Policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
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Standard operating policies and procedures for primary care

Issue Date: June 2013

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Prepared by: Primary Care Commissioning (PCC)
Policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

Information Reader Box

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<td>Nursing</td>
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<td>June 2013</td>
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NHS England
Policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

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Purpose of the policy

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

2. This document forms part of a suite of policies and procedures to support
commissioning of primary care. They have been produced by Primary
Care Commissioning (PCC) for use by NHS England’s area teams (ATs).

3. The policies and procedures underpin NHS England’s commitment to a
single operating model for primary care – a “do once” approach intended to
ensure consistency and eliminate duplication of effort in the management
of the four primary care contractor groups from 1 April 2013.

4. All policies and procedures have been designed to support the principle of
proportionality. By applying these policies and procedures, Area Teams
are responding to local issues within a national framework, and our way of
working across NHS England is to be proportionate in our actions.

5. The development process for the document reflects the principles set out
in Securing excellence in commissioning primary care¹, including the
intention to build on the established good practice of predecessor
organisations.

6. Primary care professional bodies, representatives of patients and the
public and other stakeholders were involved in the production of these
documents. NHS England is grateful to all those who gave up their time to
read and comment on the drafts.

7. The authors and reviewers of these documents were asked to keep the
following principles in mind:

- Wherever possible to enable improvement of primary care
- To balance consistency and local flexibility
- Alignment with policy and compliance with legislation
- Compliance with the Equality Act 2010
- A realistic balance between attention to detail and practical
  application
- A reasonable, proportionate and consistent approach across the

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four primary care contractor groups.

This suite of documents will be refined in light of feedback from users.

This document should be read in conjunction with:

- The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and accompanying DH guidance
- The procedures listed in annex 2
- The rurality and related determinations policy

Policy aims and objectives

The purpose of this policy is to ensure that the NHS CB determines applications received under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations (the 2013 Regulations) consistently and in line with regulatory requirements. Such applications may be made by pharmacies, dispensing appliance contractors (DACs) or doctors.

Background

Persons wishing to provide pharmaceutical services in England must be included in a pharmaceutical list held by NHS England. NHS England will hold pharmaceutical and dispensing doctor lists at health and well-being board (HWB) level and is required by the 2013 regulations to prepare, maintain and publish for each HWB one list for pharmacy contractors, one for DACs (where applicable) and one for dispensing doctors (where applicable).

Applications for inclusion in one of these lists must include certain information and are to be processed and determined in accordance with the 2013 Regulations. Each AT will have a committee (the pharmaceutical services regulations committee) to determine such applications.

Decisions made by the NHS England can generally be appealed to the NHS Litigation Authority’s Family Health Services Appeal Unit (FHSAU), although some appeals on fitness issues go to the First-tier Tribunal. If the 2013 Regulations make no provision for an appeal, or if someone is dissatisfied with a decision of the FHSAU, any challenge would need to be through the courts. Robust audit trails will therefore be maintained for each application and all determinations will be fully reasoned.
Scope of the policy

14 This policy covers market entry applications made in connection with inclusion in a pharmaceutical list or dispensing doctor list held by NHS England. For each type of routine or excepted application that could be submitted there is an application form, procedure, template letters and flowchart. Annex 2 contains a list of the types of application that may be submitted and the reference for the relevant procedures and accompanying resources.

15 Applications that are to be notified to interested parties are to be determined within four months of receipt. Applications that are not to be notified are to be determined within 30 days of receipt. The NHS CB may only take longer where there is good cause e.g. there is a delay in completing all the required fitness to practice checks for reasons that are outside the control of the AT.

16 ATs are to follow the relevant procedure when processing an application for inclusion in a pharmaceutical list.

Governance arrangements

17 Establishing a clear decision-making process is an essential element of good governance arrangements for handling applications for inclusion in one of NHS England's pharmaceutical lists or dispensing doctor lists.

18 Applications for inclusion in a list will be received by the pharmacy contracts manager and will then be passed to the FHS function for checking and processing.

19 Where missing information or documentation is identified and requested the contractor may ask for the request to be reviewed. The pharmacy contracts manager will deal with reviews.

20 The pharmaceutical services regulations committee will make decisions required while an application is being processed, for example whether a routine application is to be deferred so other applications may be invited. The committee will also make decisions on routine applications.

