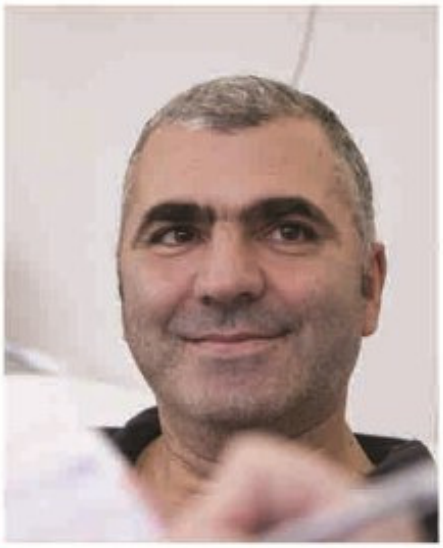
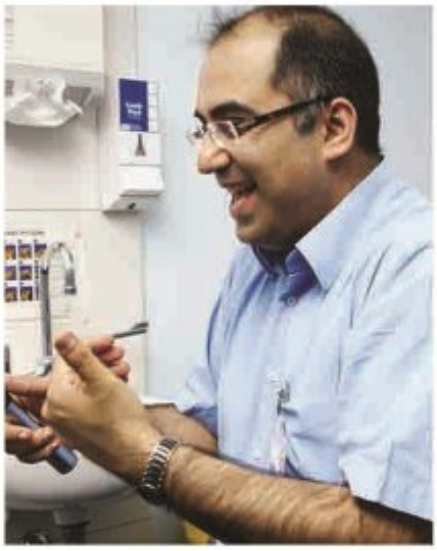
NHS England

Guidance to support delivery of primary medical services assurance framework





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Guidance to support delivery of primary medical services assurance framework

Standard operating policies and procedures for primary care

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Information Reader Box

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Author	Primary Care Commissioning 1N04, Quarry House, LEEDS E-mail: england.primarycareops@nhs.net

Document Status

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Contents

Purpose of 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 care, 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 four primary care contractor groups.

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

Policy aims and objectives

9 This policy outlines the approach to be taken by NHS England in the implementing and managing the primary medical services assurance framework.

10 This guidance provides an outline for assessing general practice through the normal contractual framework (e.g. Personal Medical Services (PMS), General Medical Services (GMS) or Alternative Provider Medical Services (APMS)) and in due course a suite of general practice high level indicators. It sets out an approach to working with GP contractors and provides a guide to managing these where there is a potential or actual breach of contract.
This policy is to be read together with the Policy for primary medical services assurance framework.

Background

11 The area teams (ATs) of NHS England are expected to understand the strengths and weaknesses of commissioned services, driving improved quality and outcomes through the provision of effective support mechanisms and where necessary, intelligence led performance management, supported by local medical committee (LMC) representation at the earliest opportunity.

12 This document has been written at a time of major NHS reorganisation. The guidance is intended to ensure consistency of approach and to help any primary care contract manager working in an AT. It is also intended to provide clarity to GP practices about the performance management routes available to their commissioner and guide them through the process. It will be a working document which will be revisited as the new structures and the new performance management functions embed themselves in practice.

13 NHS England, and those it has consulted, are aware that the pre April 2013 arrangements include many variations in the nature and scope of local services available to support general practice both in the delivery of the service and to manage those practices and practitioners whose performance is a cause for concern. These variations must always be considered when supporting practices or managing concerns.
It is important that this document is read together with any relevant contract and, if appropriate, the relevant regulatory framework. It is essential to always check clause numbers and clauses in the specific contract if taking formal action (such as issuing breach or remedial notices).

Scope of the policy

14 This policy outlines the approach to be taken by NHS England when there may be concerns of risk to quality and patient safety.

The assurance approach

15 NHS England will work with GP leaders, clinical commissioning groups (CCGs) and LMCs, to further refine this framework to assure quality service provision in primary medical services.
This will consolidate:

- a suite of consistent and nationally available general practice high level indicators recommended by the national reference group. A technical guidance document will accompany these indicators;
- a set of quality and outcome standards already developed in one regional office and agreed with the profession (to form part of the triangulation of other factual intelligence). A technical guidance document will accompany these indicators; and
- any new standards developed by clinicians that set clear expectations about what patients should expect to receive from general practice.

16 An introduction to a national approach to improve quality, access and patient experience in general practice and a summary of the general practice high level indicators will be published alongside this guidance. The standards will be reported nationally from April 2013 onwards. This will help to provide an in-depth assessment of local practice performance and enables NHS England, its regions, area teams and providers to begin to understand trends and possible reasons for variation, whether warranted or un-warranted.

17 Active contract management will enable providers and NHS England to better identify both examples of good practice and areas where services give cause for concern. Sometimes action may be required. For example, if it looks as though a contractor could be in danger of committing a breach of contract, the commissioner may be able to forewarn the practice and deal with the matter on a relatively informal basis. In other cases where a breach has already occurred, the commissioner may be left with no alternative but to put the matter on a more formal footing (e.g. by issuing a breach or remedial notice). It will also, where necessary, support improvements in quality and performance by identifying different kinds of support and helping to address specific issues where appropriate.

Principles

18 The ultimate aim of this process is to drive up quality and develop good quality services for patients.

19 There is a distinction between concerns relating to the provision of contracted services and issues around an individual's practice as a performer. In the former situation, the matter will be dealt with under the contractual framework (with which this guidance is concerned). In the latter situation, the matter will usually be dealt with under the performers' lists regulations. However, the two often overlap and AT primary medical care (PMC) managers need to be clear about which route they intend to take or if both are to be progressed simultaneously.

20 Contract management needs resources and this should be identified up front. This includes identifying who, within the AT, will have overall responsibility for the matter, its urgency and the resources which will be required, both internal and external. This can present a challenge given the management cost savings programme and drive toward affordable services. The cost of commissioning high quality general practice medical provision and appropriate and effective management of the contract will need to be considered in local decisions on future allocation of resources and to ensure this continues to be dealt with effectively.

21 This document is a guide to support maintaining the high quality of services through an assurance framework and service improvement where there is an identified need. It presents an overview of the steps and actions an AT might take to address the poor provision of services. Any concerns must be handled on a case by case basis and legal advice should be sought where appropriate.

