Classification: Official

Publication reference: PR2114

NHS England

Pharmacy Manual

Version 2 Select date

Contents

Part 1 3

Chapter 1: Introduction and glossary 3

Chapter 2: Decision-making structures and delegation 7

Chapter 3: Market entry matters 21

Chapter 4: Fitness and applicants 32

Part 2 43

Chapter 5: Procedure for application to join a pharmaceutical list – pharmacy – sole trader 43

Chapter 6: Procedure for application to join a pharmaceutical list – pharmacy – partnership 48

Chapter 7: Procedure for application to join a pharmaceutical list – pharmacy – body corporate 53

Chapter 8: Procedure for application to join a pharmaceutical list – dispensing appliance contractor – sole trader 58

Chapter 9: Procedure for application to join a pharmaceutical list – dispensing appliance contractor – partnership 63

Chapter 10: Procedure for application to join a pharmaceutical list – dispensing appliance contractor – body corporate 68

Chapter 11: Fitness and existing contractors 73

Chapter 12: Procedure – current needs 82

Chapter 13: Procedure – future needs 90

Chapter 14: Procedure – improvements or better access 98

Chapter 15: Procedure – unforeseen benefits 106

Chapter 16: Procedure – future improvements or better access 114

Chapter 17: Procedure – application for no significant change relocation 122

Chapter 18: Distance selling premises 130

Chapter 19: Procedure – change of ownership 137

Chapter 20: Consolidation onto an existing site 143

Chapter 21: Procedure – combined change of ownership and no significant change relocation 149

Chapter 22: Procedures – controlled localities and rurality matters 156

Chapter 23: Procedures – dispensing doctors 164

Chapter 24: Procedure – directed services 172

Chapter 25: Procedure – temporary listing arising from suspension 177

Chapter 26: Procedure – exercising a right of return 183

Chapter 27 189
Part 3 190
Chapter 28: General duties of NHS England 190
Chapter 29: Decision-making 209
Chapter 30: Information on determination of applications 227
Chapter 31: Fitness and applicants and existing contractors 239
Chapter 32: Procedures – controlled localities and rurality matters 258
Chapter 33: Procedures – dispensing by doctors 275
Chapter 34: Procedure – advanced services 286
Chapter 35: Enhanced services 289
Chapter 36: Procedures – opening hours 294
Chapter 37: Procedure – monitoring compliance and managing performance306
Chapter 38: Market exit, administration, bankruptcy and liquidation 326
Chapter 39: Pharmaceutical services finance 340
Chapter 40: Background and procedure – local pharmaceutical services 349
Chapter 41: Procedure – temporary arrangements 360

Part 1

Chapter 1: Introduction and glossary

1. Introduction

Following changes to the NHS Act 2006, integrated care boards (ICBs) were introduced and clinical commissioning groups abolished with effect from 1 July 2022. NHS England may delegate the commissioning of pharmaceutical services to the ICBs; however, it retains oversight for the performance of the commissioning of pharmaceutical services. Therefore, NHS England will require robust assurance that its statutory functions in relation to pharmaceutical services are being discharged effectively. It therefore requires the ICBs to follow this manual when exercising their delegated duties.

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 and wellbeing board (HWB) area) the following lists of persons (whether sole traders, partnerships or bodies corporate) who undertake to provide pharmaceutical services from premises located in England:

- those persons who undertake to provide pharmaceutical services in particular by way of the provision of drugs, ie pharmacy contractors
- those persons who undertake to provide pharmaceutical services in particular by way of the provision of appliances, ie dispensing appliance contractors (DACs).

The above lists are referred to as pharmaceutical lists.

NHS England is also responsible for the following lists by HWB area:

- doctors who undertake to provide pharmaceutical services (the dispensing doctor lists)
- local pharmaceutical services (LPS) chemists (if there are any) who provide local pharmaceutical services at or from premises situated in that area.

Where the commissioning of pharmaceutical services has been delegated to an ICB, that organisation is responsible for preparing and maintaining the pharmaceutical lists for the areas of the HWBs within its area. These lists are then to be submitted to NHS England for publication.

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 defined within the Regulations as the essential, advanced and enhanced services that are provided by pharmacy contractors and DACs and commissioned by NHS England.

The Pharmacy Manual

This 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). Where any discrepancy or contradiction between the content of this manual and the Regulations/Directions is identified, the legal underpinning documents (ie Regulations/Directions, etc) are to take precedence.

In 2022/23 some ICBs have taken on responsibility for the commissioning of pharmaceutical services, but not all. Therefore, this manual uses the term 'the commissioner' to reflect the fact that in parts of the country NHS England will continue to be responsible for pharmaceutical services until April 2023.

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

The delegation agreement

To support the delegation of pharmaceutical services to ICBs, a standard delegation agreement has been developed. The agreement sets out those functions relating to the commissioning of pharmaceutical services that are delegated to ICBs, and those that are retained by NHS England (referred to in the agreement as 'reserved functions').

It is a requirement of the delegation agreement that ICBs must comply with this manual, and any future versions of it.

Communications via emails

To ensure communications regarding decisions relating to pharmaceutical services functions are sent to the correct organisation, NHS England teams, ICBs and the primary care support service provider are required to have and use generic mailboxes.

NHS England regional teams and ICBs are required to share their pharmacy commissioning generic mailbox address with the primary care support service provider and with each other, and to advise of any subsequent changes. ICBs are also required to share their generic mailbox address with the NHS England national pharmacy team via

england.communitypharmacy@nhs.net. NHS England publishes the generic mailbox addresses for its regional teams on its website.

Certain applications for inclusion in a pharmaceutical or dispensing doctor list are to be notified to interested parties, which can include certain existing contractors. Decisions on all such applications are notified to interested parties. Such notifications to existing pharmacy contractors will be via the premises specific NHSmail accounts.

2. Glossary

AUR	appliance use review
CDAO	controlled drug accountable officer
CPAF	Community Pharmacy Assurance Framework
DAC	dispensing appliance contractor
Days	calendar days unless working days is specifically stated
DHSC	Department of Health and Social Care
DHSC guidance	guidance issued by the DHSC on the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
DoS	Directory of Services
DSP	distance selling premises
EEA	European Economic Area
EPS	Electronic Prescription Service
FPC	family practitioner committee
GP	general practitioner
GPhC	General Pharmaceutical Council
HWB	health and wellbeing board
ICB	integrated care board
IELTS	International English Language Testing System
LLP	limited liability partnership
LMC	local medical committee
LPC	local pharmaceutical committee
LPS	local pharmaceutical services
MIS	management information spreadsheet
NHS Act	National Health Service Act 2006
NHAIS	National Health Application and Infrastructure Services
NHSBSA	NHS Business Services Authority
NMS	New Medicine Service
ODS	Organisation Data Service
OJEU	Official Journal of the European Union
OOH	out of hours
PAG	performance advisory group

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
PSG	Professional Standards Group
PSNI	Pharmaceutical Society of Northern Ireland
PSRC	Pharmaceutical Services Regulations Committee
SLA	service-level agreement
SOP	standard operating procedures
SoS	social and other specific services
The commissioner	NHS England or the relevant delegated integrated care board
The committee	The Pharmaceutical Services Regulations Committee or an integrated care board equivalent committee
The Directions	The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013
The Officer	the pharmacy contract manager or an equivalent integrated care board post
The Regulations	The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended

Chapter 2: Decision-making structures and delegation

Introduction

1. This chapter sets out:

- general principles for decision-making
- the terms of reference for the pharmaceutical services regulations committee/ICB equivalent
- those decisions that may be made by the pharmacy contract manager/ICB equivalent
- the role of the performers lists decision panel
- the role of the medical director for system improvement and professional standards
- the role of the primary care support service provider.

General principles for decision-making

2. All decisions must be:

- made in line with the timescales set out within the Regulations (unless there is good cause to take longer – see below)
- fully reasoned
- documented in the minutes of the relevant committee meeting (if the decision has been made by that committee) or, otherwise, in a note made by the relevant officer.

3. There may be occasions where applications for inclusion in a pharmaceutical list take longer than the regulatory 30 days or four months to process and determine, and two reasons for such a delay are included in the Regulations.

4. The first is where an application is deferred in accordance with the Regulations, namely:

- due to a LPS designation (Regulation 32)
- on fitness grounds (Regulation 34), or
- to make a controlled locality determination (Regulation 36).

5. The second is where there is good cause to take longer. While the Regulations do not define what good cause may be, examples could include where there is a delay in references being provided, or where alternative referees need to be sought.

Pharmaceutical services regulations committee, or equivalent, terms of reference

6. NHS England has established local committees to be known as pharmaceutical services regulations committees (PSRCs). Each PSRC is authorised by NHS England to undertake any activity within these terms of reference.

7. ICBs are required to establish committees that are the equivalent of NHS England's PSRCs. Where such a committee is established and is properly constituted in line with the Regulations, it is authorised by NHS England to undertake any activity within these terms of reference.

8. For the purpose of this document, 'the committee' or 'committee' is either the PSRC or the ICB equivalent.

9. NHS England has delegated decision-making to each committee in relation to matters under the Regulations listed in this chapter where the decision-maker is listed as the committee.

10. The membership of each committee is as follows:

    - director of commissioning or equivalent post in the ICB (or their suitable, nominated deputy) who will chair the meeting in the absence of the head of primary care
    - head of primary care or equivalent post in the ICB (or their suitable, nominated deputy) who will chair the meeting
    - up to two lay members (or equivalent).

11. 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. ICB boards will need to have regard to their volunteering policy, or equivalent, in relation to their lay members.

12. All members of the committee must have a good knowledge and understanding of the Regulations to reduce the likelihood of a successful appeal against decisions made. NHS England recognises that ICBs may occasionally not be able to appoint

members to the committee who have the required level of knowledge and expertise. It is therefore essential that the committee is supported by officers or persons who have the relevant expertise. It is essential that members build up expertise in the Regulations and therefore consistency of attendance is expected.

13. Each member of the committee has a vote and the chair has the casting vote, if necessary.

14. Each committee will be quorate if any two of the members are present, one of whom must be an officer from the commissioner organisation.

15. Each committee must ensure it has access to expert knowledge on the Regulations and 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.

16. The following persons may be co-opted to each committee, but will not have a vote:

    - pharmacy contract manager (or equivalent)
    - pharmacy professional adviser (or equivalent) (as required).

17. Persons ineligible to be voting or co-opted members of a committee are listed in Regulation 62 and in paragraph 26(1), 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 meeting 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.

Persons barred from taking part in decision-making on applications for inclusion in a pharmaceutical list or a dispensing doctor

- A person who is included in a pharmaceutical list or is an employee of such a person.
- A person who assists in the provision of pharmaceutical services under Chapter 1 or Part 7 of the NHS Act 2006.
- A person who is an LPS chemist, or a person who provides or assists in the provision of LPS.
- A person who is a provider of primary medical services.

- A person who is a member of a provider or primary medical service that is a partnership, or a shareholder in a provider of primary medical services that is a company limited by shares.
- A person who is employed or engaged by a primary medical services provider.
- A person who is employed or engaged by an alternative provider medical services contractor in any capacity relating to the provision of primary medical services.

18. 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), Schedule 2 to the Regulations apply (reasonable suspicion of bias).

19. Members must advise the chair of any potential conflict of interest on 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/virtual meeting before discussion of that matter and will not return until the relevant decision has been made and the reasons for it have been recorded.

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

21. Each committee will meet monthly (or earlier if needed to discuss a case urgently) where there is a need. Where a meeting is not required the committee will document this in line with local procedures. Meetings may be held virtually or face to face.

22. Each committee 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. ICB committees will also be required to report to NHS England in line with the assurance framework or on request.

23. 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 committee 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.

Joint committees

24. Section 71 of the Health and Care Act 2022 inserted section 65Z5 of the NHS Act 2006 to allow an ICB to arrange for any of its functions to be exercised by, or jointly with, any one or more of the following:

    - a relevant body (defined as NHS England, an ICB, an NHS trust established under Section 25, an NHS foundation trust or such other body as may be prescribed in regulations)
    - a local authority (within the meaning of section 2B)
    - a combined authority.

25. Two or more ICBs could therefore form a joint committee which operates as described in the previous section. The terms of reference set out above apply to such a committee.

Pharmacy contract manager or equivalent decision-making terms of reference

26. NHS England has established local pharmacy contract managers (PCMs).

27. ICBs are required to have an appropriately experienced officer in a role that is similar to the NHS England PCMs. Where such a person meets the requirements of the Regulations, they are authorised by NHS England to make the decisions listed within these terms of reference.

28. For the purpose of this document, ‘the officer’ or ‘officer’ is either the PCM or the ICB equivalent.

29. NHS England has delegated decision-making through the committee to the officer, or their suitable nominated deputy when they are on leave, in relation to matters under the Regulations listed in this chapter where the decision-maker is listed as ‘officer or committee’.

30. Regulation 62 and paragraph 26(1), Schedule 2 to the Regulations lists those persons who may take no part in determining or deferring an application (see above for the full list). Before considering an application or making a decision that has been delegated to them, the officer must document that they are not barred by virtue of the relevant regulation or paragraph mentioned at the beginning of the paragraph.

31. The officer may not make a decision if the circumstances set out in paragraph 26(2), Schedule 2 to the Regulations apply (reasonable suspicion of bias).

32. The officer will be responsible for such matters listed in this chapter where the decision-maker is listed as ‘officer or committee’. If, for whatever reason, the officer is unable to make a decision within the required timeframe (or at all), that decision shall be taken by the committee.

33. The officer will report monthly to the committee on decisions taken and the outcome of any appeals on those decisions.

34. Where, as part of the workforce model agreed between NHS England and a delegated ICB, a person employed by a ‘relevant body’ (as defined in section 65Z5 of the NHS Act 2006) fulfils the role of the ICB’s post that is the equivalent of the PCM, that person is delegated to make those decisions listed in this chapter as ‘officer’ or ‘officer or committee’ as described above.

Role of the performers lists decision panel

35. NHS England has established local performers lists decision panels (PLDPs).

36. Until 1 April 2023, NHS England may delegate fitness decision-making through the PSRC to each PLDP in relation to matters under the Regulations listed later in this chapter where the decision-maker is listed as ‘committee or panel’. Where it does so it must ensure that the membership of the PLDP complies with the Regulations, in particular Regulation 62 of the Regulations and in paragraph 26(1), Schedule 2 to the Regulations (see paragraph 17 above). In addition, it must ensure that decisions are made by the PDLP in a timely manner so that the regulatory timescales for the determination of applications for inclusion in a pharmaceutical list are met.

37. 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 of the Regulations or in paragraph 26, Schedule 2 to the Regulations.

38. The PSRC will be responsible for such matters listed in this chapter where the decision-maker is listed as ‘committee or PLDP’. The PSRC may, until 1 April 2023, delegate fitness matters to the PLDP for whatever reason.

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

Role of the medical director for system improvement and professional standards

40. NHS England has established local medical directors for system improvement and professional standards.

41. NHS England has also established local performance advisory groups (PAGs).

42. With effect from 1 April 2023, each PAG will – subject to approval of NHS England policy at draft stage as of January 2023 – be superseded by a local professional standards group (PSG).

43. With effect from 1 April 2023, ICBs' committees will be responsible for all fitness decisions. The committee may seek professional advice in making these decisions. By local agreement, such advice might be from a pharmacy advisor or a person who is a member of a PAG, PSG or PLDP; and nominated by a medical director for system improvement and professional standards. For the avoidance of doubt, 'fitness matters' are defined as follows.

    - Determining whether or not an applicant is a fit and proper person to be included in the relevant pharmaceutical list when applying to be included in it for the first time.
    - Considering whether or not an applicant body corporate remains a fit and proper to be included in the relevant pharmaceutical list following the grant of an application for inclusion in that list, but before the body corporate is so included, where it notifies the commissioner that it has appointed a new superintendent.
    - Review of conditions following the conditional inclusion of an applicant in a pharmaceutical list.
    - Use of the fitness powers in connection with a person who is already included in a pharmaceutical list or lists as set out in the NHS Act 2006 and the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended, to include removal, contingent removal, suspension and applying for a national disqualification. This could be as a result of a contractor notifying the commissioner of a fitness matter, the commissioner otherwise becoming aware of a fitness matter, or through contract management alongside, or instead of, use of the performance related sanctions.

Primary care support service provider

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

45. The primary care support service provider is not authorised to make decisions on pharmacy or DAC matters and is not commissioned to provide advice on such matters to the commissioner.

46. Once an application is completed the primary care support service provider will send an electronic, zipped folder of all the relevant documents and communications to the relevant office of the commissioner. This folder is to be securely filed and kept by the commissioner for future reference.

47. A service specification setting out the administrative tasks to be undertaken by the primary care support service provider is provided here. 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.

48. On an annual basis the primary care support service provider will send a report to each committee detailing those of its applications that remain undetermined and have exceeded the regulatory timescale for determination. The report will also include details of changes of director and/or superintendent that have not been determined within four months.

Delegated decision-making

49. If the decision-maker is listed as ‘committee’, only the local committee may make that decision.

50. If the decision-maker is listed as ‘officer or committee’, the decision may be made by the local officer, their suitable nominated deputy or by the local committee.

51. If the decision-maker is listed as the ‘committee or PLDP’, the decision may, until 1 April 2023, be made by the local committee or by the relevant NHS England PLDP. With effect from 1 April 2023 those decisions can only be made by the local committee.

52. 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 committee or PLDP may nominate an officer 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 committee or PLDP will be required to make the decision on the applicant's fitness.

Regulatory provision	Decision-maker	Chapter of manual
Regulations 13, 14 and 21A – determination of application(current need)	Committee	Chapter 12 Chapter 22
Regulations 15, 16 and 21A – determination of application (future need)	Committee	Chapter 13 Chapter 22
Regulations 17, 19 and 21A – determination of application (current improvement/better access)	Committee	Chapter 14 Chapter 22
Regulations 18 and 19 – determination of application (unforeseen benefits)	Committee	Chapter 15 Chapter 22
Regulations 20, 21 and 21A – determination of application (future improvement/better access)	Committee	Chapter 16 Chapter 22
Regulation 23 – determination of application (application from NHS chemist in respect of providing directed services)	Committee	Chapter 24
Regulation 24 – determination of application (relocation involving no significant change)	Committee	Chapter 17 Chapter 22
Regulation 25 – determination of application (distance selling pharmacies)	Committee	Chapter 18
Regulation 26(1) – determination of application (change of ownership)	Officer or committee	Chapter 19
Regulation 26(2) – determination of application (relocation involving no significant change/change of ownership)	Committee	Chapter 21 Chapter 22
Regulation 26A – determination of preliminary matters including refusal of application for reasons set out in Regulation 26A(5)(b)	Officer	Chapter 20
Regulation 26A – determination of application (consolidation onto an existing site)	Committee	Chapter 20
Regulation 27 – determination of application (for temporary listing arising out of suspension)	Committee	Chapter 25
Regulation 28 – determination of application (exercising right of return to the pharmaceutical list)	Officer or committee	Chapter 26
Regulation 29 – determination of application (temporary arrangements during emergencies/because of circumstances beyond the control of NHS chemists)	Officer or committee	Chapter 27
Regulation 30 – refusal on language requirement for some NHS pharmacists	Committee or PLDP	Chapter 4

Regulatory provision	Decision-maker	Chapter of manual
Regulation 31 – refusal: same or adjacent premises	Committee	Not discussed
Regulation 32 – deferrals arising out of LPS designations	Officer or committee	Not discussed
Regulation 33 – determination of suitability of an applicant to be included in a pharmaceutical list on fitness grounds	Committee or PLDP	Chapter 4
Regulation 34 – determination of deferral of application to be included in a pharmaceutical list on fitness grounds	Committee or PLDP	Chapter 4
Regulation 35 – determination of conditional inclusion of an applicant to be included in a pharmaceutical list on fitness grounds	Committee 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)	Committee	Chapter 33
Regulation 37 – process for determining controlled localities: preliminary matters	Committee	Chapter 33
Regulation 40 – applications for new pharmacy premises in controlled localities: refusals because of preliminary matters	Committee	Not discussed
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)	Committee	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	Committee	Chapter 32
Regulation 48(2) - determination of patient application ('serious difficulty' applications)	Officer or committee	Chapter 34
Regulation 48(5) to (9) – making of arrangements with a dispensing doctor to dispense to a particular patient or patients	Committee	Chapter 34
Regulation 50 – consideration of 'gradualisation' (ie the postponement of the discontinuation of services by dispensing doctors) for an application in relation to premises in, or within 1.6km of, a controlled locality	Committee	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	Committee	Chapter 34

Regulatory provision	Decision-maker	Chapter of manual
where premises approval has not taken 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	Officer or committee	Not discussed
Regulation 65(5) to (7) – direction to increase core opening hours	Officer or committee	Chapter 36
Regulation 67 – agreement of a shorter notice period for withdrawal from a pharmaceutical list	Committee	Not discussed
Regulation 69 – determination of whether there has been a breach of terms of service	Committee	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	Committee	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	Committee	Chapter 38
Regulation 72 – determination of whether to withhold remuneration	Committee	Chapter 38
Regulation 73 – determination of whether to remove premises or a chemist from the pharmaceutical list (following remedial or breach notice)	Committee	Chapter 38
Regulation 74 – determination of whether to remove premises or a chemist from the pharmaceutical list (death, incapacity or cessation of service)	Committee	Chapter 38
Regulation 79 – determination of review of fitness conditions originally imposed on the grant of an application	Committee or PLDP	Chapter 32
Regulation 80 – determination of removal of a contractor for breach of fitness conditions	Committee or PLDP	Chapter 31
Regulation 81 and 82 – determination of removal or contingent removal	Committee or PLDP	Chapter 32
Regulation 83 – suspensions in fitness cases	Committee or PLDP	Chapter 32
Regulation 84 – reviewing suspensions and contingent removal conditions	Committee or PLDP	Chapter 32
Regulation 85 – general power to revoke suspensions in appropriate circumstances	Committee or PLDP	Chapter 32
Regulation 94 – overpayments	Committee	Chapter 39
Regulation 99 – designation of an LPS area	Committee	Chapter 40
Regulation 100 – review of designation of an LPS area	Committee	Chapter 40
Regulation 101 – cancellation of an LPS area	Committee	Chapter 40

Regulatory provision	Decision-maker	Chapter of manual
Regulation 104 – selection of an LPS proposal for development and decision to adopt proposal	Committee	Chapter 40
Regulation 108 – right of return for LPS contractor	Committee	Chapter 40
Schedule 2, paragraph 1(10) – whether a best estimate is acceptable	Officer or committee	Chapter 29
Schedule 2, paragraph 11(1) – determination of whether there is missing information	Officer	Chapter 29
Schedule 2, paragraph 11(2)(b) – determination of review of reasonableness of request for missing information	Officer or committee	Chapter 29
Schedule 2, paragraph 14 – whether to defer consideration of application	Officer or committee	Chapter 29
Schedule 2, paragraph 19 – determination of who is to be provided with notice of a notifiable application	Officer	Chapter 29
Schedule 2, paragraph 21(4) – determination of whether the full disclosure principle applies to information contained within a notifiable application	Committee	Chapter 29
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)	Officer or committee	Chapter 29
Schedule 2, paragraph 25 – decision to hold an oral hearing to determine an application	Committee	Not discussed
Schedule 2, paragraph 28 – determination of who is to be notified of decisions on routine and excepted applications	Officer or committee	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	Officer or committee	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 committee	Officer or committee	Chapter 29
Schedule 2, paragraph 32 – determination of whether to accept a change to premises	Officer or committee	Not discussed
Schedule 2, paragraph 33 – determination as to whether the future circumstances have arisen	Officer	Not discussed
Schedule 2, paragraph 34 – decisions as to whether notices of commencement are valid, and whether a shorter notice period can be given	Officer	Not discussed
Schedule 2, paragraph 34A – decisions as to whether notices of consolidation are valid, and whether a shorter notice period can be given	Officer	Not discussed
Schedule 2, paragraph 34(4)(c)(i) and 34A(4)(b)(i) – extension of latest date for receipt of notice of commencement or consolidation	Officer or committee	Chapters 12–21, 24–27

Regulatory provision	Decision-maker	Chapter of manual
Schedule 2, paragraph 35 – notice requiring the commencement of pharmaceutical services	Officer or committee	Not discussed
Schedule 4, paragraph 23(1)/Schedule 5, paragraph 13(1) – consideration of a request to temporarily suspend the provision of services (fixed period)	Committee	Not discussed
Schedule 4, paragraphs 23–25/Schedule 5, paragraphs 13–15 – decision to direct a contractor to open at certain times on certain days	Committee	Chapter 37
Schedule 4, paragraph 23(10)/Schedule 5, paragraph 9 – review of reason for temporary suspension within the control of the contractor	Committee	Not discussed
Schedule 4, paragraph 26/Schedule 5, paragraph 16 – determination of core opening hours instigated by the contractor	Committee	Chapter 37
Schedule 4, paragraph 27/Schedule 5, paragraph 17 – temporary opening hours and closures during an emergency requiring the flexible provision or pharmaceutical services	Officer or committee	Not discussed
Schedule 4, paragraph 27B – flexible provision of relevant immunisation services during a pandemic	Officer	Not discussed
Schedule 4, paragraph 28A – premises requirements in respect of consultation rooms – decisions that a pharmacy premises is too small	Officer or committee	Not discussed
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)	Officer or committee	Chapter 37
Decisions relating to compliance with the dispensing doctor terms of service	Committee	Not discussed
Approval of responses to an appeal against, or challenge to, decisions of the committee	Officer or committee	Not discussed
Approval of responses to an appeal against, or challenge to, decisions of the officer	Officer or committee	Not discussed
Determination of further action where community pharmacy assurance framework identifies concerns	Officer or committee	Chapter 38
Determination of further action where the contractor fails or refuses to agree a date and time for a visit	Officer or committee	Chapter 38
Determination of action where any of the following are identified: • patient safety issues • the commissioner is at risk of material financial loss, and/or • possible fraudulent or criminal activity.	Officer or committee	Chapter 38

Regulatory provision	Decision-maker	Chapter of manual
Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report	Officer or committee	Chapter 38
Determination of action where the contractor exceeds the maximum number of appliance use reviews that may be done in any one year	Officer	Chapter 38

Chapter 3: Market entry matters

Introduction

1. This chapter sets out information on a number of matters relating to applications for inclusion in a pharmaceutical list, including:

    - application fees, record-keeping and appeals against decisions
    - managing different versions of pharmaceutical needs assessments
    - types of applicants
    - representatives
    - treating applications as withdrawn
    - withdrawal of market entry applications
    - notices of commencement
    - allocation of organisation data service codes (ODS or F codes).

Fees, records and appeals

2. 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 been received or cleared. The commissioner 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 of the Regulations.

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

4. Decisions made by the commissioner 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.

Managing versions of pharmaceutical needs assessments

5. For some types of routine applications, the Regulations require the commissioner to have regard to ‘the relevant PNA’, which is defined as the PNA that is current at the time the decision is made. It should however be noted that there may be occasions where the applicant has prepared their submission in accordance with a PNA that has subsequently been replaced by a new PNA but the applicant will expect their application to be determined against the previous PNA. Where this doesn’t happen, the applicant could claim that their application has not been dealt with justly.

6. The Regulations require the decision to be made against the new PNA unless in the commissioner's opinion the only way to determine the application justly is with regard to an earlier PNA (Regulation 22(2)).

7. Where a new PNA is published during the 45-day notification period, a letter will be prepared by the commissioner 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 previous PNA. Wherever a decision is made relating to which PNA is to be used in determining the application, this must be clearly recorded in the decision letter, including reasoning for that decision and any additional actions (such as seeking additional representations) that have been taken as a consequence of that decision.

8. The relevant committee 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.

9. 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 commissioner 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 previous PNA.

10. The relevant committee 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.

11. Decisions are not to be made against draft versions of a PNA; only against final, published versions of PNAs.

12. It should be noted that where a new PNA is published between the commissioner determining an application and NHS Resolution hearing any appeal on that decision, then NHS Resolution will need to determine which PNA to hear the appeal against. Where it is determined that the appeal is to be heard against the new PNA, the commissioner will need to submit representations afresh as to whether or not the application should be granted.

13. There may also be occasions where new HWBs are created, either as a result of the merger of two or more councils, or the splitting of a council into two. Where this occurs each new HWB will have 12 months to produce its first PNA. In the interim period, the commissioner will use the previous HWB's PNA to determine applications.

Types of applicants

14. Section 69 of the Medicines Act 1968 sets out who can carry on a retail pharmacy business, namely:

    - a pharmacist
    - a partnership of pharmacists
    - a body corporate and the conditions specified in section 71 of the Medicines Act 1968 are fulfilled, or
    - a representative of a pharmacist (as defined in section 72 of the Medicines Act 1968) and the conditions specified in section 72(2) are fulfilled and the period applicable in section 72(3) has not expired.

15. There are no regulatory provisions relating to who can operate a DAC business.

16. For the purposes of applications for inclusion in a pharmaceutical list, a pharmacy applicant will be either a registered pharmacist, a partnership or a body corporate (which includes limited liability partnerships).

17. To submit an application for inclusion in a pharmaceutical list either as a pharmacy or a DAC, a body corporate must be incorporated. Bodies corporate must therefore be included in the register maintained by Companies House before they can submit such an application. However, it is to be noted that the Financial Conduct Authority is responsible for the registering of the following types of mutual societies:

- registered societies including co-operative societies and community benefit societies
- credit unions
- building societies
- friendly societies.

18. As with bodies corporate that are included in the Companies House register, mutual societies must be included in the Mutuals Public Register before submitting an application for inclusion in a pharmaceutical list.

Representatives

19. Applicants may choose to engage a representative to act on their behalf in relation to the submission and determination of an application. It is expected that in this situation the application will include a letter of authorisation from the applicant. Where such a letter is received all subsequent communications in relation to the application are to be sent to the applicant's representative.

20. On occasion a contractor may choose to engage a representative to prepare and submit their representations on a notified application. In this situation all communications relating to that application are to continue to be sent to the contractor and not to the representative (to meet the requirements of the Regulations), unless a letter of authorisation is received from the contractor. Where such a letter is received all subsequent communications in relation to the application are to be sent to the applicant's representative.

Treating applications as withdrawn

21. Where it is identified that there is missing information, documentation or undertakings in relation to an application for inclusion in a pharmaceutical list, the Regulations include a provision for this to be requested.

22. Where there is missing information, documentation or undertakings, it is, or they are, to be requested using the template letters within this manual.

23. Missing information or documentation must be provided within the specified timescale; otherwise the application is treated as withdrawn. There is no right of appeal against this, and there is no provision for the commissioner to extend the timescale once it has passed.

24. The applicant can notify the commissioner that there is to be a delay in providing the requested information or documentation and must advise of the reasons for the delay and confirm the date by which it will be provided. The commissioner must, however, be satisfied that a delay beyond the specified timescale and the length of the delay are for good cause.

25. The applicant can also ask for a review of the request.

26. Missing undertakings must also be provided within the specified timescale. There is no ability to ask for an extension to that timescale, nor can the applicant ask for a review of the request.

27. There is no right of appeal against an application being treated as withdrawn in the circumstances described in this section, and once an application has been treated as such it cannot be re-opened.

Withdrawal of market entry applications

28. While there is no provision within the Regulations which sets out how an application for inclusion in a pharmaceutical list can be withdrawn by the applicant, they do contain unambiguous references to an application being withdrawn. For example, paragraph 9, Schedule 2 requires the applicant to provide an undertaking to notify the commissioner within seven days of any material changes to the information provided in the application that occur before the application is withdrawn.

29. Where an applicant wishes to withdraw their application, they are to advise the primary care support service provider of this.

30. Where the application has yet to be determined, Annex 1 is to be sent to them, the relevant commissioner is to be advised accordingly and the application is closed. Where the application has been notified to interested parties, Annex 2 is to be sent to those persons and the commissioner. Where it has not been notified, there are no further actions to be undertaken other than to tell the commissioner.

31. Where the application has been determined, Annex 3 is to be sent to the applicant, the relevant commissioner is to be advised accordingly and the application is closed. Annex 4 is to be sent to the interested parties that were notified of the decision.

Notices of commencement – submission

32. If an application for inclusion in a pharmaceutical list is granted, the applicant has a specified period of time within which to submit a ‘notice of commencement’. The

notice of commencement advises the commissioner of the date on which the applicant intends to start to provide services, and it is on this date that the applicant and their premises are included in the relevant pharmaceutical list and the contractual relationship between the two parties commences.

33. In most instances the applicant will have 12 months within which to submit a valid notice of commencement (the Regulations set out the two exceptions to that rule – see paragraph 34, Schedule 2). The table below sets out when that 12-month period starts for the most common scenarios. Paragraph 34(4), Schedule 2 is to be referred to for all other types of scenario.

Scenario	Date the 12 month period starts
The applicant identified the premises at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution.	The date on which the applicant was sent the decision letter by the primary care support service provider on behalf of the commissioner.
The applicant identified the premises at which they wish to provide pharmaceutical services. The application was granted, and an appeal against that decision was received by NHS Resolution. NHS Resolution upheld the decision to grant the application.	The date on which the appeal is determined by NHS Resolution.
The applicant identified the premises at which they wish to provide pharmaceutical services. The application was refused, and an appeal against that decision was received by NHS Resolution. NHS Resolution granted the application.	The date on which the appeal is determined by NHS Resolution.
The applicant gave a best estimate of the address at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution. The applicant notifies the Commissioner of the address of the premises at which they wish to provide pharmaceutical services. This notification is accepted as valid.	The date on which the commissioner confirm the notification is valid.

Scenario	Date the 12 month period starts
The applicant gave a best estimate of the address at which they wish to provide pharmaceutical services. The application was granted and no appeal against that decision was received by NHS Resolution. The applicant notifies the commissioner of the address of the premises at which they wish to provide pharmaceutical services. This notification is not accepted as valid. The applicant appeals this decision and NHS Resolution accepts it as a valid notification.	The date on which the appeal is determined by NHS Resolution.

34. It is to be noted that the above does not apply to the submission of notices of consolidation which are to be submitted within six months, not 12 months.

35. Since November 2020, notices of commencement must be submitted no fewer than 30 days prior to the date on which the applicant intends to commence service provision. There is one exception to this rule and that is where the commissioner agrees to a shorter notice period. The form to be used by applicants who wish to ask for a shorter notice period can be found at Annex 5.