21 The pharmacy contracts manager will decide on change of ownership applications (excluding combined change of ownership and no significant change relocation applications) and right of return applications. On all other excepted applications, the pharmaceutical services regulations committee will decide.
22 Where the pharmacy contracts manager makes decisions they will be reported to the next meeting of the pharmaceutical services regulations committee for information.

23 The terms of reference for decision-making can be found in annex 3.

24 Each AT will maintain a register of applications received (annex 4). The pharmacy contracts manager will enter details of applications when received and the register will be kept up to date as the application progresses. The FHS function will ensure the database is updated as the application advances. This will enable NHS England and/or ATs to respond to Freedom of Information Act or other requests and also to complete the NHS Information Centre’s annual pharmaceutical services return.

**Timescales**

25 The 2013 Regulations provide overall timescales for applications to be included in a pharmaceutical list. For applications where interested parties must be notified, ATs must process them, make a decision and notify that decision within four months of receipt. Those applications that are not to be notified must be determined within 30 days.

26 The clock only stops where an application is formally deferred, e.g. because there is missing information. NHS England could take longer to determine an application where it has good cause, e.g. there has been a delay in receiving references. ATs will therefore ensure they process applications promptly to meet the required timescales.

27 The 2013 Regulations and the procedures accompanying this policy refer specifically to various timescales. To avoid doubt these references are to calendar days unless they state otherwise. Where a period of time is referred to, day one is the day after something occurring. For example, if an applicant is given a period of 10 working days to submit missing information and they are written to on Friday 11 January, the information is to be submitted by Friday 25 January.

28 For the purposes of this policy and accompanying procedures working days are Monday to Friday, excluding any public and bank holidays.
Payments

29 The Pharmaceutical Services (Fees for Applications) Directions 2013 require NHS England to charge a fee for certain types of applications for inclusion in a pharmaceutical list. The directions allow the NHS CB to waive the fee where it invites applications under the 2013 Regulations. ATs will do so for the specified types of applications. They will reimburse the fee paid by an applicant when a decision is made to defer their application in order to invite other applications that offer to:

- meet the same current or future need,
- secure the same current or future improvement or better access, or
- secure the same unforeseen benefit.

30 Fees are to be paid by Bankers’ Automated Clearing Services (BACS) or cheque at the point the application for inclusion in a pharmaceutical list is submitted to the AT. ATs will ensure they have systems in place to make sure payment is made and cleared.

31 Applicants who indicate on their application form that they have paid the required fee will have their application processed in good faith. Applications will not be held until confirmation is received that the payment has cleared. ATs must, however, ensure that payment has cleared before a decision is made on the application.

Missing information and/or documentation

32 On receipt of a routine or excepted application the first step is to ensure that all the required information and documentation is provided. The 2013 Regulations show the process to be followed where missing information and/or documentation are identified. The detail of the process is included in the accompanying procedures, but in summary ATs are to request the missing information and documentation and to specify the timescale within which it is to be provided.

33 The amount of time to be given to applicants is:

- 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 2013 Regulations but not supplied – five working days; and
failure to provide the undertakings required by paragraph 9, Schedule 2 of the 2013 Regulations – five working days.

Identifying interested parties

Interested parties and notifiable applications

Paragraph 19, Schedule 2 of the 2013 Regulations requires NHS England to give notice of notifiable applications to certain persons. The types of application to be notified are listed in paragraph 18, Schedule 2 of the 2013 Regulations.

This section of the policy outlines how ATs will identify those they will give notice to regarding such applications. It cannot cover every potential scenario and therefore ultimate responsibility to determine who is to be notified of an application rests with the pharmaceutical services regulations committee.

The AT must notify those persons listed in paragraph 19, Schedule 2 of the 2013 Regulations. This section of the policy provides a framework for ATs to work within when identifying persons who might be significantly affected by the grant of a notifiable application, and who might have a significant interest in the outcome of such an application.

a. Contractors included in a pharmaceutical list

Contractors included in one of the pharmaceutical lists are considered to be significantly affected if:

- their premises are located within 2km in a direct line from the premises or best estimate given in the application (urban areas), or
- their premises are located within 8km in a direct line from the premises or best estimate given in the application (rural areas).

b. Persons entitled to be included in a pharmaceutical list

This category relates to those whose application to be included in a pharmaceutical list was granted by the AT, the preceding primary care
trust or, on appeal, the FHSAU, but they have not yet submitted their notice of commencement and so are not yet included in the relevant pharmaceutical list.

