter notice period is to be accepted. Send Annex 6 to the contractor.
20. It should be noted that once the contractor and the specified premises are removed from the relevant pharmaceutical list it will not be possible for NHS England to use the performance related sanctions in relation to the failure to provide the required notice period. Under regulation 76 (limitation on withdrawal from pharmaceutical lists while fitness investigations or proceedings are ongoing) where NHS England is considering removing a contractor and their premises from a pharmaceutical list on fitness grounds it must not remove the contractor under regulation 75 (voluntary and automatic removal of listings: change of

⁷ <https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/organisation-and-prescriber-changes/area-teams>

ownership, relocation, temporary provision and voluntary closure) until the relevant fitness investigation or proceedings have been concluded. There is no similar provision where NHS England is considering removing a contractor and specified premises as a result of use of the performance related sanctions.

21. The actions in paragraphs 7 to 12 above will need to be completed as far as possible, with the time periods shortened as necessary.
22. If the contractor withdraws their notice of closure at any point before the pharmaceutical list is amended a further memo will need to be sent to the persons listed in paragraphs 9 and 10 above.
23. On the day after the closure date update the relevant pharmaceutical list and ask the Primary Care Support Service Provider to send Annex 4 to those persons listed in paragraph 9 above. Send Annex 5 to the contractor.

Removal where no notice has been given

24. There may be instances where NHS England becomes aware that a contractor has closed premises without giving any period of notice. Should that occur the NHS England communications team will need to be briefed immediately and attempts are to be made to contact the contractor to find out whether this is a permanent or temporary closure.
25. Where the contractor confirms that it is a temporary closure refer to chapter 36 and go no further with this chapter.
26. Where the contractor confirms that it is a permanent closure annex 7 is to be sent as a matter of urgency by NHS England to the following:
 - The relevant DoS lead
 - Local GP practices (using data published by NHSBSA⁸ to identify where prescriptions dispensed at the premises come from where necessary)
 - Other pharmacies within 2km in a direct line where the closing premises are not in a controlled locality, or 8km in a direct line where they are in a controlled locality
 - The relevant LPC and LMC
 - The relevant RA
 - The relevant CDAO
 - The relevant Out of Hours provider
 - The relevant CCG
 - The public health team at the relevant local authority
 - The relevant HWB
 - The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager,
 - Binleys and
 - The organisation that cascades safety alerts.

⁸ <https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/dispensing-contractors-data>

27. Consideration should be given as to whether there are any other persons to be notified of the closure in line with paragraph 10 above.
28. Where the contractor cannot be contacted annex 8 is to be sent by NHS England as a matter of urgency to the following:
 - The relevant DoS lead
 - Local GP practices (using data published by NHSBSA to identify where prescriptions dispensed at the premises come from where necessary)
 - Other pharmacies within 2km in a direct line where the closing premises are not in a controlled locality, or 8km in a direct line where they are in a controlled locality
 - The relevant LPC and LMC
 - The relevant RA
 - The relevant CDAO
 - The relevant Out of Hours provider
 - The relevant CCG
 - The public health team at the relevant local authority
 - The relevant HWB
 - The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager, and
 - Binleys
29. Consideration should be given as to whether there are any other persons to be notified of the closure in line with paragraph 10 above.
30. NHS England regional teams should use the performance related sanctions within regulations 69 to 73 of the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, in relation to a failure to provide pharmaceutical services during core opening hours. This may lead to the subsequent removal of the contractor and the closed premises.

EPS nominations and changes of ownership or consolidation

31. To use the Electronic Prescription Service (EPS) patients choose where their prescriber will electronically send their prescriptions. This is called 'nomination' and further guidance on it has been produced by NHS England and NHS Digital⁹.
32. In advance of a change of ownership or consolidation the old owner/contractor should seek to inform patients in advance of this change wherever possible. Where it is not feasible to notify all patients in advance then this should happen as soon as possible after the change. This may include face to face when a patient first collects their medication or appliances from the new owner/contractor.

