

# Pharmaceutical Services Regulations Subgroup Terms of Reference

**Version 1**

**Better health  
and wellbeing for all...**

## Version Control

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## **1. Establishment**

The Pharmaceutical Services Regulations (PSRC) is a formal subgroup established by the Quality and Safety Committee, in conjunction with the Safe and Effective Care Group.

## **2. Terms of reference**

The terms of reference are defined by the ICB.

The terms of reference will be maintained by the ICB Governance Team and published in the ICB's Governance Handbook which is accessible here:

<https://northeastnorthcumbria.nhs.uk/about-us/corporate-information/governance/governance-handbook/>

## **3. Authority**

The subgroup is authorised to:

- Investigate any activity within its terms of reference
- Seek any information it requires within its remit, from any employee or member of the ICB
- Commission any reports it deems necessary to help fulfil its obligations
- Obtain legal or other independent professional advice and secure the attendance of advisors with relevant expertise if it considers this is necessary to fulfil its functions. In doing so the subgroup must follow any procedures put in place by the ICB for obtaining legal or professional advice

For the avoidance of doubt, the subgroup will comply with the ICB Standing Orders, Standing Financial Instructions, and the Scheme of Reservation and Delegation (SoRD). However, as a subgroup there is no financial delegation to the group.

## **4. Purpose**

The purpose of the subgroup is to support the Quality and Safety Committee to discharge its duties relating to receiving and determining, on behalf of the ICB, applications submitted under the NHS (Pharmaceutical Services and Local Pharmaceutical Services) Regulations 2013 as amended ('the Regulations').

## **5. Roles and responsibilities**

This section describes the duties, authority, accountability and reporting.

The subgroup's duties are defined under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and will be authorised by the ICB Board. They include:

- a. Determine those applications and notifications received under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the 2013 Regulations)
- b. 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;
- c. Make decisions on whether an essential small pharmacy local pharmaceutical services (EPSLPS) contract is to be terminated in line with the provisions of the contract
- d. Health and Wellbeing Boards 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). The PSRC is required to review the PNAs in its area and to record the actions taken to address identified needs, improvements or better access whether this is via the market entry process or through local commissioning processes.

Delegated authority is given to the nominated Primary Care Contract Manager (PCM) to determine those applications and notifications delegated in the regulations. Where necessary the nominated PCM may escalate an application of notification to the PSRC. If, due to annual or sick leave, the nominated PCM is unable to determine an application or notification with the regulatory timescale it is to be determined by the PSRC.

## **6. Delegation by Scheme of Reservation & Delegation (SoRD)**

Determination of applications submitted under the NHS (Pharmaceutical Services) Regulation 2005 (as amended), which fall to be determined by virtue of the transitional provisions set out in the Pharmacy Manual, Version 2, February 2023.\*

## **7. Accountability and reporting**

As a formal subgroup, the subgroup is accountable to its Parent Committee and reports (via minutes/actions) to its Parent Committee on how it discharges its responsibilities. The secretary formally records the minutes of each meeting and all confirmed minutes will be provided to the Parent Committee once approved, providing assurances on the business considered and escalating any concerns, where necessary.

In order to aid agenda planning, the subgroup may produce a cycle of business in consultation with its Parent Committee.

## **8. Membership and attendance**

### **Chair and Vice Chair**

- Senior Head of Commissioning (GPOD) (Chair)
- Deputy Director of Commissioning (Vice Chair)

In the absence of the Chair, or Vice Chair, the remaining members present elects one of their number to Chair the meeting.

### **Membership (subject to ICB Chair's approval as above)**

- Senior Head of Commissioning (GPOD) (Chair)
- Deputy Director of Commissioning (Vice Chair)
- Lead Pharmacist
- Senior Commissioning Manager (Pharmacy)
- One Lay Member

Deputies as agreed by the Chair have the same voting rights as those that they are deputising for.

All members of the PSRC must have a good knowledge and understanding of the Regulations to reduce the likelihood of a successful appeal against decisions made. It is essential that members build up expertise in the Regulations and therefore consistency of attendance is expected. Subject to the provision of this paragraph deputies may be appointed.

The following persons will be co-opted to each PSRC but will be **non-voting** members:

- ICB Clinical Advisor (Fitness to Practice)
- ICB England Clinical Advisor (Market Entry applications)
- Commissioning Manager(s)

Persons ineligible to be voting or co-opted members of a PSRC are listed in Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations. All voting and co-opted members must sign a declaration to confirm that they are not barred by virtue of this regulation or paragraph. The Chair can require any co-opted member to leave the 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

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

### **Attendees**

Only members of the subgroup have the right to attend meetings, however all meetings of the subgroup may also be attended by the appropriately nominated individuals who are not members.

The Chair may ask any or all of those who normally attend, but who are not members, to withdraw to facilitate open and frank discussion of particular matters. Other individuals may be invited to attend all or part of any meeting as and when appropriate to assist it with its discussions on any particular matter.

