Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Meeting of Integrated Care Board

Date: 1st December 2022
Time: 12:15pm
Location: MS Teams

Agenda Number :	6.2
Title:	NHS England and BNSSG ICB Memorandum of Understanding and draft response to the Consultation on Enforcement Guidance.
Confidential Papers	

Commercially Sensitive	No
Legally Sensitive	No
Contains Patient Identifiable data	No
Financially Sensitive	No
Time Sensitive – not for public release at this time	No
Other (Please state)	No

Purpose: Decision

Key Points for Discussion:

The NHS Oversight Framework outlines the core areas of accountability for the Integrated Care Board and is measured against a core set of metrics. The memorandum of understanding between NHS England and BNSSG ICB is to document the way of working between the ICB and NHS England in the delivery of both the operational plan and the Oversight Framework.
The Memorandum of Understanding compliments the NHS operating framework and SW compact.
The National Consultation on the Enforcement Guidance closes on the 9th December. The consultation seeks feedback on how enforcement action would be applied to both holders of the provider licence and Integrated Care Boards.

Recommendations:	To approve the Memorandum of Understanding and the response to the enforcement consultation.
Previously Considered By and feedback :	ICB Executive Team
Management of Declared Interest:	Enforcement Action applies to all NHS Partners on the ICB Board.
Risk and Assurance:	Due to the nature of the consultation the Enforcement Action applies to all NHS Partners on the ICB Board. The key risk is to ensure that the ICB's response supports the collaboration needed to deliver the outcomes of the system as opposed to being divisive.

Financial / Resource Implications:	There are no financial implications of this paper.
Legal, Policy and Regulatory Requirements:	The Consultation on Enforcement is how NHS England will implement its legal powers on both the ICB and providers of NHS Services.
How does this reduce Health Inequalities:	One of the key outcomes for the Integrated Care Board is to address health inequalities of its population and is measures as part of the operational plan.
How does this impact on Equality & diversity	This paper is based on national documents and templates, so EIA would be completed at national level.
Patient and Public Involvement:	This paper is based on national documents and templates, so patient and public involvement would be completed at national level.
Communications and Engagement:	This paper is based on national documents and templates, so communication and engagement would be completed at national level.
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Sponsoring Director / Clinical Lead / Lay Member:	Lisa Manson

Agenda item:6.2

Report title: NHS England and BNSSG ICB Memorandum of Understanding and draft response to the Consultation on Enforcement Guidance.

1. Background

NHS England have published a range of documents which set out the regulatory framework within which they intend to work with Integrated Care Boards. These documents and the memorandum of understanding are the basis of this paper. The intention of these documents is to support and develop the Integrated Care System and support the Integrated Care Board in demonstrating the management of the system.

2. Consultation on Enforcement Guidance

NHS England has published a consultation on the enforcement guidance that will apply to both Providers of NHS Services that hold a provider licence and to Integrated Care Boards. The consultation outlines the separate parts of the legislation.
The provider licence changes are to reflect the NHS Act (2022) and endorsing the need for all providers of NHS services to hold a provider licence including NHS Trusts and therefore the associated regulation.
Delivery against the NHS Oversight Framework metrics and the corresponding segmentation are the key triggers against which the Integrated Care Board would be asked to recommend enforcement actions against an individual provider. The recommendation of enforcement action would need to be considered by Integrated Care Board prior to any recommendation passing to NHS England.
The consultation has also recommended that Integrated Care Boards have a two-tier enforcement approach, so action can be taken if there is a risk of an ICB failing as well as when there are significant issues.
The draft consultation response is in Appendix 1, but the key elements of the proposed response are:-

Provider Regulation
The key issues that providers around our ICB face in delivering against the provider licence are those issues which can only be addressed by the system working collectively. It is difficult to see how the regulatory framework will distinguish between those issues that a provider can address independently, without either requiring the support of other system partners or adversely impacting on other partners.
We recognise that, under the current legislation with the provider licence, the statutory role of the ICB is to recommend action. But in any regulatory action the ICB will need to support the partner with the delivery of regulatory action along with all partners that form the ICB. **It may be more**

effective for the whole ICB to be in receipt of regulatory action in order to support one individual partner to deliver against their licence.

Integrated Care Board
The initial phase of the regulation approach is very subjective in contrast to the regulatory action for providers and would therefore propose that the ongoing engagement and relationship with the Regional Teams would address the first phase of regulation and would not need to be documented in the enforcement guidance.
In regard to the Phase Two of Regulatory Action, it would be helpful to clarify if it relates to the statutory responsibility that only the ICB can undertake, e.g. Continuing Healthcare, or due to a provider who is deemed to be in breach of its licence.
It would also be beneficial if the actions that can be taken in finding an ICB in breach are consistent with those of finding a provider in breach of its licence.

3. Memorandum of Understanding

NHS England has developed a national template structure which outlines the engagement approach between NHS England and the Integrated Care Board. The national template has been localised to reflect BNSSG Integrated Care Board governance. The memorandum of understanding is to reinforce that the intention (subject to segmentation status which is outlined in the NHS England operating framework), that NHS England is to work through the ICB.
This is also reflected in the approach to quality and is outlined in the National Quality Board guidance on quality risk response and escalation in ICS (appendix 5) and replicated in how NHS England will work through the ICB in ensuring that the ICS can manage its financial position.
The Board is asked to approve the memorandum of understanding subject to a review in February 2023 when the final Enforcement Guidance has been published and the South West Compact has been agreed.

4. Financial Implications

The changes proposed in the Enforcement Guidance and in the Memorandum of Understanding do not have direct financial implications. The Memorandum of Understanding and the Enforcement Guidance use the existing governance in the ICB for making financial decisions and monitoring financial delivery.

5. Legal implications

The Consultation on Enforcement Guidance is how NHS England will enact its legislative powers with providers of NHS Services and Integrated Care Boards .

6. Risk implications

The Consultation on Enforcement Guidance and the Memorandum of Understanding support the role of the Integrated Care System leading and delivering on behalf of its population.

7. How does this reduce health inequalities

One of the key outcomes for the Integrated Care Board is to address health inequalities of its population and is measures as part of the operational plan.

8. How does this impact on Equality and Diversity?

This paper is based on national documents and templates, so EIA would be completed at national level.

9. Consultation and Communication including Public Involvement

This paper is based on national documents and templates, so communication and engagement would be completed at national level.

Appendices

NHS
Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Ref:

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Switchboard 0117 947 4400
Direct dial 07557 191164
Email lisa.manson@nhs.net

Recipient name
Recipient address
Address
Address
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<date>

Dear Recipient Name

Re: Enforcement Guidance

Thank you for the opportunity to provide feedback on the consultation on the Enforcement Guidance.
We absolutely support the changes that have been made to the enforcement guidance in reflecting the role of the Integrated Care Boards and the fact the Integrated Care board recommendations can influence the regulatory actions on providers.

Provider Regulation
The key issues that providers around our ICB face in delivering against the provider licence are those issues which can only be addressed by the system working collectively. It is difficult to see how the regulatory framework will distinguish between those issues that a provider can address independently, without either requiring the support of other system partners or adversely impacting on other partners.
We recognise that, under the current legislation with the provider licence, the statutory role of the ICB is to recommend action. But in any regulatory action the ICB will need to support the partner with the delivery of regulatory action along with all partners that form the ICB. **It may be more effective for the whole ICB to be in receipt of regulatory action in order to support one individual partner to deliver against their licence.**

Integrated Care Board
We have concerns around the two phased proposal regarding regulation, particularly as the initial phase is very subjective in contrast to the regulatory action for providers.

We would suggest that the ongoing engagement and relationship with the Regional Teams would address the first phase of regulation.
In regard to the Phase Two of Regulatory Action, it would be helpful to clarify if it relates to the statutory responsibility that only the ICB can undertake, e.g. Continuing Healthcare, or due to a provider who is deemed to be in breach of its licence. We do believe that it may be more effective for the whole ICB to be in receipt of regulatory action in order to support one individual partner to deliver against their licence.

The section in the enforcement guidance which allows the removal of the ICB Chief Executive, is inconsistent with the actions that can be taken under a breach of a provider licence and would require the same level of evidence, we believe this should be consistent with the actions that can be taken in the same context.

Yours sincerely,

Name
On behalf of Bristol, North Somerset and South Gloucestershire ICB

Classification: Official

Publication reference: PR1421

NHS England

NHS Enforcement Guidance

Draft

27 October 2022

Contents

1. Introduction

Background

1. Under the National Health Service Act 2006 ('the NHS Act 2006'), and the Health and Social Care Act 2012 ("the 2012 Act"), as amended by the new Health and Care Act 2022, NHS England has statutory accountability for oversight of both integrated care boards (ICBs) and providers of NHS services.[1] NHS Improvement (Monitor and the TDA) has been abolished and NHS England has assumed responsibility of the regulation for providers of NHS services, the exercise of provider enforcement powers, and producing and revising guidance on those powers.

2. The Health and Care Act 2022 ('the 2022 Act') amended the NHS Act 2006 by inserting a new section 14Z61 to give NHS England powers to direct ICBs when it is satisfied that (a) an ICB is failing or (b) is at risk of failing to discharge its functions. The NHS Act 2006, as amended by the 2022 Act, also gives NHS England powers to oversee and take enforcement action in relation to ICBs' compliance with patient choice requirements.[2]

3. It also introduced[3] licensing for NHS trusts. Once licensed, NHS trusts may be subject to statutory enforcement action as described in this guidance, along with NHS foundation trusts, licensed independent providers and NHS controlled providers. This guidance should therefore be read in conjunction with the provider licence as updated for April 2023.

[1] Note that persons providing primary medical services (GPs) or primary dental services only are currently outside the licensing and enforcement regime described in this document.

[2] Monitor had an oversight role and enforcement powers over clinical commissioning groups and NHS England in relation to compliance with The National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013 and certain provisions in the NHS Standing Rules. Under the Health and Care Act 2022, when the provisions come into force, NHS England will have a similar oversight role and enforcement powers over ICBs in relation to compliance with patient choice requirements.

[3] The NHS provider licence was introduced in 2013, under the provisions of the Health and Care Act 2012, and is held by all NHS foundation trusts as well as independent sector providers that deliver more than £10 million of NHS services annually or are designated as commissioner requested services (excluding providers that exclusively provide primary medical or primary dental services, or NHS continuing healthcare and NHS-funded nursing care). The Health and Care Act 2022 applied the requirement to hold a licence to NHS trusts for the first time.

4. This document outlines how NHS England intends to exercise its enforcement powers for both ICBs (including in relation to patient choice requirements) and providers, including setting out how it would use the powers to direct an ICB and the licence enforcement mechanisms that apply to foundation trusts, NHS trusts, licensed independent providers of NHS services and licensed NHS controlled providers. It explains the regulatory and statutory processes in the event of enforcement action and the subsequent rights of appeal.

5. NHS England's enforcement guidance is published pursuant to NHS England's duty under section 108 of the 2012 Act to publish guidance about the use of its enforcement powers under that Act and its duty under section 14Z51 of the NHS Act 2006 (as amended) to publish guidance about the exercise of ICB functions.

6. In relation to patient choice, it is also made pursuant to NHS England's duty under section 6G of the NHS Act 2006 (as amended) to publish guidance about how it intends to exercise the enforcement powers conferred by section 6F and Schedule 1ZA. In so far as this document sets out the procedures for entering into undertakings under the 2012 Act and in relation to patient choice, the document is made pursuant to paragraph 9 of Schedule 11 to the 2012 Act and paragraph 2 of Schedule 1Z1 to the NHS Act 2006, respectively. All references to legislation in this document should be read as amended by the 2022 Act.

Purpose and scope of this guidance

7. The guidance applies to all ICBs and providers of NHS healthcare services in England subject to the provider licence (referred to in this guidance as 'providers'). It describes NHS England's intended approach to using its enforcement powers over ICBs and those providers. It explains:

    i. when NHS England may decide to take action, and what action it can take;
    ii. how NHS England is likely to decide what kind of sanctions to impose using its powers under the Acts; and
    iii. the high-level processes NHS England intends to follow when taking enforcement action, including the procedure for entering into undertakings, both in relation to providers under paragraph 9 of Schedule 11 to the 2012 Act and ICBs, including in relation to patient choice under paragraph 2 of Schedule 1ZA to the NHS Act 2006.