⁹ <https://www.england.nhs.uk/digitaltechnology/info-revolution/erd-guidance/>

33. In all cases patients must be notified within six months of the change taking place. This ensures there is a basis for implying the patient's continued consent to this nomination. Throughout this period the nomination will automatically continue with the new owner/contractor. A patient who informs either the old or new owner/contractor that they no longer wish to have the pharmacy/dispensing appliance contractor set as their nominated contractor must be given appropriate assistance to remove the nomination.
34. The above applies equally where a change of ownership occurs as a result of a consolidation application or a combined change of ownership and no significant change relocation application.

Electronic Prescription Service nominations and closures

35. Where a contractor closes one of its premises and wishes to transfer patient EPS nominations to another of its premises, it must ensure that patients are told in advance of this intention and given the opportunity to change their nomination to another contractor if they wish to do so.

CHAPTER 39

Pharmaceutical Services Finance

Chapter aims and objectives

1. This chapter deals with pharmaceutical services finance. It should be read alongside the Drug Tariff¹⁰ and the Directions.

Background

2. Pharmacies and DACs receive two main types of payment for the provision of pharmaceutical services:
 - Reimbursement for the drugs and appliances that have been dispensed against a valid NHS prescription (this includes the retained medicines margin), and
 - Remuneration for the provision of services provided.
3. The retained medicines margin (£800m nationally as of April 2018) contributes to the amount paid for service provision (remuneration) but it is delivered via the reimbursement of items that have been dispensed.
4. DHSC is responsible for setting the prices of drugs and appliances.
5. Each year the total amount of funding that is to be paid to pharmacies for the provision of essential and advanced services is agreed as part of the annual negotiations between DHSC, NHS England and PSNC. This is then delivered to pharmacies via the fees and allowances set out in the Drug Tariff. At the end of each financial year an exercise is undertaken to ensure that the funding envelope has been paid to pharmacies. Where it hasn't the fees and allowances are adjusted for the following financial year. Payments made under LPS contracts are not included in this calculation.
6. Regional teams should therefore not look to make Quality, Innovation, Productivity and Prevention (QIPP) savings on the nationally set fees and allowances.
7. NHS England is responsible for setting the prices for the enhanced services it commissions locally – see the section on locally authorised payments below.
8. Claims for reimbursement and remuneration relating to the provision of essential and advanced services are to be made and paid in line with the requirements of the Drug Tariff and the Directions. Claims for enhanced services are to be made and paid in line with the requirements of the locally agreed service specification and SLA.

¹⁰ <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>

9. This chapter does not serve to replace the requirements of the Drug Tariff or Directions. Instead it acts to ensure consistency of application of these requirements across England.

Making payments outside of the Drug Tariff and the Directions

10. Unlike for other primary care contractors, NHS England does not have discretionary powers to make payments to pharmacies or DACs outside of the Drug Tariff and the Directions. Regional teams therefore cannot authorise requests for payments from contractors relating to essential and advanced services where errors have been made in claims submissions. PCMs should ensure that finance teams are aware of this.

Local authorised payments

11. The payments for enhanced services are made through the Local Payments Application process that is administered by the Primary Care Support Service Provider.
12. The mechanism currently used to reimburse contractors for these services requires regional teams to input payment information into a spreadsheet which is then sent to the Primary Care Support Service Provider on a monthly basis to be entered into the local payment application.
13. The information entered forms part of the payment to contractors which are processed monthly by the NHSBSA. This spreadsheet must be received by the Primary Care Support Service Provider before the 7th of each month to ensure that the Primary Care Support Service Provider is able to process these payments to meet the NHSBSA cut-off date for making payments to contractors.

Payments in respect of Pre-Registration Trainees

14. The Drug Tariff makes provision for a grant (£18,440 as of April 2018) to be paid per year to pharmacy contractors who provide the pre-registration training experience needed by pharmacy graduates and certain undergraduates for admission to the GPhC's Register of Pharmacists. The grants are payable at annual rates in respect of each pre-registration training place filled by a pharmacy graduate or an undergraduate on a sandwich course recognised by the GPhC as pre-registration training.
15. Pharmacy contractors who have undertaken to provide pre-registration training should submit a claim¹¹ to NHS England at the start of the training period. Claims are to be sent to the NHS England regional team in whose area the contractor's premises are located.

