

Item: 9.2
Appendix: 11

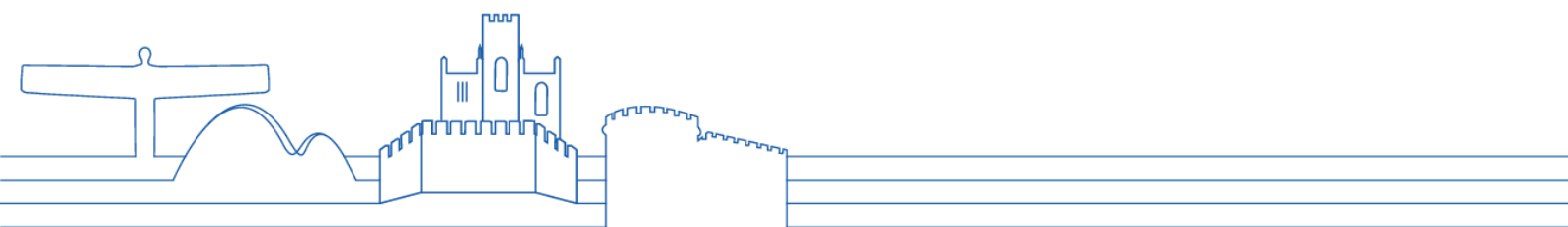
Appendix 11



**North East and
North Cumbria**

Integrated Care Board

Pharmaceutical Services Regulations [Sub] Committee Terms of reference



1. Constitution

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 (ToRs).

ICBs are required to establish committees that are the equivalent of NHS England's PSRCs as part of the delegation arrangements for ICBs to undertake the commissioning of community pharmacy services on behalf of NHS England. Where such a subcommittee is established and is properly constituted in line with the Regulations, it is authorised by NHS England to undertake any activity within these ToRs.

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

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

2. Authority

The PSRC is a formal Subcommittee of the ICB Executive Committee. The Board has delegated authority to the Subcommittee as set out in the Scheme of Reservation and Delegation and may be amended from time to time.

The PSRC holds only those powers as delegated in these terms of reference (as defined by the Pharmacy Manual (Version 2, 10 February 2023) and approved by the ICB Board.

The PSRC will determine all matters within its ToRs and is authorised by the ICB to obtain such outside legal or other independent professional advice and to co-opt persons with the relevant experience and expertise if it considers this necessary. Co-opted persons will not have voting rights and if required by the Chair will leave the meeting whilst the decision is made.

3. Purpose of the Committee

The PSRC has been established to receive and determine, on behalf of the ICB, applications submitted under the NHS (Pharmaceutical Services) Regulations 2013 as amended ('the Regulations').

4. Membership and Attendance

The PSRC members shall be appointed by the Board in accordance with the ICB Constitution and in line NHS (Pharmaceutical and Local Pharmaceutical Services) Regulation 2013.

In line with the above requirements the Board will appoint the following to be the membership of the PSRC:

- Head of Primary Care (or their suitable, nominated deputy) who will Chair the meeting (Chair)
- Executive Area Director (Senior Responsible Officer (SRO)) who will chair the meeting in the absence of the Head of Primary Care (Vice-Chair)
- Up to two PSRC Lay Members 'NHSE Expert volunteers'

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 not be voting members:

- Pharmacy Contract Manager (or equivalent post in the ICB)
- Pharmacy Professional Advisor (or equivalent post in the ICB)

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).

Chair and Vice-Chair

The Chair will be the Head of Primary Care (or their suitable, nominated deputy) and the Executive Area Director (Senior Responsible Officer (SRO) or their suitable nominated deputy) will chair the meeting in the absence of the Head of Primary Care. If the Chair is not present, then the Vice Chair will chair the meeting.

The Chair will be responsible for agreeing the agenda and ensuring matters discussed meet the objectives as set out in these ToRs and in line with the general principles for decision making outlined in the Pharmacy Manual (Version 2, 10 February 2023).

The PSRC shall satisfy itself that the ICB's policy, systems and processes for the management of conflicts, (including gifts and hospitality and bribery) are effective including receiving reports relating to non-compliance with the ICB policy and procedures relating to conflicts of interest.

If a Chair has a conflict of interest, then the Vice-Chair or, if necessary, another Member of the PSRC will be responsible for deciding the appropriate course of action.

The Chair may agree other nominated individuals to attend regularly or for specific agenda items but, at the request of the Chair, will leave the meeting while decisions are made.