36. The box below contains examples of how this regulatory provision works.

Examples

1. An application to open a new DAC premises has been granted, and the applicant has until 30 November to submit a valid notice of commencement. The applicant wishes to commence service provision on 30 November. They must therefore submit a valid notice of commencement no later than 31 October.

2. A change of ownership application for a pharmacy has been granted and the applicant has until 28 February to submit a valid notice of commencement. The sale of the business is due to complete on 1 February and the applicant intends to commence service provision on 2 February. The latest date for submission of a valid notice of commencement is therefore 3 January.

   On 7 December the buyer and seller agree that the sale of the business can complete earlier, and the buyer will commence service provision on 4 January. As that is less than 30 days away, the applicant will need to ask the commissioner to agree to a shorter

notice period. Only if that is agreed to can the notice of commencement be submitted giving 4 January as the date on which service provision is to commence.

3. An application to open a new pharmacy has been granted and the applicant has until 1 November to submit a valid notice of commencement. The applicant submits their notice on 19 October stating that they intend to commence service provision on 9 November.

   The notice of commencement is invalid as it has been submitted fewer than 30 days before service provision is to commence. The applicant would need to either:

   - submit a new notice of commencement ensuring that the new date for service provision to commence is no fewer than 30 days from the date the notice is submitted or
   - ask the commissioner to agree to a shorter notice period.

4. An application to relocate an existing pharmacy into new premises has been granted and the applicant has until 16 November to submit a valid notice of commencement. They submit such a notice on 16 October, but it did not include all the required information and so is not in the correct form as required by paragraph 34(3), Schedule 2. The applicant was advised of this on 19 October. The applicant would be required to submit a new notice of commencement and either change the date that service provision is to commence to meet the requirements of paragraph 34(2) and (3A), Schedule 2 or ask the commissioner to agree to a shorter notice period.

37. Where a valid notice of commencement is received, the commissioner is required to amend the relevant pharmaceutical list to include the applicant and their premises. This is done on the date given in the notice of commencement.

38. Following the change to the regulations in 2020, there is no longer a maximum time period between the date on which the notice of commencement is submitted and the date on which service provision will commence.

Notices of commencement – changing the commencement date

39. Where the applicant has submitted a notice of commencement, they may change the date on which service provision is to commence. The applicant may notify the commissioner, via the primary care support service provider, as soon as practicable of any change to the date on which service provision is to commence. The form to use can be found at Annex 6.

40. However, where an applicant has submitted a notice of commencement specifying the date on which service provision will commence and subsequently wishes to change that date, they may only do so in advance of the original date on the notice of commencement.

Examples

1. A change of ownership application was granted, and the applicant submitted a notice of commencement to the commissioner advising that service provision will commence on 16 November.

   The sale of the business is delayed at the last minute and the applicant completes the relevant form and submits it to the commissioner on 15 November, advising that they will commence service provision on 26 November.

   As the applicant has notified the commissioner in advance of 16 November (the original date on the notice of commencement), the relevant pharmaceutical list will now be amended on 26 November.

2. An unforeseen benefits application was granted, and the applicant submitted a notice of commencement to the commissioner, advising that service provision will commence on 30 November.

   For reasons outside their control the applicant is unable to open on 30 November and contacts the commissioner later that week to advise that they will now open on 7 December.

   However, as the pharmaceutical list was amended with effect from 30 November, the applicant is required to provide services from that date. They may now be seen to be breaching the requirement to provide pharmaceutical services during their core and supplementary opening hours. The applicant is advised that if there is likely to be any change to the date on which services are to commence, they must discuss this with the commissioner at the earliest opportunity.

41. It should be noted that this change does not apply to the submission of notices of consolidation. Once a valid notice of consolidation has been submitted, the date on which the consolidation will be affected cannot be unilaterally changed by the applicant.

42. There is no limit within the Regulations as to the number of times the date of commencement is changed, as long as the applicant notifies the primary care support service provider of any change as soon as reasonably practicable and in advance of both the original commencement date and the new commencement date.

Allocation of organisation data service codes

43. The following table sets out NHS England's policy in relation to the allocation of organisation data service codes (also known as ODS or F codes).

Type of application	New or existing code?
Applications for inclusion in a pharmaceutical list under Regulations 13,	New code will be issued

Type of application	New or existing code?
15, 17, 18 and 20 (those offering to meet an identified current or future need, or secure identified current or future improvements or better access, or unforeseen benefits)	
Regulation 23 (applications in respect of providing directed services)	Contractor uses existing code
Regulation 24(1) (relocations that do not result in significant change within the same health and wellbeing board area)	Contractor uses existing code
Regulation 24(2) (relocations that do not result in significant change to a neighbouring health and wellbeing board's area)	Contractor uses existing code
Regulation 25 (distance selling premises)	New code will be issued
Regulation 26(1) (change of ownership where the applicant is buying the retail pharmacy business or DAC business on a debts and liabilities basis)	Previous owner's code will be retained
Regulation 26(1) (change of ownership where the applicant is not buying the retail pharmacy business or DAC business on a debts and liabilities basis)	New code will be issued
Regulation 26(2) (combined change of ownership and relocation within the same health and wellbeing board area, where the applicant is buying the retail pharmacy business or DAC business on a debts and liabilities basis)	Previous owner's code will be retained
Regulation 26(2) (combined change of ownership and relocation within the same health and wellbeing board area, where the applicant is not buying the retail pharmacy business or DAC business on a debts and liabilities basis)	New code will be issued
Regulation 26(2) (combined change of ownership and relocation to a neighbouring health and wellbeing board's area, where the applicant is buying the retail pharmacy business or DAC business on a debts and liabilities basis)	Previous owner's code will be retained
Regulation 26(2) (combined change of ownership and relocation to a neighbouring health and wellbeing board's area, where the applicant is not buying the retail	New code will be issued

Type of application	New or existing code?
pharmacy business or DAC business on a debts and liabilities basis)	
Regulation 26A(3) (consolidation application where the applicant owns both sites)	The code of the remaining site will be retained
Regulation 26A(3) (consolidation application where the applicant owns the remaining site but not the closing site)	The code of the remaining site will be retained
Regulation 26A(4) (consolidation application where the applicant owns the closing site but not the remaining site, and is buying the retail pharmacy business at the remaining site on a debts and liabilities basis)	Previous owner's code will be retained
Regulation 26A(4) (consolidation application where the applicant owns the closing site but not the remaining site, and is not buying the retail pharmacy business at the remaining site on a debts and liabilities basis)	New code will be issued
Regulation 27 (temporary listings arising out of a suspension)	New code will be issued
Regulation 28 (right of return)	Previous code to be retained, unless the contractor asks for a new code
Conversion of a society to a body corporate under the Co-operative and Community Benefit Society Act 2014	Previous code to be retained, unless the contractor asks for a new code

44. Buying a retail pharmacy business or DAC business on a debts and liabilities basis means that the electronic prescription nominations do not need to be transferred to a new code. However, it also means that the new owner of the pharmacy or DAC premises will be liable for any monies owed to the commissioner by the previous owner. Applicants should therefore seek their own professional advice before submitting an application that involves a change of ownership.

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
    - notification of fitness decisions.

5. The committee will consider and determine fitness matters but may, until 1 April 2023, 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 a dispensing

doctor list 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 31.

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. This includes fitness information provided in support of an application relating to a different pharmaceutical list.

8. 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 the commissioner 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 the commissioner cannot locate the information previously provided after using reasonable efforts, this will be treated as missing information and the primary care support service provider will ask that the information is provided. Where the applicant fails, or refuses, to comply with the request, the application will be treated as withdrawn in line with the Regulations.

9. Applicants must first be assessed as suitable to be included in the pharmaceutical list that they are applying to be included in, and only then can the ‘market entry’ aspect of their application be considered.

10. 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.

11. 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.

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

    - pharmacists are registered with the General Pharmaceutical Council (GPhC) or the Pharmaceutical Society of Northern Ireland (PSNI)
    - 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).

13. Regulation 12(1) states that only a 'person' can apply for inclusion in, or amendment to, a pharmaceutical list. In these circumstances, the legal 'person' is a sole trader, partnership or body corporate. Where the 'person' is a body corporate it must be incorporated and registered with Companies House at the point the application is submitted to the primary care support service provider.

14. Limited liability partnerships (LLPs) (which may have non-pharmacist members) are bodies corporate and are therefore required to have a superintendent. For the purposes of the Regulations, the word 'director' includes a member of an LLP. Therefore, any requirement for a director to provide fitness information applies equally to a member of an LLP and the usual checks are to be undertaken on that information.

15. Where a director of a body corporate is a 'corporate director', ie is another corporate body and is not a natural person, then the fitness information on the directors or members of that other body corporate or LLP (and superintendent where applicable) is to be provided and the fitness checks undertaken on those persons to assess the applicant's fitness. The same approach is to be taken when the members of an LLP that is applying for inclusion in a pharmaceutical list are not natural persons.

16. In late 2020/early 2021, the government consulted on implementing a ban on corporate directors and has published a White Paper on its position on reforming Companies House ahead of introducing legislation into Parliament. No action is required at the time of publication with regard to those bodies corporate included in a pharmaceutical list that have corporate directors.

17. 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.

18. The Companies House registration of bodies corporate is to be checked to ensure that it is current and that no director is disqualified. This can be done via the Companies House website.

19. Where a procedure in Chapters 5 to 11 requires the commissioner to contact an organisation for information, this will be done via email if deemed appropriate.

Determining an applicant's fitness to practise

20. 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. Paragraph 23, Schedule 2 of the Regulations states that where an applicant is not already included in the relevant pharmaceutical list, NHS England must undertake a series of checks on the fitness information provided and form an opinion as to whether the applicant is a fit and proper person. This is irrespective of whether they are already included in another pharmaceutical list or lists.

21. The office of the commissioner 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. There are, however, two exceptions to this.

    - where an applicant simultaneously submits a number of applications for inclusion in a number of different pharmaceutical lists across the country
    - notifications of changes of director and/or superintendent where the body corporate is included in a number of different pharmaceutical lists across the country (see Chapter 11).

22. To minimise the administrative burden on the commissioner and the primary care support service provider it has been agreed that where the applicant is a:

- Sole trader or partnership, the office of the commissioner with the majority of the applications will make the decision on the applicant's fitness on behalf of all the commissioners who have received the applications.
- Body corporate, the office of the commissioner in whose area its registered office is located will make the decision on the applicant's fitness on behalf of the other offices of the commissioner who have received the applications unless the majority of the applications are in another office's area, in which case that office will make the decision on the applicant's fitness on behalf of all the offices that have received the applications.

23. Annex 1 describes the process that will be followed.

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

24. 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, eg 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 the commissioner for a decision to be made.

25. It should be noted that where an individual has previously provided fitness information in relation to one legal entity, that information cannot be relied on 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, and 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 the commissioner can assure itself that the company is a fit and proper person to be included in the relevant pharmaceutical list.

26. Decisions should be consistent across England and it is not expected that commissioners will come to different decisions based on the same information. Where new information is now available that would lead to a different decision, this should be shared with the commissioner who determined the previous application as it may need to take appropriate action if that application was granted and the

applicant is subsequently included in the relevant pharmaceutical list in respect of the premises identified in the application.

27. Where there is missing information, this is to be requested from the applicant.

28. If the information cannot be found this will be treated as missing information and the applicant is to be asked to provide the information again. Where the applicant fails or refuses to comply with the request, the application will be treated as withdrawn in line with the Regulations.

29. Where an applicant applies to two or more commissioners 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.

30. 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 on 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

31. 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 (ie 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).

32. It has determined that such pharmacists are to provide one of the following:

    - 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

- a recent pass of the Pharmacy Occupational English Language Test with a score of at least a B in each of the four areas of reading, writing, listening and speaking, at one sitting of the test.

33. ‘Recent’ means evidence relating to either test that is less than two years old at the point of making the application for inclusion in a pharmaceutical list.

References

34. 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 or each member of an LLP who is a pharmacist.

35. 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.

36. The referee should be a pharmacist registered with the GPhC or the PSNI and must be able to comment on the pharmacist’s knowledge, skills and competence.

37. The commissioner 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
    - persons with significant control (and where this is another body corporate, any director or superintendent of, or person with significant control of, that second body corporate) of the body corporate
    - trainee pharmacists/pre-registration trainees
    - the applicant’s (and this includes partners, directors and superintendents) designated supervisor/pre-registration trainer.

38. Where the commissioner accepts one of the above persons as a referee, it must clearly document its reasons for doing so.

39. 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 the commissioner in this situation.

40. First, the commissioner could treat the references as missing information. In this instance the missing information template letter is to be sent to the applicant giving them 10 working days to ensure the references are received by the primary care support service provider (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 commissioner 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 is to be sent to the applicant. There are no appeal rights for the applicant.

41. Where the commissioner chooses to treat the references as missing information, the 30 days/four-month clock stops and only restarts when/if the references are provided.

42. Second, the commissioner 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.

43. Third, the commissioner could decide to conditionally grant the application on fitness grounds. The applicant would have the right of appeal against both of these decisions to the First-tier Tribunal.

44. Whichever option the commissioner chooses, it must ensure that its reasoning is fully documented.

Other checks

45. The Regulations require other checks to be undertaken, eg with NHS Counter Fraud Authority. Generally these checks are completed more quickly than the references are received. Where there is a delay in receipt of the references, the commissioner will accept the outcome of these other checks for a period of three months. Should the references be received outside this time period, then the checks are to be undertaken again.

46. For the avoidance of doubt, these other checks are to be undertaken each time an applicant applies to be included in a pharmaceutical list. Checks undertaken in

relation to a previous application are not deemed to be portable to subsequent applications.

Mandatory refusal of applications on fitness grounds

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

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

49. Regulation 33(1)(b)(ii) states that where the applicant has been sentenced to a term of imprisonment of over six months, the application must be refused. For the purposes of this provision, the applicant is defined as the sole trader, any partner in the partnership, or if a body corporate, any director or superintendent.

50. When considering the length of any term of imprisonment, any period of suspended sentencing is to be included.

Discretionary refusal of applications on fitness grounds

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

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

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

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

Deferral of applications on fitness grounds

55. Applications for inclusion in a pharmaceutical list may be deferred by the decision-maker for any of the reasons set out in Regulation 34.

56. 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.

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

Granting applications subject to conditions

58. 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.

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

Notification of fitness decisions

60. Where an application for inclusion in a pharmaceutical list is refused on fitness grounds or is granted subject to conditions, the commissioner, via the primary care support service provider, must notify the persons listed in Regulation 88(2). Such notifications are to be undertaken at either the end of any appeal period, or once any appeal is dealt with, whichever is the later.

61. 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 the commissioner must therefore ensure that it confirms with the primary care support service provider all the persons who are to be notified having due regard to Regulation 88(2). It must also provide the name of, and contact details for, a person at the commissioner’s offices who is in a position to respond to further enquiries.

62. With regard to internal notifications, the primary care support service provider will be aware of any other commissioner that is dealing with or subsequently receives an application from the applicant and therefore will be able to advise that other commissioner 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, 8th Floor, 10 South Colonnade, Canary Wharf, London E14 4PU nhsr.appeals@nhs.net
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 via nwssp-primarycareservices@wales.nhs.uk), regional health boards (in Scotland), and the Regional Health and Social Care Board (in Northern Ireland)

Part 2

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 the commissioner.

3. Fitness procedures must be completed, and a decision made before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application; however, the commissioner may take longer where it has good cause. The commissioner 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.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 1. Where the applicant is relying on 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. Where the applicant qualified as a pharmacist in Switzerland or an EEA member state other than the United Kingdom, the commissioner must be satisfied that the pharmacist

	has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services. Ensure the applicant has provided evidence of either: • 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; or • a recent pass of the Pharmacy Occupational English Language Test with a score of at least a B in each of the four areas of reading, writing, listening and speaking, at one sitting of the test. If the applicant has provided such evidence, go to step 2. If the applicant has not provided such evidence, identify this as missing information in the 'first referral'.
2.	Send the 'first referral' to the relevant commissioner (Annex 2). Include the completed fitness information form.
3.	Where the commissioner confirms all relevant information, documentation and undertakings have been provided, send Annex 3 to the applicant. Go to step 13. If any of the information, documentation or undertakings is missing, go to step 4.
4.	If information and/or documentation 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.
10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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. 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 commissioner. No further action is necessary.
13.	Send Annex 12 to check the registration status of the applicant. This is to be sent to the GPhC or PSNI, whichever is applicable.
14.	If registration of the applicant with the GPhC/PSNI is confirmed, go to step 15. If registration of the applicant with the GPhC/PSNI is not confirmed, send Annex 13 (unable to confirm GPhC/PSNI registration). Diarise follow-up action.
15.	Send Annex 14 by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Check that referees who are pharmacists are registered with the GPhC or PSNI as applicable, and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where the registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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 18.

	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
18.	Diarise date for receipt of responses and follow-up action as below.
19.	If a reference is received, go to step 20. 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 17. 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. Diarise the date for receipt of responses. If no responses are received refer the matter to the Commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 18) on the applicant and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • 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. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant. Go to step 27.

25.	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. Once the outcome of the investigation is known, send Annex 26 (no further grounds to defer) to the applicant.
26.	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 commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the commissioner and return to step 20 above for a decision.
27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known go to step 28. If no appeal is made, to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 29 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner.

3. Fitness procedures must be completed before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application; however, the commissioner may take longer where it has good cause. The commissioner 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.	Check that each partner has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 1. Where the applicant is relying on 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. Where a partner of the applicant qualified as a pharmacist in Switzerland or a European Economic Area member state other than the United Kingdom, the commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services.

	Ensure the applicant has provided evidence of either: • 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; or • a recent pass of the Pharmacy Occupational English Language Test with a score of at least a B in each of the four areas of reading, writing, listening and speaking, at one sitting of the test. If the applicant has provided such evidence, go to step 2. If the applicant has not provided such evidence, identify this as missing information in the 'first referral'.
2.	Send the 'first referral' to the relevant commissioner (Annex 2). Include the fitness information form.
3.	Where the commissioner 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 is 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.

10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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. 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 commissioner. No further action is necessary.
13.	Send Annex 12 to check the registration status of each partner. This is to be sent to the GPhC or PSNI, whichever is applicable.
14.	If registration of the partners with the GPhC/PSNI is confirmed, go to step 15. If registration of a partner with the GPhC/PSNI is not confirmed, send Annex 13 (unable to confirm GPhC/PSNI registration). Diarise follow-up action.
15.	Send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Check that referees who are pharmacists are registered with the GPhC or PSNI as applicable and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where the registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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 18. 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).
18.	Diarise date for receipt of responses and follow-up action as below.

19.	If a reference is received, go to step 20. 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 17. 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. Diarise the date for receipt of responses. If no responses are received, refer the matter to the commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 18) on the applicant and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the commissioner that in the event of a refusal or conditional inclusion this applies collectively to the partnership as an entity and not to an individual.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • 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. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant. Go to step 27.

25.	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. Once the outcome of the investigation is known, send Annex 26 (no further grounds to defer) to the applicant.
26.	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 commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the commissioner and return to step 20 above for a decision.
27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known, go to step 28. If no appeal is made, go to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 29 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. Once the outcome of the appeal is known, no further steps are necessary in relation to this element of the application.

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 the commissioner.

3. Fitness procedures must be completed before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application; however, the commissioner may take longer where it has good cause. The commissioner 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.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 to 4 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 1. Where the applicant is relying on 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. Check: • that the company is registered on the Companies House website (or if it is a mutual society check it is included in the Financial Conduct Authority's Mutuals Public Register)

	• that the date of incorporation of the company is before the date of the application for inclusion in the relevant pharmaceutical list (the body corporate must be incorporated before the application is submitted) • that none of the referees are listed as a person with significant control of the body corporate on Companies House • that the registered office address matches the address given on the form • that the superintendent is registered as such for the body corporate on the GPhC register. It should be noted that if the body corporate does not already run a pharmacy, then the superintendent will not appear as such on the GPhC register as superintendents can only be nominated where a body corporate has registered premises with the GPhC or is registering premises.
2.	Send the 'first referral' to the relevant commissioner (Annex 2). Include the fitness information form.
3.	Where the commissioner 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 is 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.

10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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. 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 commissioner. No further action is necessary.
13.	Send Annex 12 to check the registration status of each director and the superintendent. This is to be sent to the GPhC (superintendent and directors) or PSNI (directors only), whichever is applicable.
14.	If registration of all of the directors with the GPhC/PSNI is confirmed, go to step 15. If registration of the superintendent with the GPhC is not confirmed, send Annex 13 (unable to confirm registration of superintendent). If registration of any director who states they are registered with the GPhC/PSNI cannot be confirmed, send Annex 14 (unable to confirm registration of director). Diarise follow-up action.
15.	Send Annex 15 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the company, superintendent and any director, noting that there are separate email addresses for checks on the company and checks on the directors and superintendent. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the company, superintendent and any director (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Check that referees who are pharmacists are registered with the GPhC or PSNI as applicable and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. Where registration is confirmed and there are no fitness matters recorded against the referee, send Annex 16 (reference request) to each referee nominated by the applicant and go to step 18.

	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 19).
18.	Diarise date for receipt of responses and follow-up action as below.
19.	If a reference is received, go to step 20. 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 17. If no response is received, send Annex 17 (letter to referee – chasing response) to that referee and if there is still no response send Annex 18 (letter to applicant – non-receipt of reference) to the applicant. Diarise the date for receipt of responses. If no responses are received, refer the matter to the commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 19) on the applicant and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the commissioner that in the event of a refusal or conditional inclusion this applies collectively to the body corporate as an entity and not to an individual.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 20 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • 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. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant. Go to step 27.

25.	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. Once the outcome of the investigation is known, send Annex 26 (no further grounds to defer) to the applicant.
26.	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 commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the commissioner and return to step 20 above for a decision.
27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known, go to step 28. If no appeal is made, go to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 29 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. Once the outcome of the appeal is known, no further steps are necessary in relation to this element of the application.

Chapter 8: Procedure for application to join a pharmaceutical list – 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 the commissioner.

3. Fitness procedures must be completed before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application, however the commissioner may take longer where it has good cause. The commissioner 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.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out at Annex 1. Where the applicant is relying on 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. Where the applicant qualified as a pharmacist in Switzerland or an EEA member state other than the United Kingdom, the commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who

	make use of the services to which the application relates, is necessary for the provision of those services. Ensure the applicant has provided evidence of either: • 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; or • a recent pass of the Pharmacy Occupational English Language Test with a score of at least a B in each of the four areas of reading, writing, listening and speaking, at one sitting of the test. If the applicant has provided such evidence, go to step 2. If the applicant has not provided such evidence, identify this as missing information in the 'first referral'.
2.	Send the 'first referral' to the relevant commissioner (Annex 2). Include the fitness information form.
3.	Where the commissioner 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 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.

10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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. 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 commissioner. No further action is necessary.
13.	Where the applicant is a pharmacist, send Annex 12 (email to the GPhC or PSNI whichever is applicable) to check the registration status of the applicant.
14.	If registration of the applicant with the GPhC/PSNI is confirmed, go to step 15. If registration of the applicant with the GPhC/PSNI is not confirmed, send Annex 13 (unable to confirm GPhC/PSNI registration). Diarise follow-up action.
15.	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. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	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://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Where the applicant is a pharmacist, check that referees who are pharmacists are registered with the GPhC or PSNI as applicable, and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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 18. 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).
18.	Diarise date for receipt of responses and follow-up action as below.

19.	If a reference is received, go to step 20. 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 17. 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. Diarise the date for receipt of responses. If no responses are received, refer the matter to the commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 18) on the applicant and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • 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. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner will arrange an oral hearing in case the applicant wishes to make oral representations. Send Annex 23 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant. Go to step 27.
25.	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. Once the outcome of the investigation is known, send Annex 26 (no further grounds to defer) to the applicant.

26.	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 commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the commissioner and return to step 20 above for a decision.
27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known, go to step 28. If no appeal is made, go to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 29 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner and any other commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. Once the outcome of the appeal is known, no further steps are necessary in relation to this element of the application.

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 the commissioner.

3. Fitness procedures must be completed before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application; however, the commissioner may take longer where it has good cause. The commissioner 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.	Check that each partner has submitted all relevant fitness information required by paragraphs 2 and 3 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out at Annex 1. Where the applicant is relying on 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. Where a partner of the applicant qualified as a pharmacist in Switzerland or an EEA member state other than the United Kingdom, the commissioner must be satisfied that the pharmacist has the level of knowledge of English which, in the interests of the pharmacist and people who make use of the services to which the application relates, is necessary for the provision of those services.

	Ensure the applicant has provided evidence of either: • 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; or • a recent pass of the Pharmacy Occupational English Language Test with a score of at least a B in each of the four areas of reading, writing, listening and speaking, at one sitting of the test. If the applicant has provided such evidence, go to step 2. If the applicant has not provided such evidence, identify this as missing information in the 'first referral'.
2.	Send the 'first referral' to the relevant commissioner (Annex 2). Include a copy of the fitness information form.
3.	Where the commissioner 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. If any of the information, documentation or undertakings is 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.

10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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. 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 commissioner. No further action is necessary.
13.	Where a partner is a pharmacist, send Annex 12 to check their registration. This is to be sent to the GPhC or PSNI, whichever is applicable.
14.	If registration of the partner(s) with the GPhC/PSNI is confirmed, go to step 15. If registration of a partner with the GPhC/PSNI is not confirmed, send Annex 13 (unable to confirm GPhC/PSNI registration). Diarise follow-up action.
15.	Send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the applicant. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Where a partner is a pharmacist, check that referees who are pharmacists are registered with the GPhC or PSNI as applicable, and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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 18. 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).
18.	Diarise date for receipt of responses and follow-up action as below.

19.	If a reference is received, go to step 20. 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 17. 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. Diarise the date for receipt of responses. If no responses are received, refer the matter to the commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 18) on the applicant for the decision-maker and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the commissioner that in the event of a refusal or conditional inclusion this applies collectively to the partnership as on entity and not to an individual.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • 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. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner 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. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 24 (conditions) to the applicant. Go to step 27.

25.	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. Once the outcome of the investigation is known, send Annex 26 (no further grounds to defer) to the applicant.
26.	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 commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 28 (application proceeding), refer to the commissioner and return to step 20 above for a decision.
27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known, go to step 28. If no appeal is made, go to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 29 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. 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 the commissioner and any commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. Once the outcome of the appeal is known, no further steps are necessary in relation to this element of the application.

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 the commissioner.

3. Fitness procedures must be completed before the market entry element of the application is determined under the relevant procedure (including where deferred on fitness grounds). Applications for inclusion in a pharmaceutical list must be determined within either 30 days or four months of receipt depending on the type of application, however the commissioner may take longer where it has good cause. The commissioner 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.	Check that the applicant has submitted all relevant fitness information required by paragraphs 2 to 4 of Part 1, Schedule 2 to the Regulations. This is particularly important if the applicant has not used the fitness information form set out in Annex 1. Where the applicant is relying on 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 directors are listed in that document against the previously provided fitness information. Check: • that the company is registered on the Companies House Website (or if it is a mutual society, check it is included in the Financial Conduct Authority's Mutuals Public Register)

	• that the date of incorporation of the company is before the date of the application for inclusion in the relevant pharmaceutical list (the body corporate must be incorporated before the application is submitted) • that none of the referees are listed as a person with significant control of the body corporate on Companies House • that the registered office address matches the address given on the form.
2.	Send the 'first referral' to the commissioner (Annex 2). Include a copy of the fitness information form.
3.	Where the commissioner 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 is 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 (and this applies to any further requests for missing information and/or documentation).
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 commissioner 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 commissioner. No further action is necessary.
10.	Where there are missing undertakings, complete and send Annex 9 (request for missing undertakings) to the applicant. 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.

	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 commissioner. No further action is necessary
13.	Where a director is also a pharmacist, send Annex 12 (email to the GPhC or PSNI whichever is applicable) to check the registration status.
14.	If registration of the director(s) with the GPhC/PSNI is confirmed, go to step 17. If registration of a director who states they are registered with the GPhC/PNSI cannot be confirmed, send Annex 13 (unable to confirm GPhC/PSNI registration of director). Diarise follow-up action.
15.	Send Annex 14 (enquiry) by email to NHS Counter Fraud Authority, requesting a fraud check to be carried out on the company and the director(s) noting that there are separate email addresses for checks on the company and checks on the directors. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
16.	Where a director is also a pharmacist, initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the applicant (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
17.	Where a director is also a pharmacist, check that referees who are pharmacists are registered with the GPhC or PSNI as applicable, and whether there is any fitness to practise information recorded in relation to them on the relevant register via the GPhC website or PSNI website. Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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 18. 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)
18.	Diarise date for receipt of responses and follow-up action as below.
19.	If a reference is received, go to step 20. 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 17. 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 (letter to applicant – non-receipt of reference) to the applicant. Diarise the date for receipt of responses.

	If no responses are received, refer the matter to the commissioner.
20.	Once all the checks are completed, prepare the committee report (Annex 18) on the applicant and send to the commissioner. Set the date for return of the decision in order to ensure the overall decision (ie including market entry provisions) is made within 30 days or four months of receipt as appropriate. Advise the commissioner that in the event of a refusal or conditional inclusion this applies collectively to the body corporate as an entity and not to an individual.
21.	If the applicant is suitable for inclusion, go to step 22. If the application is refused, go to step 23. If the commissioner is minded to conditionally include the applicant, go to step 24. If the application is deferred, go to step 25.
22.	If the applicant is suitable for inclusion on fitness grounds, send Annex 19 (fitness reviewed letter) to the applicant. No other steps are necessary in relation to this element of the application.
23.	If the application is refused: • under Regulation 33(1) (mandatory refusal), send Annex 20 (mandatory refusal) to the applicant; or • under Regulation 33(2) (discretionary refusal), send Annex 21 (discretionary refusal) to the applicant. Go to step 27.
24.	If the commissioner is minded to conditionally include the applicant, the commissioner will arrange an oral hearing in case the applicant wishes to make oral representations and send Annex 22 (minded to place conditions) to the applicant. Following consideration of the written and/or oral representations, if the applicant is to be conditionally included, send Annex 23 (conditions) to the applicant. Go to step 27.
25.	If the application is deferred, send Annex 24 (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. Once the outcome of the investigation is known, send Annex 25 (no further grounds to defer) to the applicant.
26.	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 26 (application withdrawn) to the applicant. Advise the commissioner. No further steps are necessary. If the applicant updates the application and confirms that they wish to proceed, send Annex 27 (application proceedings), refer to the commissioner and return to step 20 above for a decision.

27.	If notice of an appeal against refusal or conditional inclusion is received, advise the commissioner and assist in the production of a response. Once the outcome of the appeal is known, go to step 28. If no appeal is made, go to step 28.
28.	If the application is refused on fitness grounds (either by the commissioner or on appeal by the First-tier Tribunal), send Annex 28 to the interested parties. However, this annex is not to be sent if the application has not been notified. Send Annex 29 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. If the applicant is to be conditionally included on fitness grounds if the market entry element of the application is granted, send Annex 30 to the relevant bodies set out in Regulation 88 and as confirmed by the commissioner and any commissioners that have the applicant included in one or more of the pharmaceutical lists in their area. Once the outcome of the appeal is known, no further steps are necessary in relation to this element of the application.

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 the commissioner where concerns are identified in relation to a contractor who is included in 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 committee will consider and determine fitness matters but may, until 1 April 2023, 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

4. Where a pharmacy body corporate included in one or more pharmaceutical lists appoints a new director or superintendent or a DAC body corporate appoints a new director, it must notify the commissioner within 30 days (paragraph 32(4), Schedule 4 and paragraph 22(4), Schedule 5 of the Regulations) of the person taking up the post. 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.

6. Whether a body corporate that only holds a LPS contract or contracts with the commissioner is required to notify of changes of director and/or superintendent will depend on the terms of the contract. This will be confirmed as part of the first referral process.

7. There may be occasions where the bank account into which payments for the provision of pharmaceutical services changes as a result of changes to the directors and/or superintendent. In these instances the commissioner will agree to the change being made by NHSBSA as long as the required fitness information has been provided.

Procedure

	Action
1.	Check that the contractor has submitted all relevant fitness information required by paragraphs 2 to 4 of Part 1, Schedule 2 to the Regulations. This is particularly important if the contractor has not used the relevant fitness information form. Where the change relates to a director, check that they are listed as a director of the body corporate on Companies House (or if it is a mutual society check it is included in the Financial Conduct Authority's mutuals Public Register). Where the change relates to the superintendent, check that they are registered as such for the body corporate on the GPhC register. Check that: • none of the referees are listed as a person with significant control of the body corporate on Companies House • the registered office address on Companies House matches the address given on the form.
2.	Send the 'first referral' to the relevant commissioner (Annex 3). Include copies of the fitness information form. The relevant commissioner is: • the one in whose area the body corporate's registered office is located; or • if the body corporate has no premises in that commissioner's area, to the commissioner in whose area its premises are located, or where the majority of its premises are located. Advise the other commissioners that a change of director and/or superintendent has been received, which commissioner is making the decision, and that they will be informed of the final decision.
3.	Where the commissioner confirms it is happy with the information provided, send Annex 4 (confirmation of receipt of information) to the contractor. Go to step 6.
4.	If the commissioner requires further information, send Annex 5. The amount of time to be given for submission is 10 working days. Diarise the date for the information to be submitted.
5.	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. If the information and/or documentation is not received by the due date, refer the matter to the commissioner.
6.	Send Annex 7 (email to the GPhC or PSNI as applicable) to check the registration status of the new superintendent and/or director if they are a registered pharmacist.