8. The NHS Oversight Framework details the overall principles, responsibilities and ways of working for oversight, including the key metrics and factors NHS England will consider when determining support needs, and the circumstances in which it considers formal regulatory intervention may be necessary to address particular issues. This guidance should therefore be read alongside the NHS Oversight Framework.

9. For licensed independent providers and certain NHS controlled providers,[4] the relevant framework that sets out NHS England's approach to oversight is the Risk Assessment Framework and reporting manual for independent sector providers of NHS services, and not the NHS Oversight Framework. They should therefore read this guidance alongside the Risk Assessment Framework.

2. Legal framework

10. ICBs are expected to lead the day-to-day oversight of providers, working alongside NHS England. However, the legal remit for taking enforcement action at organisation level continues to sit with NHS England for both ICBs and providers. This guidance explains the processes in the event of enforcement action (as listed below) and subsequent rights of appeal. These processes also apply to enforcement in relation to compliance with patient choice requirements under the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ('the NHS Standing Rules').

11. ICBs may be subject to:

    a. directions[5]
    b. undertakings.

12. Providers may be subject to:

[4] NHS controlled providers are not trusts or foundation trusts but are ultimately controlled by one or more NHS trusts or foundation trusts. NHS controlled providers may be overseen either under the NHS Oversight Framework or the Risk Assessment Framework and reporting manual for independent sector providers of NHS services. This will depend on factors such as the scope of the services provided, size of turnover and whether the provider is a wholly owned subsidiary or is jointly owned by a number of providers.

[5] In addition, where an ICB fails to comply with a notice to provide information requested by NHS England in connection with its 'regulatory functions' (in particular, licence enforcement and pricing) under s104 of the 2012 Act, then it may be subject to statutory undertakings and discretionary requirements, in the same way as a provider.

c. discretionary requirements
d. undertakings
e. additional governance licence conditions (foundation trusts only)
f. monetary penalties
g. revocation of licence
h. directions for NHS trusts (s27B NHS Act 2006).

13. The guidance sets out NHS England's enforcement mechanisms. It is not intended to give legal advice to ICBs and providers that find themselves subject to enforcement action. In such circumstances, ICBs and providers may need to seek independent legal advice.

Legal requirements governing how NHS England works

14. In keeping with a system-led approach, NHS England will discharge its duties in collaboration with ICBs, asking the ICB to oversee and seek to resolve local issues before escalation. Where NHS England intervenes directly with individual providers, this will happen with the awareness of the relevant ICB.

15. NHS England's regulatory work is conducted within the relevant legal framework which is made up of the legal duties and powers given to it under the NHS Act 2006 and 2012 Act, and the terms of the NHS provider licence and general principles of public law.

16. As for any public body, NHS England must exercise its powers fairly, reasonably and rationally, using them only for their proper purposes. NHS England is also bound by laws to protect fundamental rights and interests, such as human rights, data protection and equality laws, to ensure that people are treated with dignity, basic freedoms are not overridden, personal information is not misused, and characteristics fundamental to everyone's identity are respected and do not lead to unfair treatment. The enforcement procedures are designed to observe these laws and principles when NHS England deals with regulatory enforcement matters.

ICB enforcement legislation – the NHS Act 2006

17. The NHS Act 2006 was amended by the 2022 Act to establish ICBs and give NHS England powers to give directions to an ICB if it is satisfied that:

a. the ICB is failing or has failed to discharge any of its functions (properly or at all), or

b. there is a significant risk that the ICB will fail to do so.

18. Under the NHS Act 2006, a failure to discharge a function is:

    a. a failure to discharge it properly

    b. this includes a failure to discharge it consistently with what NHS England considers to be the interests of the health service.

19. This guidance aligns with the NHS Act 2006, which forms part of the oversight architecture for the NHS, provides the legal mechanism for any formal regulatory intervention and underpins mandated support at some of our most challenged ICBs. The guidance sets out the steps NHS England will follow when considering its ICB enforcement powers under the NHS Act 2006.

20. The NHS Act 2006 sets out a number of general duties that apply to an ICB in exercising its functions, including:

    i. The duty to bring improvement in the quality of services.

    ii. The duty to reduce inequality of access and outcome.

    iii. The duty to obtain appropriate advice.

    iv. The duty to promote research and its use in health services

    v. The duty to have regard to the likely effect of decisions on health and wellbeing, quality of services and efficiency and sustainability of resources (the ‘triple aim’).

    vi. The duty to involve patients and the public in decisions that affect them.

    vii. The duty to act with a view to enabling patients to make choices with respect to aspects of the health services provided to them.

21. ICBs are also subject to various financial duties and other duties relating to planning and contributing to wider local strategies.

22. NHS England expects ICBs to engage with it voluntarily to bring an ongoing failure to an end or to establish whether there has been a failure to discharge a function or comply with choice requirements in the past.

23. Where this does not prove possible and the available evidence indicates that the legal test for intervention is met, NHS England will consider formal steps to ensure compliance. If NHS England is considering acting formally, it will review the information in its possession, consult the ICB and assess the range of available options to determine the most appropriate action, having regard to the legal framework described above.

24. In addition to the general enforcement power, the legislation as amended by the 2022 Act, also confers on NHS England specific enforcement powers in relation to ICB compliance with requirements concerning patient choice (section 6F of the NHS Act 2006) and pricing (section 14B of the 2012 Act).

25. In relation to patient choice, NHS England may investigate whether an ICB has failed or is likely to fail to comply with a requirement imposed by regulations under section 6E(1A) or (1B) (a 'patient choice requirement').

NHS England's ICB enforcement actions

26. NHS England's powers to apply directions to an ICB offer a number of options, including the power to:

    i. Direct the ICB to discharge any of its functions, in such manner and within such period or periods as may be specified in the direction;

    ii. Direct the ICB, or its chief executive, to cease to perform any functions for such period or periods as may be specified in the direction – where such a direction is given, NHS England may:

        a) exercise, on behalf of the ICB/chief executive (as the case may be), any of the functions that are the subject of the direction;

        b) direct another ICB (or in the case of a direction to a chief executive, the chief executive of another ICB) to perform any of those functions on behalf of the ICB/chief executive, in such manner and within such period or periods as may be specified in the direction. In the case of a direction to another ICB to perform the functions of the failing ICB, this may include provision prohibiting or restricting

the failing ICB from making delegation arrangements[6] in relation to those functions;

iii. Terminate the appointment of the ICB's chief executive and direct the chair of the board as to who to appoint as a replacement and on what terms.

27. Before directing another ICB to perform the required functions on behalf of an ICB, or directing a chief executive of another ICB to perform its functions on behalf of the chief executive of the failing ICB, NHS England must consult the ICB in question.

28. Where a direction is given to the chief executive of the ICB to cease to perform any functions for a specified period, the ICB's board must co-operate with any ICB chief executive NHS England has directed to perform those functions.

29. Directions should only be issued to an ICB as a last resort or where other intervention or support measures have failed to adequately address the identified issue(s).

30. An ICB may be subject to statutory undertakings or discretionary requirements[7] where it refuses to respond to formal information notice from NHS England relating to its regulatory functions (e.g. provider licence enforcement or pricing). The relevant processes for provider enforcement set out in this guidance would then apply.

31. NHS England has specific enforcement powers in relation to ICB compliance with patient choice requirements. Section 6F of the NHS Act 2006 gives NHS England the power to:

i. investigate whether an ICB has failed or is likely to fail to comply with a patient choice requirement;

ii. direct an ICB: (a) to put in place measures for the purpose of preventing failures to comply with patient choice requirements or mitigating the effect of such failures, or (b) where an investigation as mentioned above has been carried out, to remedy a failure to comply with patient choice requirements; and

[6] 'Delegation arrangements' are arrangements made by a person for the exercise of a function by someone else.

[7] Sections 105 and 106 of the 2012 Act.

iii. where an investigation as mentioned above is being or has been carried out, accept from the ICB an undertaking that it will take any action falling within (ii) above that is specified in the undertaking, within a period that is so specified.[8]

ICB undertakings

32. NHS England has introduced a two-tier intervention process for ICBs. This is in conjunction with ICB legislation in relation to patient choice and ensures parity with the provider enforcement regime by introducing undertakings as the first step of NHS England's enforcement action for ICBs.

33. Where NHS England has reasonable grounds to suspect a potential failure or is concerned that an ICB is at risk of failing to discharge its function, NHS England may accept undertakings from that ICB. If the undertaking is then breached, this may justify the use of directions. As with provider undertakings, an undertaking may be accepted on the basis of reasonable suspicion, rather than the higher threshold which applies for directions (where NHS England must be satisfied there is a failure). In the case of undertakings relating to patient choice, NHS England may accept undertakings where an investigation into an alleged failure to comply with patient choice undertakings is being or had been carried out.

34. As is the case with provider undertakings, ICB undertakings would be agreed by NHS England and the ICB, and set out the remedial actions to be taken to address the specific challenges identified. By offering and agreeing undertakings, the ICB gives a commitment that it will comply and carry out the relevant actions. ICB undertakings should contain monitoring and reporting commitments to ensure progress.

35. As a minimum, ICB undertakings would be expected to include a commitment that the specified failing, if ongoing, is brought to an end within the stipulated timescales and does not recur. Where an ICB fails to bring the failing to an end within the agreed time, NHS England can impose directions.

[8] Where NHS England accepts an undertaking it is not permitted to: (a) continue to carry out any ongoing investigation so far as relating to matters to which the undertaking relates, or (b) give a direction in relation to those matters, unless the ICB fails to comply with the undertaking.

Provider enforcement legislation – the licence and the 2012 Act

36. The NHS provider licence was introduced in 2013, under the provisions of the 2012 Act, and is held by all NHS foundation trusts as well as independent sector providers that deliver more than £10 million of NHS services annually or are designated as commissioner requested services (excluding providers that exclusively provide primary medical or primary dental services, or NHS continuing healthcare or NHS-funded nursing care).[9] NHS trusts will be required to hold a licence from April 2023 following commencement of changes introduced in the 2022 Act.[10] Please follow these links for the provider licence guidance as updated for April 2023 and the NHS controlled provider licence.

37. This enforcement guidance aligns with the updated provider licence, which reflects the requirement for NHS trusts to be licensed. The provider licence sets the conditions that providers must meet, including those relating to pricing, integrated care and patient choice. For some providers, the continuity of service (CoS) conditions will also apply. Specific conditions also apply to NHS trusts and foundation trusts relating to governance, co-operation, the 'triple aim' and digital.

38. As set out in the 2012 Act, breach or suspected breach of those conditions may provide the basis for formal regulatory intervention. In particular, NHS England may accept an undertaking from a provider to remedy suspected non-compliance where NHS England has reasonable grounds to suspect a breach; and NHS England may impose requirements on a provider, designed to remedy non-compliance, where NHS England is satisfied there is a breach (discretionary requirements).

39. The licence and related enforcement action underpins mandated support at some of our most challenged providers as set out in the NHS Oversight Framework. The NHS enforcement guidance sets out the steps NHS England intends to follow when considering the use of its enforcement powers under the licence provisions of the 2012 Act.

[9] Section 81(1) of the 2012 Act and the National Health Service (Licence Exemptions etc) Regulations 2013 (SI 2013/2677). For independent providers, guidance on how to apply for a licence is available on our website.
[10] Section 51 of the Health and Care Act 2022.

40. As with ICBs, NHS England expects providers to engage with it voluntarily, in conjunction with the relevant ICB, to bring an ongoing breach to an end or to establish whether there has been a breach in the past. Where this does not prove possible and the available evidence indicates that the legal test for intervention is met, NHS England will consider formal steps to ensure compliance.

41. If NHS England is considering acting formally, it will review the information in its possession, consult as required including with the relevant ICB(s) and assess the range of available options to determine the most appropriate action, having regard to the legal framework described above.

42. To ensure compliance with the licensing regime, NHS England may:

    a. require certain people or bodies to provide information to it in any format at any time[11]

    b. accept undertakings to remedy a breach of the requirement to hold a licence; or a breach of a licence condition; or a failure to comply with a notice NHS England issues to provide information[12]

    c. impose discretionary requirements to remedy a breach of the requirement to hold a licence; or a breach of a licence condition; or a failure to comply with a notice NHS England issues to provide information[13]

    d. impose on a foundation trust (only) an additional licence condition relating to governance[14]

    e. include or modify a special condition in a licence after consulting the licence holder[15]

    f. revoke a licence for breach (although such action is likely to be rare and applied only in extreme circumstances).[16]

[11] s104 of the 2012 Act.