The AT will notify such persons where their (yet to open) premises are located within:

- 1.6km in a direct line from the premises or best estimate given in the application (urban areas), or
- 8km in a direct line from the premises or best estimate given in the application (rural areas).

c. Local pharmaceutical services (LPS) and essential small pharmacy local pharmaceutical services (ESPLPS) contractors

The AT will notify such persons where their premises are located within:

- 1.6km in a direct line from the premises or best estimate given in the application (urban areas), or
- 8km in a direct line from the premises or best estimate given in the application (rural areas).

d. Patient, consumer or community groups in the HWB’s area

The AT will notify such groups where the application is:

- in a controlled locality, the relevant Parish Council.
- offering unforeseen benefits to a specific patient group, any group that is representative of that group of patients.

e. GP practices

The AT will notify dispensing practices that have dispensing patients within 1.6km of the proposed premises or best estimate.

f. GP performers included in the dispensing doctor list

The AT will notify performers included in the dispensing doctor list that
have dispensing patients within 1.6km of the proposed premises or best estimate if the practice has not already been identified in the paragraph above.

g. Other persons

The AT may also give notice to any other person that it believes has a significant interest in the outcome of the application. This will be at the AT’s discretion based on local circumstances and what need, improvement, better access or unforeseen benefit the application is offering.

Interested parties and controlled locality determinations

37 Before determining whether or not an area is a controlled locality or part of one, regulation 38 of the 2013 Regulations requires NHS England to give notice of the proposed determination.

38 This section of the policy outlines how ATs will identify whom they will notify of proposed controlled locality determinations. It cannot cover every potential scenario and therefore ultimate responsibility to determine who is to be notified of a determination rests with the pharmaceutical services regulations committee.

39 The AT must notify those persons listed in regulation 38(1) of the 2013 Regulations. This section of the policy provides a framework for ATs to work within when identifying persons who may be affected by a controlled locality determination.

- Pharmacy and dispensing appliance 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.
- Dispensing doctors included in a dispensing doctor list who have dispensing patients living in the area to be determined, or have premises within 1.6km of the edge of that area.
- LPS contractors with premises within the area to be determined, or have premises within 1.6km of the edge of that area.
- Providers of primary medical services with premises within the area that is to be determined, or have premises within 1.6km of the edge of that area.
Third party rights of appeal

40 Paragraph 30, Schedule 2 of the 2013 Regulations shows who is to be given third party rights of appeal where a routine or excepted application is granted. Third party rights of appeal in connection with applications made by doctors are set out in regulation 63.

41 Third party rights will only be given in line with those two regulatory provisions. There is an element of discretion in paragraph 30(3)(c), Schedule 2. For the avoidance of doubt, the pharmaceutical services regulations committee will not give third party rights of appeal where a person who meets the requirements of paragraph 30(3)(a) and (b) failed to set out their grounds for opposing the application. The following will not be sufficient to gain third party rights of appeal:

- “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.”
- Where the interested party does not state that they oppose the application.
- Where the interested party gives no grounds for opposing the application.

42 A decision not to give third party rights of appeal can be challenged, so the pharmaceutical services regulations committee and pharmacy contracts manager must fully document the reasons for not giving third party rights of appeal.