¹¹ http://www.psn.org.uk/wp-content/uploads/2013/07/Pre_reg_grant_application.pdf

16. Claims for the allowance are to be added to the specific tab in the local payment application along with the name of the pre-registration trainee. Payments are made monthly, in arrears.
17. Claims which are received later than three months after the start of the training period should be referred to the PCM with the mitigating reasons for authorisation. Where appropriate, the matter may be referred to the PSRC for a decision as to whether it should be paid.
18. Where a contractor ceases to provide pre-registration training in respect of a specific pharmacy graduate/undergraduate they are required to advise the relevant NHS England regional team immediately in writing. In this instance the regional team should stop the payment via the local payment application. Where the notification is received late and an overpayment has ensued then the overpayment should be recovered via the overpayment process.
19. Where an individual fails the GPhC's Registration Assessment twice the subsequent additional six months training is not pre-registration training and therefore does **not** attract payment of the grant. Regional teams can confirm the status of the training period with the GPhC if they are in any doubt as to whether pre-registration payment should be authorised.

Establishment payments top-up payments

20. The ability for pharmacy contractors to claim a top-up payment in relation to their establishment payment no longer exists in the Drug Tariff. Any claims that are received should be returned to the contractor.

Recharge of payments

21. NHS Prescription Services, which is part of the NHSBSA, calculates and makes the payments to pharmacies and dispensing appliance contractors for the provision of pharmaceutical services in line with the provisions of the Drug Tariff.
22. Payments to dispensing doctors and doctors who have personally administered items to patients are also calculated by NHS Prescription Services in line with the General Medical Services Statement of Financial Entitlements Directions 2013. This information is then passed to either NHS England or the relevant CCG who then pays the practice.
23. With regard to the payments to pharmacies and DACs, these are then recharged by NHS Prescription Services to NHS England and CCGs, and may also recharge some costs to local authorities and hospitals. Further information on how costs are recharged can be found the NHS and LA Reforms Factsheet 4¹² produced by NHS Prescription Services.

¹² <https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/nhs-and-local-authority-reforms>

24. Those payments which are recharged to NHS England are allocated to regional teams as follows:

- Establishment payments are recharged to the regional team in whose area the pharmacy is based
- Fees and allowances that can be linked to a prescription and therefore a prescriber are recharged to the regional team that holds the contract
- Infrastructure payments for dispensing appliance contractors are fair-shared across all regional teams
- All other fees and allowances are fair-shared across all regional teams.

25. There are three different formulas for those fees and allowances that are fair-shared. The majority are fair-shared using this formula:

Total of professional fees directly attributable to the regional team

Total professional fees for all prescriptions dispensed as part of pharmaceutical services

26. The two exceptions to this are the fees relating to the provision of MURs and AURs.

Withholding of payments

27. Alongside the issuing of a breach or remedial notice, NHS England has the ability to withhold all or any part of the remuneration that would be paid to a contractor. However, a withholding may only be made if:

- The PSRC is satisfied that the breach to which the withholding relates is, or was, without good cause,
- The amount to be withheld is justifiable and proportionate, having regard to the nature and seriousness of the breach and the reasons for it,
- The PSRC includes in the breach or remedial notice its duly justified reasons for both the decision to withhold remuneration the amounts that are, and (where applicable) are to be, withheld.

28. Prior to issuing a breach or remedial notice and making a withholding NHS England will make every reasonable effort to communicate with the contractor in order to discover the reasons for the breach. However, if the contractor fails to respond or provides an inadequate response, NHS England need not take into account the reasons for the breach as it will not have been able to establish them.

29. Withholdings may relate to the fees and allowances set out in the Drug Tariff for the provision of essential and advanced services.

30. It should be noted that the ability to withhold payments is not a fines system – further information can be found in the DHSC market exit guidance¹³.