[12] s106 of the 2012 Act.

[13] s105 of the 2012 Act.

[14] s111(1) of the 2012 Act.

[15] s95(1) of the 2012 Act.

[16] s89 of the 2012 Act. NHS England may also revoke at the licence holder's request.

43. NHS England's powers to impose discretionary requirements or accept undertakings for failure to comply with a section 104 formal notice requesting information in relation to provider enforcement apply not only to providers but also to ICBs.

44. NHS England also has a general power to give directions to NHS trusts about the exercise of their functions, under section 27B of the NHS Act 2006. This could include giving a direction to an individual NHS trust. Generally, NHS England intends to use the 2012 Act enforcement powers in relation to failures to comply with licence requirements, and to mandate support under the NHS Oversight Framework NHS England retains the discretion to use a direction in an appropriate case.

45. Sections 3 and 4 below provide details on:

    a. how NHS England will assess whether enforcement action may be necessary

    b. where NHS England believes that enforcement action is necessary, how it will select an appropriate and proportionate remedy.

Provider discretionary requirements

46. NHS England may impose various types of discretionary requirements on providers.[17]

47. For any provider, this may be a monetary penalty of an amount that NHS England determines, up to a maximum of 10% of the turnover in England of the party on whom it is imposed[18] (known as a variable monetary penalty).[19]

[17] As indicated at paragraph 42, these powers also apply to an ICB that fails to comply with an information notice under s104 of the 2012 Act.
[18] s105(4) of the 2012 Act.

[19] s105(2)(a) of the 2012 Act. Part 2 section 3 of the National Health Service (Licensing and Pricing) Regulations 2013/2014. Pursuant to Schedule 11 to the 2012 Act, a monetary penalty may not be imposed unless notice is given to the provider within five years of the last day of the period in which the provider was in breach.

48. It may be a requirement to take steps within a certain period that NHS England specifies to ensure that the breach is terminated or does not recur (known as a compliance requirement).[20]

49. Or it may be a requirement to take steps within a certain period to ensure that to the extent possible the position is restored to what it would have been had the breach not occurred (known as a restoration requirement).[21]

50. NHS England may take a range of considerations into account to decide whether to impose a requirement and, if so, which one. These may include:

    a. Seriousness of the breach – including its nature, scale, gravity, impact, duration and the extent to which it is capable of being remedied or reversed. In broad terms, the more serious the breach, the greater the likelihood that a discretionary requirement would be an appropriate remedy.

    b. Securing provider compliance – including whether the breach is first-time or repeated; whether non-compliance was deliberate or foreseeable or accidental; and the extent to which any undertakings offered by the infringer may adequately remedy the breach.

    c. Deterrence effect – including whether proportionate adjustments to the remedy may be necessary to deter future breaches by the infringer or by other providers in similar circumstances; how common breaches of the type under consideration are in the health and social care sector; and the effectiveness of previous remedies in deterring future breaches.

    d. Restoring the position to what it would have been without the breach – including the extent to which it is desirable, for instance, to ensure that the infringer does not financially or otherwise profit from the breach, and practicable, for instance whether it could be readily achieved.

51. Any remedial action must be clear cut, readily implementable and proportionate to the breach. NHS England will balance the need to swiftly bring to an end and deter harmful conduct with the need to ensure the continued provision of healthcare services.

[20] s105(2)(b) of the 2012 Act.

[21] s105(2)(c) of the 2012 Act.

52. To ensure a proportionate outcome, NHS England will weigh the expected impact and burden of the requirement on the provider. Such factors would include the provider's current and likely future financial position, and the cost of complying with a requirement including on quality and safety.

53. Currently, NHS England does not have a fixed monetary penalty scale. NHS England reserves its right to determine an appropriate penalty on a case-by-case basis in accordance with legislation. In doing so, NHS England will take into account relevant matters as set out in paragraph 49 and other factors such as the impact of a monetary penalty on the quality and safety of services provided by the licensee. Where relevant, NHS England may apply a discount for voluntary reporting of breaches in respect of which a penalty is imposed.

Giving notice of intention to impose provider discretionary requirement

54. Where NHS England proposes to impose a discretionary requirement, it is required to issue a notice of intent to the provider it considers has committed the breach.[22] The notice will set out the nature, reasons for and effect of the requirement NHS England proposes to put in place. It will explain the effect of NHS England's powers relating to undertakings and whether NHS England would consider accepting undertakings in lieu of requirements to remedy the breach. It will specify the deadline for submitting written representations to it on the proposed action[23] and, if appropriate, also set out the circumstances in which NHS England may not impose the proposed requirement.

55. NHS England may also invite the notice recipient to a meeting to make oral representations to supplement its written response to the notice. A recipient may choose to take up this invitation if it wishes to give further elucidation

[22] Paragraph 1 of Schedule 11 to the 2012 Act. This would also apply to a discretionary requirement proposed for an ICB in relation to a failure to comply with a s104 information notice.

[23] Pursuant to s1(3) of Schedule 11 to the 2012 Act, the consultation period must be at least 28 days, starting on the day after the notice is received. However, where the proposed action is to impose a compliance requirement or restoration requirement and NHS England considers that a shorter consultation is necessary – to prevent or minimise further potential breaches of the requirement to hold a licence or to comply with an information notice under s104 of the 2012 Act or to comply with licence conditions – NHS England may shorten the consultation period as appropriate subject to a minimum of five days starting on the day after the notice is received. See paragraph 1(4) of Schedule 11 to the 2012 Act.

(representation)/evidence to its written response, for example. Equally, a recipient may request a meeting for these purposes.

56. Oral representations should not be regarded as an alternative to written observations and evidence, and NHS England will not draw any adverse inferences if a notice recipient chooses not to accept or request a meeting. Typically, the meeting should add further explanation and clarification to written observations and should not simply repeat arguments already made in writing.

57. NHS England may also invite interested third parties to comment on a non-confidential version of the proposal. The extent and duration of any third-party consultation will be assessed on the facts of each case, including whether the interests of patients would be better served by taking swift action or by obtaining views from a range of parties through a broader consultation exercise.

58. Alongside a confidential submission, third parties should provide a non-confidential version that clearly identifies any confidential information they wish to be redacted, and explain how disclosure of that information would significantly harm the legitimate interests of the party or person to whom it relates.

59. NHS England will consider all representations made to it in relation to its proposed action prior to giving notice of its final decision. The notice will set out whether its final decision is to impose the requirement in its original form or with modifications; or whether NHS England has decided to impose any other requirement.[24] The notice will also set out the effect of the requirement; the reasons for imposing it; the consequences of non-compliance; and the right of appeal.[25]

60. In the case of a variable monetary penalty, it will also specify how and by when payment should be made;[26] and give details of any discount for early payment and the applicable interest rate for late payment.[27] Payment must be made within the payment period specified in the notice. Failure to pay on time may result in interest being payable and, in addition to any other action to recover the amounts due,

[24] Paragraph 2(1) and 2(2) of Schedule 11 to the 2012 Act.

[25] Paragraph 2(3) of Schedule 11 to the 2012 Act.

[26] Pursuant to paragraph 2(4) of Schedule 11 to the 2012 Act, the minimum period for payment is 28 days starting on the day after that on which the final notice is received.

[27] Paragraph 2(3)(c) of Schedule 11 to the 2012 Act.

NHS England may take action to collect the money, and any interest owed, through the civil courts as a civil debt.

61. In certain circumstances, NHS England may make changes to a discretionary requirement after it has served a final notice. NHS England may withdraw the requirement entirely; or reduce the amount of a penalty; or extend the deadline for payment; or extend the deadline for putting in place a compliance or restoration requirement.[28] Generally, NHS England will publish on its website any changes that it makes after issuing a final notice together with the reasons for doing so.

62. Discretionary requirements may be appealed. Further details are set out in the 'How to Appeal' section below.

Penalty for non-compliance with a provider discretionary requirement

63. If a provider fails to comply with a compliance or restoration requirement imposed on it by NHS England, NHS England may impose a financial penalty on it, known as a 'non-compliance penalty'.[29]

64. Prior to taking this action, NHS England will issue a non-compliance notice to the infringer that sets out key information about the penalty, unless NHS England considers that there are particular circumstances that would make it inappropriate to do so.[30]

65. If all or any part of a non-compliance penalty is not paid by the deadline, NHS England may increase the penalty by up to 50% of its amount.[31]

66. NHS England may by notice to the infringer reduce the penalty or extend the period for payment.[32]

[28] Paragraph 4 of Schedule 11 to the 2012 Act. This would also apply to a discretionary requirement proposed for an ICB in relation to a failure to comply with a s104 information notice.

[29] Pursuant to paragraph 5 of Schedule 11 to the 2012 Act.

[30] Ibid. The notice should set out the penalty amount; the reasons for imposing it; how and by when payment should be made; any discount for early payment and the consequences of late payment; and the right of appeal.

[31] Ibid.

[32] Ibid.

67. Both financial penalties and non-compliance financial penalties paid to NHS England are recoverable as civil debts and are transferred to the government Consolidated Fund.[33]

68. A decision to impose a non-compliance penalty may be appealed. Further details are set out in the 'How to appeal' section below.

Provider undertakings

69. NHS England may also seek and accept undertakings from providers under section 106 of the 2012 Act.[34] Following the introduction under the 2022 Act of the requirement for NHS trusts to hold a licence, this provision includes NHS trusts.

70. NHS England may propose and accept undertakings where it has reasonable grounds to suspect that there is or has been a breach. This means that the evidence must point to more than a suspicion but may be of a lesser degree of certainty than that required to impose a discretionary requirement.

71. As a minimum, an undertaking would be expected to include a commitment to take action that would mean that the breach, if ongoing, is brought to an end within the stipulated timescales and does not recur. A provider may also undertake to restore the position to what it would have been had the breach not occurred or take action to benefit another licence holder or party that has suffered harm because of the breach (including the payment of a sum of money).

72. By offering or agreeing undertakings, the provider demonstrates that it intends to comply with them voluntarily. Nevertheless, it is usual practice for undertakings to contain monitoring and reporting commitments to ensure progress. Failure to deliver on undertakings can lead to further and more serious enforcement action.

Entering into discussions about ICB and provider undertakings

73. An ICB or provider can approach NHS England NHS England about offering undertakings at any point after NHS England has indicated it has reasonable concerns that an ICB may be failing or at risk of failure or a provider may be

[33] https://www.gov.uk/government/collections/hmt-central-funds

[34] As indicated at paragraph 43 of this guidance, such undertakings may also be accepted by an ICB which fails to comply with an information notice under s.104 of the 2012 Act.

breach of its licence conditions. Any proposal should be credible, with a sufficient amount of detail and explanation of how the undertakings would remedy NHS England's concerns in practical terms.

74. Similarly, NHS England may initiate discussions with an ICB or provider and propose undertakings where it considers these would be a viable solution to any concerns about a failure by an ICB or suspected breach for a provider. These can also bring an end to an ongoing ICB concern or provider breach, and any associated harm, more swiftly than might otherwise be the case.

75. Any discussions regarding undertakings are expected to take place in good faith with the sole aim of finding a clear-cut and comprehensive solution to concerns relating to ICBs or a suspected breach for a provider. Where NHS England believes that an ICB or provider does not demonstrate this intent, NHS England will continue to investigate or consider the (suspected) failure or breach. In the case of undertakings relating to patient choice, NHS England may accept undertakings where an investigation into an alleged failure to comply with patient choice undertakings is being or had been carried out.

76. It may take a number of attempts to finalise suitable undertakings and the process is usually iterative. However, where NHS England believes that, notwithstanding serious efforts, a workable solution is unlikely to emerge in a timely manner, it may decide to draw the discussions to a close. Before doing so, NHS England will make any relevant considerations such as how far its enquiries have progressed, and the availability of further evidence that may satisfy it that there is or has been a failure by an ICB or breach for a provider. This may enable NHS England to consider imposition of directions (ICB) or discretionary requirements (provider) in the first instance as a remedy.