Responsibilities

22 This document clearly sets out the primary responsibility of NHS England for ensuring and assuring that high quality primary medical service is provided to the local population. However it is important to acknowledge that, by accepting and working within the agreed contract, the contractor is accepting responsibility for the quality of care delivered. The contractor also acknowledges the legitimate role of NHS England as commissioner of primary medical services and should be prepared to engage constructively in any fair and reasonable process of review and remedy. NHS England recognises the importance of engaging with the relevant local medical as necessary, at the very outset of this process.

23 In reality most contractors are clinicians who will also have their wider professional responsibilities to patient safety and quality and this should also be recognised by NHS England. This will develop the culture of respect and understanding that will ensure the approaches taken to assurance can be seen by all parties as mutually beneficial and effective.

Assurance monitoring – recognising and identifying underperformance

Principles for setting clear expectations

24 Where possible, there should be a shared vision between NHS England, LMCs and individual practices of what good, acceptable and unacceptable practice looks like. Ultimately however, responsibility for ensuring the proper and adequate provision of services rests with ATs on behalf of NHS England.

25 It is helpful to have a clear and consistent policy for dealing with contractual issues, and where possible agreed by all the key stakeholders. If there are concerns around the provision of services, then any resulting actions taken by the AT should be fair, proportionate and reasonable. Where possible, this should be underpinned by open and transparent dialogue between NHS England and GP contractors, supported by LMCs.

Good assurance management

26 Good assurance management requires sufficient capacity and capability in the responsible organisation. Managers should know their own organisation's escalation procedures before dealing with any matter or having to enact them. There should be a regular review of data and good record keeping. Face-to-face meetings with GP contractors should happen, when an intelligence-led review of practices highlights a potential cause for concern and where alternative prior steps to address any concerns have not realised a positive outcome. From any such meeting, agreed minutes or notes should be recorded and kept as a joint record. Those responsible for local implementation of the assurance policy must ensure that sources of intelligence used in any discussion with a provider are both accurate and factual.

Failure to comply with contractual requirements

27 Primarily, contract management is about ensuring that services provided to patients are, as a minimum, in line with the agreed contractual requirements. Poor or unacceptable service provision will occur where a contractor is in breach of their contract. One of the functions of the commissioner therefore is to monitor the contract to ensure the relevant contractual provisions are being complied with.

28 Effective monitoring of contracts also means that NHS England should be able to identify potential problems at an early stage and help GP contractors to try and deal with them before they escalate into a formal breach.

29 However, once a breach occurs, the commissioner may be left with no alternative but to take formal action (for example, issuing a remedial or breach notice). Please refer to the policy for Managing contract breaches, sanctions and terminations for primary medical services.

Sources of information

30 There are a number of sources of information that may be relevant in the context of managing and monitoring contractors and the provision of services that they are responsible for. They are set out below:

Table 1: Information sources

Key sources of data and information	Other optional sources of data and information which may provide additional context
Quality outcomes framework (QOF) General practice high level indicator set Practice profile Practice declaration Financial systems Prescribing data Referrals Clinical governance systems IT control Visits to the practice (QOF / CQC) Serious untoward incident (SUI)	Referral and out of hours (OOHs) data Infection control Public health targets Complaints and other PALS information Employment law and workforce Clinical audit HR policies Whistle blowing Patient experience Accident & Emergency (A&E) data Expected health outcomes Controlled drugs Safeguarding Children

31 Good information governance (Information security management: NHS codes of practice and Records management: NHS codes of practice) is essential. AT PMC managers should have a practice file where all relevant sources of information are kept. For example, the file may include all

relevant correspondence and notes of any meeting held with the contractor.

2. Early warning and support

32 In many cases, the best opportunity to address concerns successfully is if potential problems are identified early.

The process for recognition

33 Good record keeping is essential for early recognition of any emerging problems. All the available information should be kept up to date to build a complete picture of the GP contractors and the quality of services they are responsible for. Where appropriate, this should be done with expert support and with clinical input. In many cases, it may be helpful to have input from the AT's medical director or other GP advisers. It is important there is the right expertise when analysing the information, as incorrect conclusions and faulty judgments based on non-factual or subjective information can bring the whole process into disrepute.

34 Where the AT is considering the provision of services and comparing, for example, different GP contractors, the AT will need to take into account the local context in which the services are being provided. Accordingly, it may be appropriate to benchmark against practices across a spectrum of options such as the same geographical area (CCG/AT) and those with similar characteristics, including list size, index of multiple deprivation (IMD), Association of Public Health Observatory grouping and so on, as well as against professional standards. It is also important the ATs understand the variability of practice populations (e.g. a practice with large numbers of students in an otherwise deprived urban area).

35 If there is any indication from data and information sources that a GP contractor is failing to provide adequate and improving primary medical services, then depending on how serious this is, it may trigger discussion in the first instance with the contractor.

36 In any event, there should normally be ongoing communication, including regular informal contact, as well as face-to-face meetings, between the contractor and a member of the AT primary medical services commissioning team to discuss relevant data and information or issues faced by the contractor. This should help identify issues at the earliest opportunity and facilitate a joint approach to resolution, facilitated by the relevant LMC as required. These communications will help to establish a transparent relationship where GP contractors will feel comfortable to be open and honest about the services they are responsible for providing. This

is where there is the highest chance of a successful outcome for all concerned.

Early warning

37 ATs' regular review of data and information is only part of the picture. This will help support early identification of a performance issue, but a good relationship between the AT primary medical services manager and the contractors, supported by LMCs will also help. When NHS England really engages with practices, and fully understands the context in which they work, this builds a constructive relationship where support required is identified and issues are resolved at the earliest opportunity.

38 Where there is early warning of a problem then the first step would normally be to discuss this with the practice, to identify the extent of the problem and whether it can be easily resolved.

39 There are many reasons why systems and processes can break down, some of which can be resolved quickly. For example, clinical and non-clinical absence and recruitment or if there is a change in management or staffing at a practice. In this situation the AT may want to identify sources of support that the GP contractor could access.