7.	If registration of the new superintendent with the GPhC is confirmed, go to step 8. If registration of the new superintendent with the GPhC is not confirmed, send Annex 8 (unable to confirm registration of superintendent). If registration of the new director who states they are registered with the GPhC or PSNI cannot be confirmed, send Annex 9 (unable to confirm registration of director). Diarise follow-up action.
8.	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. Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
9.	Initiate an online enquiry to NHS Resolution in respect of past or current investigations relating to the superintendent and/or director (http://nww.fhsau.nhsla.nhs.uk/Login.aspx log-in required). Diarise date for receipt of response and follow up if necessary. If anything is identified in the response, refer it to the commissioner, particularly if it wasn't identified in the fitness form.
10.	Check that referees who are pharmacists are registered with the GPhC or PSNI as applicable and whether there is any fitness to practise information recorded in relation to them on the GPhC/PSNI register via the GPhC website or PSNI website. Where registration cannot be verified or there are fitness matters recorded against the referee, refer the matter to the commissioner. 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. 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).
11.	Diarise date for receipt of responses and follow-up action as below.
12.	If a reference is received, go to step 13. 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. 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. Diarise the date for receipt of responses. If no responses are received refer the matter to the commissioner.
13.	Once all the checks are completed, prepare the committee report (Annex 14) on the new superintendent and/or director and send to the commissioner.

14.	If the commissioner is satisfied that the contractor remains a fit and proper person, go to step 15. If the commissioner is minded to remove the contractor on fitness grounds, go to step 16. If the commissioner is minded to contingently remove the contractor, go to step 17. If the contractor is to be suspended, go to step 18.
15.	Where the contractor remains a fit and proper person, send Annex 15 to them. Send Annex 15 to any other commissioner that has the contractor included in one or more of its pharmaceutical lists for information. There are no further actions to be undertaken with regard to this procedure.
16.	If the commissioner 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 commissioner 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 commissioner 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. Send Annex 19 to any other commissioner that has the contractor included in one or more of its pharmaceutical lists for information. There are no further actions under this procedure.
22.	If notice of an appeal against removal is received, advise the commissioner and assist in the production of a response. Where the commissioner's decision is upheld on appeal, ie the contractor is to be removed from the relevant pharmaceutical list or lists, send Annex 20 as the Regulation 88 notification. Send Annex 21 to: • other commissioners that have the contractor included in one or more of the pharmaceutical lists in their area • HWB • public health team • local medical committee (LMC) • Directory of Services (DoS) lead • registration authority • controlled drugs accountable officer (CDAO) • out of hours (OOH) provider • unwanted medicines collection and disposal contractor • the organisation that cascades safety alerts

	• the primary care support service provider's pharmacy payments team in relation to the local pharmaceutical committee (LPC) levy and the data manager. The commissioner will provide the required contact details for all but the last of the above listed persons. Send Annex 22 to the contractor. Where the commissioner's decision is not upheld on appeal, ie the contractor is not to be removed from the relevant pharmaceutical list or lists, send a copy of the appeal decision to other commissioners that have the contractor included in one or more of the pharmaceutical lists in their area. There are no further actions to be undertaken with regard to this procedure. If no appeal is made, send Annex 23 to the contractor, Annex 20 as the Regulation 88 notification and Annex 21 to those organisations listed above.
23.	If notice of an appeal against contingent removal is received, advise the commissioner and assist in the production of a response. Where the commissioner's decision is upheld on appeal, ie the contractor is to be contingently removed from the relevant pharmaceutical list or lists, send Annex 24 as the Regulation 88 notification. It is also to be sent to the other commissioners that have the contractor included in one or more of the pharmaceutical lists in their area. Send Annex 25 to the contractor. Where the commissioner's decision is not upheld on appeal, ie the contractor is not to be contingently removed from the relevant pharmaceutical list or lists, send a copy of the appeal decision to other commissioners that have the contractor included in one or more of the pharmaceutical lists in their area. There are no further actions to be undertaken with regard to this procedure. If no appeal is made, send Annex 26 to the contractor and Annex 24 as the Regulation 88 notification. Annex 24 is also to be sent to the other commissioners that have the contractor included in one or more of the pharmaceutical lists in their area.

Changes of director name and name and/or address of the superintendent

8. 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 the commissioner 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 using Annex 27.

9. On receipt of such information, forward it to the commissioner or commissioners in whose area the body corporate has premises.

10. There are no further actions in relation to this issue.

Resignation of directors

11. Linked to the above, where a director resigns (whether or not they are replaced) this change to the names of the body corporate's directors is to be notified to the commissioner 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 using Annex 28.

12. On receipt of such information, forward it to the commissioner or commissioners in whose area the body corporate has premises.

13. There are no further actions in relation to this issue.

Provision of information on fitness matters as they arise

14. The Regulations require all contractors to provide the commissioner with 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).

15. Where the contractor is a body corporate this information will be forwarded to:

    - the commissioner in whose area the body corporate's registered office is located; or
    - if the body corporate has no premises in that commissioner's area, to the commissioner in whose area its premises are located, or where the majority of its premises are located.

16. For sole traders and partnerships this information will be sent to the commissioner in whose area:

    - all the contractor's premises are located, or
    - the majority of its premises are located.

17. The committee (or, until 1 April 2023, the 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 the commissioner 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 while considering use of the other powers – section 154(1) of the NHS Act 2006.

18. Notification of the decision to the contractor will be undertaken by the primary care support service provider. The committee/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).

19. 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.

20. If the body corporate is to be suspended, the Regulation 88 notification (Annex 29) will be sent at the same time as the contractor is notified.

21. For removals (whether on mandatory or discretionary grounds), the Regulation 88 notification is to be undertaken at the end of the 28-day appeal period if there are no appeals, or once any appeal has been heard and the commissioner's decision to remove has been upheld. Annex 30 is to be used for the Regulation 88 notification and is also to be sent to commissioners that have the contractor included in one or more of the pharmaceutical lists in their area. In addition, the following persons are to be notified by the primary care support service provider using Annex 31:

    - HWB
    - public health team
    - LMC
    - DoS lead
    - registration authority
    - CDAO
    - OOH provider
    - unwanted medicines collection and disposal contractor
    - the organisation that cascades safety alerts

- 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 the commissioner.

22. For contingent removals, the Regulation 88 notification is to be undertaken at the end of the 28-day appeal period if there are no appeals, or once any appeal has been heard and the commissioner's decision to remove has been upheld. Annex 32 is to be used for the Regulation 88 notification and is also to be sent to commissioners that have the contractor included in one or more of the pharmaceutical lists in their area.

23. Regulation 88 notifications to the person/organisation shown in the left-hand column of the table below are to 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, 8th Floor, 10 South Colonnade, Canary Wharf, London E14 4PU nhsr.appeals@nhs.net
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 via nwssp-primarycareservices@wales.nhs.uk), Regional health boards (in Scotland), and the Regional Health and Social Care Board (in Northern Ireland)

Use of the fitness powers

24. There may be occasion where the commissioner identifies concerns relating to the fitness of a contractor. In this instance, the committee will need to consider use of the fitness powers set out in the NHS Act 2006 and Part 11 of the Regulations.

25. In general, the powers available to the commissioner are set out in the NHS Act 2006 and the procedures to follow are set out in the Regulations. Where a committee (or, until 1 April 2023, PLDP) is considering use of the fitness powers it should first liaise with other commissioners in whose area the contractor has premises so that a consistent approach is taken across the country.

26. Options available to the commissioner 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 while considering use of the other powers – section 154(1) of the NHS Act 2006.

27. Where the commissioner 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 the commissioner.

28. A notification under Regulation 88 is to be made where the commissioner:

- varies a condition that was placed on 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; or
- suspends a contractor.

29. Annexes 33 to 37 contain template letters that can be used for the Regulation 88 notifications for decisions to vary a conditional inclusion (Annex 33), to suspend (Annex 34), remove (Annex 35), contingently remove (Annex 36) a contractor, or to vary a contingent removal (Annex 37).

Chapter 12: Procedure – 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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

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

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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant Commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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 commissioner. Go to step 22.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go to step 13. Where the commissioner confirms that the application is to be deferred, go to step 17. Where the commissioner confirms that the best estimate is not acceptable, go to step 20.
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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Then go to step 22.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7. Where the applicant is offering to meet an identified current need for enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided. Go to step 22.
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 commissioner. This is the end of the process.
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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). 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. Go to step 22.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
18.	If the commissioner 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.

	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.
19.	Once the reason for deferral ceases, send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant. If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so, and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
20.	If the commissioner confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 16) to the applicant. Diarise the date for the further best estimate to be submitted.
21.	On receipt of the revised best estimate, send it to the commissioner for confirmation that it is acceptable. If the revised best estimate is acceptable, and where the application is complete, send Annex 17 and go to step 22. If the revised best estimate is not acceptable, write back to the applicant for a further best estimate.
22.	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 commissioner of the application (Annex 18) enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 27), notify the interested parties using Annex 19.
23.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared, send a request for payment (Annex 20) 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 21). Copy in the commissioner.
26.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 22). Advise the commissioner. This is the end of the process.
28.	If an oral hearing is to be held, the commissioner will make the arrangements. Confirm these with the applicant (Annex 23) and any additional presenters (Annex 24) that the commissioner 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, go to the next step.
30.	Prepare a report (Annex 25) on the application and send to the Commissioner.
31.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The granted decision letters for applications where the address of the premises is known are: • granted – to the applicant (Annex 26) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 28) • granted – to a third party with appeal rights (Annex 29). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • granted – to the applicant (Annex 30) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 31) • granted – to a third party with appeal rights (Annex 32). The refusal decision letters for applications where the address is known or a best estimate has been given are: • refused – to the applicant (Annex 33) • refused – to a third party (Annex 34).

	If the application is in or near a controlled locality, please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
34.	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 35) to the applicant. Include a copy of the banking mandate. 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 36 to the applicant.
35.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 37 where the address of the proposed premises was provided or Annex 38 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate where the applicant gave an address for the proposed premises.
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37. Where the application contains the address of the proposed premises, go to step 38.
37.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address, forward it to the commissioner to determine whether or not it is a valid notification. If the notification wasn't received in time, send notification of receipt of premises not valid (Annex 39) and copy in the commissioner. If the commissioner is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 40) to the applicant and send notification of premises (Annex 41) to those parties notified of the decision on the original application. If the commissioner is not satisfied that the notification is valid, send notification of non-valid premises (Annex 42). 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 43).

38.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 44 to the interested parties.
39.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 45. If the application is refused, send Annex 46.
40.	If a request for an extension within which to open is received (Annex 47), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 48 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 41. If the request is refused, send Annex 49 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 41. 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, go to step 41.
41.	On receipt of a completed notice of commencement, check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 50 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 51 where it has been submitted fewer than 30 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 the commissioner, or (where the applicant gave a best estimate) the address approved by the commissioner. • 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 on premises@pharmacyregulation.org.

	• The notice is signed and dated. If any information is missing or incorrect, send Annex 52 to the applicant and return to this step when the required information is received. Where no issues are identified, forward the notice to the relevant decision-maker for confirmation it is valid. Where it is valid, send Annex 53. Go to step 42. Where it is not, send Annex 54 and return to this step when a new notice of commencement is received.
42.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
43.	Send the notification of the NHS Pharmacy Contractor Code (Annex 55), advising the applicant of their contractor number when received from NHS Prescription Services.
44.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 56, copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 57, copying in the commissioner. Go to step 45. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 58 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 45.
45.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 59) the usual parties, which includes the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

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

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.	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). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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 commissioner. Go to step 22.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that the application is to be deferred, go to step 17. Where the commissioner confirms that the best estimate is not acceptable, go to step 20.
7.	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). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Go to step 22.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). 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. Go to step 22.
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 commissioner. This is the end of the process.
13.	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). 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). 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. Go to step 22.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22

18.	If the commissioner 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. 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.
19.	Once the reason for deferral ceases, send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant. If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
20.	If the commissioner confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 16) to the applicant. Diarise the date for the revised best estimate to be submitted.
21.	On receipt of the revised best estimate, send it to the commissioner for confirmation that it is acceptable. If the revised best estimate is acceptable, and where the application is complete, send Annex 17 and go to step 22. If the revised best estimate is not acceptable, write back to the applicant for a further best estimate.
22.	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 commissioner of the application (Annex 18) enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 27), notify the interested parties using Annex 19.
23.	During the 45-day notification period, ensure that payment has cleared. If payment hasn't cleared, send a request for payment (Annex 20) 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 21). Copy in the commissioner.
26.	Send copies of the representations to the commissioner 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.	During the 14-day period, ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 22). Advise the commissioner. This is the end of the process.
28.	If an oral hearing is to be held, the commissioner will make the arrangements. Confirm arrangements with the applicant (Annex 23) and any additional presenters (Annex 24) that the commissioner 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, go to the next step.
30.	Prepare a report (Annex 25) on the application and send to the commissioner.
31.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The granted decision letters for applications where the address of the premises is known are: • granted – to the applicant (Annex 26) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 28) • granted – to a third party with appeal rights (Annex 29). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • granted – to the applicant (Annex 30) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 31) • granted – to a third party with appeal rights (Annex 32). The refusal decision letters for applications where the address is known or a best estimate has been given are:

	• refused – to the applicant (Annex 33) • refused – to a third party (Annex 34). If the application is in or near a controlled locality, please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
34.	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 35) to the applicant. Include a copy of the banking mandate. 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 36 to the applicant.
35.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 37 where the address of the proposed premises was provided or Annex 38 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate where the applicant gave an address for the proposed premises.
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37. Where the application contains the address of the proposed premises, go to step 38.
37.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address, forward it to the commissioner to determine whether or not it is a valid notification. If the notification wasn't received in time, send notification of receipt of premises not valid (Annex 39) and copy in the commissioner. If the commissioner is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 40) to the applicant and send notification of premises (Annex 41) to those parties notified of the decision on the original application. If the commissioner is not satisfied that the notification is valid, send notification of non-valid premises (Annex 42).

	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 43).
38.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 44 to the interested parties.
39.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 45. If the application is refused, send Annex 46.
40.	If a request for an extension within which to open is received (Annex 47), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 48 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 41. If the request is refused, send Annex 49 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 42. 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, go to step 41.
41.	On receipt of a completed notice of commencement, check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 50 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 51 where it has been submitted fewer than 30 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 the commissioner, or (where the applicant gave a best estimate) the address approved by the commissioner. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 52 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 53. Go to step 42. Where it is not, send Annex 54 and return to this step when a new notice of commencement is received.
42.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
43.	Send the notification of the NHS Pharmacy Contractor Code (Annex 55), advising the applicant of their contractor number when received from NHS Prescription Services.
44.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 56 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 57, copying in the commissioner. Go to step 45. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 58 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 45.
45.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 59) the usual parties, which include the relevant: • LPC • HWB • the commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision making process.

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

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 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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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 commissioner. Go to step 22.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that the application is to be deferred, go to step 17. Where the commissioner confirms that the best estimate is not acceptable, go to step 20.
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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Go to step 22.

11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7. Where the applicant is offering to secure identified improvements or better access to enhanced services, enclose with the acknowledgement copies of the specifications for these services if these have not already been provided. Go to step 22.
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 commissioner. This is the end of the process.
13.	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). 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). 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. Go to step 22.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
18.	If the commissioner 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. 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.

19.	Once the reason for deferral ceases, send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant. If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
20.	If the commissioner confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 16) to the applicant. Diarise the date for the revised best estimate to be submitted.
21.	On receipt of the revised best estimate, send it to the commissioner for confirmation that it is acceptable. If the revised best estimate is acceptable, and where the application is complete, send Annex 17 and go to step 22. If the revised best estimate is not acceptable, write back to the applicant for a further best estimate.
22.	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 commissioner of the application (Annex 18), enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid - see step 27), notify the interested parties using Annex 19.
23.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 20) 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 21). Copy in the commissioner.

26.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 22). Advise the commissioner. This is the end of the process.
28.	If an oral hearing is to be held, the commissioner will make the arrangements. Confirm these with the applicant (Annex 23) and any additional presenters (Annex 24) that the commissioner 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, go to the next step.
30.	Prepare a report (Annex 25) on the application and send to the commissioner.
31.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The granted decision letters for applications where the address of the premises is known are: • granted – to the applicant (Annex 26) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 28) • granted – to a third party with appeal rights (Annex 29). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • granted – to the applicant (Annex 30) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 31) • granted – to a third party with appeal rights (Annex 32). The refusal decision letters for applications where the address is known or a best estimate has been given are: • refused – to the applicant (Annex 33) • refused – to a third party (Annex 34). If the application is in or near a controlled locality, please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
34.	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 35) to the applicant. Include a copy of the banking mandate. 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 36 to the applicant.
35.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 37 where the address of the proposed premises was provided or Annex 38 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate where the applicant gave an address for the proposed premises.
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37. Where the application contains the address of the proposed premises, go to step 38.
37.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address, forward it to the commissioner to determine whether or not it is a valid notification. If the notification wasn't received in time, send notification of receipt of premises not valid (Annex 39) and copy in the commissioner. If the commissioner is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 40) to the applicant and send notification of premises (Annex 41) to those parties notified of the decision on the original application. If the commissioner is not satisfied that the notification is valid, send notification of non-valid premises (Annex 42). 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 43).
38.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 44 to the interested parties.

39.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 45. If the application is refused, send Annex 46.
40.	If a request for an extension within which to open is received (Annex 47), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 48 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 41. If the request is refused, send Annex 49 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 41. 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, go to step 41.
41.	On receipt of a completed notice of commencement, check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 50 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 51 where it has been submitted fewer than 30 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 the commissioner, or (where the applicant gave a best estimate) the address approved by the commissioner. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 52 to the applicant and return to this step when the required information is received.

	Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it was valid, send Annex 53. Go to step 42. Where it is not, send Annex 54 and return to this step when a new notice of commencement is received.
42.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
43.	Send the notification of the NHS Pharmacy Contractor Code (Annex 55), advising the applicant of their contractor number when received from NHS Prescription Services.
44.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 56 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 57 copying in the commissioner. Go to step 45. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 58 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 45.
45.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 59) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision making process.

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

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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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 commissioner. Go to step 22.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go to step 13. Where the commissioner confirms that the application is to be deferred, go to step 17. Where the commissioner confirms that the best estimate is not acceptable, go to step 20.
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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Go to step 22.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7. 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. Go to step 22.
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 commissioner. This is the end of the process.
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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 22.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
18.	If the commissioner 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.

	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.
19.	Once the reason for deferral ceases, send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant. If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
20.	If the commissioner confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 16) to the applicant. Diarise the date for the revised best estimate to be submitted.
21.	On receipt of the revised best estimate, send it to the commissioner for confirmation that it is acceptable. If the revised best estimate is acceptable, and where the application is complete, send Annex 17 and go to step 22. If the revised best estimate is not acceptable, write back to the applicant for a further best estimate.
22.	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 commissioner of the application (Annex 18) enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 27), notify the interested parties using Annex 19.
23.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared, send a request for payment (Annex 20) 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 21). Copy in the commissioner.
26.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 22). Advise the commissioner.
28.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm arrangements with the applicant (Annex 23) and any additional presenters (Annex 24) that the commissioner 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, go to the next step.
30.	Prepare a report (Annex 25) on the application and send to the commissioner.
31.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The granted decision letters for applications where the address of the premises is known are: • granted – to the applicant (Annex 26) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 28) • granted – to a third party with appeal rights (Annex 29). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • granted – to the applicant (Annex 30) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 31) • granted – to a third party with appeal rights (Annex 32). The refusal decision letters for applications where the address is known or a best estimate has been given are: • refused – to the applicant (Annex 33) • refused – to a third party (Annex 34). If the application is in or near a controlled locality please use the decision letters in Chapter 22.

	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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
34.	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 35) to the applicant. Include a copy of the banking mandate. 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 36 to the applicant.
35.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 37 where the address of the proposed premises was provided or Annex 38 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate where the applicant gave an address for the proposed premises.
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37. Where the application contains the address of the proposed premises, go to step 38.
37.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address, forward it to the commissioner to determine whether or not it is a valid notification. If the notification wasn't received in time, send notification of receipt of premises not valid (Annex 39) and copy in the commissioner. If the commissioner is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 40) to the applicant and send notification of premises (Annex 41) to those parties notified of the decision on the original application. If the commissioner is not satisfied that the notification is valid, send notification of non-valid premises (Annex 42). 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 43).
38.	Diarise the latest date by which the template notice of commencement can be submitted.

	If no notice of commencement is received, advise the commissioner and send Annex 44 to the interested parties.
39.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 45. If the application is refused, send Annex 46.
40.	If a request for an extension within which to open is received (Annex 47), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 48 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 41. If the request is refused, send Annex 49 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 41. 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, go to step 41.
41.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 50 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 51 where it has been submitted fewer than 30 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 the commissioner, or (where the applicant gave a best estimate) the address approved by the commissioner. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated.

	If any information is missing or incorrect, send Annex 52 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 53. Go to step 42. Where it is not, send Annex 54 and return to this step when a new notice of commencement is received.
42.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
43.	Send the notification of the NHS Pharmacy Contractor Code (Annex 55), advising the applicant of their contractor number when received from NHS Prescription Services.
44.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 56 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 57 copying in the commissioner. Go to step 45. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 58 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 45.
45.	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 59) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision making process.

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

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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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. Go to step 22.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go to step 13. Where the commissioner confirms that the application is to be deferred, go to step 17. Where the commissioner confirms that the best estimate is not acceptable, go to step 20.
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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 10.

	If the information is not provided, go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 8). Go to step 12.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7. Where the applicant is offering to secure identified future improvements or better access to enhanced services, enclose with the acknowledgement copies of the specifications for these services if this has not already been provided. Go to step 22.
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 commissioner. This is the end of the process.
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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 22.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.

18.	If the commissioner 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. 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.
19.	Once the reason for deferral ceases, send the notification of cessation of deferral – non-fitness grounds (Annex 15) to the applicant. If the applicant is required to update their application and confirm they still wish to proceed, diarise the date by which they are to do so and do not progress further until they respond. The timescale must be reasonable in light of the reasons for deferral and extent of any likely changes necessary. It must not be less than 30 days in any event. If the applicant fails to respond, their application is treated as withdrawn. Once the applicant has responded and where they wish to proceed, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 22.
20.	If the commissioner confirms that an acceptable best estimate has not been given, send the notification that the best estimate is unacceptable (Annex 16) to the applicant. Diarise the date for the revised best estimate to be submitted.
21.	On receipt of the revised best estimate, send it to the commissioner for confirmation that it is acceptable. If the revised best estimate is acceptable, and where the application is complete, send Annex 17 and go to step 22. If the revised best estimate is not acceptable, write back to the applicant for a further best estimate.
22.	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 commissioner of the application (Annex 18) enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 27), notify the interested parties using Annex 19.
23.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared, send a request for payment (Annex 20) 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 21). Copy in the commissioner.
26.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 22). Advise the commissioner. This is the end of the process.
28.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm arrangements with the applicant (Annex 23) and any additional presenters (Annex 24) that the commissioner 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, go to the next step.
30.	Prepare a report (Annex 25) on the application and send to the commissioner.
31.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The granted decision letters for applications where the address of the premises is known are: • granted – to the applicant (Annex 26) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 28) • granted – to a third party with appeal rights (Annex 29). The granted decision letters for applications where a best estimate of the location of the proposed premises has been given are: • granted – to the applicant (Annex 30) and include Annex 27 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 31) • granted – to a third party with appeal rights (Annex 32). The refusal decision letters for applications where the address is known or a best estimate has been given are:

	• refused – to the applicant (Annex 33) • refused – to a third party (Annex 34). If the application is in or near a controlled locality, please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
32.	Diarise the latest date for appeals to be made.
33.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
34.	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 35) to the applicant. Include a copy of the banking mandate. 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 365 to the applicant.
35.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 37 where the address of the proposed premises was provided or Annex 38 where a best estimate of the location of the proposed premises was provided). Include a copy of the banking mandate where the applicant gave an address for the proposed premises.
36.	Where the application contains a best estimate of the location of the proposed premises, go to step 37. Where the application contains the address of the proposed premises, go to step 38.
37.	Diarise the date by which the applicant must provide the address of the premises from which they intend to provide pharmaceutical services. On receipt of the notification of the address, forward it to the commissioner to determine whether or not it is a valid notification. If the notification wasn't received in time, send notification of receipt of premises not valid (Annex 39) and copy in the commissioner. If the commissioner is satisfied that the notification is valid, send acknowledgement of the receipt of premises (Annex 40) to the applicant and send notification of premises (Annex 41) to those parties notified of the decision on the original application. If the commissioner is not satisfied that the notification is valid, send notification of non-valid premises (Annex 42).

	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 43).
38.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 44 to the interested parties.
39.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 45. If the application is refused, send Annex 46.
40.	If a request for an extension within which to open is received (Annex 47), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 48 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 41. If the request is refused, send Annex 49 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 41. 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, go to step 41.
41.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 50 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received, unless the commissioner has previously agreed to a shorter notice period. Send Annex 51 where it has been submitted fewer than 30 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 the commissioner, or (where the applicant gave a best estimate) the address approved by the commissioner. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 52 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 53. Go to step 42. Where it is not, send Annex 54 and return to this step when a new notice of commencement is received.
42.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
43.	Send the notification of the NHS Pharmacy Contractor Code (Annex 55), advising the applicant of their contractor number when received from NHS Prescription Services.
44.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 56 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 57 copying in the commissioner. Go to step 45. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 58 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 45.
45.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 56) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

Chapter 17: Procedure – application for no significant change relocation

Chapter aims and objectives

7. The purpose of this chapter is to ensure that no significant change relocation applications are dealt with in line with the Regulations.

8. 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.

9. This chapter does not apply to contractors who hold LPS contracts as they are not included in a pharmaceutical list.

10. Applications are to be determined within four months of receipt unless the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

11. This chapter must be read in conjunction with the Regulations.

12. 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 to meet a need or to secure improvements 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.

13. The second type is an excepted application that falls under Regulation 24. 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.

14. 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
- 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.	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). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (Annex 4). 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.
5.	Where the commissioner 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. 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 commissioner. Go to step 17.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7.

	Where the commissioner confirms that there are missing undertakings in the application, go to step 12.
7.	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). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information (where applicable) – 10 working days • 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 commissioner 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 12.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 10). If further missing information is identified, return to step 7. 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. Go to step 17.
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 11). Advise the commissioner. This is the end of the process.
13.	Where there are missing undertakings in the application, complete and send the applicant the acknowledgement of receipt of application and request for missing undertakings (Annex 12).

	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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 13). 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. Go to step 17.
16.	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 commissioner. This is the end of the process.
17.	Where the application relates to a relocation within the same HWB area, once the application meets all requirements, interested parties must be notified of the application. Where the application relates to a relocation to 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). 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.
18.	Notify the interested parties of the application (Annex 15), enclosing a copy of the application. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. Where the relocation is to a neighbouring HWB and different commissioners are involved, both are to be notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 22), notify the interested parties using Annex 16.
19.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared, send a request for payment (Annex 17) to the applicant. 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).
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 18). Copy in the commissioner.

21.	Send copies of the representations to the commissioner ask for a decision on whether oral representations are to be heard and if so, who it wishes to invite as additional presenters.
22.	During the 14-day period, ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 19). Advise the commissioner. This is the end of the process.
23.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm these with the applicant (Annex 20) and any additional presenters (Annex 21) that the commissioner wishes to hear from. At least 14 days' notice must be given.
24.	At the end of the 14-day period, prepare a report (Annex 22) on the application and send to the commissioner.
25.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The application granted decision letters are: • granted – to the applicant (Annex 23) and include Annex 24 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 25) • granted – to a third party with appeal rights (Annex 26). The application refused decision letters are: • refused – to the applicant (Annex 27) • refused – to a third party (Annex 28). If the application is in or near a controlled locality, please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified. Where the relocation is to a neighbouring HWB and different commissioners are involved, both are to be notified.
26.	Diarise the latest date for appeals to be made.
27.	If notice of an appeal is received, advise the commissioner 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 commencement and notification (Annex 29) to the applicant.

29.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 30).
30.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 31 to the interested parties. Where the relocation is to a neighbouring HWB and different commissioners are involved, both are to be advised.
31.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 32. If the application is refused, send Annex 33.
32.	If a request for an extension within which to open is received (Annex 34), pass it to the commissioner for a decision. If the request is granted, send Annex 35 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 33. If the request is refused, send Annex 36 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 33. 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, go to step 33.
33.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the Commissioner or NHS Resolution has allowed. Send Annex 37 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 38 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org.

	• The notice is signed and dated. If any information is missing or incorrect, send Annex 39 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the commissioner for confirmation it is valid. Where it is valid, send Annex 40. Go to step 34. Where it is not, send Annex 41 and return to this step when a new notice of commencement is received.
34.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
35.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 42 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 43, copying in the commissioner. Go to step 36. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 44 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 36.
36.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 45) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details. Where the relocation is to a neighbouring HWB, that HWB is to be sent Annex 42 along with the following persons if they are different to those listed above: • LPC • commissioner • public health team • DoS lead

	• unwanted medicines collection and disposal contractor.

Chapter 18: Distance selling premises

Chapter aims and objectives

1. The purpose of this chapter is to ensure that applications regarding distance selling premises are dealt with in line with the Regulations.

2. Applications are to be determined within four months of receipt unless the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision making process.

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

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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (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/who might have a significant interest in the outcome of the application.
5.	Where the commissioner 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. 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 commissioner. Go to step 18.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go 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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Go to step 13.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7.

	If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7.
	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. Go to step 18.
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 commissioner. This is the end of the process.
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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Where the applicant is offering to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 18.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, where the application is complete and the best estimate, if relevant, has been accepted by the commissioner, go to step 18.
18.	Where the application is complete and is not to be deferred on fitness grounds, notify the interested parties as determined by the commissioner 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 the commissioner confirms that the full disclosure principle doesn’t apply. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified.

	If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 22), notify the interested parties using Annex 15.
19.	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. 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).
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 17). Copy in the commissioner.
21.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 18). Advise the commissioner.
23.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm these with the applicant (Annex 19) and any additional presenters (Annex 20) that the commissioner wishes to hear from. At least 14 days' notice must be given.
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, go to the next step.
25.	Prepare a report (Annex 21) on the application and send to the commissioner.
26.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The application granted decision letters are: • granted – to the applicant (Annex 22) • granted – to a third party with no appeal rights (Annex 23) • granted – to a third party with appeal rights (Annex 24). The application refused decision letters are: • refused – to the applicant (Annex 25) • refused – to a third party (Annex 26). When the letters are completed, distribute to the applicant and interested parties, enclosing the notice of commencement where relevant with the applicant's letter. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.

27.	Diarise the latest date for appeals to be made.
28.	If notice of an appeal is received, advise the commissioner 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 27) 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 28). 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 commissioner and send Annex 29 to the interested parties.
32.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 30. If the application is refused, send Annex 31.
33.	If a request for an extension within which to open is received (Annex 32), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 33 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 34. If the request is refused, send Annex 34 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go 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, go to step 34.
34.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 35 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 36 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 37 to the applicant and return to this step when a new notice of commencement is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 38. Go to step 35. Where it is not, send Annex 39 and return to this step when a new notice of commencement is received.
35.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
36.	Send the notification of the NHS Pharmacy Contractor Code (Annex 40) advising the applicant of their contractor number when received from NHS Prescription Services.
37.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 41, copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 42 copying in the commissioner. Go to step 38. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 43 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 38.
38.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 41) the usual parties, which includes the relevant: • LPC • HWB • commissioner • public health team • DoS lead

	• unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

3. This chapter 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.

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 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 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 and 2). It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (Annex 3).

	Annex 4 will assist in identifying certain parties to be notified of the decision – 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.
5.	Where the commissioner 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 5) to the applicant. Where the applicant will be required to provide enhanced services, enclose copies of the specifications for these services with the acknowledgement. Go to step 17.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go 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 6). The timescales to be set out in the request to provide the missing information are: • payment of the relevant fee – five working days • submission of the required fitness information – 10 working days • 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 commissioner 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 7). 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 8). Go to step 13.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 9). If further missing information is identified, return to step 7.

	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. Go to step 17.
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 commissioner. This is the end of the process.
13.	Where there are missing undertakings in the application, 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 17.
16.	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 commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known, go to step 18.
18.	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 14) to the applicant.
19.	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 15). Advise the commissioner. This is the end of the process.
20.	On receipt of the fitness to practise recommendation/decision, where relevant, prepare a report (Annex 16) on the application and send to the commissioner.
21.	After the meeting, prepare the relevant decision and enclose the decision report provided by the commissioner. The application granted decision letters are: • granted – to the applicant (Annex 17) and include Annex 18 where advised to do so by the commissioner

	• granted – to a third party with no appeal rights (Annex 19) • granted – to a third party with appeal rights (Annex 20). The application refused decision letters are: • refused – to the applicant (Annex 21) • refused – to a third party (Annex 22). If granted, complete as far as possible the notice of commencement. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
22.	Diarise the latest date for appeals to be made.
23.	If notice of an appeal is received, advise the commissioner 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 23) 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 24). 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 commissioner and send Annex 25 to the interested parties.
27.	If the applicant asks to submit the notice of commencement within 30 days pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 26. If the application is refused, send Annex 27.
28.	If a request for an extension within which to open is received (Annex 28), pass it to the relevant commissioner 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. Go to step 29. If the request is refused, send Annex 30 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 29. 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, go to step 29.

29.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner 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 no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 32 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 33 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid and check with them that Annex 35 can be sent to the old owner of the premises. (Where the commissioner is considering removing, contingently removing or suspending the old owner of the premises on fitness grounds, they are to remain on the relevant pharmaceutical list until that action is concluded by virtue of Regulation 76.) Ask for a contact email address for the old owner of the premises. Where the notice of commencement is valid, send Annex 34. Send Annex 35 to the old owner of the premises where the commissioner confirms that it can be sent. Go to step 30. Where the notice of commencement is not valid, send Annex 36 to the applicant and return to this step when a new notice of commencement is received.
30.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed banking mandate.
31.	Send the notification of the NHS Pharmacy Contractor Code (Annex 37) advising the applicant of their contractor number when received from NHS Prescription Services where a new code is issued.
32.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date.

	If the notification was made on or after the original commencement date, send Annex 38, copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 39, copying in the commissioner. Go to step 33. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 40 to the applicant. If Annex 35 has already been sent to the previous owner, complete and send Annex 41 to the previous owner. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 33.
33.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 42) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision making process.

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

4. This chapter does not apply to contractors who hold LPS contracts as they are unable to submit this type of application.

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 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 (Annexes 1 and 2).
3.	Send the 'first referral' to the relevant commissioner (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 commissioner 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 commissioner. Go to step 17.