Recovery of overpayments

31. Regulation 94 of the Regulations makes provision for the recovery of overpayments. Where a PSRC considers that a payment has been made to a contractor relating to the provision of essential and/or advanced services where it was not due, it must draw the overpayment to the attention of the contractor.
32. Where the contractor admits the overpayment then the amount may be recovered via the local payment application. Where that is not possible, for example the contractor and the relevant premises have since been removed from the relevant pharmaceutical list and no further remuneration or reimbursement payments are due, then recovery may need to be made as a civil debt.
33. Where the contractor does not admit that they have been overpaid, then the PSRC will need to undertake an investigation, allowing the contractor to submit written representations which support their view that there has not been an overpayment.
34. At the end of the investigation, where the PSRC concludes that there has not been an overpayment no further action needs to be taken. However, where the PSRC concludes that there has been an overpayment they will write to the contractor accordingly and provide them with a right of appeal. The recovery of the overpayment via the local payment application may not be made until either the end of the 30 day appeal period or once any appeal has been dealt with, whichever is the latest.
35. Where an overpayment is found proven and a recovery is made, then the PSRC will also need to consider whether there has been a related breach of the contractor's terms of service.

Management information spreadsheet report

36. The management information spreadsheet (MIS) report is produced monthly by NHSBSA and is available to authorised users within regional teams via the Information Services portal¹⁴.
37. This report consists of a management information file detailing monthly pharmacy and DAC payments by type of payment and contractor account. Payments include all drug costs, fees, patient charges, locally authorised payments etc. Other details such as the numbers of items dispensed, patient charges collected

¹³

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/255964/nhs_pharm_servs_market_entry_performance_sancts.pdf

¹⁴ <https://www.nhsbsa.nhs.uk/information-services-portal-isp/isp-report-information>

are also included. The management information files reflect the contractor's payment and prescription data associated with the previous NHS England area team structure at the relevant payment date.

38. This information is provided to fulfil a number of requirements including:
 - Pharmacy and appliance contractor payment monitoring
 - Contract management
 - Reconciling payments
 - Audit, and
 - Fraud prevention.
39. NHSBSA has enhanced the support it currently offers to regional teams to manage the performance of pharmacy contracts by providing enriched information, analysis and insight on contractor payment and prescription data.
40. A monthly reporting tool has been developed to help regional teams to identify unusual/inappropriate behaviour, potential fraudulent activity and areas of interest. Insight will be delivered for metrics defined by NHS England as key areas of interest.
41. A cumulative reporting tool has been developed to allow users to look at the data over a specific financial year. A dashboard has been created in the tool which accumulates the monthly data and produces year-to-date information on the payment metrics, providing an overall picture of a pharmacy contractor's activity over a financial year in these areas.
42. Regional teams will wish to review the monthly MIS report and utilise the reporting tools in order to identify outliers. Particular issues to review in relation to the MIS report include:
 - Contractors who have submitted no prescriptions in a particular month,
 - Contractors who begin to provide an advanced service but who have not provided the required paperwork (except the flu advanced service where sign-up is via the NHSBSA portal),
 - Abated payments.
43. Contractors are required by the Regulations to comply with the obligation within the Drug Tariff to submit dispensed prescriptions to the NHSBSA not later than the 5th day of the month following that in which the supply was made. (Pharmacy contractors that are enrolled in the Pharmacy Earlier Payment Scheme will need to secure delivery as outlined on the NHSBSA website to be able to access funds early - www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/payments-and-pricing/pharmacy-earlier-payment).

44. Where a contractor fails to meet this requirement, a discussion should be had with them to understand the reasons why. Depending on their response and whether this is a one-off failure or not, use of the performance related sanctions will need to be considered. Failure to submit prescriptions within the required timescale will also have implications for the CCG in whose area the contractor's premises are located as reimbursement of the drugs and appliances dispensed are mostly recharged to it. The CCG should be alerted to this matter so that it can accrue funds accordingly.
45. Abated payments relate to prescriptions which have not been submitted within the prescribed timescale and are shown on a separate sheet within the MIS report. Where a contractor has received an abated payment, a discussion should be had with them to understand the reasons why. Depending on their response and whether this is a one-off failure or not, use of the performance related sanctions will need to be considered.