Support

40 There are a wide variety of sources of support available to practices. Some of these are set out in annex 3 to this guidance.

Managing contractual underperformance

Contractual underperformance

41 It is not really possible to define the full range of contractual under-performance that may give rise to a concern that a GP contractor is in breach of their contract. However, concerns can range from a one-off specific incident, such as a complaint or an SUI, through to a range of ongoing minor issues around the quality of services being provided. Often, in these types of situations, early engagement with the practice, and if appropriate their LMC, can be crucial to resolving the concerns.

42 All options to support practices to improve and remedy any breach notices should be explored over a sufficient period of time. However in a small number of circumstances where, for example, the safety of the contractor's patients is at serious risk if a contract is not terminated or the commissioner considers that it is at risk of material financial loss, then it may need to look

to terminate the contract and, possibly, quickly. See the policy for Management of contract breaches, sanctions and termination for primary medical services.

Individual performer or the contractual route

43 There is often an overlap between a failing GP practice and the performance of individual clinicians, so there should be clarity in managing performance and contractual issues. In some cases AT PMC managers will need to instigate both contractual review and individual performer proceedings simultaneously. The steps NHS England may take under the performers' lists regulations to regulate the performance of GPs are separate (i.e. subject to different regulatory frameworks) from the arrangements they have for ensuring that GMS, PMS and APMS contractors comply with their contracts to provide services.

44 The National Clinical Assessment Service (NCAS), in collaboration with the Royal College of General Practitioners (RCGP) and the NHS Clinical Governance Support Team (CGST) published Local GP performance procedures (November 2007 – second edition. The document provides information on local procedures for handling concerns about the performance of GPs working in England. It offers advice and a suggested approach on the principles, structures and processes for local arrangements, and builds on extensive work already undertaken in this field (the key messages are outlined in annex 4). The document is written primarily for NHS England in England, which is directly involved in handling concerns about individual GP performance. Please see the Policy for identification management and support of independent contractors whose performance gives cause for concern.

Governance

45 The AT should bear in mind the following general principles when dealing with contract management.

46 i. Identify who has overall responsibility for contract management within the AT.

ii. Daily management of the practice should be dealt with by the responsible member of the contract team, ie the person/team appointed to deal with the practice. They will then be responsible for liaising with the practice; collecting and collating information; arranging for meetings (such as annual contract reviews) and generally forming a point of contact between the GP practice and the commissioning body.

iii. Where a situation is identified that could give rise to concerns, it would usually be good practice for the person or team with daily responsibility for the relationship, to discuss the matter with the contractor concerned in the first instance. In some circumstances it may also be necessary to report the concern to their line manager at the same time. If the concern is minor and there is no actual breach, then all that might be required is a visit telephone call to the practice, followed up in writing confirming what was discussed.

iv. If the potential concern is substantiated or is more serious, then the matter may have to be escalated to the person with overall responsibility for contract management within the AT and the LMC should definitely be engaged. That person can then decide whether the matter can be dealt with informally or whether formal action needs to be taken, such as the issuing of a remedial or breach notice or in certain situations a contract sanction. If the matter is very serious, then that person may need to consider whether or not the AT should be considering if there is sufficient factual evidence to seek termination of the contract, on the grounds that regulation has not been adhered to.

v. If a remedial or breach notice needs to be issued, then the AT should agree a process which identifies who will be responsible for signing the notices off. Please see the Policy for contract breaches, sanctions and termination for primary medical services.

vi. NHS England must be informed where breach or remedial notices have been issued. The board can then review these regularly. This will also ensure consistency and proportionality as well as help to identify wider trends or concerns.

vii. Where the AT is considering the issue of a termination notice, due process must be followed as outlined in the policy for Managing contract breaches, sanctions and terminations for primary medical services. The AT must also ensure it meets its obligations to notify other associated bodies of any failure in service delivery, such as CQC, CCG and LMCs.

viii. Termination of a contract is a serious step, and generally requires a higher level of risk than applies to the decision not to award a contract [Family Health Services Appeal Unit (FHSAU) Case ref SHA/16023 Para 10]. Where a termination notice is issued, then there are a number of implications that the AT will need to take into account. These include the risk that any decision to terminate will be challenged by reference to the FHSAU. Where the contract is

terminated, then issues around what happens to the contractor's staff, the premises, and whether there are any ongoing consultation and procurement issues, will also need to be considered.

ix. The AT needs to be clear about how contracts will be managed daily and where more formal action needs to be taken, how that will be dealt with.

The initial diagnosis

47 Clearly in a perfect world issues about quality of care and performance in general practice would arise from analysis of multiple data sets, looking at different aspects of the services provided that could be considered in a measured and balanced way, and leading to a robust diagnosis of the issues and potential remedies. In reality this cannot always be the case and it is often necessary to make a more rapid assessment of the issue(s) presented, to protect patient safety and make key decisions about next steps.

48 In these circumstances it is usually important to have agreed in advance who will consider the issues and to ensure they have the position and authority to act. This is likely to be a director with primary care responsibility working with a suitable clinical director/adviser.

49 It may be useful to consider the following questions as part of these discussions:

i. Is this practice already known to have performance issues?
ii. Is it already subject to receiving practice support or remedial action?
iii. How reliable is the source of the information on the issue? Can it be triangulated from other sources?
iv. Have other matters been brought to the attention of NHS England in the last month? Last three months? Last six months?
v. Are these issues predominantly about the operation of the practice or the practice of the practitioners or both?
vi. Is the issue consistent with existing issues or does it come as a surprise?
vii. Does the issue put patients at actual or potential risk?
viii. How likely is the issue to reoccur?
ix. Have there been any changes or issues in key staff in the practice recently? E.g. sickness absence, maternity leave, retirements, staff turnover
x. What is happening with the practice list? Growing? Shrinking? Staff turnover? Has this changed recently?
xi. What is known about practice income e.g. as a result of list

cleansing reductions or reduction in QOF achievement?

xii. Have there been changes in use of other services e.g. OOHs services, A&E?

xiii. What else is known about overall performance?

50 After considering these and other relevant questions, it is helpful to visit the practice and work with it to establish a mutually agreed profile of the practice's strengths and weaknesses.