Consulting other parties

77. Where NHS England determines that the proposed undertakings represent a comprehensive solution to the identified concerns and it is minded to accept them, NHS England may consult third parties with a material interest in the matter, such as the Care Quality Commission (CQC).

78. NHS England will consider the extent of any consultation having regard to the circumstances of the matter. Typically, relevant considerations include the best

interests of patients, for instance any risks to patient safety, and the benefits that testing the proposed undertakings may bring through wider engagement. NHS England will consider any responses to its consultation prior to deciding whether to modify, accept or reject the undertakings.

3. Gathering, handling and evaluating information

Ongoing monitoring

79. There are various ways in which a potential failure to discharge functions or comply with the patient choice requirements (for an ICB) or licence breach (including a failure to hold a licence, for a provider) may come to the attention of NHS England. NHS England can investigate these circumstances on its own initiative or in response to third-party information. In respect of patient choice requirements, NHS England, in line with its oversight function, may consider concerns raised by patients and providers about ICBs that it may seek to resolve as live issues via direct collaboration with ICBs.

80. By collaborating at the local level with ICBs and maintaining records of complaints raised about compliance with patient choice requirements, NHS England is able to identify any potential concerns at a particular organisation within the system. For independent providers, the NHS England will gather information and monitor for risks to continuity of services using the approach set out in the Risk Assessment Framework and reporting manual, and the national choice team will continue to lead on patient choice-related matters.

81. For ICBs, NHS trusts and foundation trusts, and some NHS controlled providers[35] NHS England will monitor and gather information about performance for each of the themes of the NHS Oversight Framework, using both quantitative data and qualitative information.

[35] NHS controlled providers are not trusts or foundation trusts but are ultimately controlled by one or more NHS trusts or foundation trusts. They are overseen under the NHS Oversight Framework or the Risk assessment framework and reporting manual for independent sector providers of NHS services. This will depend on factors such as the scope of the services provided, size of turnover and whether the provider is a wholly owned subsidiary or is jointly owned by a number of providers.

82. Guidance on performance monitoring and information gathering for independent providers is set out in the Risk Assessment Framework and reporting manual.

83. Should any material concerns emerge, ongoing oversight meetings will be complemented by focused engagement with the provider and/or ICB concerned, and there may also be a requirement to provide additional information to assist NHS England in deciding whether to take action.

84. NHS England may also receive information from other sources such as a third-party ICB or provider, or another third-party entity. This can be either voluntarily or in response to a notice NHS England issues under the licence or legislation to provide information to it.[36] Individuals working in an ICB or provider can be a valuable source of information and NHS England encourages them to come forward in confidence with evidence of potential concerns.[37]

Gathering information

85. NHS England prefers to give parties an opportunity to provide information voluntarily to assist its enquiries. However, in certain circumstances, it may be more appropriate for NHS England to exercise its formal information gathering powers – for instance, at the request of a party; or because it has concerns that not all relevant evidence will be handed over; or because it has concerns about the accuracy of the information given to it.

86. When considering compliance with licence requirements, NHS England may issue a formal notice for the provision of information to a licence applicant, a licence holder, a provider of NHS healthcare services that is exempt from the requirement to hold a licence, a provider of NHS healthcare services that is in breach of the requirement to hold a licence, or an ICB.[38] Licence holders must also comply with requests for information under Licence condition G1.

87. NHS England has a power to require ICBs to provide information to it.[39] Where NHS England reasonably suspects that an ICB has failed to comply with this

[36] In relation to providers, see Licence General Condition 1, and s104 of the 2012 Act. For ICBs, NHS England has a power to require an ICB to provide information under s14Z60 of the NHS Act 2006.

[37] external-whistleblowing-policy-v4.pdf (england.nhs.uk)

[38] s104 of the 2012 Act.

[39] s14Z60 of the NHS Act 2006.

requirement, NHS England may accept undertakings from the infringing ICB to remedy the failure.

88. In practice, NHS England teams use a combination of informal (voluntary) information requests and formal information notices to gather evidence. Information gathering is typically an iterative process. The provision of information can often trigger a request or notice for further information, explanation or clarification. NHS England will look for evidence to establish the existence of a potential breach, but also to confirm that no breach is occurring or has occurred.

How NHS England handles confidential and sensitive information

89. NHS England aims to be open and transparent in its work. As a public body, NHS England must comply with the Freedom of Information Act 2000, which requires it to disclose information unless an exemption can be applied.[40] NHS England also publishes information about its enforcement activities.

90. In carrying out its regulatory and assurance functions, NHS England receives and handles a large amount of information. Some of this is confidential and sensitive, such as deceased and living personal data, disclosure of which may significantly harm the legitimate personal interests of the person to whom it relates.[41] NHS England may disclose information obtained by it in exercise its enforcement functions in the cases set out in section 13Z3 of the NHS Act 2006. In addition, in relation to personal data, NHS England is bound by data protection legislation[42] and has a designated data protection officer[43] who oversees compliance with the relevant legal provisions on data processing.[44] Further information on how NHS England protects personal data is set out in its privacy policy.

91. Significant harm may be caused to the legitimate commercial interests of an ICB or provider, or NHS England's ability to carry out its functions, if confidential

[40] Further information on the Freedom of Information Act 2000 is available at www.ico.org.uk

[41] Including to that person's relatives and other close acquaintances.

[42] The Data Protection Act 2018 and the UK General Data Protection Regulation ('UK GDPR'). Further information on data protection rules is available at www.ico.org.uk

[43] https://www.england.nhs.uk/nhse-nhsi-privacy-notice/joint/data-protection-officer/

[44] For guidance on applicable data protection rules: https://ico.org.uk/for-organisations/guide-to-data-protection/

information relating to the ICB or licensee or confidential regulatory information is disclosed. For these reasons, NHS England handles confidential and sensitive information with great care, ensuring that it is only used for the appropriate purposes[45] and that it is shared within NHS England or more widely only to the extent strictly necessary for the intended purpose.

92. Pursuant to section 109 and paragraph 10 of Schedule 11 to the 2012 Act, NHS England is not permitted to publish information that prejudices a person's commercial or personal interests. This includes when publishing information in its annual report about its enforcement action against licenced providers, or an enforcement undertaking.

Information evaluation and analysis, and investigations

93. In consultation with the ICB or provider in question and with the assistance of central specialist advisers as appropriate (such as medical, legal, financial and economic experts), NHS England will evaluate and analyse the gathered information to determine whether initial concerns about an ICB or a provider's potential failure/breach are sufficient to warrant further investigation.

94. This may be done as part of NHS England's ongoing considerations of an ICB or provider's support needs, or as a standalone exercise.

95. During this exercise, frequent and ongoing dialogue is likely between the ICB with significant concerns, or provider suspected of committing a breach, and NHS England. There will also be engagement with relevant third parties, as appropriate, and other regulators, such as the CQC, so that NHS England can get as full a picture as possible.

96. NHS England will seek to test the veracity of the evidence in its possession to ascertain whether the legal threshold for enforcement action is met. Analysis is a fluid exercise tailored to the particular facts and circumstances of the matter in hand. Information provided in relation to one potential concern may shed light on another. Equally, early enquiries may suggest concerns of a broad nature but subsequently the focus may narrow or vice versa.

[45] Information NHS England demands under s104(1) of the 2012 Act may be used for any of its regulatory functions, namely its licensing, pricing and special administration functions, and certain functions relating to foundation trusts.

97. The time taken to complete this phase of work can vary considerably, depending on a range of factors including the scope and complexity of the matter; the number and co-operation of parties; the available resources; and the priority of the matter relative to NHS England's other workstreams.

98. In limited circumstances, it may be appropriate for the information gathering and analysis to be conducted in the context of a formal investigation. An investigation may be opened when NHS England considers a greater level of formality and governance needs to be adopted with respect to its enquiries and/or to ensure appropriate independence. NHS England will keep the ICB or provider informed of any intent to open an investigation, the identity of the investigation team (who may be subject matter experts) and the terms of reference. NHS England will also inform the ICB or provider of the timescales and potential outcomes.

4. Outcomes

99. In the case of ICBs, NHS trusts and foundation trusts the enforcement outcome may be closely connected to decisions about support needs based on the NHS Oversight Framework. Specifically, a decision about mandated support may be subject to formal enforcement action by NHS England as set out in this guidance (in the case of individual trusts this will happen in partnership with the ICB).

Potential outcomes – ICBs

100. NHS England's enquiries or investigation may result in any of the outcomes outlined below.

    a. **No action/informal action** – NHS England may not pursue a formal enforcement where the evidence does not indicate a requirement for immediate action or there are other good reasons for not taking formal action (e.g. because the issues are not of sufficient priority or the ICB is already taking effective remedial action). NHS England may agree informal action with the ICB, including providing guidance and support, and maintain dialogue and oversight of the ICB in relation to the areas of concern. Should further relevant information come to light suggesting that NHS England should revisit its decision, NHS England may do so at any point and will notify the ICB.

b. **Acceptance of undertakings to remedy a potential failure** – NHS England may accept undertakings from the ICB to remedy the failure where it reasonably suspects an ICB is failing or has failed to discharge its functions properly or at all; or is concerned that an ICB is at of risk of so failing; or is carrying out an investigation as to whether an ICB has failed or is likely to fail to comply with patient choice requirements; or reasonably suspects that there is a failure to comply with a requirement to provide information to it. Undertakings set out actions formally agreed between the ICB and NHS England to tackle any concerns identified. Further details on the process relating to undertakings is set out in paragraphs 72 to 75 and 108 to 119 below.

c. **Direct the ICB** – NHS England may issue directions where it is satisfied an ICB is failing or has failed to discharge its functions properly or at all; or is at risk of so failing; or has failed or is likely to fail to comply with patient choice requirement, NHS England may give directions to the ICB. Paragraphs 25 to 30, set out NHS England's powers in respect of issuing directions to ICBs.

NHS England also has the power to vary an ICB's constitution/area and to abolish an ICB and merge it with another ICB. NHS England may consider use of these powers if it is satisfied that enforcement action would not adequately address the failure of an ICB that is failing or has failed, although this is likely to be rare and only in extreme cases

Potential outcomes – providers

101. NHS England's enquiries or investigation may result in any of the outcomes outlined below.

a. **No action/informal action** – NHS England may not pursue a formal enforcement where the evidence does not indicate a requirement for immediate action or where there are other good reasons for not taking formal action (e.g. because the issues are not of sufficient priority or the provider is already taking effective remedial action), NHS England may agree informal action with the provider, including providing guidance and support, and maintain dialogue and oversight of the provider directly or through the relevant ICB in relation to the areas of concern. Should further relevant

information come to light suggesting that NHS England should revisit its decision, NHS England may do so at any point and will notify the provider and relevant ICB.

b. **Acceptance of undertakings to remedy a breach** – NHS England may accept undertakings from the infringing provider to remedy the breach, in conjunction with the relevant ICB, where it reasonably suspects that either healthcare services have been or are being provided without a required licence; or that healthcare services have been or are being provided in breach of a licence condition; that there is a failure to comply with a requirement to provide information to it. Further details on the process relating to undertakings is set out in paragraphs 72 to 75 and 108 to 119 below.

c. **Imposition of one or more discretionary requirements to remedy a breach** – NHS England may require that the infringing party fulfils certain requirements to remedy the breach where it is satisfied that either healthcare services have been or are being provided without a required licence; or that healthcare services have been or are being provided in breach of a licence condition; or that there is a failure to comply with a requirement to provide information to it. These requirements include one or a combination of the following measures:

    i. A compliance requirement that obliges the provider to take specified actions within a specified period to end the breach and ensure that it does not recur. The principal focus of this measure is to ensure swift and comprehensive compliance.

    ii. A restoration requirement that obliges the provider to take specified actions within a specified period to restore the situation to what it would have been but for the breach. This measure may be used to compensate any affected party, including healthcare service users and other providers. For instance, an infringing provider may be required to give up any gains it has made from the breach and restore the position of those who have suffered harm as a consequence of the breach.

    iii. A requirement on the provider to pay a monetary penalty determined by NHS England of no more than 10% of its turnover in England.

102. NHS England also has the power to impose an additional governance licence condition under section 111 on foundation trusts (only) or revoke a licence if it is satisfied that the licence holder has failed to comply with a licence condition.[46] NHS England can also direct an NHS trust – see paragraph 43.