Monitoring and review of policy

43 This policy will be reviewed regularly, with frequency determined by NHS England. There are robust arrangements for the maintenance and storage of all records, minutes, and reports associated with the procedure to ensure a clear audit route through the procedure for each contractor. NHS England may instigate an internal audit, or be required to submit information to an external body for scrutiny.
Annex 1: abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>A&amp;E</td>
<td>accident and emergency</td>
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<td>APHO</td>
<td>Association of Public Health Observatories (now known as the Network of Public Health Observatories)</td>
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<td>APMS</td>
<td>Alternative Provider Medical Services</td>
</tr>
<tr>
<td>AT</td>
<td>area team (of NHS England)</td>
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<td>AUR</td>
<td>appliance use reviews</td>
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<td>BDA</td>
<td>British Dental Association</td>
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<tr>
<td>BMA</td>
<td>British Medical Association</td>
</tr>
<tr>
<td>CCG</td>
<td>clinical commissioning group</td>
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<tr>
<td>CD</td>
<td>controlled drug</td>
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<tr>
<td>CDAOO</td>
<td>controlled drug accountable officer</td>
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<td>CGST</td>
<td>NHS Clinical Governance Support Team</td>
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<td>CIC</td>
<td>community interest company</td>
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<td>CMO</td>
<td>chief medical officer</td>
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<td>COT</td>
<td>course of treatment</td>
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<td>CPAF</td>
<td>community pharmacy assurance framework</td>
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<td>CQC</td>
<td>Care Quality Commission</td>
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<td>CQRS</td>
<td>Calculating Quality Reporting Service (replacement for QMAS)</td>
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<td>DAC</td>
<td>dispensing appliance contractor</td>
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<td>Days</td>
<td>calendar days unless working days is specifically stated</td>
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<td>DBS</td>
<td>Disclosure and Barring Service</td>
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<td>DDA</td>
<td>Disability Discrimination Act</td>
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<td>DES</td>
<td>directed enhanced service</td>
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<td>essential small pharmacy local pharmaceutical services</td>
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<td>family health shared services</td>
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<td>FPC</td>
<td>family practitioner committee</td>
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<tr>
<td>FTA</td>
<td>failed to attend</td>
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<tr>
<td>FTT</td>
<td>first-tier tribunal</td>
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<td>GDP</td>
<td>general dental practitioner</td>
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<td>General Dental Services</td>
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GMC General Medical Council
GMS General Medical Services
GP general practitioner
GPES GP Extraction Service
GPhC General Pharmaceutical Council
GSMP global sum monthly payment
HR human resources
HSE Health and Safety Executive
HWB health and wellbeing board
IC NHS Information Centre
IELTS International English Language Testing System
KPIs key performance indicators
LA local authority
LDC local dental committee
LETB local education and training board
LIN local intelligence network
LLP limited liability partnership
LMC local medical committee
LOC local optical committee
LPC local pharmaceutical committee
LPN local professional network
LPS local pharmaceutical services
LRC local representative committee
MDO medical defence organisation
MHRA Medicines and Healthcare Products Regulatory Agency
MIS management information system
MPIG minimum practice income guarantee
MUR medicines use review and prescription intervention services
NACV negotiated annual contract value
NCAS National Clinical Assessment Service
NDRI National Duplicate Registration Initiative
NHAIS National Health Authority Information System (also known as Exeter)
NHS Act National Health Service Act 2006
NHS BSA NHS Business Services Authority
NHS CB NHS Commissioning Board (NHS England)
NHS CfH NHS Connecting for Health
NHS DS NHS Dental Services
NHS LA NHS Litigation Authority

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Annex 2: Reference system for related procedures

Pharm01 – Applications offering to meet an identified current need where the premises are known
Pharm02 – Applications offering to meet an identified current need where a best estimate is given
Pharm03 – Applications offering to meet an identified future need where the premises are known
Pharm04 – Applications offering to meet an identified future need where a best estimate is given
Pharm05 – Applications offering to secure identified improvements or better access where the premises are known
Pharm06 – Applications offering to secure identified improvements or better access where a best estimate is given
Pharm07 – Applications offering to secure identified future improvements or better access where the premises are known
Pharm08 – Applications offering to secure identified future improvements or better access where a best estimate is given
Pharm09 – Applications offering to secure unforeseen benefits where the premises are known
Pharm10 – Applications offering to secure unforeseen benefits where a best estimate is given
Pharm11 – Applications for relocations within the same HWB area that do not result in significant change
Pharm12 – Applications for relocations between HWB areas that do not result in significant change
Pharm13 – Applications for distance selling premises
Pharm14 – Applications for changes of ownership
Pharm15 – Combined applications for changes of ownership and relocations within the same HWB area that do not result in significant change
Pharm16 – Combined applications for changes of ownership and relocations between HWB areas that do not result in significant change
Pharm17 – Applications for temporary listings arising out of suspensions
Pharm18 – Applications from persons exercising a right of return to a pharmaceutical list
Pharm19 – Applications for temporary arrangements during declared emergencies
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Pharm20 – Applications for temporary arrangements because of circumstances outside the contractor’s control
Pharm21 – Applications in respect of providing directed services
Pharm22 – Determination of applications for outline consent and/or premises approval
Rurality01 – Controlled locality determinations
Rurality02 – Additional procedure for routine applications in a controlled locality
Rurality03 – Additional procedure for certain applications near a controlled locality
Annex 3: Terms of reference for the pharmaceutical services regulations committee