51 Critical to this assessment will be how well the practice/practitioners seem to understand their own strengths and weaknesses, their insight into their significance and steps taken – or being prepared – to address areas of concern.

52 This initial assessment is important to determine necessary speed of response and to decide whether any identified concerns would be best managed contractually or through individual performer route or both.

The formal and informal contract management process

53 Whether a matter is dealt with informally or formally will depend on the nature of the concerns and the assessed risk to the safety and quality of services provided by that contractor.

54 For example, if a minor concern is identified that could escalate, then all that is likely to be required is a visit/telephone call to the practice by a member of the contracting team, to explain the concern and discuss in an open and transparent way how this could be addressed. This should then be followed up in writing and kept under review for a defined period of time as agreed with the provider and LMC representative.

55 If the concern is more serious (but it is not clear whether there has been a breach of contract) it may be necessary to have a more formal meeting with the practice. In this situation, the AT should send a letter to the contractor setting out the basis of any identified concerns, a request for a meeting and details of which officers from the AT will be attending. The practice should also be invited to have someone from the LMC present, although it is recommended the LMC would already be involved at this stage.

56 If following any meeting the concerns identified are considered to be low risk and the AT is satisfied there is no breach of contract, then no formal action will be required. However, the AT should follow the meeting up with a letter confirming the outcome.

57 If the concern is more serious, for example, the practice is providing

services in such a way that could give rise to a breach of contract in future, then the AT may wish to agree a more formal action plan to try and help the practice to prevent a breach from occurring.

58 In this situation the following actions could be considered:

- An action plan to be agreed by both parties with specific, measurable, achievable, realistic and timely (SMART) deliverables and timescales for completion.
- A process for monitoring and reviewing the steps taken, at agreed timed intervals.
- Identifying ways in which the practice should be seeking support, whether from the AT or other organisations.
- A process for ensuring all steps taken are clearly documented and all relevant evidence is kept on the contractor's file.

59 If during the currency of the action plan, further concerns come to light or the AT considers that the practice is not taking the necessary steps in good time, and it becomes clear that a breach has occurred or is occurring, then it may need to take action under the formal contract management process outlined below.

60 The commissioner may also consider that if appropriate, a more formal investigation should be carried out before considering the scope of any action plan or whether more formal action needs to be taken.

The formal contract management process

61 In undertaking formal contract management it is important to ensure that the AT is referencing all relevant contracts; that they are up to date and any variation to the contract is in writing and, where necessary, signed by and on behalf of NHS England, or its predecessors and the contractor.

62 Each type of contract is underpinned by a regulatory framework whether it be a GMS, PMS or APMS contract. For example, GMS contracts are underpinned by the NHS (General Medical Services Contract) Regulations 2004 (SI No.2004/291, as amended from time to time). There is also a standard GMS contract, published by the Department of Health, which is used by NHS England and contractors as the core contract. Equivalent regulatory frameworks exist for PMS and APMS contracts. However, these contracts are less standardised than GMS contracts, since they tend to be agreed locally.

63 It is also helpful to have a good understanding of the contractual provisions in the main body of any contract and any relevant schedules. It is important

to recognise that there are substantive differences between GMS/PMS and APMS contracts.

64 The following lists some of the provisions that can be breached regarding PMS and GMS contracts. This is not definitive, but gives an idea of the range and varying severity of breaches that can occur.

Breach	NHS (General Medical Services Contract) Regulations 2004	Standard GMS contract	NHS (Personal Medical Services Agreements) Regulations 2004
Failure to provide essential contracted services	Various. Eg Regulation 15	Clause 46	Various. Eg Schedule 5 paragraph 1
Premises are not suitable for the delivery of services	Schedule 6 paragraph 1	Clause 27	Schedule 5 paragraph 2
Inappropriate storage of vaccines	Schedule 6paragraph 8	Clause 40	Schedule 5 paragraph 6
Excessive prescribing	Schedule 6 paragraph 46	Clause 304	Schedule 5 paragraph 44
Practice leaflet	Schedule 6 paragraph 76	Clause 438	Schedule 5 paragraph 72
Failure to have an effective system of clinical governance	Schedule 6 paragraph 121	Clause 488	Schedule 5 paragraph 112
Inadequate patient records	Schedule 6 paragraph 73	Clause 427	Schedule 5 paragraph 70
Failure of the contractor to carry out his obligations under the agreement with	Schedule 6 paragraph	Clause 25	Schedule 5 paragraph 67

reasonable care and skill	67		
Failure by the contractor to adequately check the qualifications and other matters relating to a healthcare professional seeking to perform services under the contract. For example, this includes (but is not limited to):			
Failing to check, in the case of any healthcare professional (including medical practitioners) that the contractor is seeking to employ or engage to provide clinical services, that he is registered with his relevant professional body and his registration is not suspended and/or allowing such a person who is not so registered or suspended to perform clinical services.	Schedule 6 paragraph 54 and 58	Clause 342 and 348	Schedule 5 paragraph 54 and 58
Failing to ensure, in the case of any medical practitioner that the contractor is seeking to employ or engage to perform medical services, that he has provided the name and address of the AT on whose medical performers list he appears and/or allowing a person who is not so included in a list to perform medical services.	Schedule 6 paragraph 53 and 57	Clause 340 and 345	Schedule 5 paragraph 53 and 57
Failing to ensure that, in the case of any healthcare professional that the contractor is seeking to employ or engage to perform medical services, that s/he has provided two clinical references relating to two recent posts which lasted three months without a significant break, or where this is not possible, a full explanation and alternative referees and the contractor has checked and is satisfied with the references (this applies to both medical	Schedule 6 paragraph 59	Clause 351	Schedule 5 paragraph 59

practitioners and other healthcare professionals).			
That the contractor has failed to take reasonable care to satisfy itself that any person the contractor is seeking to employ or engage is both suitably qualified and competent to discharge the duties for which he is to be employed or engaged.	Schedule 6, paragraph 60(1)	Clause 354	Schedule 5 paragraph 60(1)
That the contractor, when considering the competence and suitability of any person that it is seeking to employ or engage as above, has failed to have regard to: • that person's academic and vocational qualifications; • their education and training; and • their previous employment or work experience.	Schedule 6, paragraph 60(3)	Clause 355	Schedule 5, paragraph 60(3)
NB: Depending on the urgency of the situation or the exact circumstances there may be exceptions to the above requirements. It is therefore always important to check the precise facts and cross reference to the relevant clause and/or paragraph of the regulation/contract. Please also note there are specific requirements relating to GP registrars and those undertaking a post registration programme.			