103. To note also, the statutory powers to accept undertakings and impose discretionary requirements set out above may be applied to an ICB, where it refuses to comply with a formal notice to provide information in relation to NHS England's regulatory functions (including investigation or enforcement of a (potential) licence breach by a provider).[47]

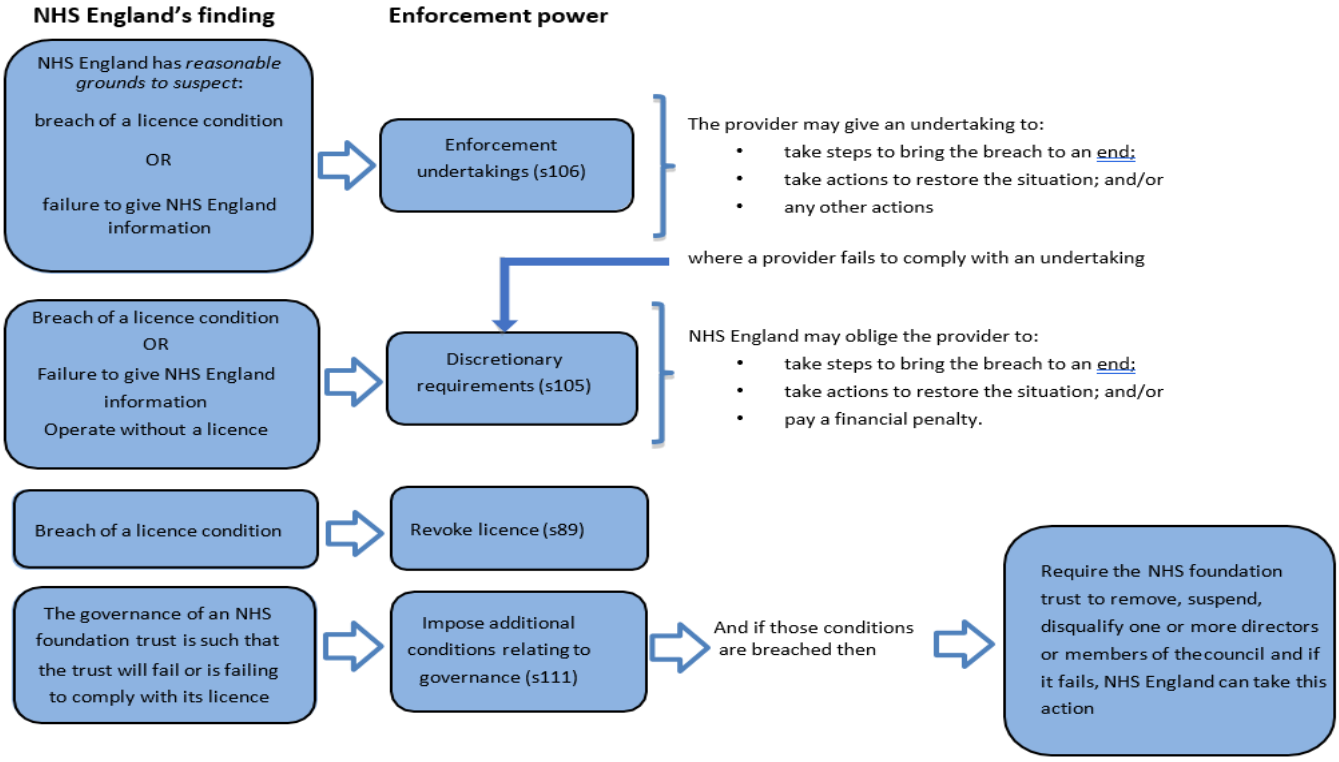
104. Further details on licence revocation are set out in paragraphs 125 to 127 below.

105. Figure 1 summarises NHS England's provider enforcement powers.

Figure 1: Overview of NHS England's formal provider enforcement powers
(the wording of the Health and Social Care Act 2012, as amended by the Health and Social Care Act 2022, is simplified)

[46] s89 of the 2012 Act. In legal terms, our power to revoke is distinct from our enforcement powers as upon revocation the licence ceases to exist.

[47] Notices issued under s104 of the 2012 Act.



Who decides the appropriate outcome for ICB and provider enforcement?

106. For ICBs, NHS trusts and foundation trusts, and certain NHS controlled providers, NHS England's regional teams take the lead in progressing enforcement matters. Teams are responsible for making recommendations on whether, and if so what, enforcement action is necessary having regard to the evidence. For patient choice, the national choice team takes the lead in enforcement matters, including decisions about opening and conducting investigations, and informal action to support compliance.

107. For certain NHS controlled providers and licensed independent providers of NHS services, the national independent provider team is responsible for ongoing monitoring and also takes the lead in licence enforcement matters, including opening and conducting any necessary investigations.

108. NHS England's regional or national committees (depending on the type of enforcement action or, in specific circumstances, the geography of the provider) make the decision on whether to take enforcement action. The committee considers the recommendations in detail before deciding the outcome, and the

regional team then communicates the outcome to the relevant party. In the case of ICBs, NHS trusts and foundation trusts, those decisions are often made alongside support needs decisions based on the NHS Oversight Framework.

Relationship between undertakings and discretionary requirements/directions

109. Undertakings can be accepted if NHS England has reasonable grounds to suspect a relevant breach or failure. In the case of undertakings relating to patient choice, NHS England may accept undertakings where an investigation into an alleged failure to comply with patient choice undertakings is being or had been carried out. Discretionary requirements (providers) and directions (ICBs), on the other hand, can be imposed only where NHS England is **satisfied** there is a relevant breach or failure – that is, in the case of an ICB, NHS England must be satisfied that the ICB is failing or has failed to discharge its functions, or that there is a significant risk it will do so.

110. In the case of a provider, NHS England must be satisfied there is a breach of the licence. For these types of enforcement actions, the evidence must provide a degree of certainty of a failure or breach higher than reasonable grounds for suspicion.

111. Even where the higher evidence threshold is met – that is, NHS England is **satisfied** there is a failure/breach, for both ICBs and providers – NHS England may opt to accept undertakings rather than impose directions or requirements if it believes that undertakings would represent a viable and appropriate remedial option. Equally, NHS England may consider undertakings in the first instance but later decide based on the circumstances that imposing directions or requirements would be preferable so long as the higher threshold of certainty is met.

112. If NHS England has accepted undertakings in respect of a particular failure or breach, it will not then impose a direction or discretionary requirement[48] in respect of that same breach, provided that the ICB or provider has complied or may yet comply with the undertaking. NHS England will also not impose a direction or

[48] For providers, this is required by s106(4) of the 2012 Act; for ICBs, NHS England will apply the same approach as a matter of policy

discretionary requirement on more than one occasion in relation to the same breach.[49]

Accepting ICB and provider undertakings

113. The relevant committee of NHS England will take the formal decision to accept undertakings. The undertakings may be agreed in principle, then confirmed with the committee. In other cases, the relevant committee may agree a proposal to seek undertakings, or an outline proposal for undertakings, while authorising that an officer of NHS England approves the final undertakings. Similarly, the ICB or provider will need to confirm its agreement to the undertakings, and this is typically done by way of a board decision.

114. A non-confidential version[50] will be published shortly after the undertakings have been accepted.[51] The ICB or provider should identify any confidential information it wishes to be redacted prior to publication and provide an explanation as to why disclosure would significantly harm the interests of the person or business to whom or which it relates. NHS England will not accept blanket redactions.

115. Once undertakings are agreed and in place, NHS England will notify certain stakeholders of the action that has been taken. For ICBs this will depend on the relevant issues. Stakeholders may include:

    a. the relevant integrated care partnership;
    b. NHS bodies within the system; and
    c. other relevant regulators, such as the CQC.

[49] For providers, this is required by s105(3) of the 2012 Act; for ICBs, NHS England will apply the same approach as a matter of policy.

[50] In the case of provider undertakings, s109 of the 2012 Act prohibits NHS England from publishing commercial information, disclosure of which would or might significantly harm the legitimate business interests of the person to whom it relates, and information relating to the private affairs of an individual, disclosure of which would or might significantly harm that person's interests. Paragraph 3 of Schedule 1ZA to the NHS Act 2006 (as amended by NHS Act 2022) applies a similar restriction in relation to ICB undertakings relating to patient choice.

[51] Publication is required by paragraph 10(1) of Schedule 11 to the 2012 Act in the case of s.106 provider undertakings and paragraph 3(1) of Schedule 1ZA to the NHS Act 2006 in the case of ICB undertakings relating to patient choice. As a matter of policy, the same approach is to be adopted for other ICB undertakings.

116. In the case of provider undertakings, the notification is a statutory requirement. The listed stakeholders[52] are:

    a. the relevant ICB(s); and
    b. other relevant regulators, such as the CQC.

117. By agreement with the ICB or provider, NHS England may vary undertakings that have been accepted, including terms relating to action to be taken and the period within which such action must be taken. The new undertakings will be published following the same procedure on confidentiality set out in paragraph 113.

118. Where NHS England is satisfied that an ICB or provider has complied with an enforcement undertaking, NHS England will issue a compliance certificate to that effect. Typically, NHS England will voluntarily propose a compliance certificate when it is satisfied that there is sufficient evidence of compliance. However, the ICB or provider may apply to NHS England at any time for a certificate and NHS England will give its decision within 14 days.[53]

119. Should NHS England refuse an application for a compliance certificate in relation to a provider undertaking[54] or a patent choice undertaking, its refusal decision may be appealed on the grounds that it was based on a factual error; was wrong in law; or was unfair or unreasonable[55]. See the 'How to appeal' section below.

120. After accepting an undertaking, if information comes to NHS England's attention that indicates the ICB or provider has supplied it with inaccurate, misleading or incomplete information relating to matters relevant to the undertakings, NHS England may treat the ICB or provider as having failed to comply with the

[52] s110 of the 2012 Act.

[53] A response within 14 days (starting on the day after the day on which the application is received) is required by paragraph 12(4) of Schedule 11 to the 2012 Act (in the case of provider undertakings) and paragraph 5(4) of Schedule 1ZA to the NHS Act 2006 (in the case of ICB undertakings relating to patient choice). ICB undertakings (other than in relation to patient choice) are not subject to these statutory requirements, but as a matter of policy NHS England will take the same approach.

[54] This would include an ICB undertaking accepted where it was in breach of a requirement to provide information by a notice under s104 of the 2012 Act.

[55] Paragraph 13 of Schedule 11 to the 2012 Act (provider undertakings) and paragraph 6 of Schedule 1ZA to the NHS Act 2006 (patient choice undertakings).

undertakings. In that case, after giving notice, NHS England may revoke any compliance certificate it may have previously issued to the ICB or provider.

Imposing additional provider licence conditions and removing, suspending or disqualifying directors or governors (trusts and foundation trusts only)

121. Section 111 of the 2012 Act gives NHS England specific powers to take action where the governance of a foundation trust is such that it is failing, or will fail, to comply with one or more conditions of its licence. In those circumstances, NHS England may impose an additional governance licence condition and, if that condition is breached, NHS England can remove directors or governors.

122. Before imposing an additional licence condition on a foundation trust, NHS England will follow a similar process to that set out above for undertakings or discretionary requirements. That is, NHS England will gather information to determine whether there is evidence of governance failure and, if the appropriate threshold is met, it will set out the case for imposing the additional condition.

123. NHS England will explain to the foundation trust any action it proposes to take by issuing a notice of intention to impose an additional licence condition, and will give the trust an opportunity to submit representations on its proposal before it makes a final decision. The decision will be made by the relevant NHS England committee.

124. Where an additional condition is in place, NHS England's regional team will monitor compliance with the condition and if NHS England is satisfied that the governance risk has been mitigated, it will remove the additional condition from the foundation trust's licence.

125. On the other hand, if the foundation trust has failed to comply and action for breaching the condition is a potential outcome, NHS England will engage with the foundation trust and advise on the process to be followed. That outcome may be the removal of directors or governors and/or a requirement to appoint new temporary directors or governors determined by NHS England.

Revocation of a provider licence

126. NHS England may revoke a provider's licence if it is satisfied that the licence has been breached and that enforcement action would not adequately address the breach. Such action is however likely to be rare and applied only in extreme circumstances.