5.	Where the commissioner confirms that one or both premises listed in the application are distance selling premises or dispensing appliance contractor premises, send Annex 6. This is the end of the process.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go 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: • payment of the relevant fee – five working days • 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 commissioner 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, forward it to the commissioner and ask for confirmation that the application may now be notified. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 10). If further missing information is identified, return to step 7. 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. Go to step 17.
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 11). Advise the commissioner. This is the end of the process.

13.	Where there are missing undertakings in the application, complete and send the acknowledgement of receipt of application and request for missing undertakings (Annex 12). 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. Where there are further undertakings required following step 4 (provision of enhanced services), 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). 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.
14.	Diarise the date for the missing undertakings to be submitted.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 14). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 17.
16.	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 15). Advise the commissioner. This is the end of the process.
17.	Where the application is complete, notify the interested parties (except the HWB) as determined by the commissioner 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. Notify the HWB of the application (Annex 17) and enclose a copy of the application. Liaise with the commissioner 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. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 22), notify the interested parties using Annex 18.
18.	The commissioner 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 19 to the HWB.

19.	During the 30-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 20) to the applicant.
20.	At the end of the 30-day notification period, circulate representations to the applicant and those interested parties who responded using the notification of circulation of comments (Annex 21). Copy in the commissioner. If the HWB's representations are received outside the 30-day notification period (but before the application is determined), such that they were not included in the representations circulated pursuant to the paragraph above, they are to be circulated to all parties to which the other representations were circulated once received and 14 days is to be given from the date the HWB's representations were sent for comments. Please see Annex 22. Any other representations that are received are not to be circulated to the HWB. 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.
21.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 30-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as withdrawn (Annex 23). Advise the commissioner. This is the end of the process.
23.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm arrangements with the applicant (Annex 24) and any additional presenters (Annex 25) that the commissioner wishes to hear from. At least 14 days' notice must be given.
24.	Prepare a report (Annex 26) on the application and send to the commissioner.
25.	After the meeting, prepare the relevant decision and enclose the decision report provided by the commissioner. The granted decision letters are: • granted – to the applicant (Annex 27) and include Annex 28 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 29) • granted – to a third party with appeal rights (Annex 30). The application refused decision letters are: • refused – to the applicant (Annex 31) • refused – to a third party (Annex 32).

	If granted, complete as far as possible the notice of consolidation. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
26.	Diarise the latest date for appeals to be made.
27.	If notice of an appeal is received, advise the commissioner 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 33) to the applicant.
29.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 34).
30.	Diarise the latest date by which the template notice of consolidation can be submitted. If no notice of consolidation is received, advise the commissioner and send Annex 35 to the interested parties.
31.	If a request for an extension within which to open is received (Annex 36), pass it to the commissioner for a decision. If the request is granted, send Annex 37 to the applicant and diarise the latest date by which the notice of consolidation can be submitted. Go to step 32. If the request is refused, send Annex 38 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go 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, go to step 32.
32.	On receipt of a completed notice of consolidation check the following points: • It has been received within the six-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 39 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 40 where it has been submitted more than 14 days before the date the consolidation takes effect. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 41 to the applicant. Where no issues are identified, forward it to the commissioner for confirmation it is valid. Where it is valid, send Annex 42. Complete and enclose Annex 43 where the applicant owned site 1 (the remaining site) before the application was submitted. Complete and enclose Annex 44 where the applicant did not own site 1 (the remaining site) before the application was submitted and therefore a new ODS code has been issued for that site. Where it is not valid, send Annex 45.
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 46 to the contractor whose premises are to be removed from the relevant pharmaceutical list.
35.	If a new ODS code is to be issued for site 1 (the remaining site) because the applicant did not own it prior to the consolidation taking effect and is not buying the pharmacy on a debts and liabilities basis, send the notification of the NHS Pharmacy Contractor Code (Annex 47), advising the applicant of their contractor number when received from NHS Prescription Services.
36.	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 48) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • registration authority • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details. Where the same contractor owns both sites, delete the row 'Name of the previous owner and trading name, if any' in Annex 48.

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 as 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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

4. This chapter must be read in conjunction with the Regulations.

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
    - 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 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 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). It should be noted that where the applicant is not already included in the relevant 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.
4.	Send the 'first referral' to the relevant commissioner (Annex 4). 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.
5.	Where the commissioner 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. 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 commissioner. Go to step 17.
6.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 7. Where the commissioner confirms that there are missing undertakings in the application, go 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: • payment of the relevant fee – five working days • submission of the required fitness information (where applicable) – 10 working days • 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 commissioner 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, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of missing information (Annex 10). If further missing information is identified, return to step 7. 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. Go to step 17.
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 11). Advise the commissioner. This is the end of the process.
13.	Where there are missing undertakings in the application complete, and send the acknowledgement of receipt of application and request for missing undertakings (Annex 12). 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 13). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 17.
16.	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 commissioner. This is the end of the process.

17.	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). Once the outcome of the deferral is known, where the application is complete, go to step 18.
18.	Where the application is complete and is not to be deferred on fitness grounds, notify the interested parties as determined by the commissioner 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. 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. Copy the commissioner into the emails or where the application is notified by post, advise the commissioner that it has been notified. If the application is treated as withdrawn at any point after it has been notified but before it is determined (eg further missing information is requested but is not provided or the fee isn't paid – see step 22), notify the interested parties using Annex 16.
19.	During the 45-day notification period ensure that payment has cleared. If payment hasn't cleared send a request for payment (Annex 17) to the applicant. 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).
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 18). Copy in the commissioner.
21.	Send copies of the representations to the commissioner 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.	During the 14-day period ensure that payment has cleared if it hadn't during the initial 45-day notification period. The application cannot be determined until payment has cleared. If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as being withdrawn (Annex 19). Advise the commissioner. This is the end of the process.
23.	If an oral hearing is to be held the commissioner will make the arrangements. Confirm arrangements with the applicant (Annex 20) and any additional presenters (Annex 21) that the commissioner wishes to hear from. At least 14 days' notice must be given.

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, go to the next step.
25.	Prepare a report (Annex 22) on the application for the and send to the commissioner.
26.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The application granted decision letters are: • granted – to the applicant (Annex 23) and include Annex 24 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 25) • granted – to a third party with appeal rights (Annex 26). The application refused decision letters are: • refused – to the applicant (Annex 27) • refused – to a third party (Annex 28). If the application is in or near a controlled locality please use the decision letters in Chapter 22. 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
27.	Diarise the latest date for appeals to be made.
28.	If notice of an appeal is received, advise the commissioner 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 29) 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 30).
31.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 31 to the interested parties.
32.	If the applicant asks to submit the notice of commencement within 30 days pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 32. If the application is refused, send Annex 33.

33.	If a request for an extension within which to open is received (Annex 34), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 35 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 34. If the request is refused, send Annex 36 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go 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, go to step 34.
34.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 37 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received. Send Annex 38 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 39 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid and check with them that Annex 41 can be sent to the old owner of the premises. (Where the commissioner is considering removing, contingently removing or suspending the old owner of the premises on fitness grounds they are to remain on the relevant pharmaceutical list until that action is concluded by virtue of Regulation 76.) Ask for a contact email address for the old owner of the premises. Where the notice of commencement is valid send Annex 40. Go to step 35.

	Send Annex 41 to the old owner of the premises where the commissioner confirms that it can be sent. Where the notice of commencement is not valid, send Annex 42 to the applicant and return to this step when a new notice of commencement is received.
35.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
36.	Send the notification of the NHS Pharmacy Contractor Code (Annex 43), advising the applicant of their contractor number when received from NHS Prescription Services.
37.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 44 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 45 copying in the commissioner. Go to step 38. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 46 to the applicant. If Annex 41 has already been sent to the previous owner, complete and send Annex 47 to the previous owner. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 38.
38.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and in the date that service provision will commence inform (using Annex 48) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details. Where the relocation is to a neighbouring HWB, that HWB is to be sent Annex 44 along with the following persons if they are different to those listed above: • LPC • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor.

Chapter 22: Procedures – controlled localities and rurality matters

Chapter aims and objectives

1. This chapter deals with applications in controlled localities, specifically the additional steps for:

    - pharmacy routine applications in a controlled locality
    - certain pharmacy applications within 1.6km of a controlled locality.

2. This document must be read in conjunction with the relevant market entry chapter and the Regulations. Further information on the background to the current regulatory framework for rurality matters can be found in the Clothier Report[1] which was published in December 1977.

Background

3. A controlled locality is an area determined by the commissioner (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 commissioner.

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

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

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

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

- an area that was rural in character may cease to be a controlled locality if there has been substantial economic or social development
- an area that was previously industrialised or had characteristics associated with more urban areas (eg 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.)

6. The commissioner may need to consider afresh whether an area is or is not a controlled locality:

- as a result of receiving a routine application for pharmacy premises
- at the request of a LPC or LMC, or
- of its own volition, eg as a result of validating dispensing patient lists.

History of controlled localities and information available

7. 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.

8. 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.

9. 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).

10. The commissioner may therefore find itself with a variety of forms of information including:

- lists of villages that were determined to be rural in character before 1 April 1983
- descriptions of areas that were determined to be rural in character before 1 April 1983
- maps of controlled localities that were determined from 1 April 1983
- a mixture of the above
- none of the above.

11. 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 issued 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 historical rights to dispense to that area.

12. The commissioner may need to consider afresh whether an area is or is not a controlled locality as a result of receiving a routine application, at the request of a LPC or LMC, or of its own volition, eg as a result of validating dispensing patient lists.

Gradualisation

13. Gradualisation – that is, the postponement of any requirement for dispensing by doctors to cease to dispense to a patient or patients – is to be considered by the commissioner:

    - where it is determined than an area is no longer a controlled locality, or part of one
    - determinations of pharmacy 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.

14. 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 may be necessary, such as reducing stock holdings and altering staff duties.

15. 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 the commissioner considers whether a period of gradualisation is to be given:

    - number of patients affected, and
    - proportion of the GP practice's dispensing patient list that this represents.

Reserved locations

16. The issue of reserved location status is to be considered by the commissioner in relation to all pharmacy routine applications where the premises or best estimate are in a controlled locality.

17. 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'.

18. Where the applicant gives a best estimate, then the commissioner 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 commissioner should fully document how it determined this centre point.

19. 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.

20. 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 commissioner.

21. The reserved location determination is made based on the circumstances as they pertained on the day the application was received (Regulation 41(2)).

22. 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 (ie are registered with a GP practice, excluding temporary residents) is less than 2,750; and
    - the commissioner 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.

23. 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.

24. If the commissioner 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.

25. Where a reserved location takes effect, then the commissioner must:

    - delineate the boundary of the reserved location on a map
    - publish that map
    - make that map available as soon as is practicable to the HWB that has all or part of that reserved location in its area.

26. At the point the reserved location takes effect, dispensing patients who live within it can remain as such with their dispensing practice but may choose to have their prescriptions dispensed at a pharmacy, or both.

Additional steps for pharmacy applications in a controlled locality

27. 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 a controlled locality. It does not apply to applications for distance selling premises.

	Action
1.	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. Where the commissioner 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. Where the commissioner confirms the premises/best estimate is in a controlled locality, go to step 2. Where the commissioner confirms the premises/best estimate is near a controlled locality, go to step 3. Where the commissioner confirms that the application is to be deferred while a controlled locality determination is made, go to step 4.
2.	Where the premises/best estimate is in a controlled locality, as soon as possible calculate the total GP registered population that resides within a 1.6km radius of the proposed premises. Where the applicant has given a best estimate, the commissioner is to confirm the centre point to use for the 1.6km radius. If the radius extends to an adjoining non-controlled locality, patients in this area should be included. Temporary residents should not be included. Identify each GP practice that has dispensing patients within 1.6km of the proposed premises/best estimate and the number of such patients by practice. This information is to be included in the letter to interested parties and in the committee report that is prepared for the commissioner and referred to in the market entry procedures. 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 commissioner for checking and sign-off. Go to step 5.
3.	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. Identify each GP practice that has dispensing patients within 1.6km of the proposed premises/best estimate and the number of such patients by practice. This information is to be included in the committee report that is prepared for the commissioner and referred to in the market entry procedures. 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 commissioner for checking and sign-off. Go to step 5.
4.	Where the commissioner confirms the application is to be deferred pending a controlled locality determination, send Annex 1 to the applicant. Calculate the total GP registered population that resides within a 1.6km radius of the proposed premises. Where the applicant has given a best estimate, the commissioner is

	to confirm the centre point to use for the 1.6km radius. If the radius extends to an adjoining non-controlled locality, patients in this area should be included. Temporary residents should not be included. Identify each GP practice that has dispensing patients within 1.6km of the proposed premises/best estimate and the number of such patients by practice. No further action is required under this procedure until the determination has been made and the commissioner advises the next steps. This may take a number of months, especially if there is an appeal. 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. Where the outcome is that the premises/best estimate is in a controlled locality, send Annex 3. 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 commissioner for checking and sign-off and go to step 5.
5.	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 go to step 6.
6.	Where the premises/best estimate is near a controlled locality, go to step 11. Where the premises/best estimate is in a controlled locality, go to step 7.
7.	Where the commissioner has confirmed that Regulation 40(2) does not apply, go to step 11. Where the commissioner has confirmed that Regulation 40(2) does apply, send Annex 4 to the applicant, diarise the date for their response and go to step 8.
8.	Once the date for the applicant to submit any representations on Regulation 40(2) has passed, send a copy of the application to the commissioner and any representations the applicant has made for a decision as to whether the application must be refused by virtue of that regulation. Go to step 9.
9.	If the commissioner determines that the application is not to be refused by virtue of Regulation 40(2), send Annex 5 to the applicant and go to step 11. If the commissioner determines that the application is to be refused by virtue of Regulation 40(2), send Annex 6 to the applicant. Diarise the latest date for an appeal to be made. If notice of an appeal is received, advise the commissioner and assist in the production of a response. Go to step 10.

10.	If there are no appeals, the application has been refused. Update the market entry tracker to reflect the outcome and advise the commissioner. There are no further actions to be completed regarding this procedure. If the commissioner's decision is upheld on appeal, ie 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. If the commissioner's decision is overturned on appeal, send Annex 7 to the applicant and go to step 11.
11.	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.

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

28. This section of the chapter sets out the additional steps that are to be undertaken when processing certain pharmacy applications where the premises or best estimate is within 1.6km of a controlled locality. It does not apply to applications relating to distance selling premises.

	Action
1.	If an application is: • made pursuant to Chapters 12 – 17 and 21; and • is for pharmacy premises where the commissioner has confirmed that the address or best estimate is not in a controlled locality but is within 1.6km of one go to step 2.
2.	Identify which GP practices have dispensing patients in the adjoining controlled locality within 1.6km of the proposed premises or best estimate and the number of such patients. If there are practices affected in this way, go to step 3. If there are no practices affected in this way, no further action is necessary pursuant to this procedure.
3.	Add the GP practices that have dispensing patients in the adjoining controlled locality within 1.6km of the proposed premises or best estimate to the list of interested parties list, and ask the relevant commissioner to check and sign off the revised list. 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.
4.	If the application is granted by either the commissioner or on appeal and the notice of commencement is received, prepare lists of dispensing patients by practice within 1.6km of the pharmacy (ie those who will be removed from dispensing lists) and send a letter to the commissioner. 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
    - relocations after outline consent takes effect.

2. This chapter must be read in conjunction with Part 8 of the Regulations.

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 in 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 historical 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 historical 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 relevant commissioner (Annex 2). Annex 3 will assist in identifying certain parties to be notified.

3.	Where the commissioner confirms the required information has been provided, go to step 4. If the information has not been provided, send the request for further information (Annex 4). Allow five working days for receipt of the information. On receipt of the information, go to step 4. If the information is not received by the due date, advise the decision-maker.
4.	Where the commissioner confirms that the area for which outline consent is sought is in a controlled locality or localities, send Annex 5 and go to step 5. Where the commissioner wishes to defer the application, send Annex 6. No further action is required under this procedure until the determination has been made and the commissioner 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 go to step 5.
5.	Notify interested parties of the application using Annex 8, copying in the commissioner. Do not circulate copies of patient requests to be dispensed that were submitted with the application.
6.	At the end of the 45-day notification period, circulate representations to the applicant and those interested parties who responded, using Annex 9.
7.	Prepare a report (Annex 10) on the application for the commissioner and send to the commissioner.
8.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted letters are: • granted – to the applicant (Annex 11) • granted – to an interested party with no appeal rights (Annex 12) • granted – to an interested party with appeal rights (Annex 13). The refused letters are: • refused – to the applicant (Annex 14) • refused – to an interested party (Annex 15). When the letters are completed, send to the applicant and interested parties. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner 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 commissioner and assist in the production of a response. If no notice of an appeal is received, advise the commissioner.

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 commissioner 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 include the relevant: • LPC • LMC • HWB • NHSBSA • team that maintains NHAIS or its replacement • Healthwatch • CDAO.
15.	Where there are outstanding pharmacy applications for premises that fall within 1.6km of the doctor's premises, advise the commissioner and send Annex 18.
16.	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: • the application was determined by the commissioner, 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.	Check: • with the commissioner that primary medical services are being provided at the premises • whether pharmaceutical services are being provided at the pharmacy premises to which the outstanding pharmacy application related.

	If primary medical services are being provided and pharmaceutical services are not being provided at the pharmacy premises to which the outstanding pharmacy application related, go to step 20. 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.
20.	Send Annex 20 to the applicant and go to step 21.
21.	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 include the relevant: • LPC • LMC • HWB • NHSBSA • team that maintains NHAIS or its replacement • Healthwatch • 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 commissioner and assist in the production of a response.
25.	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. Update other databases as appropriate and inform (using Annex 17) the usual parties, which include the relevant: • LPC • LMC • HWB • NHSBSA • the team that maintains NHAIS or its replacement, • Healthwatch • 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 relevant commissioner (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 commissioner.
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 and send to the commissioner.
6.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted decisions letters are: • granted – to the applicant (Annex 28) • granted – to an interested party with no appeal rights (Annex 29) • granted – to an interested party with appeal rights (Annex 30). The refused decision letters are: • refused – to the applicant (Annex 31) • refused – to an interested party (Annex 32). When the letters are completed, send to the applicant and interested parties. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
7.	Diarise the latest date for appeals to be made.
8.	If notice of an appeal is received, advise the commissioner 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 include the relevant: • LPC • LMC • HWB • NHSBSA • team that maintains NHAIS or its replacement • Healthwatch • 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.
16.	Put a note in the outstanding pharmacy application file to send Annex 37 to the doctor if the pharmacy opens. If the pharmacy does not open, send Annex 38 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. There are no further actions.

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.	Annex 39 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 the tracker is updated as the application progresses.
2.	Send the 'first referral' to the commissioner (Annex 40). Annex 41 will assist in identifying certain parties to be notified.

3.	Notify interested parties of the application using Annex 42, copying in the commissioner.
4.	At the end of the 45-day notification period, circulate representations to the applicant and those interested parties who responded, using Annex 43.
5.	Prepare a report (Annex 44) on the application and send to the commissioner.
6.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made. The granted decision letters are: • granted – to the applicant (Annex 45) • granted – to an interested party with no appeal rights (Annex 46) • granted – to an interested party with appeal rights (Annex 47). The refused decision letters are: • refused – to the applicant (Annex 48) • refused – to an interested party (Annex 49). When completed, send to the applicant and interested parties. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified and to whom.
7.	Diarise the latest date for appeals to be made.
8.	If notice of an appeal is received, advise the commissioner 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 50 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 51) the usual parties, which include the relevant: • LPC • LMC • HWB

	• NHSBSA • team that maintains NHAIS or its replacement • Healthwatch • 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 (ie advanced and enhanced services) are dealt with in line with the Regulations.

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

3. This document must be read in conjunction with the Regulations and 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, the commissioner will follow the procedure in Chapter 35.

5. A 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 relevant commissioner (Annex 3).
4.	Where the commissioner confirms the application is fully completed and all relevant information, documentation and undertakings have been provided, send Annex 4. Include copies of the specifications for any enhanced services the applicant is applying to provide. Go to step 16.

5.	Where the commissioner confirms that there is missing information and/or documentation in the application, go to step 6. Where the commissioner confirms that there are missing undertakings in the application, go to step 12.
6.	Where there is missing information and/or documentation, send the request for missing information set out at Annex 5. The relevant timescale for information required by paragraph 1, Schedule 2 to the Regulations is five working days.
7.	Diarise the date for the missing information/documentation to be submitted.
8.	If the applicant requests a review of the request for missing information/documentation, forward this to the commissioner for a decision and go to step 9.
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 6). The timescale for providing the information is five working days. If the information is provided, go to step 10. If the information is not provided, go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send to the applicant notification of the outcome of the review and withdrawal of the original request (Annex 7), then go to step 16.
10.	On receipt of the missing information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 6. If it can be notified, send 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. If further missing information is identified, return to step 6. Go to step 16.
11.	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 commissioner. This is the end of the process.
12.	Where there are missing undertakings in the application, send the acknowledgement of receipt of application and request for missing undertakings (Annex 10). 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.
13.	Diarise the date for the missing undertakings to be submitted.

14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 11) and include copies of the specifications for the enhanced services the applicant is applying to provide if not already provided. Go to step 16.
15.	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 commissioner. This is the end of the process.
16.	Check that payment has cleared. If it has cleared, go to step 18. If payment hasn't cleared, send a request for payment (Annex 13) to the applicant.
17.	If the second attempt at payment does not clear, send to the applicant notification that the payment has not cleared and the application is being treated as withdrawn (Annex 14). Advise the commissioner. This is the end of the process.
18.	Once payment has cleared, prepare a report (Annex 15) for the decision-maker.
19.	After the meeting, prepare the relevant decision letter and enclose the decision report provided by the commissioner. The decision letter to the applicant where the application has been granted is provided at Annex 16. The decision letter to the applicant where the application has been refused is provided at Annex 17. If granted, complete as far as possible the notice of commencement. When the letter is completed distribute to the applicant, enclosing the notice of commencement where relevant. Copy the commissioner into the email or where the decision is notified by post, advise the commissioner that the decision has been notified.
20.	Diarise the latest date for appeals to be made where the application was refused.
21.	If notice of an appeal is received, advise the commissioner and assist in the production of a response.
22.	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.
23.	If no appeal is made and the application was granted, advise the decision-maker and send confirmation to the applicant (Annex 19).
24.	Diarise the latest date by which the notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner.
25.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made.

	If the application is granted, send Annex 20. If the application is refused, send Annex 21.
26.	If a request for an extension within which to open is received (Annex 22), pass it to the relevant commissioner for a decision. 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. Go to step 27. If the request is refused, send Annex 24 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 27. 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, go to step 27.
27.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner 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 no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 25 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 26 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 27. Go to step 28.

	Where it is not, send Annex 28 and return to this step when a new notice of commencement is received.
28.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 29 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 30 copying in the commissioner. Go to step 29. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 31 to the applicant. Go to step 29.
29.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 32) the usual parties, which include: • LPC • HWB • public health team • DoS lead • 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 that 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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

4. This chapter must be read in conjunction with the Regulations, 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 particularly important if the applicant has not used the national application forms – Annexes 1 and 2. It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (Annex 3). Annex 4 will assist in identifying certain parties to be notified of the decision – 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.
5.	Where the commissioner 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 5). Where the applicant is required to provide enhanced services, include copies of the specifications for these services where these have been provided by the commissioner. Go step 18.
6.	Where the commissioner confirms that there is missing information and/or documentation, go to step 7. Where the commissioner confirms that there are missing undertakings, go to step 14.
7.	Where there is missing information and/or documentation, complete and send the request for missing information set out at Annex 6. The timescales to be set out in the request to provide the missing information are: • submission of the required fitness information – 10 working days • information required by paragraph 1, Schedule 2 to the Regulations – 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 asks for a review of a request for missing information/documentation, forward this to the commissioner (set out in Chapter 3) for a decision.

10.	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 14. 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.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send an acknowledgement of receipt of the missing information/documentation to the applicant (Annex 9). If further missing information is identified, return to step 7. Where the applicant is required to provide enhanced services, include copies of the specifications for these services if they have not already been provided. Go to step 17.
12.	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 10). Advise the commissioner. This is the end of the process.
13.	Where there are missing undertakings, complete and send the acknowledgement of receipt of the 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Where the applicant is required to provide enhanced services, enclose with the acknowledgement copies of the specifications for these services if not already provided. Go to step 17.
16.	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 13). Advise the commissioner. This is the end of the process.
17.	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). Once the outcome of the deferral is known and where the application is complete, go to step 18.

18.	On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 14) and send to the commissioner.
19.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The decision letters where the application has been granted are: • granted – to the applicant (Annex 15) and include Annex 16 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 17) • granted – to a third party with appeal rights (Annex 18). The decision letters where the application has been refused are: • refused – to the applicant (Annex 19) • refused – to a third party (Annex 20). 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
20.	Diarise the latest date for appeals to be made.
21.	If notice of an appeal is received, advise the commissioner and assist in producing a response.
22.	If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 21 to the applicant. Include a copy of the banking mandate.
23.	If no appeal is made and the application was granted, advise the decision-maker and send Annex 22 to the applicant. Include a copy of the banking mandate.
24.	Diarise the latest date by which the notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 23 to the interested parties.
25.	If the applicant asks to submit the notice of commencement within 30 days, pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 24. If the application is refused, send Annex 25.
26.	If a request for an extension within which to open is received (Annex 26), pass it to the relevant commissioner for a decision. If the request is granted, send Annex 27 to the applicant and diarise the latest date by which the notice of commencement can be submitted. Go to step 27.

	If the request is refused, send Annex 28 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 27. 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 go to step 27.
27.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 29 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has previously agreed to a shorter notice period. Send Annex 30 where it has been submitted fewer than 30 days before the commencement date. Go to step 28. • 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 31 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 32. Go to step 29. Where it is not, send Annex 33 and return to this step when a new notice of commencement is received.
28.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
29.	Send the notification of NHS Pharmacy Contractor Code (Annex 34) advising the applicant of their contractor number when received from NHS Prescription Services.

30.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 35 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 36 copying in the commissioner. Go to step 31. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 37 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 31.
31.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision will commence inform (using Annex 38) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.
32.	The commissioner 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 that point send Annex 36 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 35) the usual parties, which include the relevant: • LPC • HWB • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

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 the commissioner has good cause to take longer, eg a delay in receiving references. Any delay in determining the application should be clearly recorded as part of the decision-making process.

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 complement the national contractual framework for pharmacy, but are an important local commissioning tool in their own right. LPS provide 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.
3.	Check that the application has been fully completed and that all relevant information, documentation and undertakings have been provided. This is particularly important if the applicant has not used the national application forms – Annexes 1 and 2. It should be noted that where the applicant is not already included in the relevant 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 must be completed so that it can be compared to the previously provided fitness information.
4.	Send the 'first referral' to the relevant commissioner (Annex 3). Annex 4 will assist in identifying certain parties to be notified of the decision – 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.
5.	Where the commissioner confirms the application is fully completed and all relevant information, documentation and undertakings have been provided, send acknowledgment of receipt of the application (Annex 5) to the applicant. Where the applicant undertakes to provide enhanced services, include copies of the specifications for these services where these have been provided by the commissioner. Go to step 17.
6.	Where the commissioner confirms that there is missing information and/or documentation, go to step 7. Where the commissioner confirms that there are missing undertakings, go to step 14.
7.	Where there is missing information and/or documentation complete and send Annex 6. The relevant timescales are as follows: • submission of the required fitness information – 10 working days • information required by paragraph 1, 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 commissioner) for a decision.
10.	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 14. 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.
11.	On receipt of the information/documentation, forward it to the commissioner and ask for confirmation that the application may now be notified. If further missing information is identified, return to step 7. If it can be notified, send the applicant an acknowledgement of receipt of the missing information/documentation (Annex 9). If further missing information is identified, return to step 7. 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.
12.	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 10). Advise the commissioner. This is the end of the process.
13.	Where there are missing undertakings complete and send the acknowledgement of receipt of the 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.
15.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). 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.
16.	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 13). Advise the commissioner. This is the end of the process.
17.	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).

	Once the outcome of the deferral is known and where the application is complete, go to step 18.
18.	On receipt of the fitness to practise recommendation/decision (if relevant), prepare a report (Annex 14) for the commissioner.
19.	After the meeting, prepare the relevant decision letters and enclose the decision report provided by the commissioner. The decision letters where the application has been granted are: • granted – to the applicant (Annex 15) and include Annex 16 where advised to do so by the commissioner • granted – to a third party with no appeal rights (Annex 17) • granted – to a third party with appeal rights (Annex 18). The decision letters where the application has been refused are: • refused – to the applicant (Annex 19) • refused – to a third party (Annex 20). 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. Copy the commissioner into the emails or where the decision is notified by post, advise the commissioner that the decision has been notified.
20.	Diarise the latest date for appeals to be made.
21.	If notice of an appeal is received, advise the commissioner and assist in producing a response.
22.	If NHS Resolution grants or confirms the grant of the application, complete and send a new notice of commencement and Annex 21 to the applicant (including a copy of the banking mandate).
23.	If no appeal is made and the application was granted, advise the decision-maker and send Annex 22 to the applicant. Include a copy of the banking mandate.
24.	Diarise the latest date by which the notice of commencement can be submitted. If no notice of commencement is received, advise the commissioner and send Annex 23 to the interested parties.
25.	If the applicant asks to submit the notice of commencement within 30 days pass the application to the commissioner for a decision to be made. If the application is granted, send Annex 24. If the application is refused, send Annex 25.
26.	If a request for an extension within which to open is received (Annex 26), pass it to the relevant commissioner for a decision.

	If the request is refused, send Annex 28 to the applicant. If notice of an appeal is received, advise the commissioner 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. Go to step 27. 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, go to step 27.
27.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 29 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has agreed to a shorter notice period. Send Annex 30 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 31 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant commissioner for confirmation it is valid. Where it is valid, send Annex 32. Go to step 28. Where it is not, send Annex 33 and return to this step when a new notice of commencement is received.
28.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.
29.	If the applicant has asked for a new ODS code, send the notification of NHS Pharmacy Contractor Code (Annex 34) advising them of the new number when received from NHS Prescription Services.

30.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date. If the notification was made on or after the original commencement date, send Annex 35 copying in the commissioner. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 36 copying in the commissioner. Go to step 31. If the notification was made before both the original commencement date and the new commencement date, send the notification to the commissioner for information and send Annex 37 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 31.
31.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision commences inform (using Annex 38) the usual parties, which include the relevant: • LPC • HWB • commissioner • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • any other organisation for which the commissioner has provided contact details.

Chapter 27

This chapter is intentionally left blank.

Part 3

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, providing examples to illustrate how they might affect decision-making.

Where the commissioner is a delegated integrated care board (ICB), it is required by the Delegation Agreement to perform the delegated functions in such a matter as to ensure NHS England's compliance with its statutory duties in respect of those delegated functions and to enable NHS England to fulfil its reserved functions. Delegated ICBs are therefore required to ensure they comply with the duties set out in this chapter.

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.

Below is a summary of the duties that are covered by this manual. The full wording from the legislation is provided at the end of the chapter. The chapter goes on to look at each of the duties in more detail.

1.1 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:

- eliminate discrimination that is unlawful under the Equality Act
- advance equality of opportunity between people who share a relevant protected characteristic and people who do not share it
- 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 (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.

1.2 The 'regard duties'

The 'regard duties' are the duty to have regard to the:

- need to reduce health inequalities (see section 13G of the NHS Act 2006),
- 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)
- 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)
- wider effect of decisions including all likely effects of the decision in relation to the health and wellbeing of the people in England, the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, and the efficient and sustainable use of resources (see section 13NA NHS Act 2006)
- need to contribute towards compliance with section 1 of the Climate Change Act 2008 (UK net zero emissions target) and section 5 of the Environment Act 2021 (environmental targets) and adapt current or predicted impacts of climate change (see section 13NC NHS Act 2006).

1.3 The 'view to duties'

The 'view to duties' are the duty to act with a view to:

- delivering services in a way that promotes the NHS constitution (see section 13C(1)(a) of the NHS Act 2006)
- securing continuous improvement in the quality of services in health and public health services (see section 13E of the NHS Act 2006)
- enabling patients to make choices about their care (see section 13I of the NHS Act 2006)
- 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).

1.4 The ‘promote duties’

The ‘promote duties’ are the duty to promote:

- awareness of the NHS Constitution among patients, staff and members of the public (see section 13C(1)(b) of the NHS Act 2006)
- the involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)
- innovation in the health service (see section 13K of the NHS Act 2006)
- or facilitate research and the use of research on matters relevant to the health service (see section 13L of the NHS Act 2006).

1.5 The ‘involvement duty’

NHS England has a duty to make arrangements to secure that service users and potential service users (and their carers and representatives, if any) are involved in:

- the planning of commissioning arrangements by NHS England
- 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
- NHS England’s decisions affecting the operation of commissioning arrangements, if those decisions would have such an impact (see section 13Q of the NHS Act 2006).

1.6 Duty to act reasonably

NHS England has a duty to act reasonably when making its decisions. This duty derives from case law that applies to all public bodies.

1.7 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).

1.8 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).

1.9 Duty as to reducing inequalities

NHS England must, in the exercise of its functions, have regard to the need to reduce inequalities between persons with respect to:

- their ability to access health services
- the outcomes achieved for them (including the effectiveness and safety of services and the quality of experience undergone by patients) by the provision of health services (see section 13G of the NHS Act 2006).

1.9 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 (see section 13P of the NHS Act 2006).

2. Equality duties

2.1 The protected characteristics

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 (which can include an absence of belief)
- sex
- sexual orientation.

Not every protected characteristic is 'relevant' to discrimination in the provision of services/ exercise of public functions or to the PSED.

2.2 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:

- 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.
- 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 that 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.
- 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 (eg a person has multiple sclerosis) but because of the behaviour caused by the disability (eg 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.
- 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, eg 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 patient who uses a wheelchair and 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, ie 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.)

2.3 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:

- eliminate discrimination that is unlawful under the Act
- advance equality of opportunity between people who share a relevant protected characteristic and people who do not share it
- 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 (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, eg 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 (eg 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, eg 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).

- A need to explicitly recognise that the PSED applies and equalities issues need to be considered.
- The duty is an ongoing one – to be considered at all stages of decision-making not just at the end.
- A need to be clear about the factors driving a decision, even if these are unpalatable, eg budgetary pressures.
- 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.
- If a decision is made that will impact negatively on a protected group, that should be acknowledged and the rationale explained.
- 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.
- The duty must be complied with at the time of the decision. After the event reasoning is rarely allowed.