### **Attendance**

Where a member of the subgroup is unable to attend a meeting, a nominated deputy may be agreed with the Chair. Once agreed, that person will have the same voting rights and responsibilities as the member. Conflicts of interest will need to be considered for any nominated deputies.

Where an attendee of the subgroup (who is not a member) is unable to attend a meeting, a nominated alternative may be agreed with the Chair (or Vice Chair in his/her absence).

## **9. Meeting Quoracy and Decisions**

The subgroup will meet in private.

The subgroup will meet at least (10) times a year and arrangements and notice for calling meetings are as set out in the Standing Orders. Additional meetings may take place as agreed by the Chair (or Vice Chair in his/her absence).

The Parent Committee may ask the subgroup to convene further meetings to discuss particular issues on which they want the subgroup's advice.

In accordance with the Standing Orders, the subgroup may meet virtually when necessary and members attending using electronic means will be counted towards the quorum.

### **Quoracy**

As this is a formal subgroup quoracy is required.

No business shall be transacted at a meeting unless at least three of the voting members are present two of which must officers from the ICB.

If any member has been disqualified from participating in an item on the agenda, by reason of a declaration of conflicts of interest, then that individual shall no longer count towards the quorum.

In the event that the quorum cannot be achieved due to a member or members being disqualified from taking part in a vote or discussion due to a declared interest the Chair of the meeting will determine the action to be taken in accordance with the constitution.

In these circumstances, an alternative quoracy of one third of the non-conflicted members will apply.

### **Decision making and voting**

The subgroup does not have any financial delegated authority.

Decisions will be taken in accordance with the Standing Orders and regulations outlined in the NHS England Pharmacy Manual (appendix 1 of terms of reference) and will ordinarily reach conclusions by consensus. When this is not possible the Chair may call a vote.

Only members of the subgroup may vote. Each member is allowed one vote and a majority will be conclusive on any matter.

Where there is a split vote, with no clear majority, the Chair will hold the casting vote.

If a decision is needed which cannot wait for the next scheduled meeting, the chair may conduct business on a 'virtual' basis through the use of telephone, email or other electronic communication.

## **10. Behaviours and Conduct**

### **ICB values**

Members will be expected to conduct business in line with the ICB values and objectives. Members of, and those attending shall behave in accordance with

the ICB's Constitution, Standing Orders, and Standards of Business Conduct Policy.

### **Conflicts of interest**

In discharging duties transparently, conflicts of interest must be considered, recorded and managed. Members should have regard to the NHS guidance on managing conflicts of interest and the ICB Standards of Business Conduct and Declarations of Interest Policy.

Conflicts of interest must be declared and recorded at the start of each meeting. A register of interests is maintained by the ICB with an extract considered before and during each meeting. If a conflict of interest arises, the Chair may require the affected member to withdraw at the relevant point.

### **Equality and diversity**

Members must demonstrably consider the equality and diversity implications of decisions they make.

## **11. Secretariat and Administration**

The Chair is responsible for agreeing the agenda and ensuring matters discussed meet the objectives as set out in these terms of reference.

The subgroup shall be supported with a secretariat function which will ensure that:

- The agenda and papers are prepared and distributed in accordance with the Standing Orders having been agreed by the Chair with the support of the relevant executive lead.
- Attendance of those invited to each meeting is monitored and highlighting to the Chair those that do not meet the minimum requirements.
- Any additional conflicts of interest are recorded and handled appropriately.
- Good quality minutes are taken in accordance with the standing orders and agreed with the chair and that a record of matters arising, action points and issues to be carried forward are kept and taken forward between meetings.
- The Chair is supported to prepare and deliver reports to the Parent Committee and/or Board.
- Confirmed minutes and areas of escalation from agreed subgroups are reported to each meeting.

## **12. Review**

These terms of reference will be reviewed at least annually and more frequently if required. Any proposed amendments to the terms of reference will be submitted to the Parent Committee for approval.

### 13. Appendix 1 – NHS England Pharmacy Manual Regulations

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

<b>Regulatory provision</b>	<b>Decision-maker</b>
Regulation 31 – refusal: same or adjacent premises	Subcommittee
Regulation 32 – deferrals arising out of LPS designations	Officer or Subcommittee
Regulation 33 – determination of suitability of an applicant to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
Regulation 34 – determination of deferral of application to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
Regulation 35 – determination of conditional inclusion of an applicant to be included in a pharmaceutical list on fitness grounds	Subcommittee or PLDP
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)	Subcommittee
Regulation 37 – process for determining controlled localities: preliminary matters	Subcommittee
Regulation 40 – applications for new pharmacy premises in controlled localities: refusals because of preliminary matters	Subcommittee
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)	Subcommittee
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	Subcommittee
Regulation 48(2) - determination of patient application ('serious difficulty' applications)	Officer or Subcommittee
Regulation 48(5) to (9) – making of arrangements with a dispensing doctor to dispense to a particular patient or patients	Subcommittee
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	Subcommittee