65 Where a breach has occurred, then normally the steps open to the AT to manage this will be to issue a breach or remedial notice, or in certain circumstances applying a contract sanction.

66 The stages are set out in more detail below and full details provided in the Policy for managing contract breaches, sanctions and terminations for primary medical services.

Stage 1: Review of evidence

67 As with the early warning and informal processes good information governance is key. Before issuing any breach notices NHS England must ensure there is clear evidence of a breach of a specific clause or clauses of the contract.

Stage 2: Remedial notices and breach notices

68 Generally the provisions relating to the remedial and breach notices under the GMS contract are mirrored in the PMS contract. APMS contracts will also have similar provisions. It is, however, important to check the provisions that are being referred to and to ensure they are incorporated into the relevant remedial or breach notices.

Remedial notice

69 Where the contractor has breached the contract, other than in certain specified situations, and the breach is capable of remedy, the AT of NHS England shall, before taking any action it is otherwise entitled to take under the contract, serve a notice on the contractor requiring it to remedy the breach (this is a remedial notice).

70 A remedial notice shall specify:

- details of the breach;
- the steps a contractor must take to the satisfaction of NHS England to remedy the breach; and
- the period during which the steps must be taken (this is known as the notice period).

71 The notice period shall, unless NHS England is satisfied that a shorter period is necessary to protect the safety of the contractor's patients or protect itself from material financial loss, be no less than 28 days from the date that notice is given.

72 If NHS England is satisfied that the contractor has not taken the required steps to remedy the breach by the end of the notice period, the board may terminate the contract with effect from such date as the AT may specify in a further notice to the contractor. This is a discretionary power so the AT's decision needs to be proportionate, reasonable and fair.

73 The specified situations where a remedial notice (and also a breach notice) would not be appropriate are where certain breaches give NHS England other grounds for terminating the contract.

74 These include:

- termination by the board for breach of a condition in regulation 4 of the GMS regulations;
- termination for the provision of untrue information;
- termination, including, where the contractor is subject to a national disqualification, the contractor has been refused admission or has been removed from the performers' list or is subject to certain convictions, where the contractor has been adjudged bankrupt or is in a partnership and it has been dissolved (this is a specific GMS ground);
- termination by the board for a serious breach; or
- termination for unlawful subcontracting.

Breach notice

75 Where the contractor breaches the contract and the breach is not capable of remedy, the AT may serve notice on the contractor requiring it not to repeat the breach (this is referred to as a breach notice).

76 The specified situations referred to above regarding remedial notices also apply to breach notices.

Example of what a breach/remedial notice should contain:

77

- Details of the breach:
  Examples might include that the contractor's record keeping is inadequate and/or any clinical governance system is inadequate and/or the contractor's premises are substandard and not fit for purpose.
- Identifying the specific clauses in the contract:
  It is important to identify the actual contract held between the board and the contractor and to ensure the relevant clause numbers are correct. Also bear in mind that the clause numbers will be different depending on whether it is a PMS/GMS or APMS contract.
- It is important to cross reference these breaches with the evidence that the AT on behalf of the board has obtained, which may include reviews of medical records, reports obtained by GP advisers, annual contract reviews, complaints and so on.
- In the case of a breach notice:
  There should be a requirement that the contractor does not repeat the breach

- In the case of a remedial notice:
  It should show the steps the contractor must take to the satisfaction of the AT to remedy the breach.

78 The steps should be clearly set out, transparent and with clear timescales.

79 The minimum time period is usually 28 days from the date of service (unless there is a clear risk to patient safety or the financial resources of the board) but the board should act proportionately and seek to apply a period that gives the contractor a reasonable time to remedy the breach.

80 So for example, where the patient records are of a poor quality, the AT may require the contractor to ensure all note-keeping complies with guidance set out in good medical practice published by the General Medical Council. Further, it may require the contractor to carry out a review to ensure all its patient records are up to date and include accurate clinical summaries. Also to ensure that the practice provides written confirmation that this has been done by a certain date followed by a further review by the AT to ensure it has been done to an adequate standard. Clear timescales also need to be shown. It is also good practice to detail the consequences of not remedying the identified breach, for example, that failure to do so may give grounds to the board for terminating the contract.

Stage 3: Review of action taken by contractor following the notice period (this applies to a remedial notice)

81 It is often helpful to use a compliance matrix. This helps to ensure a robust system for identifying the steps taken. An example is given below. To use, simply identify the actions the contractor has to address with relevant timescales and use the comment box to identify if the action was completed to the standard required by the regulations.

Table 2 Compliance matrix:

Term of the remedial notice NB: The remedial notice required the practice to carry out remedial steps by the agreed timescales unless otherwise	**Was the remedial action completed within the required timeframe?**	**Was the remedial action completed satisfactorily (regardless of timeframe)?**	**Comment**

stated.			
	Yes/no	Yes/no	

82 If the contractor has complied with all of the actions of the remedial notice, the board shall normally confirm in writing that no further action will be taken other than to continue to monitor the practice in line with other practices as part of the performance management arrangements.

83 If the contractor fails to remedy the breach within the notice period this may give rise to a right to terminate the contract.

Stage 4: Termination by NHS England

84 There are a number of grounds on which a board may look to terminate a GMS, PMS or APMS contract. Concerning remedial and breach notices, there are certain specific situations that may give rise to a right to terminate.

85 First, as outlined above, a right to terminate may arise if a contractor fails to comply with a remedial notice. Where the AT is satisfied the contractor has not taken the required steps to remedy the breach by the end of the notice period, the board may terminate the agreement with effect from such date as the AT may specify in any further notice to the contractor. (This normally needs to be at least 28 clear days from the date of service).