127. Revocation would mean that the provider could not lawfully provide NHS services. As such, NHS England considers that this remedy would only be used exceptionally after careful consideration. In making its decision, NHS England will have regard to factors such as the seriousness of the breach; ensuring provider compliance; deterring similar breaches; and whether taking away the licence would be proportionate to the breach. If revocation for breach is a possibility, NHS England will engage the provider and advise on the process to be followed.

128. There may be reasons for revoking a licence other than licence breach. Licensed independent providers and NHS controlled providers wishing to revoke their licence should refer to NHS England's guidance on how to apply to revoke their licence.

5. How to appeal certain enforcement decisions

129. A decision by NHS England to impose a discretionary requirement; or a non-compliance penalty; or to refuse to issue a compliance certificate in relation to a provider enforcement undertaking under section 106 of the 2012 Act or a patient choice undertaking under section 6F of the NHS Act 2006, may be appealed to the First-tier Tribunal.

130. In the case of a discretionary requirement, the grounds for an appeal are that:[56]

    a. the decision was based on an error of fact;

    b. the decision was wrong in law;

    c. in the case of a variable monetary penalty, the amount of the penalty is unreasonable;

[56] Paragraph 3 of Schedule 11 to the 2012 Act.

d. in the case of a compliance requirement or restoration requirement, the nature of the requirement is unreasonable; or

e. that the decision is unreasonable for any other reason

131. In the other cases, the grounds for an appeal are that the decision was:[57]

a. based on an error of fact;

b. wrong in law; or

c. unfair or unreasonable.

132. The tribunal may confirm NHS England's decision or direct that it is not to have effect.

133. In the case of an appeal against a provider discretionary requirement, the requirement is suspended pending the appeal outcome.[58] The tribunal may confirm, vary or withdraw the discretionary requirement; take such steps as NHS England could take in relation to the breach; or remit to NHS England the decision whether to confirm the requirement, or any matter relating to the decision.[59]

134. In the case of appeal against a non-compliance penalty, the penalty is suspended pending the appeal outcome.[60] The tribunal may confirm, vary or withdraw the non-compliance penalty, or remit to NHS England the decision whether to confirm the penalty, or any matter relating to that decision.[61]

135. In the case of an appeal against a decision to refuse an application for a compliance certificate, the Tribunal may confirm the decision or direct that it is not to have effect.[62]

[57] Paragraphs 6 and 13 of Schedule 11 to the 2012 Act and paragraph 6(2) of Schedule 1ZA to the NHS Act 2006.

[58] Paragraph 3(3) of Schedule 11 to the 2012 Act.

[59] Paragraph 3(4) of Schedule 11 to the 2012 Act.

[60] Paragraph 6(3) of Schedule 11 to the 2012 Act.

[61] Paragraph 6(4) of Schedule 11 to the 2012 Act.

[62] Paragraph 13(2) of Schedule 11 to the 2012 Act and paragraph 6(2) of Schedule 1ZA to the NHS Act 2006.

136. A decision of NHS England to refuse to issue a licence or to revoke a licence may also be appealed to the First-tier Tribunal.[63] The tribunal may uphold the decision; or direct that the decision is not to have effect; or remit the decision to NHS England.[64]

137. Guidance is available on how to make an application to the tribunal,

138. NHS trusts will also have a right to appeal to the tribunal in relation to the decisions specified above, once they are formally licensed.

139. The right of appeal does not apply to a decision by NHS England to give a direction to an ICB, or to refuse to issue a compliance certificate in relation to an ICB enforcement undertaking (other than a patient choice undertaking).

63 s92(1) and (2) of the 2012 Act. The grounds for appeal are that the decision is based on an error of fact; or is wrong in law; or is unreasonable.

64 s92(3) of the 2012 Act.

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This publication can be made available in a number of alternative formats on request.

Classification: Official

Publication reference: PR1421

Consultation on the revised NHS enforcement guidance

27 October 2022

Contents

1. Introduction

1. Under the new Health and Care Act 2022 (the 2022 Act), NHS England has statutory accountability for oversight of both integrated care boards (ICBs) and NHS providers. NHS Improvement (Monitor and the NHS Trust Development Authority) has been abolished and NHS England has assumed responsibility for carrying out NHS Improvement's statutory functions, including the regulation of NHS providers, the exercise of provider enforcement powers, enforcement powers over ICBs in relation to compliance with patient choice provisions, and publishing and revising the guidance on the use of those powers.

2. The current enforcement guidance was issued by Monitor (NHS Improvement) and relates primarily to providers. Monitor (NHS Improvement) also issued enforcement guidance relating to its oversight role and enforcement powers over clinical commissioning groups and NHS England in relation to compliance with

patient choice provisions. NHS England intends to issue revised and expanded enforcement guidance to ensure alignment with new legislation and its new responsibilities arising from the 2022 Act:

i. The 2022 Act inserts a new section 14Z61 of the NHS Act 2006 to give NHS England powers to direct ICBs, transfers NHS Improvement's provider enforcement powers to NHS England, and introduces licensing for NHS trusts.

ii. The NHS Act 2006, as amended by the 2022 Act, also gives NHS England powers to oversee and take enforcement action in relation to ICBs' compliance with patient choice provisions.

iii. Reflecting those responsibilities, and unlike the existing Monitor/NHS Improvement enforcement guidance, this revised guidance would not be focussed primarily on enforcement in relation to providers.

3. The revised enforcement guidance would describe NHS England's intended approach to using its enforcement powers, including by setting out the use of powers to direct an ICB and the licence enforcement mechanisms that apply to foundation trusts, NHS trusts, licensed independent providers of NHS services, and licensed NHS controlled providers. It explains the regulatory and statutory processes in the event of enforcement action and subsequent rights of appeal, including:

   i. when NHS England may decide to take action, and what action it can take;

   ii. how NHS England is likely to decide what kind of sanctions to impose using its powers under the 2022 Act; and

   iii. the processes NHS England intends to follow when taking enforcement action.

4. NHS England's revised enforcement guidance would be published pursuant to:

   i. NHS England's duty under section 108 of the Health and Social Care Act 2012 to publish guidance about the use of its provider enforcement powers under the Act;

   ii. NHS England's duty under section 14Z51 of the NHS Act 2006 to publish guidance about the exercise of ICB functions.

   iii. NHS England's duties, on commencement of the relevant provisions in the 2022 Act, under section 6G of the NHS Act 2006 to publish guidance about

the use of its enforcement powers relating to patient choice; and a procedure for entering into patient choice undertakings, under paragraph 2 of Schedule 1Z1 to the NHS Act 2006.

5. This document consults on the revised enforcement guidance.

2. The proposed changes

Summary of the proposed changes

6. The proposed revisions to the enforcement guidance focus on:

    i. The changes required due to the abolition of Monitor and the NHS Trust Development Authority (known as NHS Improvement) and the transfer of functions to NHS England.

    ii. Alignment with new legislation and NHS England's new responsibilities under the NHS 2006 and the Health and Social Care Act 2012, as amended by the 2022 Act as set out above. Updates to the guidance include:

        a. the process for ICB enforcement

        b. removal of references to enforcement action for breach of competition rules – competition functions have been removed by the 2022 Act

        c. revisions to the language to reflect the change from Monitor to NHS England as the regulatory body for NHS foundation trusts, and the extension of the provider licence to NHS trusts.

        d. NHS England's enforcement powers in relation to patient choice provisions.

    iii. Alignment with current policy including the NHS Oversight Framework and operational best practice, including:

        a. reducing the emphasis on investigations in the event of suspected provider licence breach, in line with established practice

        b. removing the 'prioritisation framework' that Monitor used to inform its decisions on whether or not to begin or continue ongoing cases (the framework has since fallen out of use).

Provider enforcement

7. The basic processes that NHS England would follow when taking provider enforcement action have not changed in the revised enforcement guidance. The

revised guidance, however, sets out that NHS England will exercise its enforcement powers in line with the principles set out in the NHS Oversight Framework, working with and through ICBs wherever possible and with an emphasis on systems working together to resolve problems.

ICB enforcement

8. NHS England is proposing to introduce a two-tier approach to enforcement that reflects:

    i. ICB legislation in relation to patient choice; and

    ii. ensures parity with NHS provider organisations in terms of NHS England's approach to enforcement.

9. NHS England's powers to direct ICBs align with the powers NHS England may apply to providers that are in breach of their licence conditions (in particular the power to impose 'discretionary requirements').

10. The revised enforcement guidance would introduce an ICB undertakings process to be applied at a lower threshold than that required for directions (e.g., reasonable grounds to suspect that the ICB has failed or is at risk of failing to discharge its functions). This is in conjunction with the enforcement provisions relating to patient choice provisions and would be aligned with the existing provider undertaking process[1].

11. These undertakings would set out the actions the ICB agrees to take to resolve the identified issues, in line with the existing provider undertakings process:

    i. ICB undertakings will be agreed by NHS England and the ICB and would set out the remedial actions that will be taken to address the specific challenges identified.

    ii. By agreeing undertakings, the ICB would be giving a commitment that it will comply and carry out the relevant actions.

3. Responding to the consultation

12. In so far as the guidance applies to providers and to patient choice provisions, the proposals to revise and extend the existing enforcement guidance are subject to

[1] These undertakings are non-statutory. For matters relating to patient choice, statutory undertakings may be required by NHS England for the ICB in the context of a formal investigation.

NHSE's statutory duties to consult[2]. Consistent with those duties, we are consulting existing and potential licence holders (including NHS trusts), ICBs, the Care Quality Commission (CQC) and its Healthwatch England Committee, and other system and sector stakeholders. Additionally, we are keen to hear from other bodies with an interest in the provision of healthcare in England. An overview of the changes made to the enforcement guidance is attached as (Appendix 1).

13. This consultation document should be read alongside the updated enforcement guidance, the 2022/23 NHS Oversight Framework, and the consultation document that sets out the proposed changes to the NHS provider licence and guidance for NHS-controlled providers.

14. We are asking those who wish to respond to this consultation to answer the two questions below and to send their answers to us using this link. The consultation ends on 09 December 2022. Following consultation, the revised NHS enforcement guidance will replace and supersede the Monitor enforcement guidance.

Consultation

1. To what extent do you agree with the proposed changes to:

    a. introduce a two-tier approach to ICB enforcement that includes an undertakings process?

    b. align the enforcement guidance with current policy and operational best practice, including reducing the emphasis on investigations and removing the prioritisation framework?

    Please explain your reasons.

2. Please provide any additional comments on how the guidance could be improved.

[2] See section 108 of, and paragraph 9 of Schedule 11 to, the 2012 Act and section 6G of, and paragraph 2 of Schedule 1ZA to, the NHS Act 2006.

Appendix 1: Proposed changes to the enforcement guidance

Theme	Overview of change
NHS England's statutory responsibilities	With the introduction of the Health and Care Act 2022, the proposed guidance reflects the abolition of NHS Improvement and NHS England's new oversight responsibilities for ICBs and providers (paragraph 1 of the revised enforcement guidance) NHS England has statutory accountability to oversee both ICBs and providers, and to intervene when necessary following principles of fairness and proportionality (paragraphs 1,2, and 3 of the revised enforcement guidance) NHS England also has new enforcement powers in relation to ICBs and their compliance with patient choice provisions (paragraph 24 and 25 of the revised enforcement guidance)
Changes to the existing enforcement guidance	Removal of references to enforcement action for breach of competition rules as Monitor's competition functions were removed by the Health and Care Act 2022 (Chapter 1 of the current enforcement guidance). NHS England's shift away from rigid application of the 'prioritisation framework' that Monitor used to inform its decisions on whether or not to begin or continue ongoing cases. The framework has since fallen out of use and the guidance has been updated to reflect current best practice and the legal framework by which NHS England oversees ICBs and providers (Chapter 2 of the current enforcement guidance). NHS England's shift away from formal investigations where possible. The revised guidance reflects the collaborative process NHS England will follow with ICBs and providers when gathering information and investigating any concerns (Chapter 4 of the current enforcement guidance).
Additions to the existing enforcement guidance	Inclusion of enforcement relating to NHS trusts, to reflect the extension of the provider licence to NHS trusts on commencement of relevant provisions under the 2022 Act (paragraph 36 of the revised enforcement guidance). Creating guidance to cover enforcement in relation to ICBs as well as providers. The proposed revised guidance would include a new approach to ICB enforcement that includes the use of undertakings entered into by ICBs as the first step of enforcement action. The guidance also sets out the options and process for using ICB directions (paragraphs 32-35 of the revised enforcement guidance). NHS England's enforcement powers relating to patient choice provisions. Monitor had an oversight role and enforcement powers

	over clinical commissioning groups and NHS England in relation to compliance with The National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013 and certain provisions in the NHS Standing Rules. Under the Health and Care Act 2022, when the provisions come into force, NHS England will have a similar oversight role and enforcement powers over ICBs in relation to compliance with patient choice provisions (paragraph 31 of the revised enforcement guidance)

Classification: Official

Publications approval reference: xxxxxx

Memorandum of Understanding Bristol, North Somerset & South Gloucestershire Integrated Care Board and NHS England

Bristol, North Somerset and South Gloucestershire Integrated Care Board

1 December 2022

Contents

Introduction

Integrated care systems (ICSs) are partnerships of health and care organisations that come together to plan and deliver joined up services and to improve the health of people who live and work in their area.