3. The ‘regard duties’

3.1 Introduction

The ‘have regard’, ‘act with a view to’ or ‘promote’ duties form a loose hierarchy of duties:

- The duty to have regard means that when taking actions, a certain thing must be considered.
- 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.
- 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 and therefore to ICBs carrying out delegated primary care functions. (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:

- 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.
- 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.
- Officers need to engage with the regard duties with rigour and an open mind.
- It is good practice for the decision-maker to make reference to the regard duties. 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.
- 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.
- 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, eg 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.

3.2 Reduce health inequalities

Of the regard duties, there is a requirement to have regard to the need to:

- Reduce inequalities between patients with respect to their ability to access health services.
- Reduce health inequalities between patients with respect to the outcomes achieved for them by the provision of health services. Outcomes include the effectiveness of services, safety of services and the quality of experience undergone by patients.

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 versus female life expectancy, say) down to very granular data taking into account a patient's 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.

3.3 Have regard to the wider effect of decisions

The Health and Care Act 2022 introduced a new duty to have regard to the likely wider effects of decisions about the exercise of its functions. This duty requires, in particular, regard to all likely effects of the decision in relation to the health and wellbeing of the people in England, the quality of services provided to individuals for or in connection with

the prevention, diagnosis or treatment of illness, and the efficient and sustainable use of resources. NHS England may publish guidance about the discharge of this duty.

3.4 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.

3.5 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.

3.6 Compliance with net zero emission and other environmental targets

The Health and Care Act 2022 introduced a new duty to have regard to the need to contribute towards compliance with section 1 of the Climate Change Act 2008 (UK net zero emissions target) and section 5 of the Environment Act 2021 (environmental targets), and adapt to any current or predicted impacts of climate change identified in the most recent report under section 56 of the Climate Change Act 2008. NHS England may publish guidance about the discharge of this duty.

4. The ‘promote duties’

The ‘promote duties’ are the duty to promote:

- awareness of the NHS Constitution among patients, staff and members of the public (see section 13C(1)(b) of the NHS Act 2006)
- the involvement of patients and carers in decisions about their own care (see section 13H of the NHS Act 2006)
- innovation in the health service (see section 13K of the NHS Act 2006)
- or facilitate research and the use of research on matters relevant to the health service (see section 13L of the NHS Act 2006).

However, a decision that 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.

5. The 'view to duties'

The 'view to duties' are the duty to:

- act with a view to delivering services in a way that promotes the NHS constitution (see section 13C(1)(a) of the NHS Act 2006)
- 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)
- act with a view to enabling patients to make choices about their care (see section 13I of the NHS Act 2006)
- 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 (eg 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

6.1 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:

- the planning of commissioning arrangements
- 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
- 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 LPS).

6.2 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 its process for assessing whether the involvement duty applies and how to document plans for public involvement.

7. The duty to act reasonably

NHS England has a duty to act reasonably when making its decisions. This duty derives from case law that applies to all public bodies.

Normally, to act reasonably 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 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 to competing considerations and it 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 the thinking behind the decision needs to be carefully documented, particularly where a controversial decision is being made.

NHS England also needs to be careful about keeping to promises made to contractors or the public, eg 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. Where the same circumstances apply and the commissioner is an ICB, the ICB should obtain its own legal advice.

It is also important to act proportionately, taking into account any adverse impact on patients and/or contractors.

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 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 its 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, for example, company, partnership, public sector, private sector, charity or not for profit organisation.

Extracts from legislation

The NHS Act 2006 – sections 13C to 13Q General duties of the NHS England

13C Duty to promote NHS Constitution

(1) NHS England 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

NHS England must exercise its functions effectively, efficiently and economically.

13E Duty as to improvement in quality of services

(1) NHS England 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 Healthand Social Care Act 2012.

13G Duty as to reducing inequalities

NHS England must, in the exercise of its functions, have regard to the need to—

(a) reduce inequalities between persons with respect to their ability to access health services, and
(b) reduce inequalities between patients with respect to the outcomesachieved for them by the provision of health services (including the outcomes described in section 13E(3)).

13H Duty to promote involvement of each patient

NHS England 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

NHS England 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

NHS England 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) NHS England 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) NHS England 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

NHS England must, in the exercise of its functions, facilitate or otherwise 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

NHS England 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 and Health Education England in the discharge of the duty under that section.

13N Duty as to promoting integration

(1) NHS England 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) NHS England 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 outcomesachieved for them by the provision of those services.

(3) NHS England must encourage integrated care boards to enter intoarrangements with local authorities in pursuance of regulations under section75 where it considers that this would secure—

(a) that health services are provided in an integrated way and that this wouldhave 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 haveany 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 LocalAuthority Social Services Act 1970).

(5) For the purposes of this section, the provision of housing accommodation, is a health-related service.

13NA Duty to have regard to wider effect of decisions

(1) In making a decision about the exercise of its functions, NHS England must have regard to all likely effects of the decision in relation to—

(a) the health and well-being of the people of England;

(b) the quality of services provided to individuals—

(i) by relevant bodies, or

(ii)in pursuance of arrangements made by relevant bodies,

for or in connection with the prevention, diagnosis or treatment of illness, as part of the health service in England;

(c) efficiency and sustainability in relation to the use of resources by relevant bodies for the purposes of the health service in England.

(2) In subsection (1)—

(a) the reference to a decision does not include a reference to a decision about the services to be provided to a particular individual for or in connection with the prevention, diagnosis or treatment of illness;

(b) the reference to effects of a decision in relation to the health and well-being of the people of England includes a reference to its effects in relation to inequalities between the people of England with respect to their health and well-being;

(c) the reference to effects of a decision in relation to the quality of services provided to individuals includes a reference to its effects in relation to inequalities between individuals with respect to the benefits that they can obtain from those services.

(3) In discharging the duty under this section, NHS England must have regard to guidance published by it under section 13NB.

(4) In this section "relevant bodies" means —

(a) NHS England,

(b) integrated care boards,

(c) NHS trusts established under section 25, and
(d) NHS foundation trusts.

13NC Duties as to climate change, etc

(1) NHS England must, in the exercise of its functions, have regard to the need to—
(a) contribute towards compliance with—
(i) section 1 of the Climate Change Act 2008 (UK net zero emissions target), and
(ii) section 5 of the Environment Act 2021 (environmental targets), and
(b) adapt to any current or predicted impacts of climate change identified in the most recent report under section 56 of the Climate Change Act 2008.

(2) In discharging the duty under this section, NHS England must have regard to guidance published by it under section 13ND.

13O Duty to have regard to impact on services in certain areas

(1) In making commissioning decisions, NHS England 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 NHS England, means decisions about the carrying out of its functions in arranging for the provisionof health services.

13P Duty as respects variation in provision of health services

NHS England 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 NHS England in the exercise of its functions ("commissioning arrangements").

(2) NHS England must make arrangements to secure that individuals to whom the services are being or may be provided, and their carers and representatives (if any), are involved (whether by being consulted or provided with information or in other ways)—
(a) in the planning of the commissioning arrangements by NHS England,
(b) in the development and consideration of proposals by NHS England for changes in the commissioning arrangements where the implementationof 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 NHS England affecting the operation of the commissioning arrangements where the implementation of the decisions would (ifmade) have such an impact.

(3) The reference in subsection (2)(b) to the delivery of services is a reference totheir delivery at the point when they are received by users.

(4) This section does not require NHS England 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—

(a) in a case where the administrator's report relates to an NHS trust, NHS England and the Secretary of State have made their decisions under section 65K(1) and (2), or

(b) in a case where the administrator's report relates to an NHS foundation trust, the Secretary of State is satisfied as mentioned in section 65KB(1) or 65KD(1) or makes a decision under section 65KD(9).

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 relevantprotected 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 the commissioner should be forwarded on with the exception of applications under Regulation 29 which are to be processed by the commissioner. While applications are processed there will be times when a decision, or decisions, need to be made by the commissioner. This chapter identifies those times and provides additional information for the commissioner to consider. It also identifies when the commissioner will be notified of progress.

3. Applications are to be determined within 30 days (applications that are not notified to interested parties) or four months (applications that are notified) unless the commissioner has good cause to take longer, eg a delay in completing the required fitness to practise checks. Any delay in determining the application should be clearly recorded as part of the decision-making process.

4. This chapter must be read in conjunction the Regulations.

Receipt and first referral

5. Routine and excepted applications (other than those under Regulation 29) are to be received by the primary care support service provider who will process them on behalf of the commissioner.

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 commissioner, ie the commissioner in whose area the proposed premises or best estimate is located.

7. The decision-maker (see Chapter 2) 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 the commissioner 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
- sign-off of the list of interested parties.

8. When considering whether the application should be deferred, the decision-maker should refer to the relevant regulation or regulations.

9. The decision-maker must ensure that all decisions are robustly documented in case of a subject appeal or challenge.

10. Where the application is for, or involves, 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 and Social Care can be found in Annex 1.

11. It should be noted that contractors who hold a LPS contract may not submit a change of ownership, a significant change relocation, or a combined change of ownership application and 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. Where a LPS contractor wishes to change ownership and/or relocate, this is to be dealt with in line with the relevant provisions of the LPS contract.

Interested parties

12. Determining the parties who must be notified of applications pursuant to paragraph 19, Schedule 2 to the Regulations is the responsibility of the decision-maker set out in Chapter 2.

13. The following paragraphs will help the decision-maker 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, the commissioner 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. Alternatively, this information is available via the Strategic Health Asset Planning and Evaluation application.[2]

a. 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 are not in a controlled locality, the contractor's premises is 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 are in a controlled locality, the contractor's premises is located within 8km in a direct line from the applicant's proposed premises or best estimate.

17. Head offices of bodies corporate are also to be notified where this information is known, but this is as a courtesy as it is the premises that are included in the relevant pharmaceutical list that are to be notified in accordance with the regulations.

18. 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 or dispensing appliance contractors as these are listed separately on the NHS website. The decision-maker will therefore need to identify any distance selling premises or dispensing appliance contractors that fall within the above distances or are considered to be significantly affected.

[2] Strategic Health Asset Planning and Evaluation application, Office for Health Improvement and Disparities, Log-in required.

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

19. 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 is not in a controlled locality, the person's proposed premises is 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 is in a controlled locality, the person's proposed premises is located within 8km in a direct line from the applicant's proposed premises or best estimate.

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

20. 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 is not in a controlled locality, the LPS contractor's premises is 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 is in a controlled locality, the LPS contractor's premises is located within 8km in a direct line from the applicant's proposed premises or best estimate.

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

21. 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.

22. The commissioner should consider whether there are any other groups that are to be notified of the application, eg residents associations.

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

23. 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.

24. For excepted pharmacy applications that include a relocation that does not result in significant change, dispensing practices that have dispensing patients within 1.6km of the applicant's proposed premises should be considered to have a significant interest in the outcome of the application and should be notified of it.

25. 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.

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

26. 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 in line with the above section (if the practice has not already been notified under paragraph 19(1)(f)(i)).

g. Welsh health boards (paragraph 19(1)(g))

27. Where the premises or best estimate is within 2km of a Welsh health board that organisation is to be notified. Applications are to be sent to NHS Wales Shared Service Partnership (nwssp-primarycareservices@wales.nhs.uk) who will forward them to the appropriate health board.

h. Any other person (paragraph 19(2))

28. Any other person who the commissioner 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 notes for patient, consumer or community groups

29. To help these groups understand why they are being notified of the application, the commissioner 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.

30. The explanatory notes can be found in Annexes 2 to 14 to this chapter. Supplementary questions relating to pharmacy applications in controlled localities can be found in Annex 15.

Best estimates

31. The commissioner must be satisfied that the applicant has given their best estimate of the proposed location of their premises. In coming to this decision the commissioner must be satisfied that:

    - it is the best estimate that the applicant can reasonably make at that time
    - 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.

32. 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.

33. The commissioner 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 the commissioner 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

34. Where a pharmacy applicant undertakes to provide pharmaceutical services for more than 40 core opening hours as part of their application, the commissioner will need to have a conversation with them 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 core opening hours.

Review of missing information

35. 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

36. 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

37. The primary care support service provider will advise the decision-maker when the application is notified to interested parties and will include the decision-maker when the representations are circulated.

When should applications be heard together?

38. Where the commissioner 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.

39. The Regulations do not set out when in the application process a decision should be made to hear applications together. The commissioner 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.

40. 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.

41. 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 the commissioner 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

42. 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.

43. When an oral hearing is to be held the decision-maker is responsible for setting the date and time, and sourcing a venue or making arrangements for a virtual hearing. 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.

44. 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).

45. Oral hearings are not required to be held for every application decision and the commissioner 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.

46. If the commissioner 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.
    - Advise the applicant who else has been invited to make representations at the hearing. This may include other applicants where the commissioner has decided to determine two or more applications together.

47. 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 the commissioner considers it would be

desirable to hear further evidence about from the person at the oral hearing, and

- The commissioner is satisfied that the person made a reasonable attempt to express their views on the application in their written representation.

48. 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 the commissioner 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, the commissioner is not required to invite them to an oral hearing if it decides to hold one.

49. If the commissioner 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 the commissioner to make a decision on and it is not obliged to hold a further hearing.

Non-payment of fee

50. 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

51. The primary care support service provider will partially complete the template report and will pass it to the commissioner for completion. Due regard should be given to the relevant regulations in the completion of the report.

Determination

52. 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.

53. 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.

54. 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 is 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, or an application for a pharmacy to relocate within or to a controlled locality, is granted).

55. 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 a routine application for a pharmacy is granted, or an application for a pharmacy to relocate within 1.6km of a controlled locality, is granted).

56. Where a regulation is not relevant, this must be fully documented.

57. 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

58. 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 [*insert name of commissioner*] 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 [*insert name of commissioner*] have agreed that the additional opening hours are [*insert times and days*]."

59. 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 83 below.

Conditions relating to providing directed services

60. Pharmacy applicants may undertake to provide specified directed services as part of their routine or excepted application where commissioned by the commissioner 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.

61. "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 three 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*]".

62. 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

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

64. "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 (eg because the availability of essential services from the applicant is limited to other categories of patients)."

Granting of applications subject to fitness conditions

65. Where it has been determined 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.

66. "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

67. 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.

68. 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)
    - 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).

69. 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

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 the commissioner, 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 committee 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

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 the commissioner, 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?

70. Persons in any of the following categories are not considered to satisfy paragraph 30(3)(c) or Regulation 63(3)(c) and they are not therefore to 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 state that they oppose the application
- a notified person who gives no grounds for opposing the application.

71. The decision-maker must fully document the reasons for giving (or not giving) third-party rights of appeal to a particular party.

72. 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

73. The primary care support service provider will advise the decision-maker when the determination is notified to interested parties.

74. 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

75. 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).

76. 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

77. 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.

78. 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

79. 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 in the correct form and is valid in line with paragraph 34, Schedule 2. The decision will be communicated to the applicant by the primary care support service provider.

Paragraph 34, Schedule 2 requirements

The commissioner may only change the relevant pharmaceutical list to give effect to a decision to grant an application for inclusion in it if the applicant gives the commissioner (via the primary care support service provider) a valid notice of commencement, in the correct form, informing the commissioner that they are to commence the provision of the pharmaceutical services listed in the application at the premises listed in the application.

A notice of commencement is in the correct form if it:

- includes the information required under paragraph 29, Schedule 2, and
- is in the same format as the version of the notice sent to the applicant with the decision letter under paragraph 28, Schedule 2.

A notice of commencement is invalid unless it is given to the commissioner (ie the primary care support service provider receives it either electronically or in hard format) no fewer than 30 days

prior to the date on which service provision will commence. The only exception is where the commissioner has agreed to a shorter notice period.

A notice of commencement is also invalid unless it is sent to the commissioner (via the primary care support service provider) within the timescale set out in paragraph 34(4), Schedule 2. For the majority of applications this will be within 12 months of the date on which the applicant was sent the decision on their application (be that by the commissioner or, on appeal, by NHS Resolution). However, the commissioner should check paragraph 34(4), Schedule 2 as there are some exceptions to this. The date that the notice of commencement is sent is the date that it was posted or sent electronically to the commissioner by the applicant.

Under paragraph 34(4), Schedule 2, the 12-month period could be extended by up to three months.

There are, therefore, a number of dates to check or look for.

- The notice of commencement must include the date on which the application was granted, the date on which the applicant intends to commence service provision, and the date of the notice (this is the date that the applicant puts on the notice after their name). The template notice of commencement asks for all three of these dates.
- Is the date on which the notice of commencement was given to the commissioner no fewer than 30 days prior to the date on which service provision will commence? The only exception to this is where the commissioner has agreed a shorter notice period.
- Did the date on which the notice of commencement was sent to the commissioner fall within the relevant timescale set out in paragraph 34(34), Schedule 2? This may be harder to check where the notice of commencement was posted as it is likely that only the date of receipt by the primary care support service provider will be known. However, this will only become an issue where the applicant leaves it until the last minute to submit their notice of commencement.

80. The applicant will have been provided with a partially completed notice of commencement by the primary care support service provider, either with the decision letter notifying them of the decision by the commissioner to grant the application, or where the application is granted on appeal. This template should then be completed and submitted at the relevant time. If the applicant provides the required information in a slightly different format, eg an older version of the template notice of commencement, that is acceptable as long as all the required information has been provided.

81. 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.

82. 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
- commissioner
- public health team
- DoS lead
- unwanted medicines collection and disposal contractor
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager
- any other organisation for which the commissioner has provided contact details, eg the registration authority and the organisation that cascades safety alerts.

Inclusion in the relevant pharmaceutical list

83. It is the responsibility of the commissioner to include the applicant and their premises in the relevant pharmaceutical list.

84. Where a pharmacy applicant:

- undertook to provide pharmaceutical services at the proposed pharmacy premises for more than 40 core opening hours per week
- the applicant and the commissioner 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 16) 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 the commissioner when determining applications.

NHS Resolution publications

2. The commissioner should ensure that it is familiar with appeal decisions and guidance notes issued by NHS Resolution.

3. NHS Resolution has launched a monthly email update, which provides details of the decisions it has made in the previous calendar month. The updates also highlight any new or updated guidance or resources that have been published.

4. Commissioners are encouraged to sign-up for the monthly updates on pharmaceutical services decisions.[3]

Consolidations

a. Preliminary matters

5. In accordance with the procedure set out in Chapter 20 of this 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 the commissioner has good cause to take longer, eg a delay in receiving the health and wellbeing board's representations.

6. The preliminary decisions include:

- rejecting the application where the application relates to distance selling premises or dispensing appliance contractor premises
- rejecting the application where the application relates to premises that are in more than one single HWB area
- whether the commissioner intends to commission enhanced services from the continuing premises.

[3] NHS Resolution Primary Care Appeals updates

b. Who can make a consolidation application?

7. 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).

8. 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 (e. Refusing a consolidation application) for more information.

c. Is fitness to practise relevant?

9. As set out paragraph 5 above, a consolidation application must be made by a person who is either already listed in the relevant 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.

d. Representations from relevant parties

10. 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:

    - meet a current or future need for pharmaceutical services; or
    - secure improvements, or better access, to pharmaceutical services.

11. Regardless of whether the HWB makes other comments on the application, it must provide a view on this.

12. The procedure set out in Chapter 20 of this manual contains template letters to the HWB, making clear that the HWB needs to provide this information.

13. The Regulations do not set out the consequence of the HWB not providing this information and the commissioner has no legal power to force the HWB to provide the required information.

14. There may be a delay in the HWB submitting its representations on a consolidation application due to purdah. This is the period leading up to an election, during which care should be taken to avoid making decisions or public announcements that could be seen to be favourable to any particular party or candidate, or otherwise question political impartiality. Purdah directly applies to local and central government organisations, as well as non-departmental public bodies and other arm's length bodies. NHS bodies are also expected to comply with election guidance issued by the Cabinet Office. The general principles of purdah are:

    - while essential business should carry on as normal, controversial decisions or announcements should be postponed until after the election, unless it would be detrimental to the national interest or wasteful of public money
    - care should be taken to avoid competition with candidates for the attention of the public
    - no activity should be undertaken which could call into question political impartiality or give rise to criticism that public resources are being used for political purposes.

15. In practice, any action or inaction that is likely to attract attention (eg making a decision to commence a controversial procurement, announcing a new policy, or controversially delaying or abandoning a previously announced course of action) may need to be delayed until after the election. Ongoing consultations can continue, but public events or engagement activities may have to be rescheduled for after the election (which may, in turn, mean extending the consultation period). However, each matter will need to be considered on a case-by-case basis.

16. While it is unlikely that provision of representations on a consolidation application by a HWB during purdah would fall within the types of activities that purdah guidance would expect not to be carried out, the HWB may take a different view.

17. If, however, the commissioner receives communication from a local authority that it will not be responding to a consolidation application notification due to purdah, this

may mean the local authority intends to provide its comments but that these will only be received after the end of the 45-day timescale.

18. There is no indication in the Regulations as to how representations received after the 45-day timescale should be managed. There is an NHS Resolution appeal[4] that considered the effect of late HWB representations on a consolidation application. NHS Resolution determined that it was appropriate in that case that NHS England 'stopped the clock' on the 45-day timescale for the provision of representations such that when the HWB actually provided the representations, they were considered to be provided in compliance with the Regulations.

19. If a HWB advises that it is unable to provide representations within the 45-day notification period due to purdah, then it is to be asked when it will be able to provide representations on the application. A decision is then to be made, having regard to the above appeal decision, whether or not there is good cause to take longer than the regulatory four months to determine the application to allow the HWB to make its representations. This decision is to be documented and included in the final decision report so that all parties are aware of the reason or reasons as to why additional time as allowed or the application was determined in the absence of the HWB's representations.

20. The commissioner will need to consider whether it is able to determine the application where a HWB does not provide representations. If the HWB does not provide the required information after the 45-day deadline has passed, the commissioner will proceed to determine the application on the information before it. The commissioner 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.

e. Refusing a consolidation application

21. Regulations 26A(5) to (7) set out matters which the commissioner must consider to determine whether or not it must refuse the application.

22. 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 6 above apply.

[4] SHA/21072 appeal 9 May 2019 NHS Resolution – available by emailing nhsr.appeals@nhs.net

- Regulation 26A(7) applies where the third bullet point in paragraph 4 above applies.

23. 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.

f. Regulation 26A(5)

24. Regulation 26A(5) states that a consolidation application must be refused if:

- either of the premises are distance selling premises (DSP) or DAC premises; or
- the commissioner 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.

25. 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.

26. It is considered 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.

27. 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.

28. 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 the commissioner to refuse the application if it (the commissioner) 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. The commissioner is likely to have received representations on this issue from the applicant and interested parties other

than the HWB. The decision-maker must consider all representations before it when considering this issue.

29. 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.

30. 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.

31. A further factor that may be relevant is the extent to which the closing premises (site 2) leads to a loss of facilities, eg 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
    - whether such a loss amounts to a gap in service provision.

32. Ultimately, the decision-maker will need to consider the extent to which representations are supported by evidence. The commissioner may determine that less weight is attributed to representations not supported by evidence.

g. Statutory duties of NHS England

33. There are a number of statutory duties that the commissioner 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 these duties.

34. Decision-makers are referred to Chapter 28, which sets out a comprehensive explanation of the duties and how to comply with them.

h. When should applications be heard together?

35. Where the commissioner is presented with more than one consolidation application in a specific area, it may consider that it is reasonable to hear the applications together. The reasons for considering them together are to be documented as part of the determination of each application.

36. 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.

37. 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.

38. It is considered 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 the commissioner 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

39. Within their application, the applicant is required to provide sufficient information to satisfy the committee 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.

40. Applicants are not required to provide their standard operating procedures (SOPs) but may choose to do so to satisfy the committee in relation to the above.

41. It is not the role of the committee, or the commissioner 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 committee in coming to a decision with regards Regulation 25(2)(b). In reading them the committee 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, eg 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

42. If an emergency is declared (through directions given by the Secretary of State under section 168A of the National Health Service Act 2006), eg 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, eg pandemic disease – the commissioner must, for a specified period, exercise (or consider exercising) one or more or its functions under various provisions of the Regulations.

43. In the case of such an emergency, the commissioner may make temporary amendments to the list entry of a contractor, eg 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.

44. In the event of circumstances arising that are beyond the control of the contractor and require the temporary suspension of pharmaceutical services at the listed premises, the commissioner may make temporary amendments to the relevant pharmaceutical 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.

45. The temporary suspension/relocation must be for no longer than six 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 relevant pharmaceutical list.

46. 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.

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

48. 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.

49. 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?

50. 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.

51. 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.

Unforeseen benefits – significant detriment to the arrangements that are in place for the provision of pharmaceutical services

52. One of the matters that the committee is to have regard to when determining an application offering unforeseen benefits is whether or not it is satisfied that granting

the application would cause significant detriment to the arrangements that the commissioner has in place for the provision of pharmaceutical services.

53. An unforeseen benefits application in a village was refused on this basis on appeal on 25 February 2019[5] and committee members may find the decision of use when considering this matter.

54. A synopsis of the application is as follows. An applicant sought to open a pharmacy in a small village with limited facilities, located in a controlled locality. Within the village there is a dispensing practice but no pharmacy. There are pharmacies within neighbouring villages. NHS England refused the application as it was not satisfied that granting it would confer significant benefits.

55. On appeal, the arguments concerning significant detriment to the arrangements in place for the provision of pharmaceutical services centred on the effect that granting the application would have on one of the neighbouring pharmacies. NHS Resolution concluded that this particular pharmacy in a neighbouring village was almost entirely reliant on the applicant's GP practice for its prescriptions. On the balance of probability, it was satisfied that an expected capture rate of these prescriptions by the proposed pharmacy of around 48% was likely.

56. The effect of that capture rate on the identified existing pharmacy was clear – it would turn a just profitable business into a clear loss-maker (based on the evidence that had been provided).

57. NHS Resolution was satisfied on the balance of probability that the identified pharmacy in the neighbouring village would close if the application was granted, leading to the loss of the only healthcare provider in that village. The replacement service, while accessible by car, was not reasonably accessible on foot or by public transport. On a wider level, the uneven distribution of service providers within the relevant area of the HWB would be upset. In short, there would be a complete cessation of a service in the village that NHS Resolution was satisfied the residents valued, was of benefit to them and that they had rightly come to expect.

58. NHS Resolution noted that the applicant did not, on appeal, claim that "the benefits of the application outweigh any significant detriment", although this has been raised in the past in relation to other appeals. NHS Resolution therefore considered the merits of the application itself to see whether it in fact provided significant benefits and if

[5] SHA/19981 appeal 25 February 2019 NHS Resolution – available by emailing nhsr.appeals@nhs.net

those benefits outweighed the significant detriment that had been identified. It was of the opinion that they did not, in this case.

59. NHS Resolution noted that the arguments concerning significant detriment covered much of the same ground as that involving prejudice (which was also considered in relation to this application) albeit the two issues are different provisions within the legislation and are not mutually determinative.

60. Committee members are advised to read the decision in full so as to fully understand the particular facts and circumstances of this case, rather than rely on this synopsis.

Changes of ownership

61. Under Regulation 26 a change of ownership application is necessary where the applicant is undertaking to provide pharmaceutical services at premises that are listed in the relevant pharmaceutical list and at which another person is providing pharmaceutical services. For example, a sole trader sells their retail pharmacy business to a body corporate, or a sole trader incorporates (ie becomes a body corporate that is registered with Companies House).

62. 'Person' could be any form of organisation, an individual or a group.

63. However, it is to be noted that the Co-operative and Community Benefit Society Act 2014 contains wording enabling a 'conversion' from a society to a body corporate. It is less clear if this means that the society and the body corporate into which it converts should be considered as two separate legal entities.

64. The courts have looked at this matter, Mount Wellington Mine Ltd v Renewable Energy Co-Operative Ltd [2021] EWHC 1486 (Ch) (07 June 2021). In view of this judgment it is considered reasonable to consider that if a community benefit society or co-operative 'converts' to a body corporate that is registered with Companies House, then this does not require a change of ownership application to be submitted under Regulation 26.

65. However, the conversion may involve a change of director or directors, and/or superintendent. Where this happens, the body corporate is required to notify of these changes within 30 days of their occurrence and to provide the required fitness information within the 30 days of the appointment of the new director/directors/ superintendent.

66. In addition, the body corporate is required to notify of the change of name and registration number (community benefit societies and co-operatives are regulated by the Financial Conduct Authority rather than Companies House), and any change to its registered office or the telephone number of its registered office is, or are, to be notified within 30 days.

67. No new ODS code is to be issued to the body corporate unless the body corporate requests one.

Chapter 31: Fitness and applicants 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 in a pharmaceutical list and those applying to be included, 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 2006 Act).

3. The committee will consider and determine fitness matters but may, until 1 April 2023, 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. Where the PLDP instigates use of the fitness powers, it must discuss this with the relevant delegated ICB or ICBs before reaching a final decision. Similarly, where a delegated ICB is considering use of the fitness powers, it must first discuss this with the relevant NHS England region or regions.

4. Letters sent to contractors in relation to use of the fitness powers are either to be sent by email (with read and delivery requests requested and filed accordingly) or by post (either via the 'tracked' or 'signed for' options with evidence of receipt filed accordingly). This is to ensure that letters are received.

Fitness first referral

5. Where a person applies to be included in a pharmaceutical list in which they are not already included in respect of other premises, paragraph 23, Schedule 2 of the Regulations requires the commissioner to undertake a series of checks relating to the applicant's fitness prior to determining the application.

6. Where a body corporate appoints a new director and/or superintendent, it is required to notify the commissioner and provide the required fitness information within 30 days of the person's appointment.

7. On receipt of the fitness information, or where the applicant has previously provided it and confirmed that there is no missing information, a 'first referral' will be undertaken. The primary care support service provider will send the information to the commissioner in whose area the applicant is seeking to open premises and ask a series of questions (see Chapters 5 to 10). Responses are due within five working

days; where this is not possible, the primary care support service provider is to be notified of when a response will be sent.

8. One of the questions asked is whether the nominated referees are acceptable. It is recognised that based on the information provided by the applicant, referees may appear to be suitable at this stage, although once the references are received this view may change.

9. In relation to changes of director/superintendent, a second question asks whether the contractor only holds a LPS contract with the commissioner. The template LPS contract does not require bodies corporate to notify of changes of director and/or superintendent, and therefore the commissioner will need to check whether or not this was included as a local requirement. If it hasn't, then the commissioner will need to decide what, if any, action to take.

10. In addition to the references, the Regulations require other checks to be undertaken, eg with NHS Counter Fraud Authority. Generally these checks are completed more quickly than the references are received. Where there is a delay in receipt of the references, the commissioner will accept the outcome of these other checks for a period of three months. Should the references be received outside this time period, then the checks are to be undertaken again.

11. For the avoidance of doubt, these other checks are to be undertaken each time an applicant applies to be included in a pharmaceutical list. Checks undertaken in relation to a previous application are not deemed to be portable to subsequent applications.

Existing contractor's grounds for action

12. The Regulations and the 2006 Act provide a framework within which the commissioner 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.

13. Action can be taken on the three grounds that are set out in the Act, namely:

    1. 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.

2. 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.
3. Suitability – the contractor is unsuitable to be included in a pharmaceutical list.

Use of the powers

14. There may be occasion where the commissioner identifies concerns relating to the fitness of a contractor. In this instance the committee (or, until 1 April 2023, PLDP) will need to consider use of the fitness powers set out in the 2006 Act and Part 11 of the Regulations.

15. While the powers that are available to the commissioner are set out in the Act, further details and the process to be followed are set out in the Regulations. Where a committee (or, until 1 April 2023, PLDP) is considering use of the fitness powers, it must first liaise with other commissioners in whose area the contractor has premises so that a consistent approach is taken across the country.

16. Options available to the commissioner include, where there are no patient safety issues, monitoring the situation.

17. Section 151 of the 2006 Act sets out grounds when the commissioner may (or must in prescribed circumstances) remove a contractor from the relevant pharmaceutical list or lists that it is included in, and these relate to efficiency, fraud and suitability grounds.

18. Regulation 81 sets out instances where the commissioner 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 United Kingdom of murder, or is the subject of a national disqualification.

19. Section 152(1) of the 2006 Act makes provision for the commissioner to contingently remove a contractor from the relevant pharmaceutical list or lists that it is included in, 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 the commissioner is satisfied that the contractor is not suitable to be included in the relevant pharmaceutical list or lists.

20. Section 154(1) of the 2006 Act makes provision for the commissioner to suspend a contractor from the relevant pharmaceutical list or lists that it is included in while:

    - it decides whether to remove or contingently remove the contractor, or
    - it waits for a decision affecting the contractor of a court or regulatory body.

21. It must be noted that suspension is a neutral act, not a disciplinary sanction. The commissioner 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, damage to the contractor's reputation, career and personal life, and waste of NHS resources.

Changes of director and/or the superintendent

22. Where a pharmacy body corporate that is included in a pharmaceutical list or lists appoints a new director and/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) of the person taking up their new post. The required checks will be undertaken and a report prepared and submitted to:

    - the commissioner in whose area the body corporate's registered office is located, or
    - if the body corporate has no premises in that commissioner's area, to the commissioner in whose area its premises are located, or where the majority of its premises are located.

23. There may be occasions where the bank account into which payments for the provision of pharmaceutical services changes as a result of changes to the directors and/or superintendent. In these instances the commissioner will agree to the change being made by NHSBSA as long as the required fitness information has been provided, even if a decision has yet to be made as to whether or not the body corporate remains a fit and proper person to be included in the relevant pharmaceutical list of lists.

24. The committee will consider the fitness information (and may, until 1 April 2023, delegate to the PLDP) to determine whether the body corporate remains a fit and proper person.

25. Options that are available to the committee/PLDP include:

- decision that the body corporate remains a fit and proper person to be included in the relevant 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 while it decides whether or not to remove or contingently remove the contractor – section 154(1) of the Act.

26. The decision, the outcomes of the checks and the information provided by the contractor are to be communicated to other commissioners in whose area the body corporate has premises that are included in a pharmaceutical list.

27. Notification of the decision to the contractor and notification under Regulation 88 will be undertaken by the primary care support service provider. The committee/PLDP is to provide a fully reasoned statement of its decision and the contact details of the person who can provide further information if required by those that are notified under Regulation 88. 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.