86 Second and more generally, the board may serve notice on the contractor terminating the contract with effect from such date as may be specified in that notice, if, following a breach notice or a remedial notice of significant severity, the contractor:

- repeats the breach that was subject of the breach notice or remedial notice; or
- otherwise breaches the contract resulting in either a remedial notice or a further breach notice.

87 As already stated it is important that the above grounds for terminating are discretionary. Accordingly, the board needs to be in a position to justify that its decision is reasonable, proportionate and fair.

88 This is reinforced by the fact that in the second situation, as set out in the second bullet point, the board cannot exercise its right to terminate the contract unless it is satisfied that the cumulative effect of the breaches is such that it would be prejudicial to the efficiency of the services to be provided under the contract to allow the contract to continue. Accordingly,

the AT has to identify why, in these circumstances, it is satisfied it would be prejudicial to the efficiency of the services to be provided under the contract to allow it to continue. This level of proof would be higher than that required to decline to offer a contract.

89 Possible grounds may include the fact that the failure to remedy any identified breach is placing patients at increased risk of receiving inadequate care and/or the AT is having to use a disproportionate amount of its resources to deal with the breaches and concerns identified.

90 Finally, if the contractor is in breach of any obligation under the contract regarding which a breach or remedial notice has been issued, then the AT may withhold or deduct monies which would otherwise be payable under the contract regarding the obligation in question which is the subject of the default.

Alternatives to termination (contract sanctions)

91 In a number of situations, where NHS England has grounds to terminate a contract it may instead impose a contract sanction if the board is reasonably satisfied the sanction is appropriate and proportionate to the circumstances giving rise to possible termination.

92 A contract sanction means:

- termination of specified reciprocal obligations under the contract;
- suspension of specified reciprocal obligations under the contract for a period up to six months; and
- withholding or deducting monies otherwise payable under the contract.

93 If the board decides to impose a contract sanction it must notify the contractor of its proposal, the date upon which that sanction will be imposed and explain the effect of the sanction's imposition.

94 The notice period shall – unless the board is satisfied that a shorter period is necessary to protect itself from material financial loss and to protect the safety of patients – be 28 days from the date the sanction notice was given.

95 If the contractor refers the dispute relating to the sanction to the NHS dispute resolution procedure within 28 days beginning on the date the AT served notice or a longer period as may be agreed in writing with the AT, and notifies the AT in writing that it has done so, the board shall not

impose the sanction unless:

- there has been a determination of the dispute and the outcome of the dispute has made clear it permits the board to impose the sanction; or
- the contractor ceases to pursue the relevant NHS dispute resolution procedure

96 If the board is satisfied that it is necessary to impose the sanction before the NHS dispute resolution procedure is concluded to protect the safety of the contractor's patients or to protect itself from material financial loss, the board shall be entitled to impose the agreement sanction forthwith, pending the outcome of that procedure; such actions have been and may in the future be subject to judicial review.

Stage 5: Relevant dispute resolution procedure and termination

97 There are a number of grounds on which NHS England may look to terminate a contract. These include termination:

- by the contractor;
- by NHS England on notice (without cause) in the case of PMS and APMS contracts;
- by NHS England for breach of conditions in regulation 4 of the GMS regulations;
- termination by NHS England for provision of untrue information;
- other grounds for termination by NHS England, including if the contractor is subject to a national disqualification; removed from a performers list adjudged bankrupt and various other grounds;
- by NHS England for a serious breach (this may also allow NHS England to expedite the notice period);
- by NHS England for unlawful subcontracting; and
- by NHS England for failure to comply with remedial notices and breach notices.

98 This is not a definitive list and it is important to refer to the actual contract before considering any of these grounds further. Again, where the grounds are discretionary the AT should act in a fair, proportionate and reasonable way, recognising that it is one thing not to grant a contract, but there are much more complex and significant considerations when taking away

established rights in possession.

99 In the context of contract management, the most important grounds are likely to be around termination arising out of failure to comply with remedial notices and breach notices and/or where there is a serious breach.

100 Where NHS England is entitled to serve written notice on the contractor terminating the contract, then in the normal cause, the board must specify a date on which a contract terminates that is not less than 28 days after the date on which the AT has served the notice on the contractor.

101 This period can be shorter, if the board is satisfied that it is necessary to do so to protect the safety of contractor's patients or protect itself from material financial loss occasioned by the contractor's financial situation. Again, normally, if the contractor invokes the NHS dispute resolution procedure before the end of the 28-day period of notice and it notifies the AT in writing that it has done so, the contract shall not terminate at the end of the notice period but instead shall only terminate where there has been a determination of the dispute and that determination permits the AT to terminate the contract or the contractor ceases to pursue the NHS dispute resolution procedure, whichever is sooner.

102 If the AT is satisfied that it is necessary to terminate the contract before the NHS dispute resolution procedure is concluded to protect the safety of contractor's patients or protect itself from material financial loss, the AT is entitled to confirm by written notice to be served on the contractor that the contract will terminate at the end of the initial notice period.

Consultation with and support from the LMC

103 Whenever the AT is considering terminating the contract, or looking to impose a contract sanction or to take certain other measures under the contract, then it shall, whenever it is reasonably practical to do so, consult the LMC (GMS Regulations 2004).

104 The LMC has an extended role in supporting practices facing remedial, breach and termination notices or those undergoing performance investigations. The LMC can advise practices on how to complete actions required by remedial notices, how to address issues to avoid further contract breaches and how to appeal against termination notices if appropriate. The LMC can signpost practices to experts who can help, eg the practices' Medical Defence Organisation or consultants who can

advise on practical issues such as practice policies. For practices undergoing performance investigations, the LMC can support them in preparatory meetings with the investigating officers and NHS England, assist with drafting terms of reference, guide them through the investigation process and sit in on interviews with clinicians and staff to ensure due process is followed.

105 The AT is encouraged to advise practices in these circumstances to make contact with their LMC as early as possible to ensure they have access to expert help and advice.

Service of notice

106 It is important to check the correct process for serving any notice under the relevant contract. Please see the policies for Managing contract variations for primary medical service contracts and Managing contract breaches, sanctions and terminations for primary medical services.