Information on payments, Drug Tariff, prescription endorsement, prescription searches and sorting and submission

46. Regional teams will often receive queries from contractors, their representatives, CCGs and others regarding remuneration and reimbursement payments. NHS Prescription Services can provide support to teams online, or by phone at: nhsbsa.prescriptionservices@nhsbsa.nhs.uk Telephone: 0300 330 1349.
47. Hints and Tips is a quarterly bulletin produced by the NHSBSA and is designed to help their customers with their interaction with NHS Prescription Services. Two versions are produced - one for dispensing contractors and one for information services users. These are good sources of information to support regional teams and can be found at: <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/hints-and-tips-open-days-and-webinars>.

Market entry application fees

48. The Pharmaceutical Services (Fees for Applications) Directions 2013¹⁵, as amended, specify the types of routine and excepted application for which a fee will be payable and the levels of such fees. The fee is submitted alongside the application and is a contribution towards the cost of processing and determining the application. As such it is not refundable if the application is treated as withdrawn, it is refused, or grant of it lapses.
49. Information produced by the then DH¹⁶ in 2008 when the fees were initially introduced may be of interest to regional teams.

¹⁵ <https://www.gov.uk/government/publications/pharmaceutical-services-fees-for-applications-directions-2013>

¹⁶

<http://webarchive.nationalarchives.gov.uk/20120503091351/http://www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/ImplementationoftheHealthAct2006/index.htm>

50. Fees are passed on to the relevant regional team by the Primary Care Support Service Provider.

CHAPTER 40

Background and Procedure – Local Pharmaceutical Services

Chapter aims and objectives

1. The purpose of this chapter is to ensure that LPS contracts are dealt with in line with Part 13 of 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 NHS England 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 NHS England 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 NHS England to decide when and in what circumstances it wishes to enter into a LPS contract. LPS provides NHS England 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. NHS England must determine, before entering into an LPS contract, whether the person is to be given a right of return to the relevant pharmaceutical list after ceasing to provide services. The principles (which may be amended from time to time) by which NHS England will make right of return determinations must be published and are set out in the box below.

Principles used to determine a right of return

The principles, by reference to which NHS England makes a determination about whether a person is to be given a right of return to a pharmaceutical list, are as follows:

- i. Where a pharmaceutical services (PhS) contractor becomes a LPS provider and ceases to be a PhS contractor, and except in exceptional circumstances (as determined by NHS England), that contractor will have a right of return in relation to those premises from which he was providing PhS, so long as he continues to provide LPS from those premises.
- ii. Where an LPS provider previously had a right of return under an LPS pilot scheme and on expiry of that LPS pilot scheme becomes an LPS provider, that provider will, except for exceptional circumstances (as determined by NHS England), have a right of return in relation to those premises from which he was providing services under the LPS pilot scheme, so long as he continues to provide LPS from those premises.
- iii. Where an LPS provider who has been granted a right of return in accordance with these principles agrees with NHS England to transfer the provision of LPS under the LPS contract to new premises, that LPS provider will have a right of return in respect of the new premises only.
- iv. Where an LPS provider who has been granted a right of return in accordance with these principles agrees with NHS England to transfer his business as a going concern to a new LPS provider and that new LPS Provider provides LPS from the same premises as the previous LPS provider, the new LPS provider will have a right of return, so long as he continues to provide LPS from those premises, and the previous provider will lose his right of return.
- v. The right of return set out in paragraph (iii) above will not apply where a change of premises results in a significant change in the arrangements for

the provision of pharmaceutical services or dispensing services in any part of a HWB's area.

- vi. Where more than one PhS contractor joins together to provide LPS, whether as a single LPS provider or as multiple LPS contractors, the number of rights of return will be limited to the number of premises from which PhS was provided. If the number of premises from which LPS is to be provided is less than the number of PhS contractors, or if there is to be any change of ownership of existing PhS premises on the move to LPS, the contractors will need to inform NHS England as to the arrangements which they wish to see made as regards rights of return. Subject to it being clear that there is agreement on those arrangements, and to it being clear how any successors to the original LPS provider or providers are to be treated as regards their potential right of return, NHS England will endorse those arrangements.