28. 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
    - relevant ICB where it is not delegated to commission pharmaceutical services
    - public health team
    - LMC
    - DoS lead
    - registration authority
    - CDAO
    - OOH provider
    - unwanted medicines collection and disposal contractor
    - organisation that cascades safety alerts
    - primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

29. This notification will take place at the end of the 30-day appeal period, or once any appeal has been heard and the commissioner'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.

30. There may be occasions where referees fail to respond and no response is received from the body corporate. In this instance the commissioner 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 the commissioner 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 pending consideration of removal or contingent removal). A template letter can be found at Annex 1 should removal be considered an appropriate step to take. This letter is to be completed and sent to the primary care support service provider who will then send it to the contractor and advise of any responses received.

31. It is recommended that arrangements for the hearing are made in advance of the letter being sent, and details of the time, date and venue for it are included in the letter.

Changes of director name and name and/or address of the superintendent

32. Where the name of a director of a body corporate or the name or address of the superintendent (pharmacy bodies corporate only) changes, the relevant form must be sent 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 commissioner or commissioners in whose area the contractor has premises.

33. Unless the change of name is related to a new person being appointed, the only action that is required is to update relevant databases.

34. If the change of name relates to a new person, then the required fitness information is to be provided, checks undertaken and a decision made as to whether or not the body corporate remains a fit and proper person to be included in the relevant pharmaceutical list or lists.

Changes of body corporate name only

35. Where a body corporate changes its name, or 'trading as' name, but all other details remain the same (same directors and superintendent, same Companies House registration number and same registered office address), then no change of ownership application is required and no fitness information is to be provided.

36. The relevant pharmaceutical list or lists will need to be updated to reflect the new name and the NHSBSA will need to be advised via the 'Change of NHS Pharmacy Contractor details' form.[6]

37. If there has been any change of director and/or superintendent, then the required fitness information must be provided on that individual or individuals so that a decision can be made as to whether or not the body corporate remains a fit and proper person to be included in the relevant pharmaceutical list or lists.

38. If the Companies House registration number has changed, then this is a change of ownership and the new body corporate will need to submit a change of ownership application. While it is processed and determined, the previous body corporate remains included in the relevant pharmaceutical list or lists and is liable for the provision of pharmaceutical services at the premises.

Provision of information on fitness matters as they arise

39. 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 of the occurrence of the matter (paragraph 31, Schedule 4 and paragraph 15, Schedule 5 of the Regulations).

40. Where the contractor is a body corporate this information will be sent to:

    - the commissioner 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 commissioner in whose area its premises are located, or where the majority of its premises are located.

41. For sole traders and partnerships this information will be sent to the commissioner in whose area:

[6] NHSBSA organisation and prescriber changes notification forms

- all the contractor's premises are located, or
- the majority of its premises are located.

42. The committee (or, until 1 April 2023, 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 the commissioner 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 while it decides whether or not to remove or contingently remove the contractor or waits for a decision by a regulatory body, eg the GPhC – section 154(1) of the Act.

43. The decision and the information provided by the contractor is to be communicated to other commissioners in whose area the body corporate has premises that are included in a pharmaceutical list.

44. 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 the commissioner is satisfied that the body corporate remains a fit and proper person. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. 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).

45. 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 the commissioner's decision has not been overturned.

46. 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
- relevant ICB where it is not delegated to commission pharmaceutical services
- public health team
- LMC
- DoS lead
- registration authority
- CDAO
- OOH provider
- unwanted medicines collection and disposal contractor
- organisation that cascades safety alerts
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

47. This notification will take place at the end of the 30-day appeal period, or once any appeal has been heard and the commissioner'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

48. Regulation 82 of the Regulations sets out the procedure to follow where the commissioner is considering:

- discretionary removal of a contractor under section 151(2) to (4) of the 2006 Act – efficiency, fraud and unsuitability cases
- mandatory removal of a contractor under section 151(5) of the 2006 Act and Regulation 81 of the Regulations
- removal of a contractor under section 152(3)(b) of the 2006 Act – removal for failure to comply with a contingent removal condition, or
- removal of a contractor under Regulation 80 of the Regulations – removal for failure to comply with a conditional inclusion condition.

49. Although Regulation 81 directs the commissioner to remove a contractor in certain circumstances, the procedure set out in Regulation 82 must first be followed.

50. Where it is considering removal of a contractor, before reaching its decision the committee (or, until 1 April 2023, PLDP) must send Annex 2 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.

51. Where the committee (or, until 1 April 2023, PLDP) is considering the removal of a contractor, it should also consider whether it should suspend the contractor while the above procedure is followed and until either the end of the appeal period or the outcome of the appeal is known, whichever is the later.

52. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made. Annex 3 is then to be sent to the contractor. The contractor may appeal the decision to the First-tier Tribunal.

53. 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 the commissioner. If the First-tier Tribunal comes to a different decision to the commissioner, that decision will over-ride the commissioner's decision.

54. Where the decision is made to remove the contractor, further actions are required as set out in Chapter 38.

55. Notification of the decision under Regulation 88 will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

56. Where a contractor is removed on fitness grounds, the following persons are also to be notified by the primary care support service provider:

    - HWB
    - relevant ICB where it is not delegated to commission pharmaceutical services
    - public health team

- LMC
- DoS lead
- registration authority
- CDAO
- OOH provider
- unwanted medicines collection and disposal contractor
- organisation that cascades safety alerts
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

57. This notification will take place at the end of the 30-day appeal period, or once any appeal has been heard and the commissioner'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

58. Regulation 82 of the Regulations sets out the procedure to follow where the commissioner is considering contingently removing a contractor under section 152(1) of the Act.

59. Where it is considering contingent removal of a contractor, before reaching its decision, the commissioner (or, until 1 April 2023, PLDP) must send Annex 4 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.

60. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made. Annex 5 is then to be sent to the contractor. The contractor may appeal the decision to the First-tier Tribunal.

61. 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 the commissioner. If the First-tier Tribunal comes to a different decision to the commissioner, that decision will over-ride the commissioner's decision.

62. Notification of the decision under Regulation 88 will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

63. 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 the commissioner decision has not been overturned.

Procedure for suspension

64. Regulation 83 of the Regulations sets out the procedure to follow where the commissioner is considering suspending a contractor from a pharmaceutical list under:

- section 154(1) of the 2006 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 2006 Act – suspension pending an appeal against a decision to remove a contractor.

65. Where it is considering suspending a contractor, before reaching its decision the committee (or, until 1 April 2023, PLDP) must send Annex 6 to the contractor.

66. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made. Annex 7 is then to be sent to the contractor.

67. Notification of the decision under Regulation 88 will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

68. 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. A spreadsheet to assist in the calculation of these payments can be found at Annex 8.

69. While a contractor is suspended they must be treated as not being included in the pharmaceutical list or lists from which it has been suspended even though its name appears in it or them.

70. Sections 154 and 155 of the 2006 Act set out the length of time that a contractor may be suspended:

- where the contractor is suspended while the commissioner 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, the commissioner 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.

71. The committee (or, until 1 April 2023, PLDP) may terminate a suspension at any time. Where it does, it must send Annex 9.

Procedure for review of some suspensions

72. Section 157(1) of the 2006 Act makes provision for the committee (or, until 1 April 2023, PLDP) to review a suspension where requested to do so by the contractor, and for the committee (or, until 1 April 2023, PLDP) to review a suspension of its own volition. This does not apply to a suspension imposed by, or continuing pursuant to, an order of the First-tier Tribunal, or a suspension pending an appeal.

73. 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 the commissioner to suspend them, or
- six months beginning on the date of the commissioner's decision on the previous review.

74. On receipt of a request to review a suspension, send Annex 10 to the contractor.

75. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made.

76. The options available to the committee (or, until 1 April 2023, PLDP) are:

- confirm the suspension
- terminate the suspension.

77. Depending on which decision is made, send either Annex 11 (suspension confirmed) or 12 (suspension terminated).

78. If the suspension is terminated, then the contractor will be able to recommence the provision of pharmaceutical services. Notification of the decision under Regulation 88(8) will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. 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.

79. Where a suspension is terminated, the following persons are also to be notified by the primary care support service provider:

- HWB
- relevant ICB where it is not delegated to commission pharmaceutical services
- public health team
- LMC
- DoS lead
- registration authority
- CDAO

- OOH provider
- unwanted medicines collection and disposal contractor
- organisation that cascades safety alerts
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

80. If as a result of their suspension, an application had been granted under Regulation 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

81. Section 157(1) of the 2006 Act makes provision for the committee (or, until 1 April 2023, PLDP) to review a contingent removal where requested to do so by the contractor, and for the committee (or, until 1 April 2023, PLDP) to review a contingent removal of its own volition. This does not apply to a contingent removal imposed by the First-tier Tribunal.

82. 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 the commissioner to contingently remove them, or
- six months beginning on the date of the commissioner's decision on the previous review.

83. On receipt of a request to review a contingent removal, send Annex 13 to the contractor. Where the committee (or, until 1 April 2023, PLDP) decides to review a contingent removal of its own volition, send Annex 14.

84. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made.

85. The options available to the committee (or, until 1 April 2023, PLDP) are:

- confirm the contingent removal
- vary the conditions
- impose different conditions
- revoke the contingent removal
- remove the contractor from the relevant pharmaceutical list or lists.

86. Notification of the decision under Regulation 88 will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

87. 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 the commissioner's decision has not been overturned.

Procedure for review of conditional inclusion

88. Regulation 79 of the Regulations makes provision for the committee (or, until 1 April 2023, PLDP) to review a conditional inclusion where requested to do so by the contractor, and for the committee (or, until 1 April 2023, PLDP) to review a contingent removal of its own volition.

89. 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 committee (or, until 1 April 2023, PLDP) determined the outcome of the previous review.

90. On receipt of a request to review a conditional inclusion, send Annex 15 to the contractor. Where the committee (or, until 1 April 2023, PLDP) decides to review a contingent removal of its own volition, send Annex 16.

91. An oral hearing, which the contractor may or may not choose to attend, will then be held by the committee (or, until 1 April 2023, PLDP) and a decision made.

92. The options available to the committee (or, until 1 April 2023, PLDP) are:

- remove the condition or conditions
- leave the condition or conditions unchanged
- vary the condition or conditions
- impose different conditions.

93. 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 2006 Act (fraud).

94. If in the course of this review, the committee (or, until 1 April 2023, 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 the section above entitled 'Procedure for removal'.

95. Notification of the decision under Regulation 88 will be undertaken by the primary care support service provider. The committee/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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

96. 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 the commissioner's decision has not been overturned.

National disqualification

97. 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 the commissioner (section 159 of the Act). This is referred to as national disqualification.

98. It may also impose a national disqualification on a contractor if it dismisses an appeal against a refusal by the commissioner to include them in a pharmaceutical list.

99. The commissioner 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.

100. Where a committee (or, until 1 April 2023, 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 on the date of the removal or refusal.

101. 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, the commissioner must remove them.

102. 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

103. 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 committee (or, until 1 April 2023, 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, as well as the contact details of the person who can provide further information if required by those that are notified under Regulation 88. It is also to confirm if the NHS Counter Fraud Authority is to be notified under Regulation 88(2)(h).

104. 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 the commissioner's decision has not been overturned.

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

105. Regulation 76 of the Regulations 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.

106. If the contractor is to be removed in any of the above circumstances but the committee (or, until 1 April 2023, 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
    - appeal rights.

2. This document must be read in conjunction with the Regulations. Further information on the background to the current regulatory framework for rurality matters can be found in the Clothier Report,[7] which was published in December 1977.

Background

3. A controlled locality is an area determined by the commissioner (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 committee.

4. The commissioner 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.[8]

5. In making a decision on controlled locality status, the commissioner will need to consider a range of characteristics and features about a locality. It will have to consider all the 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
    - overall population density

[7] www.pcc-cic.org.uk/article/clothier-report
[8] https://www.gov.uk/government/collections/rural-urban-classification

- transportation – the availability or otherwise of public transport and the frequency of such provision, including access to services such as shopping facilities
- provision of other facilities, such as recreational and entertainment facilities.

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

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

7. The commissioner may need to consider afresh whether an area is or is not a controlled locality as a result of receiving a routine application for pharmacy premises, at the request of a LPC or LMC, or of its own volition, eg 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 1983.[9]

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:

[9] http://www.legislation.gov.uk/uksi/1983/313/contents/made

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

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

- lists of villages that were determined to be rural in character before 1 April 1983
- descriptions of areas that were determined to be rural in character before 1 April 1983
- maps of controlled localities that were determined from 1 April 1983
- a mixture of the above
- none of the above.

Reserved locations

13. 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 (Regulation 41).

14. 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’.

15. 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. 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 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.

16. 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.

17. 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.

18. The decision-maker 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)).

19. 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 (ie are registered with a GP practice, excluding temporary residents) is less than 2,750, and
    - the commissioner 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.

20. The second bullet point in essence means that where the decision-maker 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 decisions SHA/18698 and SHA/18759, which were issued in September and November 2017. Copies of both decisions can be provided by NHS Resolution by emailing nhsr.appeals@nhs.net.

21. 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.

22. 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.

23. Where a reserved location takes effect, then the commissioner 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
- make that map available as soon as is practicable to the HWB that has all or part of that reserved location in its area.

24. 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.

25. 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.

Prejudice

26. Where a routine application to open new or additional pharmacy premises is received for a controlled locality and the decision-maker determines that it is not in a reserved location, the test of 'prejudice' must be applied.

27. If the decision-maker 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.

28. The onus is on the person/organisation alleging prejudice to provide evidence of this. The decision-maker will therefore need to take into account all representations it receives with regards to the issue of prejudice.

29. The Regulations do not provide any definition of the concept of prejudice. In general, it means that nothing must be done that 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".

30. 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.

31. 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 focuses only on those services that have to be provided within the terms of service of primary medical services 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

32. 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 historical rights to dispense to that area.

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

34. If a new pharmacy routine application is granted and the pharmacy is subsequently included in the relevant pharmaceutical list, and a dispensing patient now lives within 1.6km of that pharmacy, the 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
    - the commissioner has granted a serious difficulty application in respect of the patient.

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

36. Gradualisation – that is, the postponement of any requirement for dispensing by doctors to cease to dispense to a patient or patients – is to be considered:

- where it is determined than an area is no longer a controlled locality, or part of one
- determinations of pharmacy 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.

37. 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 may be necessary, such as reducing stock holdings and altering staff duties.

38. 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 the commissioner considers whether a period of gradualisation is to be given:

- number of patients affected
- proportion of the GP practice's dispensing patient list that this represents.

39. The commissioner 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."

40. 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.

41. If the commissioner determines that there will be a period of gradualisation, it is for the commissioner 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 if required.

42. While 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

43. The commissioner 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.

44. In addition, a LMC or LPC may apply in writing to the commissioner requesting that it determines whether or not a specified area is to be a controlled locality or is to be part of a controlled locality.

45. 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.	Where: • the decision-maker is considering making a determination as to whether or not an area is a controlled locality, or is part of one, or • if the LMC or LPC applies in writing for the commissioner to determine whether or not an area is to be, or is to be part of, a controlled locality refer to the controlled locality records to determine whether the area has been determined in the last five years.
2.	If the area has not been determined in the last five years, record the intention to make a determination and go to step 8. If the area has been determined in the last five years, advise the decision-maker 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.
3.	Where the decision-maker 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. If a site visit is required, ensure sufficient information on the area is gathered to answer both this issue and also to assist if a determination is subsequently to be made (see step 10 below). Complete the report at Annex 1.
4.	If the decision-maker determines that there has been no substantial change in circumstances, send Annex 2 to the LMC or LPC that made the application (where relevant) and go to step 5 below. 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 and assist in the production of a response.
7.	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. If NHS Resolution determines that there has been a substantial change in circumstances, go to the step 8.

8.	If: • no determination has been made in the last five years, or • the decision-maker or NHS Resolution determines that there has been a substantial change in circumstances go to step 9.
9.	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: • 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 pharmacy routine application, the person making that application, • any HWB whose area includes all or part of the area to be determined • where the decision is being made by a delegated integrated care board, the relevant NHS England region. 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)). Under Regulation 38(2) notice of the proposed determination may be given to such other persons as the decision-maker considers it appropriate to do so. This may include parish councils and patient participation groups.
10.	During the 30-day notification period identify any dispensing patients living in the area that is to be determined. Arrange a site visit, if required, and gather information on the area. Following the site visit, prepare a report (Annex 4), which includes the findings of the site visit and any representations that have been received, for the decision-maker.
11.	After the meeting prepare the relevant decision letters based on the minutes of the meeting at which the decision was made: • notification of determination for those with appeal rights (Annex 5) • notification of determination to dispensing practices (Annex 6), and/or • notification of determination for those with no appeal rights (Annex 7). Distribute to the interested parties.

12.	Diarise the latest date for appeals to be made.
13.	If notice of an appeal is received, advise the decision-maker and assist in producing a response.
14.	If the decision-maker or, on appeal, NHS Resolution, determines that the area is a controlled locality, or is part of a controlled locality, go to step 15. If the decision-maker or, on appeal, 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. If the decision-maker 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.
15.	If the decision-maker 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. 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. The map must be sent to the HWB that has all or part of that controlled locality in its area. Update the controlled locality database. There are no further actions in respect of this procedure.
16.	If the decision-maker 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. Advise the HWB that has all or part of the area that is no longer a controlled locality in its area. Go to step 18
17.	If the decision-maker 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. Advise the HWB that has all or part of the area that is no longer a controlled locality in its area within five working days. Go to step 18.
18.	If there are dispensing patients living in the area that has been determined not to be a controlled locality, record the date on which they must be removed from practice dispensing lists (having regard to the gradualisation decision, including any appeal relating to this). If gradualisation has been given, ask the primary care support service provider to prepare lists of dispensing patients by practice within 1.6km of the pharmacy (ie those who will be removed from dispensing lists) and send a letter to the relevant practices (Annex 8), enclosing the list of patients and a copy of the letter to be sent to the affected patients (Annex 9). Resolve any queries raised by practices, carrying out site visits if necessary.

19.	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

46. 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 on the date of the determination of the commissioner, or if that determination was appealed, the date of the decision on appeal
- unless the commissioner is satisfied (within that five years) that there has been a substantial change in circumstances in relation to that area since the question was last determined.

47. It is therefore important that accurate records are maintained of all controlled locality determinations.

Re-determinations of a reserved location

48. The applicant, or any future owner of the pharmacy, may request that the commissioner undertakes a further determination or determinations. Where this occurs, the following procedure should be followed.

49. It should be noted that the commissioner 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' if the pharmacy has not yet opened.
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. 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: • notification of determination for those with appeal rights (Annex 13) • notification of determination to dispensing practices (Annex 14), and/or • notification of determination for those with no appeal rights (Annex 15). Once the decision letters are signed, distribute to the interested parties.
6.	Diarise the latest date for appeals to be made.
7.	If notice of an appeal is received, advise the decision-maker and assist in producing a response.
8.	If the decision-maker or, on appeal, NHS Resolution, determines that the area within 1.6km of the pharmacy or 'relevant location' is still a reserved location, go to step 9. If the decision-maker or, on appeal, NHS Resolution, determines that the area within 1.6km of the pharmacy or 'relevant location' is no longer a reserved location, go to step 10.
9.	If the decision-maker or, on appeal, NHS Resolution, determines that the area within 1.6km of the pharmacy or 'relevant location' is still a reserved location, there are no further actions to take.
10.	If the decision-maker or, on appeal, NHS Resolution, determines that the area within 1.6km of the pharmacy or 'relevant location' is no longer a reserved location, the map should no longer be published and the HWB is to be advised accordingly.
11.	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). If gradualisation has been given, ask the primary care support service provider to prepare lists of dispensing patients by practice (ie 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). Resolve any queries raised by practices, carrying out site visits if necessary. Note – the timescales may need to be altered to reflect the actual period of gradualisation or if no gradualisation has been given.
12.	Diarise the date for responses from the practices
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 the primary care support service provider to change the patients' dispensing status on Exeter. There are no further actions to be completed.

Additional steps for pharmacy applications in a controlled locality

50. This section of the chapter is relevant where a pharmacy application (other than a distance selling premises 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.

	Action
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 or 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 applications near a controlled locality

51. This section of the chapter is relevant where a pharmacy application (other than a distance selling premises 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.

	Action
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 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).

	Resolve any queries that may be raised by the practices, carrying out site visits if necessary.
2.	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.
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.

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 the commissioner 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 the commissioner:

- 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 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 that were notified of the application as the commissioner 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
    - GP practices, LPS contractors and a person on a pharmaceutical or dispensing doctors list who, in the opinion of the commissioner, may be affected by the determination and who are given notice of the decision.

55. Where a LMC or LPC asks the commissioner to determine whether or not an area is, or is part of, a controlled locality but the commissioner 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
    - GP practices, LPS contractors and a person on a pharmaceutical or dispensing doctors list who, in the opinion of the commissioner, 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
- GP practices, LPS contractors and a person on a pharmaceutical or dispensing doctors list who, in the opinion of the commissioner, 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 the commissioner 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
    - another person on the dispensing doctor list of the area of the relevant HWB.

59. In both cases listed in paragraph 58, the appellant must have made representations in writing within the 45-day period and the decision-maker must be 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.

60. In the case of a GP practice listed in paragraph 58, 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

1. 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.

2. In general, applications from doctors will be received and processed by the primary care support service provider. Any applications received directly by the commissioner are to be forwarded on. While applications are processed there will be times when a decision or decisions need to be made by the commissioner in line with Chapter 2. This chapter identifies those times and provides additional information for the commissioner to consider. It also identifies when the commissioner will be notified of progress.

3. While there is no timescale within the Regulations for the determination of applications for outline consent and/or premises approval, it is expected that decisions will be made and issued within four months unless the commissioner has good cause to take longer.

4. The chapter also deals with serious difficulty applications from patients and validating dispensing patient lists.

5. This chapter must be read in conjunction with Part 8 of the Regulations.

Background

6. 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 in ensuring patients receive their medicines promptly, efficiently and conveniently.

7. 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 historical rights to dispense to that area.

Outline consent and/or premises approval applications

Receipt and first referral

8. 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 the commissioner.

9. On receipt, the primary care support service provider will send a 'first referral' to the relevant commissioner, ie the commissioner in whose area the dispensing doctor's premises are located.

10. The decision-maker will need to consider the questions asked in the first referral and respond to the primary care support service provider within five working days.

11. 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 the commissioner, following the process set out in Chapter 32. Once the controlled location determination has been made, advise the primary care support service provider so that they can continue to process the application.

12. It is for the commissioner to check the information that has been provided by the applicant is sufficient.

Identifying interested parties

13. Determining the parties who must be notified of applications pursuant to Regulation 52 of the Regulations is the responsibility of the commissioner.

14. The following paragraphs will help the commissioner 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.

15. 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 commissioner.

16. Where the commissioner 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, the commissioner 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. Alternatively, this information is available via the Strategic Health Asset Planning and Evaluation application.[10]

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

17. 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 is not in a controlled locality, the contractor's premises is within 2km in a direct line from the applicant's proposed premises
    - where the applicant's proposed premises is in a controlled locality, the contractor's premises is located within 8km in a direct line from the applicant's proposed premises.

18. Head offices of bodies corporate are also to be notified where this information is known, but this is as a courtesy as it is the premises that are included in the relevant pharmaceutical list that are to be notified in accordance with the regulations.

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

19. 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 is not in a controlled locality, the person's proposed premises is located within 2km in a direct line from the applicant's proposed premises
    - where the applicant's proposed premises is in a controlled locality, the person's proposed premises is located within 8km in a direct line from the applicant's proposed premises.

[10] Strategic Health Asset Planning and Evaluation application, Office for Health Improvement and Disparities, Log-in required.

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

20. 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 is in a controlled locality, the LPS contractor's premises is located within 2km in a direct line from the applicant's proposed premises
    - where the applicant's proposed premises is in a controlled locality, the LPS contractor's premises is 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))

21. 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.

22. The commissioner should consider whether there are any other groups that are to be notified of the application, eg residents associations.

GP practices (Regulation 52(1)(f))

23. Dispensing practices that have dispensing patients within the area identified in the application for outline consent should be considered to have a significant interest in the outcome of the application and should be notified of it. If the application is for premises approval only, it has been determined that no other dispensing practices are considered to have a significant interest in the outcome of the application and therefore need not be notified of it.

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

24. 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). If the application is for premises approval only, it has been determined that no other dispensing practices are considered to have a significant interest in the outcome of the application and therefore need not be notified of it.

Welsh health boards (Regulation 52(1)(g))

25. Where the premises or best estimate is within 2km of a Welsh health board, that organisation is to be notified. Applications are to be sent to NHS Wales Shared Service Partnership (nwssp-primarycareservices@wales.nhs.uk) who will forward them to the appropriate health board.

Explanatory note for patient, consumer or community groups

26. To help these groups understand why they are being notified of the application, the commissioner will need to complete the relevant explanatory note and send it to the primary care support service provider for inclusion with the notification letter.

Notification to interested parties

27. The primary care support service provider will advise the commissioner when the application is notified to interested parties. Patient requests to be dispensed to which accompanied the application will not be circulated.

Application report

28. The primary care support service provider will partially complete the template report and will pass it to the commissioner for completion. Due regard should be given to the relevant regulations in Part 8 of the Regulations in the completion of the report.

Determination

29. The commissioner 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.

30. 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

31. After determining the application, the commissioner 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.

32. Rights of appeal for the applicant and third parties are set out in Regulation 63 of the Regulations.

33. The commissioner must fully document the reasons for giving (or not giving) third-party rights of appeal to a particular party.

Notification of decision and appeals

34. The primary care support service provider will advise the commissioner when the determination is notified to interested parties.

35. If an appeal to NHS Resolution is notified to the primary care support service provider, this will be passed to the commissioner for a response.

Taking effect

36. Where an application for outline consent and premises approval is granted, the commissioner 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.

37. The primary care support service provider will check for outstanding applications at the end of the 30-day appeal period and advise the commissioner accordingly.

38. Where there is an outstanding pharmacy application that 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 commissioner 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.

39. While 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. The commissioner will need to liaise with the practice so that NHSBSA and NHAIS or its replacement 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, unless premises approval has been given in respect of premises that are not already included in the contract. In this case the contract will need to be varied to include those premises.

40. 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

41. 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).

42. Such instances are likely to be much rarer now than previously. Internet-based services are more common and accepted by patients, communities and populations and may have grown to enable pharmacies to be viable in more remote areas, and many pharmacies now offer home delivery services. Nonetheless, it is possible that the commissioner will have to deal with such applications.

43. 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.

44. Applications may be made whether or not the patient lives in a controlled locality.

45. 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.	On 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, as applicable.
3.	Once all information is provided and it has been validated as much as possible, pass to the committee 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.
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 NHAIS or its replacement and to add a patient note to the patient's NHAIS or its replacement record 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, eg 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

46. Patients may at any time request in writing that their GP practice provides them with pharmaceutical services. The practice would then check that the patient meets one of the conditions set out in Regulation 48. If the patient does meet a condition, the practice must apply to the commissioner enclosing the patient's request.

47. In reality, the practice would amend the patient's status on their clinical system from 'prescribing' to 'dispensing' – this is then transmitted to NHAIS or its replacement, 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

48. Validation of dispensing patient lists is to 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 historical 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?

49. In conjunction with the primary care support service provider, the commissioner will need to ensure that dispensing patient lists are accurate.

50. Where a dispensing practice is considering merging with another practice, the commissioner will need to discuss and agree with them which areas they have premises approval and either historical rights or outline consent to where this is not already documented.

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

52. 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

53. Patients who live within 1.6km of a pharmacy (as the crow flies) must meet one of the exceptions 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.

54. Once a year the commissioner should check 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: • they do not live within a reserved location that was defined in connection with that pharmacy • 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 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 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 NHAIS or its replacement to prescribing.

Patients: ensuring dispensing only takes place in controlled localities

55. 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.

56. The commissioner is required to publish its controlled locality maps. The commissioner should check these maps against the addresses of dispensing patients in its area to ensure that no patients living outside controlled localities are having drugs dispensed by their GP.

57. Once a year the commissioner should check 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 has had serious difficulty applications granted.
2.	Send Annex 5 to the relevant GP practices enclosing a list of their patients who live outside 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 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 to losing their dispensing status and for practices to adjust their working practices accordingly.

5.	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.
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 NHAIS or its replacement to prescribing.

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. This list is accurate as at November 2022. An up-to-date list of the advanced services is maintained within Part VIC of the Drug Tariff.

    - new medicine service (NMS) - pharmacy contractors only
    - stoma appliance customisation
    - appliance use review services (AUR)
    - community pharmacy seasonal influenza vaccination - pharmacy contractors only
    - NHS community pharmacist consultation service – pharmacy contractors only
    - community pharmacy hepatitis C antibody testing service – pharmacy contractors only and currently due to end 31 March 2023
    - community pharmacy hypertension case-finding service – pharmacy contractors only
    - community pharmacy smoking cessation service – pharmacy contractors only.

4. If a pharmacy contractor or DAC notifies the commissioner that it wishes to provide one or more of the advanced services set out in the Directions, the commissioner must ensure all the required information is received.

5. As at June 2022, sign-up to the following services is managed by NHSBSA NHS Prescription Services and is therefore not included in this chapter:

    - NHS community pharmacist consultation service
    - community pharmacy hepatitis C antibody testing service
    - NHS community pharmacy hypertension case-finding advanced service
    - community pharmacy smoking cessation service.

6. As at June 2022, contractors do not need to sign up to the following service and it is therefore not included in this chapter:

   - community pharmacy seasonal influenza vaccination.

7. The commissioner has agreed the arrangements for managing this process with NHS Prescription Services and they are not incorporated in this manual.

Procedure

8. For the avoidance of doubt, this procedure covers the provision of NMS, AUR and the stoma appliance customisation service.

9. On receipt of a notification of intention to provide one or more of the above listed advanced services, check the Directions to ensure that all the required information has been provided as set out in the following forms:

   - NMS notification form - https://psnc.org.uk/national-pharmacy-services/advanced-services/nms/ under the heading 'Before 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 under the heading 'Advanced Services'.

10. 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.

11. If the contractor fails to provide the information within the required timescale, write to advise it that it may not provide the service.

12. 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.

13. 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.

14. If the contractor is not compliant with its terms of service, write to advise that it may not provide the service until it is compliant and set out the actions required to demonstrate compliance with the terms of service.

15. If the contractor is compliant:

    - write to the contractor to acknowledge receipt of all necessary information and inform them that the commissioner's records have been updated to reflect the provision of the service
    - advise the relevant HWB that the service is being provided.

16. File copies of all forms relating to the provision of advanced services in the contractor's premises electronic file.

Chapter 35: Enhanced services

Chapter aims and objectives

17. This chapter deals with the commissioning of enhanced services by the commissioner. It is not to be used where a contractor applies under Regulation 23 to provide an enhanced service (see Chapter 24).

Background

18. Pharmaceutical services are defined as those services that the commissioner 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, eg NMS and the community pharmacist consultation service
    - enhanced services.

19. The Directions list the advanced and enhanced services that the commissioner may commission. These services are referred to as 'directed services' in the Regulations and 'additional pharmaceutical services' in the NHS Act 2006.

20. The enhanced services that the commissioner may currently (June 2022) 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 (OOH) 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
- a coronavirus testing service
- a coronavirus vaccination service.

21. The purpose of each service is briefly outlined in the Directions, but the commissioner is free to develop its own specification 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 that are developed at delegated ICB or NHS England region level; these should be agreed with the relevant LPC or LPCs. However, since December 2021, the Regulations have provided for an enhanced service to be developed and agreed nationally in consultation with PSNC (rather than LPC(s)) where it is considered that the service should be commissioned across England on a fixed set of terms and conditions. Service-level agreements (SLA) may be used for the commissioning of enhanced services from pharmacies.

22. Where the commissioner chooses to commission a service that is not listed in Direction 14, then it is not an enhanced service and is to be commissioned using the NHS Standard Contract.

23. If an ICB wishes to commission services from pharmacies before the commissioning of pharmaceutical services has been delegated to it, then it may do so using the NHS Standard Contract. Such services fall outside the definition of pharmaceutical services and must not be referred to as enhanced services and should instead be referred to as locally commissioned services.

24. Other organisations such as local authorities may choose to commission services from pharmacies. Where they do, eg 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.

Minimum requirements for service specifications and SLAs

25. Where a pharmacy enhanced service is commissioned, the service specification and SLA must:

    - state that the service is being commissioned as an enhanced service
    - reference the relevant part of Direction 14, eg a minor ailment service is being commissioned under Direction 14(1)(f).

26. 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 the contractor or commissioner 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
    - how complaints about the service will be managed.

Commissioning services against pharmaceutical needs assessments

27. 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.

28. 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.

29. The HWB is to be advised when the commissioner 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.

30. Where a local authority or, before 1 April 2023, an ICB that has not been delegated to commission pharmaceutical services asks the commissioner to commission a service from a pharmacy or pharmacies on its behalf, the commissioner 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.

31. 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 the commissioner rather than directly as a locally commissioned service by the local authority or ICB. In the majority of cases, it is expected that commissioning a service directly would be more suitable.

32. The administration fee that will be charged to the local authority for undertaking the commissioning will need to be considered. This fee is to include staff time and any other administration costs.

Payments

33. Payments for enhanced services are to be made via the NHSBSA local payment application.[11] The commissioner 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

34. 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. The commissioner 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.

35. Should decommissioning of enhanced services be considered by the commissioner, it should ensure that it complies with the agreed terms of the SLA regarding termination, and its general duties (see Chapter 28).

[11] https://www.nhsbsa.nhs.uk/sicbls-icbs-and-other-providers/local-payments-application-lpa

36. In particular, the commissioner 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 contract
   - 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
   - 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 the variation provisions within 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 for the pharmacy contractor to ensure that their DoS and NHS website profiles (where available) are updated in line with notified changes to supplementary opening hours and successful applications to change core opening hours. This has been a term of service for pharmacy contractors since 9 November 2020 (paragraph 29C(4), Schedule 4 of the Regulations).[12] DACs do not have either a DoS or NHS website profile.