107 Normally, any notice must be in writing and served on the other party, in the following ways:

- personally;
- by post, or in the case of any termination notice, by registered or recorded delivery post;
- by telex, electronic mail or facsimile transmission (the latter confirmed by telex or post);
- unless the context otherwise requires by electronic mail (although this cannot be used for confirming a variation to the contract); and
- by any other means that the commissioner specifies by notice to the contractor.

108 Any notice or other information shall be sent to the address specified in the contract or such other address that the commissioner or the contractor has notified to the other.

109 Any notice or other information shall be deemed to have been served or given:

- if it was served personally, at the time of service;
- was served by post, two working days after it was posted; and
- was served by telex, electronic mail or facsimile transmission, if sent

during normal hours then the time of transmission, and if sent out of hours then on the following working day.

110 If a notice is not validly served, then it will usually be treated as being invalid unless the person receiving it elects, in writing, to treat it as valid.

111 The notice shall specify a date on which the agreement terminates that is not less than 28 days after the date on which the AT has served that notice on the contractor (unless there are grounds for expediting the period).

112 The contractor will then usually have the right to invoke the NHS dispute resolution procedure within 28 days of the notice being served on him (or longer if both parties agree).

113 Please note, the AT should always check the relevant contract to ensure the necessary steps have been complied with and the relevant clauses are identified.

Annex 1: Abbreviations and acronyms

A&E	accident and emergency
APHO	Association of Public Health Observatories (now known as the Network of Public Health Observatories)
APMS	Alternative Provider Medical Services
AT	area team (of NHS England)
AUR	appliance use reviews
BDA	British Dental Association
BMA	British Medical Association
CCG	clinical commissioning group
CD	controlled drug
CDAO	controlled drug accountable officer
CGST	NHS Clinical Governance Support Team
CIC	community interest company
CMO	chief medical officer
COT	course of treatment
CPAF	community pharmacy assurance framework
CQC	Care Quality Commission
CQRS	Calculating Quality Reporting Service (replacement for QMAS)
DAC	dispensing appliance contractor
Days	calendar days unless working days is specifically stated
DBS	Disclosure and Barring Service
DDA	Disability Discrimination Act
DES	directed enhanced service
DH	Department of Health
EEA	European Economic Area
ePACT	electronic prescribing analysis and costs
ESPLPS	essential small pharmacy local pharmaceutical services
EU	European Union
FHS	family health services
FHS AU	family health services appeals unit
FHSS	family health shared services
FPC	family practitioner committee
FTA	failed to attend
FTT	first-tier tribunal
GDP	general dental practitioner
GDS	General Dental Services
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
NMS	new medicine service
NPE	net pensionable earnings
NPSA	National Patient Safety Agency

OJEU	Official Journal of the European Union
OMP	ophthalmic medical practitioner
ONS	Office of National Statistics
OOH	out of hours
PAF	postcode address file
PALS	patient advice and liaison service
PAM	professions allied to medicine
PCC	Primary Care Commissioning
PCT	primary care trust
PDS	personal dental services
PDS NBO	Personal Demographic Service National Back Office
PGD	patient group direction
PHE	Public Health England
PLDP	performers' list decision panel
PMC	primary medical contract
PMS	Personal Medical Services
PNA	pharmaceutical needs assessment
POL	payments online
PPD	prescription pricing division (part of NHS BSA)
PSG	performance screening group
PSNC	Pharmaceutical Services Negotiating Committee
QOF	quality and outcomes framework
RCGP	Royal College of General Practitioners
RO	responsible officer
SEO	social enterprise organisation
SFE	statement of financial entitlements
SI	statutory instrument
SMART	specific, measurable, achievable, realistic, timely
SOA	super output area
SOP	standard operating procedure
SPMS	Specialist Personal Medical Services
SUI	serious untoward incident
UDA	unit of dental activity
UOA	unit of orthodontic activity

Annex 2: Glossary of terms in this document

Term	Definition
British Medical Association (BMA)	The British Medical Association is an independent trade union and professional association for doctors and medical students, with over 140,000 members worldwide.
Breach of contract	A formal process should be instigated if it constitutes a breach of contract, regardless of whether the issue of concern is deemed to be low risk. If a breach of contract has occurred that is remediable, a remedial notice may be served.
Contracts	PMS (Personal Medical Services), GMS (General Medical Services), APMS (Alternative Provider Medical Services) collectively, provide contracts, that are a flexible framework with which the NHS CB can plan, commission and develop services to offer greater patient choice, improved capacity and access, and greater responsiveness to the specific needs of the community. It is currently for NHS England to decide how to use the contracting routes, and for which scenarios.
Contract management	Monitoring the delivery of the specifications of the contract by the contract holder, carried out by the commissioner.
Contractual route	Contractual proceedings where contractual performance issues arise.
Contractual underperformance	Failure to deliver services to the standard required by the contract.
Contract sanction	Termination of specified reciprocal obligations under the contract; suspension of specified reciprocal obligations under the contract for a period up to six months; or withholding or deducting monies otherwise payable under the contract.
Escalation procedures	The process of referring a matter to an organisational entity with a greater degree of expertise or authority through an established process.
Formal proceedings	Following established/official procedures.

General practice	GP contract holders and all others that make up the practice e.g. general practitioners, nurses, practice managers, reception team and so on.
General practitioners/GPs	An individual clinician that delivers medical services within a general practice.
GP contractors/contract holders	The practitioners with responsibility for delivering services as agreed in the contracts, who are also the signatories to the contract.
Individual performer	An individual general practitioner that provides clinical care to patients within a general practice setting.
Informal proceedings	Taking steps to resolve minor concerns without necessarily following formal procedures.
Information governance	The way by which the NHS/general practice handles all organisational information. In particular the personal and sensitive information of patients and employees. It allows organisations and individuals to ensure that personal information is dealt with legally, securely, efficiently and effectively, to deliver the best possible care.
Local deanery	Training and development organisation responsible for postgraduate medical and dental training.
Local medical committees (LMC)	The statutory representative body for GPs and their practice teams across the country.
National Quality and Outcome Standards	A national agreed set of outcome standards for general practice to be published from April 2013.
Medical Defence Organisations	A professional organisation that undertakes to protect, support and safeguard the character and interests of registered medical and dental practitioners in the United Kingdom and elsewhere.
National Clinical Assessment Service (NCAS)	NCAS is part of the NHS and was established to provide comprehensive support to the health service in managing doctors and dentists whose performance gives cause for concern.
National Health service Litigation Authority (NHSLA)	The NHSLA is responsible for ensuring a prompt and fair resolution of disputes between primary care practitioners and their local primary care trusts (PCTs).
Performers list	Management accountability (by the PCT or a delegated