Purpose

NHS England established the pharmaceutical services regulations committee to:

- determine those applications and notifications listed in annex A received under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the 2013 Regulations);
- determine those applications and notifications listed in annex A received under the NHS (Pharmaceutical Services) Regulations 2012, as amended and the NHS (Pharmaceutical Services) Regulations 2005, as amended, which fall to be dealt with under the transitional provisions contained within Schedule 9 of the 2013 Regulations;
- take overall responsibility for resolving issues of non-compliance with the terms of service as set out in the 2013 Regulations by pharmacy and dispensing appliance contractors;
- take overall responsibility for resolving issues of non-compliance with the terms of service for pharmacy and dispensing appliance contractors that fall to be dealt with under the transitional provisions contained within Schedule 9 of the 2013 Regulations; and
- make decisions on whether an essential small pharmacy local pharmaceutical services (EPSSLPS) contract is to be terminated in line with the provisions of the contract.

As such the committee has delegated authority from the NHS England to do so.

NHS England has also delegated the authority to determine those applications and notifications listed in annex B to the pharmacy contracts manager for each area team and as such that person has delegated authority from NHS England to do so. Where necessary the pharmacy contracts manager may escalate an application or notification to the pharmaceutical services regulations committee. If, due to annual or sick leave, the pharmacy contracts manager is unable to determine an application or notification within the regulatory timescale, it is to be determined by the pharmaceutical services regulations committee.
Membership of the pharmaceutical services regulations committee

Membership of the committee shall be as follows:

- Director of commissioning
- Head of primary care
- Lay member

These members will have voting rights.

Advice to the committee will be provided by:

- Pharmacy contracts manager
- Pharmacy professional adviser

These two members will not have voting rights and will leave the meeting while the decision is made.

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

Those who may not take part in any decision made under the 2013 Regulations, or any decision made by virtue of the transitional provisions in schedule 7 of those regulations include anyone who:

- is included in a pharmaceutical list or is an employee of such a person (to avoid doubt this includes anyone who provides services as a locum);
- assists in providing pharmaceutical services under Chapter 1 of Part 7 of the NHS Act 2006;
- is a local pharmaceutical services chemist, or provides or assists in providing local pharmaceutical services;
- is a provider of primary medical services;
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- is a member of a provider or primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- is employed or engaged by a primary medical services provider; or
- is employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

This is irrespective of whether or not their involvement would give rise to a reasonable suspicion of bias. Members will sign declarations to confirm they meet this requirement.

Also, no other person is to take part in making a decision if because of an interest or association they have, or because of a pressure to which they may be subject, their involvement would give rise to a reasonable suspicion of bias. Members are to advise the chair of any conflicts of interest on receipt of the papers.

Declarations of any conflict of interest will be made at the beginning of each meeting. Any members of the committee with conflicts of interest will be asked to leave the room before any discussion takes place on the relevant application or notification.

The director of commissioning will chair the committee. The vice chairman will be the head of primary care.

If the chairman is not present then the vice chairman will chair the meeting. A quorum shall be two of the three members with voting rights.

Administrative support will be provided by [AT to identify person and insert job title].

**Frequency of meetings**

The pharmaceutical services regulations committee will meet monthly. It may also be convened urgently to discuss an urgent case. Meetings may be held virtually anywhere that is appropriate to the subject matter.
Authority

The committee will determine all matters within its terms of reference and is authorised by NHS England to obtain such outside legal or other independent professional advice and to co-opt persons with relevant experience and expertise if it considers this necessary. Co-opted persons will not have voting rights and will leave the meeting while the decision is made.

Reporting lines

NHS England has delegated full responsibility for all decisions listed in annex A to the pharmaceutical services regulations committee.