The four key aims of an ICS are to:

- improve quality of services and outcomes in population health and healthcare
- tackle inequalities in outcomes, experience, and access
- enhance productivity and value for money
- help the NHS support broader social and economic development.

Collaborating as ICSs will help health and care organisations tackle complex challenges, including:

- improving the health of children and young people
- supporting people to stay well and independent
- acting sooner to help those with preventable conditions
- supporting those with long-term conditions or mental health issues
- caring for those with multiple needs as populations age
- getting the best from collective resources so people get care as quickly as possible.

ICSs are led by both an Integrated Care Partnership (ICP) and an Integrated Care Board (ICB). The ICP is a statutory committee bringing together all system partners to produce the ICS's integrated care strategy. The focus of this MOU is with the ICB as the statutory body with responsibility for NHS functions and budgets.

Purpose of this agreement

This MOU is between the Bristol, North Somerset and South Gloucestershire (BNSSG) Integrated Care Board, and NHS South West region, on behalf of NHS England. It is effective as of 1st December 2022. It sets out:

- the principles that underpin how the ICB and NHSE will work together to discharge their duties to ensure that people across the system have access to high quality, equitable health and care services
- the delivery and governance arrangements across the ICB and its partner organisations
- how NHSE, the ICB and NHS partner (foundation) trusts will work together to implement the requirements set out in the NHS Oversight Framework taking into consideration local delivery and governance arrangements, risks and support needs

- how the ICB and NHSE will work together to address development-specific needs in the ICS and across the region.

This MOU is not a legally binding agreement, and it does not change the statutory roles and responsibilities or functions of either party. NHSE will continue to exercise its statutory role and powers in relation to regulatory action under legislation, including to address individual organisational issues in line with the principles set out in this MOU. The accountabilities of individual NHS organisations also remain unchanged.

Ways of working

The following principles will inform how the ICB and NHSE will work together:

1. **Effective partnership working** - based on compassionate leadership behaviours, openness and transparency.

2. **Clear roles and responsibilities** - taking into consideration system maturity, risks and support needs.

3. **Build on what works** – leveraging and learning from existing arrangements and ways of working.

4. **'System first'** – encouraging actions and decisions to be made by, with and through the ICB rather than bilaterally between NHSE and individual provider organisations

5. **Improvement focused** - building a learning culture across local and regional level. Identifying opportunities and working together to address concerns / risks in a timely and proactive way; ensuring that the approach to oversight and, where necessary, intervention, is proportionate and supports improvement.

System priorities and deliverables

Our Operating Plan for 2022/23 (**Appendix 1**) has been developed and informed by our system partners recognising the sovereignty of each organisation and focusses on the areas where we can ensure maximin improvements for the people of BNSSG by working together.

It is set in the backdrop of the challenges to equitably restore services, meet the new demands for care and reduce the back logs that are a direct consequence of the Covid 19 pandemic. All whilst supporting staff recovery, addressing inequalities in access, experience and outcomes and tackling our financial challenge.

The Chief executives met in June 2022 and agreed the following outcomes as a priority for the partnership. These outcomes will be refined following the development of the BNSSG strategy later in 2022/23.

A key priority for BNSSG is Children's Services which is reflected in the BNSSG ICB Chief Executive being the Co-Chair of the SW Region Children and Young People Programme Board.

Partnership and place arrangements

BNSSG ICB has 6 place-based Locality Partnerships and has used the development of the Community Mental Health framework to support the Locality Partnerships development. The Locality Partnerships are:

- Weston, Worle and Villages
- Woodspring
- South Gloucestershire
- North and West Bristol
- Inner and central Bristol
- South Bristol

The Locality Partnerships at this time are formed from the local VCSE, GP Partnerships, Sirona Care and Health, Avon and Wiltshire Partnership NHS Trust and Vita Health, and have dedicated users by experience to support service development. Over time the Locality Partnerships will develop localised services for:

- Urgent Care
- Children services
- Ageing well

and will engage other System partners.

At this moment in time, there is no formal delegation to Locality Partnerships, but an Alliance Agreement is in place encapsulated via Memorandum of Understanding and collaboration agreements.

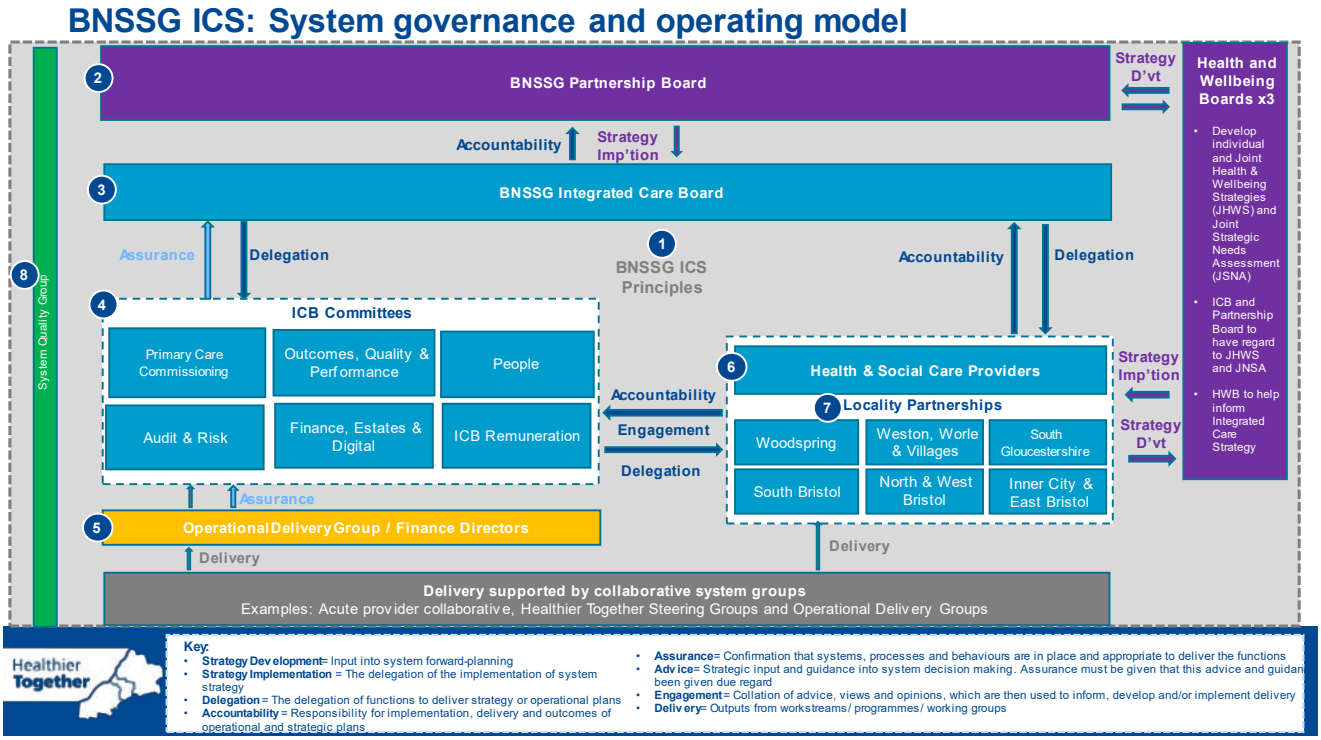
Provider Collaborative

Avon and Wiltshire Partnership NHS Trust are part of the Secure Services Provider Collaborative for the South West and are working to develop a BNSSG Provider Collaborative and a BSW (B&NES, Swindon and Wiltshire) Provider Collaborative.

University Hospitals Bristol and Weston NHS Foundation Trust and North Bristol NHS Trust are developing a Provider Collaborative and have set themselves the ambition to be a World Class Hospital System.

Governance and oversight

The governance arrangements signed off by the ICB are below



The Outcomes, Quality & Performance committee meets monthly, and has attendance from a range of Non-Executives from across the system. This committee has responsibility for the oversight of the delivery of the Operational Plan, the NHS System Oversight Framework and all aspects of quality across the system and has a direct read across from the System Quality Group. In time it is expected that this committee will move to focusing on outcomes.

The National Quality Board (NQB) has set out a framework to support systems in fulfilling this duty through effective quality management. The framework is designed around three core elements of quality planning, quality improvement, and quality assurance/ control. In line with this a local quality framework is in place and will be revised to ensure that reference is explicit to the NQB guidance on a shared commitment to quality.

As set out in our governance a System Quality Group is in place. The group defines the quality governance arrangements with the purpose of sharing intelligence and improvement. Escalation of system quality risks will follow the National Safety Boards risk guidance and will be overseen by the System Quality Group; this sits alongside an agreed risk framework which outlines how risk will be managed in the broadest sense in the ICB.

The Finance Estates and Digital Committee meets monthly and has attendance from a range of non-Executives across the system. This committee reviews the financial performance of the system and raises challenge to individual organisations at ICB level.

Reporting into the Sub Committees of the ICB are the Directors of Finance meeting where the financial elements of the NHS System Oversight Framework and corresponding segmentation are considered. This meeting is attended by NHS England, both as a regulator but also as a Commissioner. This meeting oversees the monitoring of the agreed Medium Term Financial Plan for the ICB, and escalates risk to the ICB via FED (Finance, Estates and Digital).

The Planning Oversight Group, which considers all aspects of financial and operational performance, meets weekly recognising the performance challenges of the system. This also allows the system to build in the feedback from the Tier 1 performance meetings in a timely way.
NHS England Performance Team are invited to attend this meeting.

In addition, there is a Monthly System Triumvirate Meeting, to ensure that Performance Improvement needs can be identified and supported both clinically and operationally.

The ICB is developing a decision-making framework in line with the NHS triple aim which is supporting the transition to the new ICB structures to reduce duplication and to streamline system governance. The framework is also to ensure that the wider impact of individual organisations' decisions are understood across the system and partners have agreed limits for individual decisions.

Roles and responsibilities in performance improvement

BNSSG ICB and NHSE will continue to work together to identify any further development needs and support required, as they arise at the informal monthly meetings between BNSSG ICB and NHSE. Due to the elective position of the system, there are also weekly Tier 1 meetings with the system and providers

BNSSG ICB reports system performance at Outcomes, Quality and Performance Committee. Deep dives into the performance of the system report formally to the ICB on a monthly basis.

In line with the NHS Oversight framework, BNSSG ICB will operate an oversight arrangement with NHSE which empowers BNSSG ICB to take a shared or leading role in the performance improvement of the system in the following way:

1. Lead the oversight of place-based systems and individual organisations in line with the principles of the MoU

2. Agree and coordinate any support and intervention carried out by NHSE, other than in exceptional circumstances.

NHSE South-West will:

3. Gain assurance of place-based systems and individual organisations through the ICS, other than in exceptional circumstances.

4. Undertake the least number of formal assurance meetings possible with individual organisations

5. Agree and broker the improvement support within and outside the system.

ICS development

As outlined in the establishment letter, the key area of the development for BNSSG is delivering the operational planning process for 2022/23. In particular, it is critical that the BNSSG system continues to focus on securing recurrent delivery of efficiency schemes to achieve a full year effect in 2023/24, to compensate for non-recurrent measures in 2022/23 plans whilst maintaining a focus on operational recovery.
The system needs to review its risk profile and associated approach to mitigations with the aim of reaching a consistent approach across the system

Reviewing, amending, and monitoring of the MOU

This MOU relates to an ongoing relationship between the ICB and NHSE and will run indefinitely. The ICB and NHSE agree to review the agreement every 12 months to assess whether it is still accurate and fit for purpose.