[12] Further information on this requirement can be found in Guidance on the National Health Service (Charges and Pharmaceutical and Local Pharmaceutical Services) (Amendment) Regulations 2020 NHS England and NHS Improvement 22 December 2020.

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, although it is neither a public nor bank holiday. They are encouraged to notify the commissioner well in advance so that consideration can be given as to whether the provision of pharmaceutical services on these days will meet the reasonable needs of patients and members of the public. Annex 1 contains the document to be used by contractors for this purpose.

8. There are two ways that commissioners can ensure adequate access to pharmaceutical services on public and bank holidays and Easter Sunday. They can direct a pharmacy or pharmacies to open following the procedure set out below. Alternatively, they could ask for volunteers and then commission them to open via an OOH enhanced service.

9. When considering whether or not to direct a pharmacy to open, the Regulations refer to assessments being made of access at a national level. For practical purposes the commissioner will undertake assessments of adequacy of provision at HWB level. Once it is known when the pharmacies in a HWB area will be open, 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).

10. Where a pharmacy contractor is to be open on a bank or public holiday or Easter Sunday, they are responsible for updating their DoS and NHS website profiles accordingly using the NHS Profile Manager.

Procedure: determining applications to change core opening hours

11. 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 permanently 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.

12. A contractor may apply to the commissioner to change its core opening hours under their terms of service as set out in Schedules to the Regulations. Standard application forms have been developed for this purpose (Annex 2).

13. Applications must be determined within 60 days of receipt unless the commissioner has good cause to take longer, eg 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.

14. It is particularly important that the contractor has provided the information required by paragraph 26(2), Schedule 4 or paragraph 16(2), 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.

15. 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.

16. Request any missing information from the contractor or seek clarification on the hours that have been declared. Template wording is provided at Annex 3.

17. 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.

18. 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 (ie 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.

19. 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 Regulations

- whether any previous directions have been issued about core opening hours, whether under the 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 by the most practicable route
- any needs, improvements or better access that are included in the PNA for the area within which the contractor's premises are located
- the opening hours of GP practices in the area.

20. When determining the application, the committee must bear in mind that applicants must provide the commissioner with such information as the commissioner may reasonably request in respect of any changes to the needs of the people in its area, or other likely users of the pharmacy, for pharmaceutical services that are material to the application.

21. 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.

22. The committee's decision on the application is to be recorded in the minutes of the meeting. The minutes must also include the facts relied on and the duly justified reasons for the decision.

23. 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. Annex 6 is to be sent where the application is refused; Annex 7 if it is granted.

24. 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 committee agrees to this in full or in part. Annex 8 contains wording for the direction.

25. 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.

26. 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.

27. 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.

28. Update the relevant pharmaceutical list once a change in core opening hours takes effect.

29. Permanent changes of core opening hours are to be notified to NHS Prescription Services using the 'Change of NHS pharmacy contractor details' form, which can be found under the heading 'Notify us about changes' at https://www.nhsbsa.nhs.uk/sicbls-icbs-and-other-providers/organisation-and-prescriber-changes/icbs. The email address to send completed forms to can also be found on that page. This form is also to be used where a DAC successfully applies to change its core opening hours.

30. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.

31. Remind the contractor to update their DoS and NHS website profiles using the NHS Profile Manager.

32. 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

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

34. A standard notification form has been developed for this purpose (Annex 9); however, there are slightly different provisions for pharmacy contractors and dispensing appliance contractors.

35. 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 10.

36. For dispensing appliance contractors, 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.

37. Where the dispensing appliance 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 11.

38. Where the dispensing appliance 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 committee to decide whether the change may take place sooner and write to advise the contractor accordingly. Wording is provided at Annex 12.

39. 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 by the most practicable route
- any needs, improvements or better access that are included in the PNA for the area within which the contractor's premises are located
- the opening hours of GP practices in the area.

Send the report to the committee, 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 committee refuses to reduce the three-month notice period; however, the decision should be fully reasoned and documented in case of legal challenge.

40. Update the relevant pharmaceutical list once a change in supplementary opening hours takes effect.

41. Permanent changes of supplementary opening hours are to be notified to NHS Prescription Services using the 'Change of NHS pharmacy contractor details' form which can be found under the heading 'Notify us about changes' at https://www.nhsbsa.nhs.uk/sicbls-icbs-and-other-providers/organisation-and-prescriber-changes/icbs. The email address to send completed forms to can also be found on that page.

42. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.

43. File the notification in the contractor's premises file.

44. For pharmacy contractors, the notification will either:

    - seek to reduce the total number of supplementary opening hours, in which case five weeks' notice must be given, or
    - notify of an increase in the total number of supplementary opening hours, in which case no period of notice is required and the contractor could notify the change on the day before it takes effect.

45. Where the pharmacy contractor seeks to reduce their total number of supplementary opening hours, write to the contractor acknowledging the notification and confirm the date on which the changes are to take place. Wording is provided at Annex 13.

46. Where the pharmacy contractor is seeking to increase their total number of supplementary opening hours, write to the contractor acknowledging the notification and confirm the date on which the changes are to take place, or have taken place as applicable. Wording is provided at Annex 14.

47. Update the relevant pharmaceutical list once a change in supplementary opening hours takes effect.

48. Permanent changes of supplementary opening hours are to be notified to NHS Prescription Services using the 'Change of NHS pharmacy contractor details' form which can be found under the heading 'Notify us about changes' at https://www.nhsbsa.nhs.uk/sicbls-icbs-and-other-providers/organisation-and-prescriber-changes/icbs. The email address to send completed forms to can also be found on that page.

49. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of the change.

50. File the notification in the contractor's premises file.

Procedure: directing pharmacy and dispensing appliance contractors to open

51. There may be occasion when the commissioner needs to direct a particular contractor to open on certain days or at certain times, eg on bank and public holidays. While in theory it is possible to go through the process set out in the Regulations and issue directions for all the public and bank holidays for a number of years, commissioners need to be aware that the further into the future they go the greater the risk that an appeal would overturn the decision to issue a direction. This is because as part of responding to an appeal, the commissioner will need to be able to demonstrate why there was a need to direct the pharmacy and also why that particular pharmacy has been directed rather than another. As opening hours may change, new pharmacies may open, existing pharmacies may close or relocate, it will be hard to demonstrate both the need to direct and the rationale for directing a particular pharmacy. Commissioners should note that NHS Resolution has taken the

view in recent appeal decisions that directing a pharmacy to open because it is their turn is not a robust enough argument.[13]

52. If the commissioner identifies that the current opening hours of a particular contractor may not meet the needs of people living in its area or other likely users, consult the LPC in whose area the contractor's premises are located. Wording is provided at Annex 15.

53. Following this consultation, the commissioner must give notice to the contractor of the proposed changes to the days on which, or times at which, the 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 16.

54. At the end of the 30 days, produce a report and send it to the committee, which will decide whether a direction is to be issued regarding the contractor's opening hours.

55. Where the commissioner 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 the commissioner and the contractor.

56. Notify the contractor of the decision. Wording is provided at Annex 17.

57. Any direction that is issued must meet the requirements of paragraph 25, Schedule 4 or paragraph 15, Schedule 5 of the Regulations. Annex 8 contains text for the direction.

58. 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.

59. 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.

[13] For example, SHA/24696 issued on 12 April 2022.

60. Update the relevant pharmaceutical list if the direction is for permanent or long-term changes in opening hours.

61. Advise the HWB, LPC and LMC in whose area the contractor's premises are located of permanent or long-term changes.

62. Remind the contractor to update their NHS website and DoS profiles using the NHS Profile Manager. DSPs do not have an NHS website profile but can update their DoS profile using the profile updater.

63. 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

64. 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
    - the premises have been broken into.

65. 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.

66. What is deemed to be 'beyond the control of the contractor' is to be determined on a case-by-case basis by the commissioner. Contractors are expected to use all reasonable efforts to employ or engage sufficient staffing numbers to provide pharmaceutical services throughout their opening hours.

67. Where there is a temporary closure outside the contractor's control, the contractor is required to notify the commissioner using the form at Annex 18.

68. Acknowledge receipt of a temporary suspension notification, reminding the contractor that they must update their NHS website and DoS profiles using the NHS Profile Manager and put in place mitigations to support users of the pharmacy who may be affected by the closures. DSPs do not have an NHS website profile but can update their DoS profile using the profile updater. Review the reason for the temporary

suspension. If it appears to be within the control of the contractor, refer the matter to the committee for a decision as to what, if any, further action to take in relation to performance management (Chapter 37).

69. 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.

70. Where a temporary suspension is likely to last for more than one day, notify the LPC, LMC and HWB.

71. If the temporary suspension is likely to last for a period of weeks, eg 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.

72. 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

73. 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.

74. The form at Annex 19 should be used.

75. On receipt of a request for a temporary closure that is within a contractor's control, check that three months' notice has been given.

76. 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 20.

77. 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 21.

78. 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 by the most practicable route
- any needs, improvements or better access that are included in the PNA for the area within which the contractor's premises are located.

79. Send the report to the committee for a decision to be made as to whether the temporary suspension is to be approved.

80. Advise the contractor of the decision using the wording provided at Annex 22. There are no rights of appeal against the decision; therefore, the decision should be fully reasoned and documented in case of legal challenge.

81. Notify the LPC, LMC and HWB if a temporary suspension is approved and will last for more than one day.

82. Remind the contractor to update their NHS website and DoS profiles using the NHS Profile Manager. DSPs do not have an NHS website profile but can update their DoS profile using the profile updater.

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 and the Directions.

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

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

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

6. 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
    - the stages of performance management.

7. 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.

8. 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.

9. All correspondence, file notes, reports, action plans and other documentation relating to each case will be maintained in chronological order. Electronic files are to be password protected and only a limited number of named personnel are to have access to them.

Provision of information by contractors

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

11. Paragraph 35(4), Schedule 4 requires pharmacy contractors, where asked to do so by the commissioner, to submit any information to which a person authorised in writing by the commissioner would have access to during a visit carried out under paragraph 35(1), Schedule 4. The information is to be provided in the electronic format specified in the commissioner's request.

12. The requested information is to be provided where the contractor has it in a form that can be sent electronically, or where it is reasonable for the commissioner to ask the contractor to convert the information into a form that can then be sent electronically (and the commissioner makes such a request).

13. Examples of information that may be requested include copies of:

- the responsible pharmacist log
- the practice leaflet
- material to publicise the essential and advanced services provided at or from the pharmacy premises
- the pharmacy's arrangements for owings
- the procedure by which the contractor checks the qualifications and references of all staff engaged in the provision of NHS services
- standard operating procedures
- evidence of training.

14. Requests for information will be made using the premises-specific NHSmail account.

15. The commissioner (or a person authorised in writing by the commissioner) may ask contractors to submit a completed questionnaire the purpose of which is to enable them to determine whether or not it is necessary or expedient to undertake a visit for the purposes of:

    - ascertaining whether or not the contractor is complying with the Terms of Service set out in Schedule 4
    - auditing, monitoring and analysing the contractor's provision for patient care and treatment, including any arrangement made in respect of the provision of appliances
    - auditing, monitoring and analysing the management of the pharmaceutical services that the contractor is providing.

16. The questionnaire is to be provided via an electronic communication and will be in a format approved by the commissioner. Before requesting the information, the commissioner must consult with PSNC on the terms of the request.

17. A screening questionnaire was introduced by NHS England for the purposes of monitoring compliance with the Terms of Service set out in Schedule 4. All contractors are asked to complete it and, from the responses, the commissioner will then identify which contractors are to be asked to complete the full Community Pharmacy Assurance Framework (CPAF).

18. Completion of both the screening questionnaire and CPAF has been encouraged by PSNC as a way for contractors to demonstrate that they are meeting the Terms of Service.

19. Since 9 November 2020, completion of the screening questionnaire has been mandatory for all contractors in relation to each of their pharmacy premises. Where contractors are asked to complete the CPAF, this is also mandatory. Any replacement for, or future versions of, either document will be discussed and agreed with PSNC in advance of being rolled out nationally and therefore will fall within the provisions of paragraph 35(5), Schedule 4.

20. Contractors must therefore ensure they comply with any request to complete either the screening questionnaire or the CPAF (or their replacements) to comply with the

Terms of Service. Requests will be made using the premises-specific NHSmail account.

Pre-screening questionnaire and completion of the community pharmacy assurance framework

21. The commissioner will monitor contractors against their Terms of Service based on the CPAF.

22. Each year the NHSBSA, on behalf of the commissioner will send a request to each pharmacy to complete a screening questionnaire, which is a condensed version of the CPAF.

23. Contractors will be given a minimum of four weeks to complete the questionnaire, which is facilitated by the NHSBSA.

24. 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.

25. The commissioner, 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.

26. 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 the commissioner via the NHSBSA information services portal within one month of the closure of the questionnaire.

27. The data collected from this questionnaire along with other information held by the commissioner 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 the commissioner has received the results of the full CPAF questionnaire they will then consider whether to follow up with a contract monitoring visit.

28. The commissioner will arrange visits to 1–2% of pharmacies that indicated they are compliant with the requirements referred to in the screening questionnaire to validate the answers and observe good practice. These could be face-to-face or virtual visits.

29. If concerns are identified or no CPAF return is submitted by a contractor, refer the case to committee for further action to be taken.

30. The commissioner will draw up a list of pharmacies that it considers may require a contract monitoring visit using the criteria in paragraph 37 below. All contractors who failed to submit a pre-screening questionnaire must be included in this list to ensure they are required to complete a CPAF return, regardless of other action taken against them for failure to submit the questionnaire. 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 bodies corporate, 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.

31. The NHSBSA will advise each pharmacy that has been selected to complete the full CPAF pre visit questionnaire. Contractors will be given four weeks to complete the questionnaire, which is facilitated by the NHSBSA.

32. 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 the commissioner via the NHSBSA information services portal within one month of the closure of the questionnaire. They will be reviewed by the commissioner 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.

33. 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 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).

34. 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, the NHSBSA will advise the contractor.

35. 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 the commissioner is proposing to take (and therefore able to attend any visit should they so wish).

Contract monitoring visits

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

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

37. Not all pharmacies will receive a visit each financial year (1 April to 31 March) as the commissioner has adopted a risk-based approach to visits. Once the CPAF screening questionnaires have been submitted 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 CPAF 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 that 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 the commissioner, the provider assurance team or from other NHSBSA data

- concerns relating to patient safety, complaints, adverse NHS website comments and other miscellaneous concerns (irrespective of the score for the screening questionnaire).

38. 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.

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

40. 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.

41. The commissioner representatives should not ask to see patient identifiable records. They may, however, observe the dispensing process during the visit (without intruding on patient confidentiality) to see that records are being made.

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

43. The commissioner's representatives may ask to see patient identifiable records for the purposes of monitoring compliance with the Terms of Service for those advanced services that require patient consent to be gained. In this instance, as the patient has given consent to the pharmacy to share information with the commissioner, pharmacies will not be required to make any information anonymous before it is produced to the commissioner. Only those records for which the pharmacy can produce the patient's written consent can be viewed.

44. The following procedure should be followed for contract monitoring visits.

	Action
1.	If a contractor is to be visited, contact the contractor to arrange a date for the monitoring visit and complete and send Annex 1 once the date is agreed.

	The contractor may wish to invite a representative of the relevant LPC to attend.
2.	If the contractor fails or refuses to agree a date and time for the visit, refer the matter to the committee for consideration as to what action is to be taken.
3.	Ensure that the commissioner's representatives who will undertake the visit have copies of the relevant CPAF documents and other information at least five working days before the visit.
4.	At the visit, the commissioner's representatives will identify themselves as attending on behalf of the commissioner and show their identity badge. The commissioner's representatives must make every effort during the visit to ensure the provision of pharmaceutical services is not interrupted. The commissioner's representatives must not enter any part of the pharmacy premises that is solely used as residential accommodation.
6.	Ensure that accurate records are taken at the visit, particularly where actions and timescales are agreed with the contractor. Advise the contractor that a copy of the visit report will be sent to them for review and signature.
7.	If any of the following are identified, refer the matter immediately to the committee: • patient safety issues • the commissioner is at risk of material financial loss, and/or • possible fraudulent or criminal activity. Where no such issues are identified, complete the visit report (Annex 2) within 15 working days of the visit and send a copy to the contractor giving them 10 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.
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 committee.
9.	If a contractor submits evidence that they have completed an agreed action, send Annex 3. Once a contractor has completed all the required actions, send Annex 4.
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.

NMS quarterly data

45. NMS is an advanced service within the Community Pharmacy Contractual Framework. Pharmacy contractors providing the service are required by the Directions to maintain records of the consultations. When requested, pharmacy

contractors must provide information on the NMS interventions undertaken in the previous quarter to the commissioner.

46. NHS England has previously requested that this data is provided on an ongoing basis and pharmacies must therefore complete the nationally agreed electronic reporting template with details of the NMS conducted in that quarter, using data collated from pharmacy records. This request continues where the commissioning of pharmaceutical services is delegated to an ICB or ICBs.

47. The NHSBSA now administers the collection of NMS information from pharmacy contractors on behalf of the commissioner. Pharmacy contractors therefore need to submit their quarterly NMS data to the NHSBSA rather than emailing the report to the commissioner. If a contractor normally provides 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.

48. Pharmacy contractors must submit their 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.

49. NHSBSA will send reminders to contractors and will advise the commissioner which have not submitted a return for that quarter.

Failures to open

50. 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.

51. In these circumstances, the Terms of Service require that the contractor notifies the commissioner of this temporary suspension and uses all reasonable endeavours to resume service provision as soon as is practicable. In addition, the contractor must ensure that they update their NHS website and DoS profiles using the NHS Profile Manager to show that the premises are closed.

52. If a contractor does this, they are not in breach of their Terms of Service unless the commissioner determines that the reason for the temporary suspension was within the control of the contractor.

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

	Action
1.	When advised that premises are not open, check to see if any notification has been received from the contractor. Where a notification has been received, go to step 2 Where the notification has not been received, go to step 5.
2.	Where a notification has been received, the temporary suspension of service provision should be recorded.
3.	Check to see if any previous notifications of temporary suspensions for the premises were recorded. If there were, see whether there is a pattern of failing to open. If none is found, no further action is required. Where there is a pattern, write to the contractor asking for their comments.
4.	Review the comments and escalate the matter to Stage 1 of the procedure relating to managing performance.
5.	Where no notification has been received, send Annex 5 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 (eg the cause was outside the control of the contractor such as utilities interruption, minor flooding), send Annex 6. Record the failure to open.
8.	Where there is no good cause for the temporary suspension (eg 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 7 to the contractor and refer the matter to the committee to decide what further action to take under Stage 2 of the procedure relating to managing performance.

Monitoring opening hours

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

Procedure relating to managing performance

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

- through analysis of data from the 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.

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

57. Concerns regarding the contractor's fitness to practise should be dealt with in line with Chapter 31.

58. The Regulations contain performance related sanctions that may be used where a contractor is not complying with their Terms of Service. The committee 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.

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

60. Further information, examples and suggested approaches are set out in the DHSC guidance document[14] entitled 'Regulations under the Health and Social Care Act 2012: performance sanctions including market exit for contractors providing pharmaceutical services'.

61. 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, eg where there are patient safety issues.

What constitutes a contractual breach?

62. 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

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

agreement. The commissioner does not hold a separate written contract with pharmacy contractors or DACs but a contractual relationship exists from the point 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

63. Where a contractor breaches a term of service and the breach is capable of remedy, the commissioner will issue a remedial notice requiring the contractor to remedy the breach. Examples of breaches that are capable of remedy include:

- lack of SOPs that are required by the Terms of Service
- failure to appoint a clinical governance lead.

64. The remedial notice will include:

- the nature of the breach, including the relevant regulatory reference
- the steps the contractor must take, to the commissioner's satisfaction, to remedy the breach
- the timescale during which the required steps are to be completed
- an explanation of how the contractor may exercise their right of appeal to NHS Resolution.

65. The timescale for completion of the required action or actions will be at least 30 days after sending the notice (unless the commissioner is satisfied that a shorter period is appropriate on patient safety grounds or to protect the commissioner from material financial loss).

Examples of contractual breaches which cannot be remedied

66. Where a contractor breaches a term of service and the breach is not capable of remedy, the commissioner 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.

67. The breach notice will include:

    - the nature of the breach, including reference to any relevant regulation
    - an explanation of how the contractor may exercise their right of appeal to NHS Resolution.

Rescinding breach and remedial notices

68. The commissioner 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 the commissioner cannot rescind it.

69. Where the committee decides that it is appropriate to rescind a breach or remedial notice, the reasoning for this must be fully documented.

Stages of performance management

70. 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.

71. If there are concerns about potentially criminal behaviour, refer the matter to the medical director at the ICB (if delegated to commission pharmaceutical services) and the relevant NHS England medical director. Any further action to be taken under this procedure will be guided by their advice.

72. Throughout the process remind the contractor that they may involve their LPC if they so wish.

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

	Action
1.	**Stage 1 – identification or notification of potential breaches** Where there is no evidence of fraud or criminal activity, contact the contractor and ask them to explain what has or, as the case may be, hasn't happened. It is important to establish whether or not there has been a breach of the Terms of Service and whether there was good cause for it.

2.	On receipt of the contractor's response: • where there is no breach of Terms of Service, the matter is to be closed. Advise the contractor and update the relevant file. • where there is a breach of the Terms of Service, go to step 3.
3.	Where there is a breach of the Terms of Service assess whether there is any risk to patient safety or whether the commissioner is at risk of significant material financial loss. Where there are such risks escalate the matter to Stage 2 and refer it to the committee. Where there are no such risks, go to step 4.
4.	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 the commissioner and contractor. One approach to resolving disputes informally is to develop and agree an action plan with the contractor to address the issue. Timescales for addressing the issue will depend on the nature of the issue but would normally be 30 days. Examples of situations in which it is appropriate to agree an action plan include: • failure to have an up-to-date practice leaflet • failure to complete the required audits • failure to submit the required paperwork in advance of commencing provision of an advanced service • failure to complete the community pharmacy patient questionnaire. Monitor the contractor's actions and when all actions are complete, confirm to the contractor that the matter is now closed but will remain on file. Update the relevant file. No further action is to be taken.
5.	If the contractor is unable to complete the action plan within the required timescale and has good cause for this, then one extension may be agreed with them. For example, an extension may be appropriate if an order for updated practice leaflets was placed in a timely manner but the printer was late delivering them. At the end of the extended timescale, if the action plan is completed, write to the contractor confirming that the matter is now closed but will remain on file. Update the committee (for information only) and the relevant file. No further action is to be taken.
6.	If the action plan is not completed within the extended timescale, escalate the matter to Stage 2 and refer it to the committee .
7.	If no action plan can be agreed with the contractor, escalate the matter to Stage 2 and refer it to the committee.

8.	**Stage 2 – local dispute resolution** Where a matter is escalated to or reaches Stage 2 of the process, the decision-maker will review the case and determine whether local dispute resolution should be undertaken and if so, by whom. 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.
9.	The aim of local dispute resolution is to reach agreement on whether or not the contractor is in breach of any Term of Service and to agree how the contractor will ensure the breach is either remedied or not repeated. When deciding whether local dispute resolution is to be undertaken, the decision-maker will have regard to the matters specified in Regulation 69(3) of the Regulations. The matter should be escalated directly to Stage 3 if: • the matter has already been the subject of local dispute resolution and there are no new issues of substance that would delay escalation • the premises are not, or have not been, open during core or supplementary hours without good cause, • it is necessary to protect the safety of persons who may receive services from the contractor, or • it is necessary to protect the commissioner from material financial loss. Decisions will be fully minuted and reasoned.
10.	Write to advise the contractor that local dispute resolution under Regulation 69 is taking place, and tell them who will represent the commissioner. Local dispute resolution can be conducted through: • regular telephone communications • face-to-face meetings at a mutually convenient location, and/or • written communications. Respond to the contractor's concerns and communications in a timely and reasonable manner. Ensure every reasonable effort to communicate and co-operate is made. Letters that are sent by 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. Maintain accurate and complete written records of all discussions and correspondence on the contract file. If local dispute resolution is successful, write to the contractor confirming that the matter is now closed but will remain on their file. Update the relevant file and advise the outcome to the committee. No further action is to be taken.

11.	If local dispute resolution is not successful, refer the matter back to the decision-maker for escalation to Stage 3.
12.	**Stage 3 – notices and withholding payments** Where a matter is escalated to or reaches Stage 3 of the process, the decision-maker will review the case and decide whether a breach and/or remedial notice or notices are to be issued and whether any payments are to be withheld. When deciding what steps to take, the committee may take into account previous relevant proven breaches of Terms of Service and action taken about them. Based on the contractor's history and previous use of performance related sanctions by either NHS England, a delegated ICB or a primary care trust, the matter may be escalated straight to Stage 4.
13.	A notice or notices will be issued where the contractor is in breach of their Terms of Service and there is no good cause for the breach. If the matter was escalated straight to this stage for one of the reasons set out in action 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.
14.	Where the committee is considering whether or not to issue a breach or remedial notice, it will also consider whether or not to withhold payment of fees and allowances. It is not permissible to withhold payments in the absence of a breach or remedial notice. Payments can be withheld where: • the breach relates to a failure to provide, or a failure to provide to a reasonable standard, a service that the contractor is required to provide • the committee is satisfied that the breach the withholding relates to is, or was, without good cause, and • the amount to be withheld is justifiable and proportionate having regard to the nature and seriousness of the breach and the reasons for it. All decisions to withhold payments will be fully minuted and reasoned.
15.	Following the committee meeting, draft a letter based on the minutes of the meeting. Complete Annex 8 and/or 9 where relevant and send to the contractor. If payments are to be withheld, complete that section of the relevant notice. If payments are not to be withheld, then this section can be deleted. A copy of any notice served should also be sent to the pharmacy contract manager at other regional teams where the contractor has premises (where this information is known).
16.	Where a remedial notice is issued, diarise the date for completion of the required action.
17.	Acknowledge receipt of confirmation from the contractor that the required steps were undertaken and ensure they have been completed by the required date or within the required timescale.
18.	Where all the required steps were satisfactorily completed write to the contractor to confirm that the matter is now closed but will remain on file.

	Update the relevant file and advise the outcome to the committee. 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 committee 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 committee 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 committee.
23.	Where they have are not been satisfactorily completed, refuse the claim and send Annex 10 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 will review the case and decide whether removal is justifiable and proportionate having regard to the nature and seriousness of the breach or breaches and the reason (if known) for it or them. The pharmacy contract manager at other regional teams where the contractor has premises (where this information is known) should be informed of the removal.
26.	If the committee determines that removal is not justifiable or proportionate, then the matter is to be referred back to Stage 3.
27.	If the committee determines that removal may be justifiable and proportionate, arrange an oral hearing to give the contractor the opportunity to make oral representations should they so wish and write to them advising of the proposed action and offering the opportunity to make written or oral representations. At least 30 days' notice is to be given. Consult with the LPC in whose area the contractor's premises are located.

28.	Following consideration of the written and/or oral representations by the decision-maker, send Annex 11 or 12 to the contractor as relevant.
29.	If notice of an appeal against removal is received, advise the committee and assist in producing a response.
30.	Once the outcome of the appeal is known and it is confirmed that the decision to remove is upheld: • send Annex 13 to the contractor • advise the NHSBSA of the closure using the relevant for • update the relevant pharmaceutical list.
31.	Update other databases as appropriate and inform the usual parties, which include the relevant: • LPC • HWB • GPhC • DoS lead • registration authority • 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) • CDAO • OOH provider • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager • organisation that cascades safety alerts • 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 committee 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
Stage 1: Concern(s) identified by, or reported to, the commissioner.	Informal resolution with the contractor. An action plan will be agreed where non-compliance is identified along with a timescale for completion.	• There are patient safety concerns. • The commissioner is at risk of material financial loss. • The contractor fails to complete the action plan. • The contractor fails to engage with the commissioner.
Stage 2: Informal resolution is unsuccessful or it is necessary to omit Stage 1 to protect: • the safety of persons who may receive services from the contractor, or • the commissioner from material financial loss.	Matter referred to the committee for discussion on what action to take. Options include: • agreeing a further action plan, or • undertaking local dispute resolution in line with Regulation 69 of the 2013 Regulations.	• Where the matter has already been the subject of local dispute resolution and there are no new issues of substance that would justify a delay in escalation. • The premises are not, or have not been, open during core or supplementary hours without good cause. • It is necessary to protect the safety of persons who may receive services from the contractor. • It is necessary to protect the commissioner from material financial loss.

Stage	Intervention likely to occur	Escalation to another stage
Stage 3: Local dispute resolution has either failed to resolve the issue or is not appropriate due to patient safety or material financial loss grounds.	Matter referred to the committee for discussion as to what further action may be taken. Options available include: • issuing breach or remedial notice/notices and withholding payments, and • stopping the provision of advanced services where the contractor is failing to comply with their Terms of Service as set out in the 2013 Regulations.	• The contractor has failed to comply with a previously issued remedial notice. • The contractor has been issued with repeated remedial and/or breach notices in relation to the same term of service. • The contractor has previously been issued with a remedial or breach notice in relation to the same term of service and the committee 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 committee is satisfied the contractor is likely to persist in breaching the Terms of Service without good cause.
Stage 4: Removal from the relevant pharmaceutical list.	Removal of the premises to which the breach or breaches related from the pharmaceutical list. Removal must be justifiable and proportionate having regard to the nature and seriousness of the breaches (or likely breaches) and the reasons for them.	• Not applicable.

Chapter 38: Market exit, administration, bankruptcy and liquidation

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
    - closing premises without first giving notice
    - a contractor and a specified premises being removed following use of the performance related sanctions or fitness powers, or
    - entering administration, bankruptcy or liquidation.

2. It should be read in conjunction with Chapters 31 and 37 of the manual (use of fitness powers in relation to contractors, and monitoring compliance and managing performance). It is to be noted that this chapter does not cover the termination of a LPS contract. In that scenario the termination requirements set out in the contract are to be followed, although elements of this chapter will be applicable.

3. It also sets out what is to be done when a body corporate included in a pharmaceutical list or lists enters administration.

Background – withdrawal from a pharmaceutical list

4. 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
    - dispensing appliance contractors – at least three months.

5. However, Regulation 67 of the Regulations states that where it is impracticable for the contractor to give the required notice period, they must notify the commissioner as soon as it is practicable to do so. In addition, the commissioner can agree to a shorter notice period.

6. 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 commissioner in whose area the premises are located.

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

7. 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.

8. Where a contractor is to be removed following a notice of withdrawal but the committee (or, until 1 April 2023, 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

    the commissioner 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

9. On receipt of a notice of withdrawal from a pharmaceutical list, check that the required notice period has been given. Where it hasn't, go to the next section of this chapter.

10. Send Annex 2 to the contractor and brief the communications team.

11. Add the closure to the agenda of the next committee meeting.

12. Send Annex 3 to the following persons.

    - ICB if it is not delegated to commission pharmaceutical services
    - public health team at the relevant local authority
    - HWB
    - LPC and LMs
    - DoS lead

- registration authority
- local GP practices (possibly using data published by NHSBSA to identify where prescriptions dispensed at the premises come from)
- CDAO
- OOH provider
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

13. The above must be notified. The commissioner is free to notify other relevant persons. Such persons may include:

    - Healthwatch
    - Health Overview and Scrutiny Committee (HOSC)
    - local GPhC inspector
    - parish councils if applicable, and/or local city/district/county councillors
    - local MP.

14. Contact the company which collects and disposes of unwanted medicines and ask them to liaise with the contractor to arrange a final collection.

15. Ensure the contractor provides confirmation that the actions set out in Annex 2 have been completed. Where these aren't received, follow this up with the contractor.

16. One week before the closure date:

    - complete and submit the relevant NHSBSA form[15]
    - notify the relevant DoS lead of the closure date.

17. There may be occasion where a contractor wishes to withdraw their notice of withdrawal. While Regulation 75(4) and (5) states that the commissioner must remove the premises from the relevant pharmaceutical list (and the contractor if they only have one premises included in that list), Regulation 75(6) does allow the commissioner to decide not to remove the premises (and the contractor).

18. Where a contractor wishes to withdraw their notice of withdrawal, this request is to be passed to the committee to make a decision as to whether or not to agree to the request. Such requests cannot be made after the date given in the notice of

[15] https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/organisation-and- prescriber-changes/area-teams

withdrawal. Annex 4 is to be completed and sent if the request is agreed to; Annex 5 if it is refused.

19. If the committee agrees to the request a further memo will need to be sent to the above persons.

20. The commissioner 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 the commissioner 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.

21. On the day after the closure date, update the relevant pharmaceutical list, any other local databases, any other commissioners who may need to know, and send Annex 6 to those persons listed in paragraph 12 above and any other persons who were notified under paragraph 13 above. Send Annex 7 to the contractor.

Closure where the required notice period has not been given

22. Where a contractor fails to give the required notice period pass this to the committee 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 8 to the contractor.

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

24. The actions in paragraphs 9 to 15 above will need to be completed as far as possible, with the time periods shortened as necessary.

25. If the contractor successfully asks to withdraw 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 11 and 12 above.

26. On the day after the closure date, update the relevant pharmaceutical list and send Annex 6 to those persons listed in paragraph 11 and 12 above. Send Annex 7 to the contractor.

Removal where no notice has been given

27. There may be instances where the commissioner becomes aware that a contractor has closed premises without giving any period of notice. Should that occur the commissioner's 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.

28. Where the contractor confirms that it is a temporary closure, refer to Chapter 36 and go no further with this chapter.

29. Where the contractor confirms that it is a permanent closure, Annex 9 is to be sent as a matter of urgency by the commissioner to the following:

- ICB if it is not delegated to commission pharmaceutical services
- DoS lead
- local GP practices (using data published by NHSBSA[16] 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
- LPC and LMC
- registration authority
- CDAO
- OOH provider
- public health team at the relevant local authority
- HWB

[16] https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/dispensing-contractors-data

- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

30. Consideration should be given as to whether there are any other persons to be notified of the closure in line with paragraph 12 above.

31. Complete and submit the relevant NHSBSA form.[17]

32. Where the contractor cannot be contacted, Annex 10 is to be sent by the commissioner as a matter of urgency to the following:

    - DoS lead
    - ICB if it is not delegated to commission pharmaceutical services
    - 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
    - LPC and LMC
    - registration authority
    - CDAO
    - OOH provider
    - public health team at the relevant local authority,
    - HWB
    - primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

33. Consideration should be given as to whether there are any other persons to be notified of the closure in line with paragraph 12 above.

