

SPACE FOR LOGO/S

Terms of Reference:	Pharmaceutical Services Regulations Committee
Authorship:	TBC
Board Responsible for Approving:	HNY / SY / WY ICB Integrated Care Board
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Introduction and Governance

1. In accordance with the Health and Care Act 2022 NHS England has delegated the exercise of pharmaceutical services and local pharmaceutical services functions to Humber and North Yorkshire Integrated Care Board (ICB), South Yorkshire ICB and West Yorkshire ICB from the 1 April 2023.
2. In accordance with the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended ('the Regulations'), each ICB will establish a Pharmaceutical Services Regulations Committee (PSRC) to make decisions in relation to matters under the Regulations listed in Chapter 3 of the Pharmacy Manual where the decision maker is listed as 'the committee'.
3. For the purpose of this document, 'the committee' or 'committee' is the PSRC.
4. 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.
5. 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.
6. Each ICB is responsible for fulfilling its own statutory responsibilities and is required to have its own committee to oversee certain functions. The ICBs have agreed that the PSRC should meet as 'committees in common'. This means that each committee meets simultaneously, but that each committee will retain responsibility for its own functions and will remain accountable to its own ICB Board.
7. Humber and North Yorkshire ICB, South Yorkshire ICB and West Yorkshire ICB have delegated decision making to their committee in relation to matters under the Regulations listed in Chapter 3 where the decision maker is listed as the committee.
8. The operation of a PSRC as a Committees in Common across Humber and North Yorkshire, South Yorkshire and West Yorkshire has been agreed as a

way of working as part of the transfer of delegated functions and agreed by the three ICB Boards.

Membership, Voting and Conflicts of Interest

9. The voting membership of the committee shall be as follows:
 - Senior Responsible Officer for Primary Care, NHS South Yorkshire.
 - Director of Primary Care and Commissioning, Humber and North Yorkshire ICB (Chair);
 - Community Pharmacy Clinical Lead for NHS West Yorkshire ICB; and
 - Up to three lay members.
10. 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.
11. All members of the committee must have a good knowledge and understanding of the Regulations in order to support sound and robust decision-making. It is essential that members build up and maintain their expertise in the Regulations and therefore minimum of 75% attendance at the Committee meetings is expected.
12. The Committee will ordinarily reach decisions by consensus. Where this is not possible the Chair of the Committee may call a vote. Each voting member in attendance at the Committee has one vote. Where there is a split vote, with no clear majority, the Chair of the Committee will hold the casting vote.
13. Each meeting of the committee will be quorate if one voting member, or their nominated deputy, is present from each ICB area.
14. 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.
15. The following persons from the NHSE Primary Care teams aligned to each ICB will attend each committee meeting but will not have voting rights:
 - Primary Care Manager (or equivalent); and
 - Pharmacy professional adviser (or equivalent).

In addition, relevant ICB officers will be invited to attend the Committee meeting as appropriate.

16. Persons ineligible to be voting or co-opted members of a committee are listed in Regulation 62 and in paragraph 26(1) of Schedule 2 to the Regulations. All voting members must sign a declaration to confirm that they are not barred by virtue of this regulation or paragraph. The Chair can require any member to leave the room before discussion of a matter and not return until the relevant decision has been made. The minutes will record the absences of the relevant voting member or members.

17. 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).
18. Members must advise the Chair of any potential conflict of interest as soon as they become aware that a potential conflict may exist. Discussion of those potential conflicts will take place at the beginning of each meeting and the action taken to mitigate such conflicts recorded. Any conflicts will be considered and managed in accordance with the ICB's conflict of interest policy.
19. Administrative support to the committee will be provided by for South Yorkshire ICB, with West Yorkshire or Humber and North Yorkshire ICB providing cover as required.
20. Each committee will meet monthly as Committees in Common (or earlier if needed in order to discuss a case urgently) where there is a need. Where a meeting is not required, this will be documented in line with local procedures.
21. Each committee will provide a report setting out a summary of its activity, decisions taken and outcomes of any appeals against those decisions at least every six months to an appropriate senior management committee (to be determined by each ICB).
22. 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). 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.

Pharmacy Contract Manager (PCM) Decision Making

23. The Pharmacy Manual refers to Pharmacy Contract Manager (PCM) level decision making. 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 through the approval of these terms of reference to make the decisions in accordance with Appendix 1 of these terms of reference.
24. For the purpose of this document, 'the officer' or 'officer' is either the PCM or the ICB equivalent.
25. The ICB 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'.
26. 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.

27. 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).
28. 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.
29. The officer will report monthly to the committee on decisions taken and the outcome of any appeals on those decisions.
30. 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.

Fitness to Practice Decisions

31. 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 person 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.

32. Fitness decisions will be reported monthly to the PSRC on decisions taken in line with Chapter 4 of the Pharmacy Manual.

Accountability and Reporting

33. The Committees are accountable to their own ICB.

34. The Committee will review their own effectiveness and produce a Committee annual report as determined by detail set out in their own ICB's Constitution and Standing Orders.

35. Any minutes or key messages will be presented to the ICB Board as determined by each ICB's Constitution and Standing Orders.

Review of the Terms of Reference

36. These terms of reference will be reviewed in July 2023, aligned to the transfer date of NHS England Primary Care teams and thereafter annually and/or each time the Pharmacy Manual is re-published to ensure they remain consistent with regulatory updates and changes.

Appendix 1

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
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 where premises approval has not taken effect, practice amalgamations, and lapse of outline consent and premises approval	Committee	Chapter 34
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

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
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 of 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: <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. 	Officer or committee	Chapter 38
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