In these principles "PhS contractor" refers to an entry on a pharmaceutical list. An individual, partnership or body corporate with more than one premises in an area will be counted as a separate PhS contractor for each premises.

Reference in these principles to a "right of return" will not override any grounds for refusal, deferral or conditional inclusion of an application for inclusion in a pharmaceutical list on fitness grounds (Regulations 33, 34 and 35) or where NHS England is directed to refuse a right of return application under regulation 28.

Benefits of LPS

12. 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 NHS England with the flexibility to participate in health promotion schemes in a wider context (e.g. local regeneration projects).

13. 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

14. Examples where LPS contracts may be useful include:

- NHS England 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.
- NHS England considers there is an area with a rising population of individuals with long-term conditions resident in the community. It wishes 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.
- NHS England 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.
- NHS England 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. NHS England 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.

- NHS England 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.

LPS designations

15. NHS England 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 NHS England to choose to defer consideration of routine applications to the pharmaceutical list under the Regulations in the area under designation.

Designation of areas, premises or descriptions of premises

16. Areas or premises can be designated by NHS England as priority or 'designated' areas. During the period of designation, routine applications to be added to the pharmaceutical list may be deferred.
17. NHS England may choose to use the power of designation, depending on local circumstances.
18. The aim of a designation is to allow time for an LPS proposal to be worked up, processed and implemented. Designation therefore allows NHS England to mitigate the potentially adverse impact of granting a routine application where the development or implementation of an LPS scheme is underway. This may be a critical factor where in some cases NHS England has to plan and commit to a longer-term development, e.g. commissioning and building new community health centre premises.
19. NHS England must review all designations before the end of 6 months beginning with either the date of the designation or (if later) the date it concluded its last review of the designation.
20. NHS England may designate relevant areas, premises or descriptions of premises in or at which local pharmaceutical services are to be provided under a proposed LPS scheme or an approved LPS scheme. There is no time limit on designation in the period between approval and implementation. Provided an LPS scheme has been approved, designation may continue for more than one year, subject to the necessary reviews, for example, if construction of new premises is required before implementation.

21. A designation must:

- be made in writing and dated;
- include a map showing the location of the designation; and
- include an outline of the services to be provided under the scheme to which it refers.

22. Once a designation has been made NHS England must notify:

- the HWB for the area;
- the LPC in whose area the designation is located;
- the LMC in whose area the designation is located;
- any NHS chemist whose listed chemist premises are in the area of the HWB or are in the area of a neighbouring HWB and whose interests (in the opinion of NHS England) are likely to be affected by the designation;
- any person who is entitled because of the grant of a routine or excepted application to be included in a pharmaceutical list for the area of the HWB or who is in the area of a neighbouring HWB and whose interests (in the opinion of NHS England) are likely to be affected by the designation;
- any LPS chemist whose chemist premises are in the area of the HWB or are in the area of a neighbouring HWB and whose interests (in the opinion of NHS England) are likely to be affected by the designation;
- any dispensing doctor whose listed dispensing premises are in the area of the HWB or are in the area of a neighbouring HWB and whose interests (in the opinion of NHS England) are likely to be affected by the designation; and
- any Local Healthwatch organisation for the area of the HWB.

23. NHS England must publish all its current designations, including any designations that have been varied. NHS England must also publish any current designations, including any designations that have been varied, that were made by any former PCTs. NHS England is required to ensure that each HWB has access to those designations in a way which is sufficient to enable the HWB to carry out its functions.

Variation of designation

24. NHS England may vary a designation that it has made or that was made by any former PCT, where the designation relates to;

- An area, and the services to be provided under the LPS scheme are to be provided in or from part only of that area;
- Premises, and the services to be provided under the LPS scheme are to be provided at or from a part only of those premises; or
- A description of premises, and the services to be provided under the scheme are to be provided at or from parts only of the premises described.