NHS England has delegated full responsibility for all decisions listed in annex B to the pharmacy contracts manager. This person will not:

- be included in a pharmaceutical list or be an employee of such a person (to avoid doubt this includes anyone who provides services as a locum);
- assist in providing pharmaceutical services under Chapter 1 of Part 7 of the NHS Act 2006;
- be an local pharmaceutical services chemist, or provides or assists in the provision of local pharmaceutical services;
- be a provider of primary medical services;
- be a member of a provider or primary medical services that is a partnership or a shareholder in a provider of primary medical services that is a company limited by shares;
- be employed or engaged by a primary medical services provider; or
- be employed or engaged by an APMS contractor in any capacity relating to the provision of primary medical services,

The pharmacy contracts manager will sign a declaration to confirm they meet this requirement.

The pharmacy contracts manager will report monthly to the pharmaceutical services regulations committee on decisions taken and the outcome of any appeals on those decisions.
NHS England
Policy for determining applications received for new or additional premises under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The pharmaceutical services regulations committee will report [insert frequency] to the [insert committee] on the decisions taken and the outcome of any appeals on those decisions.

Review

The terms of reference will be reviewed annually or earlier if circumstances require.

Annex A

a. The NHS (Pharmaceutical Services) Regulations 2005, as amended

The committee will receive and determine applications submitted under the NHS (Pharmaceutical Services) Regulations 2005, as amended (the 2005 Regulations) which fall to be determined by virtue of the transitional provisions set out in Schedule 9 of the 2013 Regulations:

1. Regulation 5(1) of the 2005 Regulations – applications by persons wishing to be included in a pharmaceutical list; applications from persons already so included who wish to open new premises or to change the premises from which they provide pharmaceutical services.
2. Regulation 14 – applications to vary directed services in respect of exempted premises
3. Regulation 41 – full applications following approval of a preliminary application.
4. Paragraph 22(1), Schedule 1 – requests for a temporary suspension of services for a set period
5. Paragraph 25, Schedule 1 – applications from pharmacies wishing to change their core opening hours.
6. Paragraph 13, Schedule 3 – applications from dispensing appliance contractors wishing to change their core opening hours.
7. Regulation 60(1) – applications from patients under the serious difficulty rule.
8. Regulations 61 and 62 – applications from doctors wishing to be granted the right to provide pharmaceutical services and the taking effect of outline consent and premises approval
9. Regulation 64 – premises approval: change of premises before outline consent takes effect.
10. Regulation 65 – premises approval: additional and new premises after outline consent has taken effect.

The committee will determine under:

1. Regulation 31 whether an area is or is not a controlled locality, or is or is not part of one. This may be as a result of a request for such a determination by the local medical committee or the local pharmaceutical committee, or where the committee is satisfied that such a determination is required. Where relevant the committee will also consider the issue of gradualisation; and
2. Regulation 35 whether premises/relevant locations described in an application are in a reserved location.

The committee will ensure that determined controlled localities and reserved locations are clearly delineated on a map or maps and shall ensure these are published in line with Regulations 31 and 35.

The committee will determine notifications under Regulation 39(8) – change of premises prior to opening.

In relation to applications in or within 1.6km of a controlled locality the committee will consider the issue of gradualisation under Regulation 20 as appropriate.

b. **The NHS (Pharmaceutical Services) Regulations 2012, as amended**

The committee will receive and determine applications submitted under the NHS (Pharmaceutical Services) Regulations 2012, as amended (the 2012 Regulations) which fall to be determined by virtue of the transitional provisions set out in Schedule 9 of the 2013 Regulations:
1. Regulation 12 – routine applications.
2. Regulations 23 to 25, 26(2), 27 and 29 – excepted applications.
3. Regulation 48(2) – serious difficulty applications.
4. Regulations 51 to 61 – applications by doctors relating to outline consent and premises approval.
5. Applications to vary core opening hours from pharmacy and dispensing appliance contractors.
6. Requests to vary supplementary opening hours from pharmacy and dispensing appliance contractors within a shorter period than the required three months.
7. Requests for a temporary suspension of services for a set period.

The committee will determine under:

1. Regulation 36 whether an area is or is not a controlled locality or is or is not part of one. This may be as a result of a request for such a determination by the local medical committee or the local pharmaceutical committee, or where the committee is satisfied that such a determination is required. Where relevant the committee will also consider the issue of gradualisation.
2. Regulation 41 and 42 whether premises/relevant locations described in an application are in a reserved location.