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	Subcommittee
<b>Regulatory provision</b>	<b>Decision-maker</b>
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 Subcommittee
Regulation 65(5) to (7) – direction to increase core opening hours	Officer or Subcommittee
Regulation 67 – agreement of a shorter notice period for withdrawal from a pharmaceutical list	Subcommittee
Regulation 69 – determination of whether there has been a breach of terms of service	Subcommittee
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	Subcommittee
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	Subcommittee
Regulation 72 – determination of whether to withhold remuneration	Subcommittee
Regulation 73 – determination of whether to remove premises or a chemist from the pharmaceutical list (following remedial or breach notice)	Subcommittee
Regulation 74 – determination of whether to remove premises or a chemist from the pharmaceutical list (death, incapacity or cessation of service)	Subcommittee
Regulation 79 – determination of review of fitness conditions originally imposed on the grant of an application	Subcommittee or PLDP
Regulation 80 – determination of removal of a contractor for breach of fitness conditions	Subcommittee or PLDP

Regulation 81 and 82 – determination of removal or contingent removal	Subcommittee or PLDP
Regulation 83 – suspensions in fitness cases	Subcommittee or PLDP
Regulation 84 – reviewing suspensions and contingent removal conditions	Subcommittee or PLDP
Regulation 85 – general power to revoke suspensions in appropriate circumstances	Subcommittee or PLDP
Regulation 94 – overpayments	Subcommittee
Regulation 99 – designation of an LPS area	Subcommittee
Regulation 100 – review of designation of an LPS area	Subcommittee
Regulation 101 – cancellation of an LPS area	Subcommittee
<b>Regulatory provision</b>	<b>Decision-maker</b>
Regulation 104 – selection of an LPS proposal for development and decision to adopt proposal	Subcommittee
Regulation 108 – right of return for LPS contractor	Subcommittee
Schedule 2, paragraph 1(10) – whether a best estimate is acceptable	Officer or Subcommittee
Schedule 2, paragraph 11(1) – determination of whether there is missing information	Officer
Schedule 2, paragraph 11(2)(b) – determination of review of reasonableness of request for missing information	Officer or Subcommittee
Schedule 2, paragraph 14 – whether to defer consideration of application	Officer or Subcommittee
Schedule 2, paragraph 19 – determination of who is to be provided with notice of a notifiable application	Officer
Schedule 2, paragraph 21(4) – determination of whether the full disclosure principle applies to information contained within a notifiable application	Subcommittee
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 Subcommittee
Schedule 2, paragraph 25 – decision to hold an oral hearing to determine an application	Subcommittee
Schedule 2, paragraph 28 – determination of who is to be notified of decisions on routine and excepted applications	Officer or Subcommittee
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 Subcommittee
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 Subcommittee

Schedule 2, paragraph 32 – determination of whether to accept a change to premises	Officer or Subcommittee
Schedule 2, paragraph 33 – determination as to whether the future circumstances have arisen	Officer
Schedule 2, paragraph 34 – decisions as to whether notices of commencement are valid, and whether a shorter notice period can be given	Officer
Schedule 2, paragraph 34A – decisions as to whether notices of consolidation are valid, and whether a shorter notice period can be given	Officer
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 Subcommittee
<b>Regulatory provision</b>	<b>Decision-maker</b>
Schedule 2, paragraph 35 – notice requiring the commencement of pharmaceutical services	Officer or Subcommittee
Schedule 4, paragraph 23(1)/Schedule 5, paragraph 13(1) – consideration of a request to temporarily suspend the provision of services (fixed period)	Subcommittee
Schedule 4, paragraphs 23–25/Schedule 5, paragraphs 13–15 – decision to direct a contractor to open at certain times on certain days	Subcommittee
Schedule 4, paragraph 23(10)/Schedule 5, paragraph 9 – review of reason for temporary suspension within the control of the contractor	Subcommittee
Schedule 4, paragraph 26/Schedule 5, paragraph 16 – determination of core opening hours instigated by the contractor	Subcommittee
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 Subcommittee
Schedule 4, paragraph 27B – flexible provision of relevant immunisation services during a pandemic	Officer
Schedule 4, paragraph 28A – premises requirements in respect of consultation rooms – decisions that a pharmacy premises is too small	Officer or Subcommittee
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 Subcommittee
Decisions relating to compliance with the dispensing doctor terms of service	Subcommittee

Approval of responses to an appeal against, or challenge to, decisions of the committee	Officer or Subcommittee
Approval of responses to an appeal against, or challenge to, decisions of the officer	Officer or Subcommittee
Determination of further action where community pharmacy assurance framework identifies concerns	Officer or Subcommittee
Determination of further action where the contractor fails or refuses to agree a date and time for a visit	Officer or Subcommittee
Determination of action where any of the following are identified: <ul style="list-style-type: none"> <li>• patient safety issues</li> <li>• the commissioner is at risk of material financial loss, and/or</li> <li>• possible fraudulent or criminal activity.</li> </ul>	Officer or Subcommittee
<b>Regulatory provision</b>	<b>Decision-maker</b>
Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report	Officer or Subcommittee
Determination of action where the contractor exceeds the maximum number of appliance use reviews that may be done in any one year	Officer