	organisation) for ensuring the quality of the workforce by managing their primary care medical performers list. This covers admission of doctors to the list, removal or contingent removal of doctors from the list, and doctors' disqualification for inclusion in a list.
NHS England	NHS England is the commissioning organisation that commissions primary medical services from general practice that meet the needs of their local populations.
Quality and outcomes framework (QOF)	The quality and outcomes framework (QOF) is a voluntary annual reward and incentive programme for all GP surgeries in England, detailing practice achievement results. It is not about performance management but resourcing and then rewarding good practice.
Remedial notice	Where the contractor has breached the contract, other than in certain specified situations and the breach is capable of remedy, the commissioner shall, before taking any action it is otherwise entitled to take under the contract, serve a notice on the contractor requiring it to remedy the breach.
Serious untoward incident (SUI)	The principle definition is something out of the ordinary or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest that occurs on NHS premises or in providing an NHS or a commissioned service. SUIs are not exclusively clinical issues.
Stakeholders	Stakeholders are a person, group, organisation, or system who affects or can be affected by an organisation's actions.
The Family Health Services Appeal Unit (FHSAU)	The FHSAU is the arm of the NHSLA that is responsible for ensuring a prompt and fair resolution of disputes between primary care practitioners and the NHS CB in cases where the contractor has elected to be considered as an NHS body for the purposes of the contract or has elected to use the NHS procedures, or the board has sought to use those procedures and the contractor has agreed. If the contractor is not an NHS body for the purposes of the contract the matter shall be referred to the civil

	courts for determination.
Termination of contract	The commissioner may serve notice on the contractor terminating the contract with effect from such a date as may be specified in that notice.
Whistle blowing	A whistleblower is a person who raises a concern about wrongdoing occurring in an organisation or body of people.

Annex 3: Sources of guidance and support for GPs

Medical director
PEC chair (professional executive committee) – [Subject to continuation]
LMCs – GP support
BMA (if BMA member)
BMA (guidance for professional returning after working overseas)
MDO (Medical Defence Organisation)
Deanery (continuing professional development programmes for GPs including the Fresh Start programme)
NCAS (National Clinical Assessment Service)
RCGP (Royal College of General Practitioners)
The King's Fund
Support from other local practices
Local GP trainers or training practices
Mentorship/supervision from fellow GP colleagues
Peer review and training, attending educational sessions
Recruiting a practice manager to provide part-time support
Using experts on a consultancy basis, e.g. specialist nurses, practice managers, HR consultants
External agencies (e.g. Skills for Health)

Annex 4: NCAS individual performer route – key messages

Principles of working with performance problems

- NHS England committees or sub-committees such as decision-making groups (DMGs) must be properly constituted and have properly delegated powers.

NHS England responsibilities

- A commissioning organisation is able to manage its statutory duty of quality through a number of mechanisms, including the management of the performers list. These allow NHS England to manage the quality of care provided by a full range of primary medical professionals, including GP principals, salaried GPs, locums, registrars and sessional doctors.
- All practitioners who are performing primary care services should be on a performers list. Where a GP is on a performers list and is employed by a commissioning organisation, the Performers List Regulations1 apply for patient care provided in a general practice setting. A commissioning organisation may need further advice to clarify the position with regard to an individual practitioner and where the use of Maintaining High Professional Standards (MHPS) is appropriate.
- Where serious concerns are raised about a GP on the commissioner's performers list, NHS England will need to consider whether, as well as conducting an investigation of the case, it also needs to suspend the GP. Suspension by NHS England may also be required pending consideration of whether to remove, or contingently remove, the GP from its list or while it waits for a decision of a regulatory body or court. Any suspension must comply

Structures for managing performance concerns

- NCAS advises a two-tier model, comprising a decision-making group (DMG) within the commissioning organisation and performance advisory group (PAG) or performance support unit (PSU), which may cover one or more Area Teams.

- NHS England, through its DMGs, has overall responsibility for managing performance concerns, taking decisions on individual cases and liaising with other agencies.

Actions following local investigation

- Having reached a preliminary understanding of a performance problem, the DMG or commissioning organisation individuals who are managing the case need to consider the range of possible actions. These include closing a case as unfounded, monitoring the case further or providing local support, as well as suspending or removing a GP from the performers list, and referral to another agency, for example, the General Medical Council (GMC) or the police.
- NHS England needs to understand the role of other bodies involved in handling performance concerns, in particular the criteria for referral, for example to NCAS or the GMC.
- Commissioning organisation is considering suspending a GP from a performers list (or exclusion under MHPS for other medical staff), they should contact NCAS or the GMC

Assessment

- Where local investigation identifies that assessment of a GP's performance is required, NHS England may wish to refer to NCAS for performance assessment. NCAS provides a comprehensive assessment of a doctor's health, behaviour and clinical performance.
- NCAS assessment involves trained assessors and tools that have been tried and tested. Thorough assessment is essential because the information it provides may be used to make decisions that impact on patient safety and a doctor's ability to practise.

Resolving problems: support and training

- Where required, a clear development/improvement plan should be agreed with the GP, whether this follows local investigation or NCAS assessment. NCAS has recently circulated a document to guide action planning for practitioners following local or national performance procedures, the Back on Track framework document. Copies can be downloaded from the NCAS website (www.ncas.npsa.nhs.uk).

- It is important for everyone involved to understand what the next steps might be if efforts to improve performance are unsuccessful, for example removal from the performers list or referral to the GMC.

Resourcing local procedures

- NHS England needs to commit a realistic budget to cover the cost of staff and the meetings required, and to provide some support to practices and GPs where problems are identified.
- Funding, support and training for an individual GP will need to be agreed on a case- by-case basis, and may well require the GP to make a substantial contribution to any programme put in place.

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