34. The commissioner 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.

[17] https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/organisation-and- prescriber-changes/area-teams

Removal from a pharmaceutical list on fitness grounds

35. Where the commissioner decides to remove a contractor and their premises from a pharmaceutical list on fitness grounds, this decision takes effect at the end of the 28-day appeal period, or once any appeal is heard and the decision to remove is upheld.

36. As the commissioner will not know whether or not the contractor will appeal the decision, nor the outcome of any appeal, it will need to start the process outlined in this chapter but be prepared to stop it if an appeal is made.

37. Until 1 April 2023, where fitness decisions are made by the PLDP rather than the committee, NHS England and the delegated ICB will need to liaise with each other so that the process in this chapter can be started once the decision to remove on fitness grounds letter has been sent.

38. Send Annex 11 to the contractor and brief the communications team.

39. Add the closure to the agenda of the next committee meeting if the decision to remove on fitness grounds was made by the PLDP.

40. Contact the company that collects and disposes of unwanted medicines and ask them to liaise with the contractor to arrange a final collection.

41. Ensure the contractor provides confirmation that the actions set out in Annex 11 have been completed. Where these aren't received, follow this up with the contractor.

42. If the contractor does not appeal the decision, then it takes effect on day 29 after the decision was notified to them.

43. One week before the closure date:

    - complete and submit the relevant NHSBSA form[18]
    - notify the relevant DoS lead of the closure date.

44. On the day after the closure date, update the relevant pharmaceutical list, any other local databases, and send Annex 6 to those persons listed in paragraph 11 above and any other persons who were notified under paragraph 12 above. Send Annex 12 to the contractor.

[18] https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/organisation-and- prescriber-changes/area-teams

45. If the contractor appeals the decision the process stops. However, if the decision to remove is upheld on appeal, then as soon as the decision letter is received the contractor and their premises are to be removed from the relevant pharmaceutical list.

46. In this instance, complete and submit the relevant NHSBSA form and notify the relevant DoS lead of the closure date immediately. Send Annex 6 to those persons listed in paragraphs 11 and 12 as soon as possible and liaise with the contractor to ensure that the actions required in Annex 11 are completed where possible, or where they are still relevant.

47. Update the relevant pharmaceutical list or lists if the contractor is being removed from more than one list.

Removal from a pharmaceutical list following use of the performance related sanctions

48. Where the commissioner decides to remove the premises of a contractor from the relevant pharmaceutical list following use of the performance related sanctions, this decision takes effect at the end of the 30-day appeal period, or once any appeal is heard and the decision to remove is upheld.

49. As the commissioner will not know whether or not the contractor will appeal the decision, nor the outcome of any appeal, it will need to start the process outlined in the chapter but be prepared to stop it if an appeal is made.

50. Send Annex 13 to the contractor and brief the communications team.

51. Contact the company that collects and disposes of unwanted medicines and ask them to liaise with the contractor to arrange a final collection.

52. Ensure the contractor provides confirmation that the actions set out in Annex 13 have been completed. Where these aren’t received follow this up with the contractor.

53. If the contractor does not appeal the decision, then it takes effect on day 31 after the decision was notified to them.

54. One week before the closure date:

- complete and submit the relevant NHSBSA form[19]
- notify the relevant DoS lead of the closure date.

55. On the day after the closure date, update the relevant pharmaceutical list, any other local databases, and send Annex 6 to those persons listed in paragraph 11 above and any other persons who were notified under paragraph 12 above. Send Annex 14 to the contractor.

56. If the contractor appeals the decision, the process stops. However, if the decision to remove is upheld on appeal, then as soon as the decision letter is received the premises are to be removed from the relevant pharmaceutical list.

57. In this instance, complete and submit the relevant NHSBSA form and notify the relevant DoS lead of the closure date immediately. Send Annex 6 to those persons listed in paragraphs 11 and 12 as soon as possible and liaise with the contractor to ensure that the actions required in Annex 13 are completed where possible, or where they are still relevant.

58. Update the relevant pharmaceutical list.

EPS nominations and changes of ownership or consolidation

59. 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 Digital.[20]

60. 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.

61. 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

[19] https://www.nhsbsa.nhs.uk/ccgs-area-teams-and-other-providers/organisation-and- prescriber-changes/area-teams
[20] https://digital.nhs.uk/services/electronic-prescription-service/nominating-a-dispenser

their nominated contractor must be given appropriate assistance to remove the nomination.

62. 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.

EPS nominations and closures

63. 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. There is no provision within the Regulations for nominations to be transferred to another of the contractor's premises in this scenario.

Entering administration

Background

64. There may be instances where a company that is included in a pharmaceutical list or pharmaceutical lists held by NHS England or a delegated ICB enters administration. The company could be operating as a pharmacy or a dispensing appliance contractor.

65. Going into administration means that the company has entered a legal process set out in the Insolvency Act 1986 (the 1986 Act). An administrator, a licensed insolvency practitioner, is appointed by the directors of the company, a creditor or the court and their purpose is to fulfill the administration process as described in the 1986 Act.

66. Schedule B1 the 1986 Act defines a number of terms. A company:

- is 'in administration' while the appointment of an administrator of the company has effect
- 'enters administration' when the appointment of an administrator takes effect
- ceases to be in administration when the appointment of an administrator of the company ceases to have effect under Schedule B1 of the 1986 Act
- does not cease to be in administration merely because an administrator vacates office (eg they resign, die or otherwise) or is removed from office.

67. For the purposes of the 2013 Regulations and this manual, the same definitions are adopted.

68. Under paragraph 3, Schedule B1 of the 1986 Act, options available to the administrator are:

- rescuing the company as a going concern, eg selling the business to an unrelated party
- achieving a better result for the company's creditors as a whole than would be likely if the company was wound up (without first being in administration), eg allowing the company to continue to trade for a period while seeking a sale of the business or assets such as equipment
- realising property to make a distribution to one of more secured or preferential creditors.

69. They are required to perform their functions as quickly and efficiently as is reasonably practicable. It should be noted that administrators have a duty to perform their functions with regards to the interest of the business's creditors as a whole. There is no duty to act in the interests of patients or the NHS.

70. The Companies House website describes administration as providing a company with a breathing space, freeing it from creditor enforcement actions while financial restructuring plans are prepared to rescue the company as a going concern where possible.

71. Once in administration the company can continue to trade but rather than being run by the directors, the administrator is responsible for the daily management and control of the company.

72. Administration will end automatically after 12 months unless the administrator asks the court or creditors for an extension.

73. Potential outcomes are the company:

- is rescued and is passed back to the directors
- goes into liquidation
- is dissolved if the administrator was only able to distribute funds to the secured and/or preferential creditors.

74. Under Section 72 of the Medicines Act 1968, a representative can be appointed to carry on a retail pharmacy business in certain circumstances and as along as certain actions are taken.

Notifying the commissioner

75. From 9 November 2020 if a company that is included in a pharmaceutical list, or pharmaceutical lists, enters administration it must notify the commissioner of that fact. For the avoidance of doubt, 'enters administration' is the date on which the appointment of an administrator takes effect.

76. A form has been developed for this purpose (Annex 15). It is to be completed on the date on which the appointment of the administrator takes effect and submitted to the the commissioner in whose area the premises are located.

77. Companies are required to submit separate forms for each of their premises that are included in a pharmaceutical list. It is not possible to include more than one set of premises on the form.

78. Under Section 72 of the Medicines Act 1968, the GPhC is also to be notified, but that is a matter for the company and/or the administrator and is not for the commissioner to monitor or be involved in.

Next steps

79. If the commissioner receives notification of administration, its next steps will depend on the nature and circumstances of the administration.

80. From the commissioner's perspective, the administrator will be the main point of contact for the company and the commissioner will need to maintain contact with the administrator at all stages rather than the company that is included in the relevant pharmaceutical list or lists. It is for that reason that contractors must notify the commissioner when they enter administration.

81. There is no provision within the 2013 Regulations that enables the commissioner to immediately remove a company and its premises from the relevant pharmaceutical list or lists when it enters administration.

82. On receipt of a notification that a company has gone into administration, the commissioner is to make contact with the administrator to determine whether they intend that the company will continue to trade.

    - If the intention is to continue to trade (which may include an intention to sell the business), the commissioner should carefully consider if the administration raises any patient safety concerns and, if reasonable and appropriate, take any necessary action, which may include suspension of the company from the

relevant pharmaceutical list or lists while it decides whether or not to remove or contingently remove the company from that list or lists on fitness grounds. If a change of ownership application is (or applications are) received, then this (they) should be signed by the administrator as the representative of the company that currently owns the premises listed in the application or applications. If it is not signed by the administrator, then this should be brought to their attention and the application should only be processed with the administrator's written authority.

- Where the company ceases to trade, the administrator is required to give notice of the withdrawal from the relevant pharmaceutical list or lists, although they may be of the opinion that it is impracticable to give the required notice period. See earlier in this chapter for steps to take if this happens.
- If the administrator indicates that the intention is to cease to trade, the commissioner should consider any practical implications of imminent closure, such as liaising with the administrator on undispensed prescriptions and safe and lawful arrangements in respect of controlled drugs in the same way as it would if a contractor gave notice to withdraw premises from a pharmaceutical list. See earlier in this chapter for steps to take if this happens.

83. Regardless of whether the intention is to continue to trade, if the company owes the commissioner money, eg there has been an overpayment and the commissioner has made a decision to recover the amount, and either the 30-day appeal has ended with no appeal or any appeal has been dismissed, then if the money cannot be deducted from any amount owed to the company the commissioner will need to submit details and evidence of the claim to the administrators for assessment.

84. Regardless of whether the intention is to continue to trade, any money owed to the company will be expected by the administrator to be paid. The commissioner should not therefore automatically prevent payments being made to the company (eg payments to be made by the NHSBSA for dispensing or other activity relating to the period immediately prior to the administration) simply on the basis of the company having entered administration. There may be other reasons why the commissioner might seek to withhold payment and legal advice should be sought on this.

Bankruptcy

85. As noted in the previous sections, the Regulations require a body corporate entering administration to notify the commissioner but pharmacies may be run as partnerships or by sole traders and in the event of insolvency may be subject to bankruptcy

proceedings rather than administration. The Regulations do not require a sole trader or partnership to notify the commissioner in the event of bankruptcy and in this situation the commissioner has no powers to remove the sole trader or partnership from the relevant pharmaceutical list or lists.

86. Where a sole trader or partnership is subject to bankruptcy, a trustee in bankruptcy will be appointed. The contractor is required to provide the GPhC with the trustee's details in accordance with section 72(2)(a) of the Medicines Act 1968. There is, however, no parallel requirement to notify the commissioner of the same. It is possible that the pharmacist, the trustee or the GPhC may notify the commissioner. The GPhC may explore the impact of the bankruptcy on the contractor's compliance with the GPhC's standards.

87. In the event the commissioner is notified of the bankruptcy of a sole trader or partnership by either the contractor, the trustee or GPhC, it would be appropriate for the commissioner to follow the same procedure as it would if it had been notified of administration, as detailed in the section above.

Liquidation

88. As with bankruptcy there is no requirement in the Regulations for a body corporate to notify the commissioner if it enters liquidation, which is often referred to as 'winding up'. Unlike administration or bankruptcy, which have the aim of rescue and recovery, in liquidation the assets of the body corporate are realised and the body corporate is dissolved. If a body corporate enters liquidation, the commissioner has no powers within the Regulations to remove the body corporate from the relevant pharmaceutical list or lists.

89. When a body corporate enters liquidation, an insolvency practitioner will be appointed as the liquidator. As the role of the liquidator is to wind up the body corporate, the liquidator does not become a 'representative' of the contractor as defined in section 69(1) of the Medicines Act 1968.

90. In the event the commissioner is notified of the liquidation by either the contractor, the liquidator or the GPhC, it would be appropriate for the commissioner to follow the same procedure as it would if it had been notified of administration, as detailed in an earlier section above.

Chapter 39: Pharmaceutical services finance

Chapter aims and objectives

1. This chapter deals with pharmaceutical services finance. It should be read alongside the Drug Tariff[21] 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)
    - remuneration for the provision of services provided.

3. The retained medicines margin (£800 million nationally as of November 2022) contributes to the amount paid for service provision (remuneration) but it is delivered via the reimbursement of items that have been dispensed. The prices of 'Category M drugs' are adjusted in-year to seek to ensure the margin is delivered to contractors. There are over 500 Category M drugs listed in Part VIIIA of the Drug Tariff.

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. In 2022/23 and 2023/24, that figure is £2.592 billion. This is then delivered to pharmacies via the fees and allowances set out in the Drug Tariff and the retained medicines margin. During and 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 current or the following financial year. The reimbursement prices for Category M drugs may be adjusted to ensure the retained medicines margin is delivered or, where excess margin has been retained, recovered. Payments for remuneration made under LPS contracts are not included in this calculation as LPS contracts are funded separately from the £2.592 billion.

6. The commissioner is therefore not permitted to make savings on the nationally set fees and allowances.

[21] https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff

7. The commissioner 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.

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 the Drug Tariff and the Directions

10. Unlike for other primary care contractors, the commissioner does not have discretionary powers to make payments to pharmacies or DACs outside the Drug Tariff and the Directions. The commissioner therefore cannot authorise requests for payments from contractors relating to essential and advanced services where errors have been made in claims submissions. Finance teams are to be made 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 contactors for these services requires the commissioner 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 seventh 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 claim[22] to NHS England at the start of the training period. Claims are to be sent to the regional team in whose area the contractor's premises are located and not to the relevant delegated ICB as this is a reserved function.

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 that 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 regional team immediately in writing. In this instance the regional team is to 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 set out in Regulation 94.

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. The regional team 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.

Recharge of payments

20. 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.

21. 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

[22] https://psnc.org.uk/funding-and-reimbursement/pharmacy-funding/funding-distribution/pre-registration-training-grant/

Medical Services Statement of Financial Entitlements Directions 2013. This information is then passed to the relevant commissioner who then pays the practice.

22. With regard to the payments to pharmacies and DACs, these are then recharged by NHS Prescription Services to the commissioner, and may also recharge some costs to local authorities and hospitals. Further information on how costs are recharged can be found in the NHS and LA Reforms Factsheet 4[23] produced by NHS Prescription Services. It will be updated in 2022/23 to reflect the introduction of ICBs.

23. Where an ICB is delegated to commission pharmaceutical services it will be recharged the costs of those services. NHS England has issued separate finance and payments guidance to ICBs with regard to how payments are recharged to them. NHS England has described payment and recharge processes in supplementary finance and payments guidance, available via finance colleagues in NHS England regions and ICB-led systems.

24. Where ICBs are not delegated to commission pharmaceutical services, those payments that are recharged to NHS England are allocated to regional teams as set out in the separate finance and payments guidance (see paragraph 23 above).

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

$$\frac{\text{Total of professional fees directly attributable to the relevant regional team or delegated ICB}}{\text{Total professional fees for all prescriptions dispensed as part of pharmaceutical services}}$$

26. The one exception to this are the fees relating to the provision of AUR.

Withholding of payments

27. Alongside the issuing of a breach or remedial notice, the commissioner 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 committee is satisfied that the breach to which the withholding relates is, or was, without good cause

[23] https://www.nhsbsa.nhs.uk/sicbls-icbs-and-other-providers/nhs-and-local-authority-reforms

- 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 committee 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, the commissioner will make every reasonable effort to communicate with the contractor to discover the reasons for the breach. However, if the contractor fails to respond or provides an inadequate response, the commissioner 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 guidance.[24]

Recovery of overpayments

31. Regulation 94 of the Regulations makes provision for the recovery of overpayments. It is to be noted that this provision is not a performance related sanction and is different to the ability to withhold payments alongside the issuing of a breach or remedial notice, or both. An overpayment is where a contractor has received payment of a fee or allowance that it was not entitled to and is therefore to be repaid. This could, for example, be where a pharmacy contractor has claimed and been reimbursed for out of pocket expenses and it is subsequently discovered that the claim did not meet the requirements of the Drug Tariff. In that instance the payment would be recovered under Regulation 94 following the process set out below. Separately the commissioner would consider use of the performance related sanctions to ensure that in future out of pocket expenses are claimed in line with the Drug Tariff.

32. Where a committee considers that payment of a fee or allowance under the Drug Tariff has been made to a contractor where it was not due, it must draw the overpayment to the attention of the contractor.

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

33. Where the contractor admits the overpayment, then the amount may be recovered via the local payment application. Where that is not possible, eg 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.

34. 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.

35. 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.

36. 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

37. The management information spreadsheet (MIS) report is produced monthly by NHSBSA and is available to authorised users via the Information Services portal.[25]

38. 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 and patient charges collected are also included.

39. This information is provided to fulfil a number of requirements including:

- pharmacy and appliance contractor payment monitoring
- contract management
- reconciling payments
- audit

[25] https://www.nhsbsa.nhs.uk/information-services-portal-isp/isp-report-information

- fraud prevention.

40. NHSBSA provides support to the commissioners to manage the performance of pharmacy contracts by providing enriched information, analysis and insight on contractor payment and prescription data.

41. A Pharmacy Dashboard has been developed by NHSBSA to help the commissioner identify unusual/inappropriate behaviour, potentially fraudulent activity and areas of interest. Insight will be delivered for metrics defined by NHS England as key areas of interest. Where ICBs would like different or additional metrics adding, they are to discuss this with NHS England. Metrics may be viewed on a monthly or cumulative basis for up to the preceding 12 months, providing an overall picture of a pharmacy contractor's activity over a year in these areas.

42. The commissioner will wish to review the monthly MIS report and utilise the reporting tools 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 where sign-up is via the NHSBSA portal).

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 fifth day of the month following that in which the supply was made or the service provided.

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.

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

45. The commissioner will often receive queries from contractors, their representatives 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.

46. 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 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

47. The Pharmaceutical Services (Fees for Applications) Directions 2013,[26] 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.

48. The only instances where an application fee is not payable are as follows (Direction 3(1)).

- the commissioner has invited the applicant to submit the application (Direction 3(1)(a))
- applications under Regulation 27 (temporary listings arising out of suspensions)
- applications under Regulation 29 (person exercising a right of return to a pharmaceutical list)
- applications under Regulation 29 (temporary arrangements during emergencies or because of circumstances beyond the control of NHS chemists).

49. The only instance where an application fee will be reimbursed is where an application triggers the decision by the commissioner to invite other applications offering to meet the same identified need or secure the same identified improvements or better access. Where that happens, the applicant whose application triggers the decision will have the application fee reimbursed to them.

50. The Pharmaceutical Services (Fees for Applications) Directions 2013 confirm that if the required fee is not paid, then the application is not valid. In that instance non-payment of the fee is to be treated as missing information and documentation, and requested from the applicant accordingly. Should the applicant not respond to the

[26] https://www.gov.uk/government/publications/pharmaceutical-services-fees-for-applications- directions-2013

request, then the application is to be treated as withdrawn, as described in the procedure for that type of application.

51. Information produced by the then DH[27] in 2008 when the fees were initially introduced may be of interest.

52. Fees are passed by the primary care support service provider to:

- the relevant ICB if it is delegated to commission pharmaceutical services, or
- the relevant regional team where the ICB isn't delegated.

27 https://webarchive.nationalarchives.gov.uk/ukgwa/20120503091351/http://www.dh.gov.uk/en/Healthcare/Primarycare/Communitypharmacy/ImplementationoftheHealthAct2006/index.htm

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:

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

Background to LPS

3. LPS allows the commissioner to commission pharmaceutical services tailored to meet specific local requirements. LPS complements the national contractual framework for community pharmacy but is an important local commissioning tool in its own right. LPS provides flexibility to include within a single local contract a broader or narrower range of services (including services not traditionally associated with pharmacy) than is possible under national pharmacy arrangements. However, whatever the range of services that is commissioned under a LPS contract, it must include the dispensing of drugs, ie the Terms of Service set out in paragraph 3 to 10AA, Schedule 7 of the Regulations.

4. All services currently eligible to be provided through the Community Pharmacy Contractual Framework 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 that may be required by the commissioner or where

the current providers are unable or unwilling to provide certain services. However, this does not preclude a variety of other circumstances in which LPS may be used.

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

Differences between LPS and national pharmaceutical services arrangements

7. It is for the commissioner to decide when and in what circumstances it wishes to enter into a LPS contract. LPS provides the commissioner with the flexibility to decide not just where it might wish to locate LPS schemes but also to determine the mix of services within any given scheme. Where a delegated ICB is considering the use of LPS, it must first gain approval from the relevant NHS England regional director of primary care and public health commissioning, or equivalent, to do so. The director will seek to confirm that any new LPS schemes do not undermine the national Community Pharmacy Contractual Framework payments.

8. A LPS contract may provide for any such combination of services as the parties agree between them, but must include the dispensing of drugs.

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

10. LPS is not subject to ‘market entry’ conditions.

11. The commissioner 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 the commissioner 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 the commissioner 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 the commissioner), that contractor will have a right of return in relation to those premises from which they were providing PhS, so long as the provider 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 the commissioner), have a right of return in relation to those premises from which the provider was providing services under the LPS pilot scheme, so long as they continue to provide LPS from those premises.

iii. Where the LPS contract of an LPS provider who has been granted a right of return in accordance with these principles is varied 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 the LPS contract of an LPS provider who has been granted a right of return in accordance with these principles is varied so as to transfer the 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 they continue to provide LPS from those premises, and the previous provider will lose their right of return.

In these principles 'PhS contractor' refers to an entry on the relevant 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 the commissioner 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 (eg by leading integrated teams of health professionals or working as part of such a team)
- providing the commissioner with the flexibility to participate in health promotion schemes in a wider context (eg 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
- locally based services that offer easy access, especially for those with reduced mobility.

LPS designations

14. The commissioner has the power to 'designate' areas, premises or descriptions of premises when deciding whether to develop and/or implement LPS arrangements. This has the effect of allowing the commissioner to choose to defer consideration of routine applications for inclusion in the relevant pharmaceutical list under the Regulations in the area under designation.

15. Where a delegated ICB is considering the use of LPS, it must first gain approval from the relevant NHS England regional director of primary care and public health commissioning to do so. Once approval is gained, the delegated ICB can follow the process set out in Regulation 99 to put a LPS designation in place.

Designation of areas, premises or descriptions of premises

16. Areas or premises can be designated by the commissioner as priority or 'designated' areas. During the period of designation, routine applications for inclusion in the relevant pharmaceutical list may be deferred.

17. The commissioner 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 the commissioner 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 the commissioner has to plan and commit to a longer-term development, eg commissioning and building new premises.

19. The commissioner must review all designations before the end of six months, beginning on either the date of the designation or (if later) the date it concluded its last review of the designation.

20. The commissioner may designate relevant areas, premises or descriptions of premises in or at which LPS 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, eg 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
    - include an outline of the services to be provided under the scheme to which it refers.

22. Once a designation has been made the commissioner 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 the commissioner) 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 the commissioner) 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 the commissioner) 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 the commissioner) are likely to be affected by the designation, and
- any local Healthwatch organisation for the area of the HWB.

23. The commissioner must publish all its current designations, including any designations that have been varied. The commissioner must also publish any current designations, including any designations that have been varied, that were made by any former primary care trusts or NHS England. The commissioner 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. The commissioner may vary a designation that it has made 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. The commissioner must regularly review designations. In any event, designations must be reviewed before the end of a period of six months beginning on either the date of designation or the date of the last review.

28. When conducting a review, the commissioner must take into account any responses it (or the former primary care trust) received when the designation was last notified.

29. Where a designation is not varied or is cancelled as a result of the review, the commissioner must notify those listed above at paragraph 22 of the outcome of its review.

Cancellation of designations

30. The commissioner 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 12 months beginning on the date of designation, a proposal for an LPS scheme that relates to the designation has not been submitted to the commissioner for approval. The commissioner 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.
    - 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 that leads to a variation as described in the paragraphs on ‘variation of designation’ above. In this case, the 12- month period will continue to run from the original date of designation.
    - When an LPS contractor commences the provision of services under an LPS contract at the designated location.

31. The commissioner must give notice of the cancellation of designation to those listed at paragraph 22 above.

32. Where the commissioner has cancelled a designation, it may not designate the same area, premises or description of premises within a period of six months beginning on

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 the commissioner advertising, inviting or initiating the process
    - by the commissioner specifying the services and/or location and any other details of an LPS arrangement that it wishes to commission and inviting prospective providers to come forward.

LPS proposals submitted without invitation

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

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

Inviting LPS proposals

36. Where the commissioner specifies the services and/or location and any other details of an LPS arrangement, it should seek procurement advice.

Procedure for managing LPS proposals

37. 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.

38. Ensure details have been added to any appropriate database and ensure it is updated as the proposal progresses.

39. The officer will consider whether the proposal is vexatious or frivolous. Where it is determined that it is either vexatious or frivolous (eg 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.

40. Where a delegated ICB receives a LPS proposal and is satisfied that it is neither vexatious or frivolous it must gain approval from the relevant NHS England regional director of primary care and public health commissioning to proceed with it. Where approval is gained, send Annex 3 to the proposer.

41. Where a commissioner receives a LPS proposal and is satisfied that it is neither vexatious nor frivolous, send Annex 3 to the proposer.

42. The officer 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.

43. Prepare a report (Annex 6) for the committee on whether to select the proposal for development.

44. 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).

45. If the LPS proposal is not selected for development, no further actions are necessary.

46. 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 the commissioner to fine-tune the proposal in lightof its consideration of the relevant factors, including feedback from involvement exercises.
- Should the proposal for services in a given locality not sufficiently reflect the commissioner's views as to the services that are necessary, the commissioner may negotiate the nature of the services as part of the development stage. The commissioner should contact the proposer as appropriate.

- The commissioner 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. The commissioner 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, the commissioner may need to inform the local authority again using the same process as set out earlier in the procedure.

47. 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 the commissioner to provide financial assistance to the proposer to help meet the cost of developing the proposal. The commissioner maydecide to provide funding or may need to consider the matter in response to a request from the proposer.
- The commissioner 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.

48. 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.

49. Prepare a report (Annex 10) for the committee on whether the proposal should be adopted and if so whether a right of return should be given.

50. 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.

51. If the LPS proposal is not selected, no further actions are necessary.

52. 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. Be aware of Public Contract Regulations 2015 which were not in place when the guidance was issued.

53. Clarify any final matters and arrange for the LPS contract to be signed.

54. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with the applicant's completed mandate.

55. Send the notification of the NHS Pharmacy Contractor Code advising the applicant of their contractor number when received from NHS Prescription Services.

56. On the start date of the contract update the LPS list for the relevant HWB and inform the usual parties, which include the relevant:

- LPC
- HWB
- public health team at the relevant local authority,
- DoS lead
- unwanted medicines collection and disposal contractor, and
- primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

Payments

57. When commissioning LPS the commissioner is not obliged to mirror the national fees and allowances, but may choose to do so where this is relevant.

58. The LPS element of the pharmacy payment is to be calculated by the commissioner and notified to the primary care support service provider on a monthly basis for entry into the Local Payment Application.

59. Where the LPS contract requires the contractor to provide advanced services and payments are to be made in line with the Directions, NHSBSA will contact the commissioner 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 Pharmacy Quality Scheme.

Chapter 41: Procedure – temporary arrangements

Chapter aims and objectives

60. 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. Such applications are to be processed and determined by the commissioner.

61. Applications are to be determined within 30 days of receipt unless the commissioner has good cause to take longer. Given the nature of the applications, however, they should be determined as soon as possible.

62. 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.

63. A template application form is provided at Annex 1.

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

65. It should be noted that Regulation 29 is not to be used to apply for a temporary suspension of a contract where there is no emergency, or it is not a matter that is beyond the control of the contractor.

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

Declared emergencies

67. If an emergency is declared (through directions given by the Secretary of State under section 168A of the National Health Service Act 2006), eg 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, eg the COVID-19 pandemic – NHS England or the delegated ICB must, for a specified period, exercise (or consider exercising) one or more or its functions under various provisions of the Regulations.

68. In the case of such an emergency, the commissioner may make temporary amendments to the list entry of a contractor, eg 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.

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

69. In the event of circumstances arising which require the temporary suspension of pharmaceutical services at the listed premises, NHS England or the delegated ICB 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.

70. The temporary suspension/relocation must be for no longer than six 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.

71. 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.

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

Fees

72. 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 (Annexes 1 and 2).

3.	Consider the 'first referral' questions (Annex 3) and collate the list of interested parties who are to be notified of the decision – 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.
4.	Once you are satisfied that the application is fully completed and all relevant information, documentation and undertakings have been provided, send an acknowledgement of receipt of application (Annex 5). Go to step 16.
5.	If there is missing information and/or documentation, go to step 6. If there are missing undertakings, go to step 13.
6.	Where there is missing information and/or documentation complete and send Annex 6. The relevant timescales are as follows: • submission of the required fitness information – 10 working days • information required by paragraph 1, Schedule 2 to the Regulations – five working days. Timescales for any other missing information/documentation requested must be within the timescales above provided that such timescales are reasonable.
7.	Diarise the date for the missing information/documentation to be submitted.
8.	If the applicant asks for a review of a request for missing information, this is to be dealt with in the usual way.
9.	If the outcome of the review is that the information/documentation is to be provided, send to the applicant notification of the outcome of the review and request for information (Annex 7). The timescales for providing the information are as set out in step 6 above. If the information is provided, go to step 16. If the information is not provided, go to step 11. If the outcome of the review is that the information/documentation is not to be provided, send the applicant notification of the outcome of the review and withdrawal of the original request (Annex 8), then go to step 16.
10.	On receipt of the information/documentation ensure the application is now complete. If further missing information is identified, return to step 6. If, or once, all the required information has been provided send the applicant an acknowledgement of receipt of the missing information/documentation (Annex 9). If further missing information is identified, return to step 6. Go to step 16.
11.	If the missing information and/or documentation is not received by the due date, send to the applicant confirmation that the information/documentation has not been received and the application is therefore being treated as withdrawn (Annex 10).

	This is the end of the process.
12.	Where there are missing undertakings, complete and send the acknowledgement of receipt of the 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.
13.	Diarise the date for the missing undertakings to be submitted.
14.	On receipt of the missing undertakings, send to the applicant acknowledgement of receipt of missing undertakings (Annex 12). Go to step 16.
15.	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 13). This is the end of the process.
16.	Prepare a report (Annex 14 for declared emergencies and Annex 15 for the temporary suspension of pharmaceutical services) and send to the officer or committee who will make the decision.
17.	After the meeting, prepare the relevant decision letters and enclose the decision report. The decision letters where the application has been granted are: • granted – to the applicant (Annex 16) and include Annex 17 where required • granted – to a third party (Annex 18). The decision letters where the application has been refused are: • refused – to the applicant (Annex 19) • refused – to a third party (Annex 20). 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.
18.	Diarise the latest date by which the template notice of commencement can be submitted. If no notice of commencement is received send Annex 21 to the interested parties.
19.	If the applicant asks to submit the notice of commencement within 30 days pass the application to the relevant officer for a decision to be made. If the application is granted, send Annex 22. If the application is refused, send Annex 23.

20.	If a request for an extension within which to make the change is received (Annex 24), pass it to the relevant officer 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. Go to step 21. If the request is refused, send Annex 26 to the applicant. If notice of an appeal is received, advise the officer 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. Go to step 21. 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, go to step 21.
21.	On receipt of a completed notice of commencement check the following points: • It has been received within the 12-month grant period or such longer time as the commissioner or NHS Resolution has allowed. Send Annex 27 if it has not been received within this window. • The date that the applicant intends to start to provide pharmaceutical services – this must be no fewer than 30 days prior to the date on which the notice was received unless the commissioner has agreed to a shorter notice period. Send Annex 28 where it has been submitted fewer than 30 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 on premises@pharmacyregulation.org. • The notice is signed and dated. If any information is missing or incorrect, send Annex 28 to the applicant and return to this step when the required information is received. Where no issues are identified, forward it to the relevant officer for confirmation it is valid. Where it is valid, send Annex 29. Go to step 22. Where it is not, send Annex 30 and return to this step when a new notice of commencement is received.
22.	Complete the relevant NHS Prescription Services form and send to NHS Prescription Services.
23.	If the applicant notifies in writing of a change to the commencement date given in the notice of commencement, check that both the date of the notification is in advance of both the original and new commencement date.

	If the notification was made on or after the original commencement date, send Annex 31. This is the end of the process. If the notification was made before the original commencement date but after the new commencement date, send Annex 32. Go to step 24. If the notification was made before both the original commencement date and the new commencement date send Annex 33 to the applicant. Complete the relevant NHS Prescription Services form and send to NHS Prescription Services with a covering email advising that the commencement date has changed. Go to step 24.
24.	Ensure the market entry tracker has been kept up to date and enter the outcome of the application. Update other databases as appropriate and on the date that service provision commences inform (using Annex 34) the usual parties, which include the relevant: • LPC • HWB • public health team • DoS lead • unwanted medicines collection and disposal contractor • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.
25.	Where the application relates to temporary arrangements due to a declared emergency, the procedure ends here. Where the application relates to temporary arrangements due to the suspension of services from listed premises for reasons beyond the control of the contractor, follow the subsequent steps below.
26.	Diarise the date on which the temporary arrangements are to end.
27.	One month before, send Annex 35 to the applicant.
28.	If the applicant requests an extension (Annex 36), prepare a report (Annex 37) on the application and send to the relevant officer for a decision.
29.	After the meeting, prepare the relevant decision letters. The decision letters where the application has been granted are: • granted – to the applicant (Annex 37) and include Annex 17 where relevant • granted – to a third party (Annex 38). The decision letters where the application has been refused are: • refused – to the applicant (Annex 39) • refused – to a third party (Annex 40). When the letters are completed distribute to the applicant and interested parties.
30.	If an extension is granted diarise the date on which the temporary arrangements are to end. One month before, send Annex 41 to the applicant.

31.	On the date the temporary arrangement comes to an end send Annex 42 to the applicant, and inform the usual parties (using Annex 43) which includes the relevant: • LPC • HWB • public health team • DoS lead • unwanted medicines collection and disposal contractor, and • primary care support service provider's pharmacy payments team in relation to the LPC levy and the data manager.

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

This publication can be made available in a number of alternative formats on request.

© NHS England 2023 | PR2114