25. Any varied designations must:
 - be made in writing and dated;
 - include a map showing the location of the varied designation;
 - include an outline of the services to be provided under the scheme to which it refers.
26. Notice of the variation must be given to those who were required to be notified of the original designation (see paragraph 22 above).

Review of designation

27. NHS England must regularly review designations. In any event, designations must be reviewed before the end of a period of six months beginning with either the date of designation or the date of the last review.
28. When conducting a review, NHS England must take into account any responses it (or the former PCT) received when the designation was last notified.
29. Where a designation is not varied or cancelled as a result of the review, NHS England must notify those listed above at paragraph 22 of the outcome of its review.

Cancellation of designations

30. NHS England may at any time cancel a designation which it (or a predecessor) has made. However, it must cancel a designation if:
 - required to do so by a direction given by the Secretary of State;
 - within a period of twelve months beginning with the date of designation, if a proposal for an LPS scheme that relates to the designation has not been submitted to NHS England for approval. NHS England may continue a designation where they have started the process of examining an LPS proposal. The designation may remain in place for the interval between approval and commencement of the scheme;
 - the only (or only remaining) proposal for an LPS scheme that relates to the designation has been rejected; or
 - there is a significant change to an area in which, or the premises from which, the services under an LPS contract are to be provided, other than a change which leads to a variation as described in the paragraphs on 'variation of designation' above. In this case, the twelve month period will continue to run from the original date of designation;
 - or when an LPS contractor commences the provision of services under an LPS contract at the designated location.

31. NHS England must give notice of the cancellation of designation to those listed at paragraph 22 above.
32. Where NHS England has cancelled a designation, it may not designate the same area, premises or description of premises within a period of six months beginning with the date of cancellation. This does not apply where the reason for the cancellation of the designation was the rejection of a proposal for an LPS scheme. In such cases a new designation can be made immediately following the decision to reject.

Making LPS arrangements

33. LPS arrangements can be made in two ways:
 - by a person putting forward a proposal for LPS arrangements without NHS England advertising, inviting or initiating the process; or
 - by NHS England 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

34. The Regulations allow any potential provider to make a proposal at any time to NHS England for LPS arrangements. If the proposal is not vexatious or frivolous then NHS England 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 NHS England 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.
35. When NHS England receives a proposal for LPS arrangements in this way, the procedure below should be followed. NHS England should ensure that all persons submitting LPS proposals are treated equally.

Inviting LPS proposals

36. Where NHS England 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") and the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013. Pharmacy services are categorised as "social and other specific services" ("SOS") and are sometimes referred to as "Schedule 3 Services" under the Procurement Regulations.
37. Where SOS are of a value in excess of the relevant financial threshold set by the European Commission, NHS England is required by the Procurement Regulations 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.
38. Throughout the procurement process undertaken, NHS England is obliged to be transparent, and treat bidders equally and without discrimination.
39. Where SOS are of a value under the relevant financial threshold but over £25,000, NHS England would be obliged to:
- publish information about the contract opportunity on Contracts Finder. If the information is advertised elsewhere (e.g. NHS England'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 is set out in the published Contracts Finder advertisement and that is intended by NHS England to be taken into account by those responding to the advertisement; and
 - publish a contract award notice on Contracts Finder within a reasonable time.
40. NHS England should ensure that any procurement is conducted in accordance with NHS England's standing orders and standing financial instructions.
41. NHS England 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.
42. It is strongly advised that NHS England seeks legal advice to ensure that the process adopted satisfies all the legal requirements that apply to NHS England.

Procedure for managing LPS proposals

43. 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 1.