5. Meetings, Quoracy and Decisions

The PSRC will meet in private.

The PSRC shall meet monthly (or earlier if needed in order to discuss a case urgently). The arrangements and notice for calling meetings are set out in the ICB's standing orders. Additional meetings may be convened urgently, to discuss urgent cases, on an exceptional basis at the discretion of the Subcommittee Chair. Where a meeting is not required it will be documented in line with local procedures.

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

The Subcommittee will report at least every month to the Primary Care Strategy and Delivery Subcommittee 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.

Quoracy

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

In the event that a meeting of the PSRC is not quorate, the Chair can decide that the meeting will progress, but where decisions are required, they will be deferred to the next meeting when the PSRC is quorate.

Decision making and voting

Decisions will be taken in accordance with the ICB's Standing Orders. The PSRC will ordinarily reach conclusions by consensus of voting Members. When this is not possible each voting Member will have one vote and in the event of a tied vote the Chair will have the casting vote. The result of the vote will be recorded in the minutes.

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.

6. Responsibilities of the Committee

The responsibilities of the PSRC are defined Under the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 and will be authorised by the ICB Board. It is expected that PSRC will:

- 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. 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). 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 Pharmacy Contract Manager (PCM) or ICB equivalent to determine those applications and notifications delegated in the regulations. Where necessary the nominated PCM may escalate an application or notification to the PSRC. If, due to annual or sick leave, the nominated PCM is unable to determine an application or notification within the regulatory timescale it is to be determined by the PSRC.

7. 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, the PSRC shall behave in accordance with the ICB's Constitution, Standing Orders, and Standards of Business Conduct Policy.

Equality and diversity

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

8. Accountability and Reporting

The PSRC is accountable to the ICB through the Executive Committee. The minutes of meetings shall be formally recorded and submitted to the Primary Care Strategy and Delivery Subcommittee and then onward to the Executive Committee, in private or public as appropriate.

The Chair of the PSRC shall report to the Primary Care Strategy and Delivery Subcommittee after each meeting and provide a report on assurances received, escalating any concerns where necessary.

The PRSC, through its reports and minutes to the Executive Committee and via the Primary Care Strategy and Delivery Subcommittee, will advise the on the adequacy of assurances available and contribute to the ICB's Annual Governance Statement.

The PSRC will receive scheduled assurance reports from its delegated groups. Any delegated groups or sub-committees would need to be agreed by the ICB Board.

9. Declarations of Interest

All members and those in attendance must declare any actual or potential conflicts of interest which will be recorded in the minutes. Anyone with a relevant or material interest in a matter under consideration will be excluded from the discussion at the discretion of the Sub-committee Chair.

10. Secretariat and Administration

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

- I. 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
- II. Attendance of those invited to each meeting is monitored and highlighting to the Chair those that do not meet the minimum requirements

- III. 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
- IV. The Chair is supported to prepare and deliver reports to the Primary Care Strategy and Delivery Sub-committee
- V. The Sub-committee is updated on pertinent issues/ areas of interest/ policy developments
- VI. Action points are taken forward between meetings and progress against those actions is monitored.

11. Review

The PSRC will review its effectiveness at least annually and complete an annual report submitted to the Primary Care Strategy and Delivery Subcommittee and Executive Committee.

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 Executive Committee and, if required, the Board for approval.

The PSRC will utilise a continuous improvement approach in its delegation and all members will be encouraged to review the effectiveness of the meeting at each sitting.

Version: 1-0

Date of approval: Board 28 March 2023 **TBC**

Date of review:

Regulatory provision	Decision-maker
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)
Regulatory provision	Decision-maker
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)	Sub Committee
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)	Sub Committee
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

Regulatory provision	Decision-maker
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
Regulatory provision	Decision-maker
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
Regulatory provision	Decision-maker
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

<p>Determination of action where any of the following are identified:</p> <ul style="list-style-type: none"> • patient safety issues • the commissioner is at risk of material financial loss, and/or • possible fraudulent or criminal activity. 	<p>Officer or Subcommittee</p>
<p>Regulatory provision</p>	<p>Decision-maker</p>
<p>Determination of action where the contractor fails to complete the required actions or fails to respond to a visit report</p>	<p>Officer or Subcommittee</p>
<p>Determination of action where the contractor exceeds the maximum number of appliance use reviews that may be done in any one year</p>	<p>Officer</p>