The committee will ensure that determined controlled localities and reserved locations are clearly delineated on a map or maps and shall ensure these are published in line with Regulations 36, 41 or 42 as relevant.

The committee will consider information received regarding non-compliance with the terms of service by a pharmacy contractor or a dispensing appliance contractor, and make one or more of the following decisions:

i. There is no breach of terms of service, or there was good cause for the breach of terms of service
ii. Whether to issue a breach notice and withhold payments in connection with a proven breach of terms of service
iii. Whether to issue a remedial notice and withhold payments in connection with a proven breach of terms of service
iv. Whether to remove premises from the relevant pharmaceutical list in line with regulation 74 of the 2012 Regulations.

c. The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

The committee will receive and determine applications submitted under the 2013 Regulations:

1. Regulation 12 – routine applications.
2. Regulations 23 to 25, 26(2), 27 and 29 – excepted applications.
3. Regulation 48(2) – serious difficulty applications.
4. Regulations 51 to 61 – applications by doctors relating to outline consent and premises approval.
5. Applications to vary core opening hours from pharmacy and dispensing appliance contractors.
6. Requests to vary supplementary opening hours from pharmacy and dispensing appliance contractors within a shorter period than the required three months.
7. Requests for a temporary suspension of services for a set period.

The committee will also be responsible for issuing a direction to a contractor to open their premises on certain days or at certain times.

The committee will determine under:

1. Regulation 36 whether an area is or is not a controlled locality, or is or is not part of one. This may be as a result of a request for such a determination by the local medical committee or the local pharmaceutical committee, or where the committee is satisfied that such a determination is required. Where relevant the committee will also consider the issue of gradualisation; and
2. Regulation 41 and 42 whether premises/relevant locations described in an application are in a reserved location.

The committee will ensure that determined controlled localities and reserved locations are clearly delineated on a map or maps and shall ensure these are published in line with Regulations 36, 41 or 42 as relevant.
The committee will consider information received regarding non-compliance with the terms of service by a pharmacy contractor or a dispensing appliance contractor, and make one or more of the following decisions:

1. There is no breach of terms of service, or there was good cause for the breach of terms of service.
2. Whether to issue a breach notice and withhold payments in connection with a proven breach of terms of service.
3. Whether to issue a remedial notice and withhold payments in connection with a proven breach of terms of service.
4. Whether to remove premises from the relevant pharmaceutical list in line with regulation 74 of the 2013 Regulations.

d. All regulations

The committee will respond to all appeals made to the NHS Litigation Authority’s Family Health Services Appeal Unit or the First-tier Tribunal against its decisions made under the 2005, 2012 or 2013 Regulations. It will also respond where its decisions are challenged through the courts.

Decisions will be made in line with the timescales set out within the relevant regulations. All decisions will be fully reasoned and documented within the minutes of the meeting.

e. The Local Pharmaceutical Services (Essential Small Pharmacies) Directions 2013

The committee will determine whether an ESPLPS contract is to be terminated in accordance with the terms of the contract and will respond to any appeals made to the NHS Litigation Authority’s Family Health Services Appeal Unit against such decisions.
Annex B

a. The NHS (Pharmaceutical Services) Regulations 2005, as amended
   1. Regulation 8 – change of ownership.
   2. Regulation 10 – right of return to the pharmaceutical list.

b. The NHS (Pharmaceutical Services) Regulations 2012, as amended
   1. Regulation 26 – change of ownership.
   2. Regulation 28 – right of return to the pharmaceutical list.
   3. Paragraph 31, Schedule 2 – notifications of address following a best estimate routine application.

c. The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013
   1. Regulation 26 – change of ownership.
   2. Regulation 28 – right of return to a pharmaceutical list.
   3. Paragraph 31, Schedule 2 – notifications of address following a best estimate routine application.
   4. Notifications of changes of supplementary opening hours received from pharmacy contractors and dispensing appliance contractors.

The pharmacy contracts manager will respond to all appeals made to the NHS Litigation Authority’s Family Health Services Appeal Unit against their decisions made under the 2005, 2012 or 2013 Regulations.

Decisions will be made in line with the timescales set out within the relevant regulations. All decisions will be fully reasoned and documented.
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Annex 4: Register of applications

See separate document.
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Version control tracker

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