44. Ensure details have been added to any appropriate database and ensure it is updated as the proposal progresses.
45. The PCM will consider whether the proposal is vexatious or frivolous. Where it is determined that it is either vexatious or frivolous (e.g. no serious intent to deliver services, or there is no identified need, improvements or better access in the relevant pharmaceutical needs assessment), send Annex 2 (rejection of proposal) to the proposer. No further action is required.
46. If it is determined that the proposal is not vexatious or frivolous, send Annex 3 to the proposer.
47. The Pharmacy Contract Manager will consider whether to select the proposal for development, referring to Annex 4 for guidance. Send Annex 5 to the local authority and those bodies set out in Regulation 107 and where appropriate carry out a service user involvement exercise.
48. Prepare a report (Annex 6) for the PSRC on whether to select the proposal for development.
49. After the meeting, prepare the relevant decision letters:
 - Selected – to the proposer (Annex 7);
 - Selected – to a third party (Annex 8);
 - Not selected – to the proposer (Annex 9).
50. If the LPS proposal is not selected for development, no further actions are necessary.
51. If the LPS proposal is selected for development, develop the proposal referring to the box below for further information on this stage.

Development of the proposal

- The development stage allows NHS England to fine-tune the proposal in light of its consideration of the relevant factors including feedback from involvement exercises.
- Should the proposal for services in a given locality not sufficiently reflect NHS England's views as to the services that are necessary, NHS England may negotiate the nature of the services as part of the development stage. NHS England should contact the proposer as appropriate.
- NHS England should bear in mind that the duty to involve services users continues throughout the decision making process. The need to re-involve services users is likely only to be triggered where the proposal contains a change to the services provision that was not contemplated in the original involvement exercise. NHS England does not need to go back to services users where the proposal is developed to incorporate feedback from the original involvement exercise.
- In the unlikely scenario that the development of the proposal constitutes a substantial development or substantial variation to that set out in the original

proposal, NHS England may need to inform the local authority again using the same process as set out earlier in the procedure.

52. Determine whether any funding should be provided to the proposer in respect of the development of the LPS scheme. Refer to the box below for further information.

Funding

- Regulation 104(1) allows NHS England to provide financial assistance to the proposer to help meet the cost of developing the proposal. NHS England may decide to provide funding or may need to consider the matter in response to a request from the proposer.
- NHS England should carefully consider whether to make such funding available taking into account all relevant factors. Any payment should be limited to the amount necessary to achieve specified development. A record should be kept of any decision related to the provision of funding.
- The power to provide funding relates only to the development of a scheme and may not be used to fund service provision.

53. Ensure an assessment of the equality impact of the proposal is carried out and recorded with reference to the protected characteristics and document how feedback from service user involvement has been taken into account.
54. Prepare a report (Annex 10) for the PSRC on whether the proposal should be adopted and if so whether a right of return should be given.
55. After the meeting, prepare the relevant decision letters, Annex 11 if the proposal is adopted or Annex 12 if it isn't. 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.
56. If the LPS proposal is not selected, no further actions are necessary.
57. If the LPS proposal is selected, prepare the template LPS contract with information taken from the agreed proposal, development stage and adoption determination (if relevant). Refer to NHS England's guidance 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.
58. Clarify any final matters and arrange for the LPS contract to be signed.
59. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
60. Send the notification of the NHS Pharmacy Contractor Code advising the applicant of their contractor number when received from NHS Prescription Services.
61. On the start date of the contract update the LPS list for the relevant HWB and inform the usual parties which includes the relevant:
- LPC;

- HWB;
- CCG;
- The public health team at the relevant local authority;
- DoS lead;
- Unwanted medicines collection and disposal contractor; and
- The Primary Care Support Service provider's pharmacy payments team in relation to the LPC levy and the data manager.

Payments

62. When commissioning LPS NHS England is not obliged to mirror the national fees and allowances, but may choose to do so where this is relevant.
63. The LPS element of the pharmacy payment should be calculated by NHS England and notified to the Primary Care Support Service Provider on a monthly basis for entry into the Local Payment Application.
64. Alternatively, the LPS payments can be processed by the NHSBSA who will provide a report on request to assist with calculations.
65. Where the LPS contract requires the contractor to provide the NUMSAS and flu vaccination advanced services and payments are to be made in line with the Directions, NHSBSA will contact NHS England for authorisation to make payments for these services where they are claimed by the contractor. The same process will apply where the LPS contract requires the contractor to participate in the Quality Payment Scheme.