Changes to the MOU required outside of the proposed review period can occur at any time, if agreed by both parties. With the development of the South West Compact, and the consultation on the Enforcement Guidance it is suggested that the MOU is reviewed in February 2023.

Signatures

The ICB and NHSE, as represented by the below officers, agree to honour the aspirations and commitments made in this MOU.

[insert name/title of representing officer of the ICB]

[insert name/title of regional NHSE representative]

[insert effective date]

Classification: Official

Publication approval reference: PAR1378

NHS Oversight Framework

27 June 2022

Contents

1. Introduction

1. Integrated care systems (ICSs) are partnerships of health and care organisations that together plan and deliver joined up services to improve the health of people who live and work in their area. Following several years of locally-led development, the Health and Care Act 2022 has now put ICSs on a statutory footing.

2. From 1 July 2022 integrated care boards (ICBs) will be established with the general statutory function of arranging health services for their population and will be responsible for performance and oversight of NHS services within their ICS. NHS England will work with ICBs as they take on their new responsibilities, the ambition being to empower local health and care leaders to build strong and effective systems for their communities.

3. 2022/23 will be a year of transition as ICBs are formally established and new collaborative arrangements are developed at system level. Over the course of 2022/23 NHS England will consult on a long-term model of proportionate and effective oversight of system-led care.

4. This updated NHS Oversight Framework describes NHS England's approach to NHS oversight for 2022/23. It aligns to the priorities set out in the 2022/23 priorities and operational planning guidance and the legislative changes made by the Health and Care Act 2022, including the formal establishment of ICBs and the merging of NHS Improvement (comprising Monitor and the NHS Trust Development Authority) into NHS England.

5. Building on the approach outlined in the NHS System Oversight Framework 2021/22, the 2022/23 framework reinforces system-led delivery of integrated care in line with the direction of travel set out in the NHS Long Term Plan, Integrating care: Next steps to building strong and effective integrated care systems across England and the Integration White Paper (Joining up care for people, places and populations).

6. The approach for 2021/22 provided a single, consistent NHS monitoring framework with the flexibility to support different system delivery and governance

arrangements, as well as local partnership working. This updated framework continues that approach, but updates it to take account of:

a. the establishment of statutory ICBs with commensurate responsibilities
b. NHS England's duty to undertake an annual performance assessment of these ICBs
c. early learning from the implementation of the System Oversight Framework during 2021/22
d. revised NHS priorities as set out in 2022/23 planning documentation.

7. The framework will support ICBs and NHS England to work together and develop proportionate and locally tailored approaches to oversight that reflect:

a. a shared understanding of the ambitions, accountabilities and roles between NHS England, ICBs, individual trusts and local partnerships, and how performance will be monitored
b. the unique local delivery and governance arrangements specifically tailored to the needs of different communities
c. the importance of delivery against both the shared system priorities agreed between local partners and national NHS priorities.

8. This updated framework will take effect from 1 July 2022 and the existing oversight arrangements as set out in the System Oversight Framework 2021/22 apply until this date.

2. Purpose and principles

9. The overall purpose of and approach to NHS oversight was consulted on prior to publication of the 2021/22 System Oversight Framework. This refreshed framework aligns with these key principles.

10. The purpose of the NHS Oversight Framework is to:

a. ensure the alignment of priorities across the NHS and with wider system partners

b. identify where ICBs and/or NHS providers may benefit from, or require, support

c. provide an objective basis for decisions about when and how NHS England will intervene.

11. The approach to oversight is characterised by the following key principles:

a. working **with and through ICBs**, wherever possible, to tackle problems

b. a greater emphasis on **system performance and quality of care outcomes**, alongside the contributions of individual healthcare providers and commissioners to system goals

c. matching **accountability for results** with improvement support, as appropriate

d. **autonomy** for ICBs and NHS providers as a default position

e. **compassionate leadership behaviours** that underpin all oversight interactions informed by Our Leadership Way (an agreed set of behaviours describing what good leadership should look and feel like), the National Quality Board's (NQB's) Our shared ambition for compassionate, inclusive leadership and the NHS board level competency frameworks.

3. Role of integrated care boards

12. ICBs will become formally established on 1 July 2022 and have legal duties to arrange NHS services for their ICSs. NHS England has issued statutory guidance on the preparation of the ICB constitution,. Along with the 2022/23 priorities and operational planning guidance, this sets out the governance ICBs must have in place.

13. ICBs are responsible for ensuring their delegations to place-based partnerships are discharged effectively, and for leading the oversight of individual providers within their ICSs in line with the principles outlined in this document. ICBs will also co-ordinate NHS support interventions within their system, where appropriate, working in partnership with NHS England.

14. NHS England has statutory accountability for oversight of both ICBs and NHS providers. In general, we will discharge our duties in collaboration with ICBs, asking ICBs to oversee and seek to resolve local issues before escalation. In some exceptional circumstances, such as where enforcement action is required, we will intervene directly with providers. Should such intervention be required this will happen with the full awareness of the relevant ICB.

4. Approach to oversight

15. Ongoing oversight will focus on the delivery of the priorities set out in NHS planning guidance, the overall aims of the NHS Long Term Plan and the NHS People Plan, as well as the shared local ambitions and priorities of individual ICSs.

16. To achieve this, the NHS Oversight Framework is built around:

    a. Five national themes that reflect the ambitions of the NHS Long Term Plan and apply across trusts and ICBs: quality of care, access and outcomes; preventing ill-health and reducing inequalities; people; finance and use of resources; and leadership and capability (Figure 1).

    b. A set of high-level oversight metrics, at ICB and trust level, aligned to these themes.

    c. A sixth theme, local strategic priorities. This reflects the ICB's contribution to the wider ambitions and priorities of its ICS and recognises:

        i. that systems each face a unique set of circumstances and challenges in addressing the priorities for the NHS

        ii. that each integrated care partnership[1] will set out an integrated care strategy that its ICB must have due regard to in planning and allocating NHS resources

        iii. the continuing ambition to support greater collaboration between partners across health and care, to accelerate progress in meeting the most critical

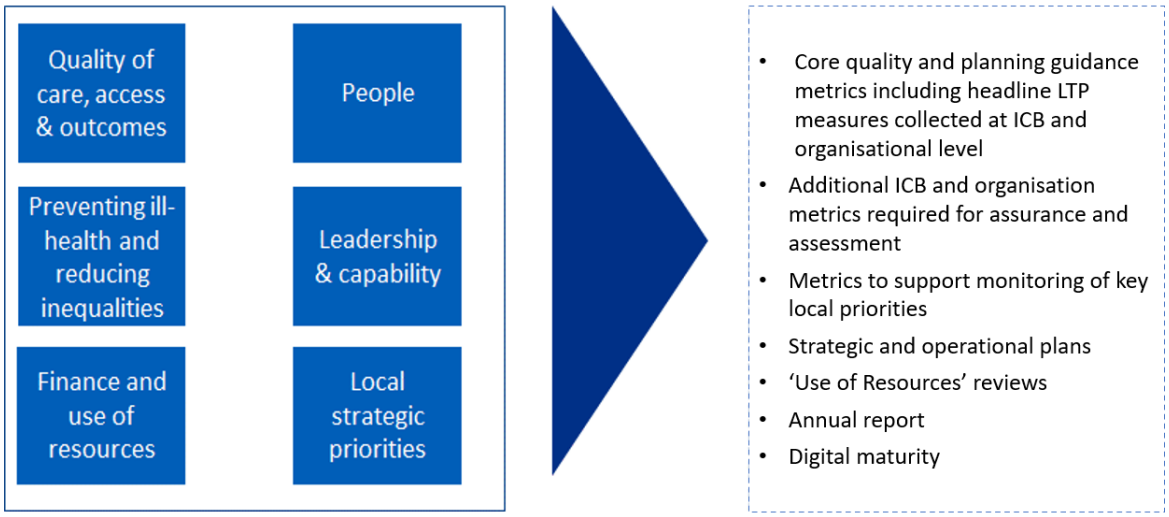
[1] Each ICB and its partner local authorities are required to establish an integrated care partnership, bringing together health, social care, public health and, potentially, representatives from the wider public space where appropriate, such as social care or housing providers.

health and care challenges and support broader social and economic development.

d. A description of how ICBs will work alongside NHS England to provide effective, proportionate oversight for quality and performance across the NHS.

e. A three-step oversight cycle that frames how NHS England teams and ICBs will work together to identify and deploy the right delivery support and intervention to drive improvement and address the most complex and challenging problems, respectively.

Figure 1: Scope of the NHS Oversight Framework for 2022/23



17. NHS England regional teams will lead the oversight of ICBs on delivery against the domains in the NHS Oversight Framework and, through them, gain assurance of place-based systems and individual organisations. Where necessary, regional teams will lead and co-ordinate support requirements identified for the ICB.

18. ICBs will lead the oversight of NHS providers, assessing delivery against these domains, working through provider collaboratives where appropriate. ICBs will consult with their NHS England regional team about any areas of concern identified, specific support requirements and, where necessary, issues requiring formal intervention by NHS England.

19. NHS England and ICBs will together agree the specific arrangements for each system to ensure effective and proportionate oversight, reflecting local delivery and governance arrangements. In 2021/22, NHS England regional teams and

ICSs worked together to establish individual memoranda of understanding (MoU) to reflect their oversight relationship and support ICSs in their journey towards becoming statutory bodies. An outline MoU and supporting guidance have been developed to support ICBs and NHS England regional teams to update individual MoUs to reflect the new statutory arrangements and the updated Oversight Framework.

20. MoUs will set out how NHS England and individual ICBs will work together to:

    a. discharge their respective roles and responsibilities to improve the quality of care and reduce inequalities, taking into consideration system maturity, risks and support needs

    b. improve partnership working at both local and regional level to ensure people across the system have access to high quality health and care services. This includes building an open and learning culture at local and regional level.

21. MoUs will also set out:

    a. The delivery and governance arrangements across the ICB and its partner organisations, including:

        i. The role of place-based partnerships and provider collaboratives in delivering the NHS priorities set out in the 2022/23 priorities and operational planning guidance.

        ii. Quality governance processes that enable the proactive identification, monitoring and escalation of quality issues and concerns. This should include cross-system quality governance as set out in the NQB's A shared commitment to quality and National guidance on system quality groups, which set out specific requirements for governance and intelligence sharing mechanism that ICSs are expected to have in place with system partners.

        iii. Financial governance arrangements in line with the National Health Service Act 2006, as amended by the Health and Care Act 2022, that will support the effective management of resources within the system financial envelope.

    b. The proportionate and robust oversight mechanisms and structures across the ICB and its partner organisations that:

        i. reflect the local delivery and governance arrangements

ii. are aligned to the arrangements set out in this framework, including the respective roles of the ICB and NHS England.

c. The local strategic priorities that the ICS has committed to deliver in 2022/23 as a partnership. These must align to the four fundamental purposes of an ICS.[2]

22. In some cases, bespoke oversight arrangements will be required; for example, where ICBs commission services under a delegated agreement, providers operate across multiple ICBs or a nominated ICB acts as a lead commissioner on behalf of the region. Regional teams will work with ICBs and service providers to ensure there are appropriate oversight arrangements in these situations.

23. There will be a need for flexibility in how the oversight role is carried out within the principles of this framework. In some cases, this may involve adjusting the specifics of the approach, for example:

a. as the NHS continues to rise to the challenge of restoring and transforming services following the COVID-19 pandemic, both tackling backlogs and meeting new care demands

b. where there is a need to respond quickly and proactively to unexpected issues in individual organisations, to national policy changes, the introduction of new service planning or delivery models, or new sector pressures.

[2] The four fundamental purposes of an ICS, set out in *Integrating Care: Next Steps To Building Strong and Effective Integrated Care Systems*, are: improving population health and healthcare, tackling unequal outcomes and access, enhancing productivity and value for money and helping the NHS support broader social and economic development

5. Oversight cycle

24. The oversight process follows an ongoing cycle (Figure 2) of:

    a. monitoring ICB and NHS organisation performance and capability under six themes (Figure 1)

    b. identifying the scale and nature of support needs

    c. co-ordinating support activity (and where necessary formal intervention) so that it is targeted where it is most needed.

Monitoring

25. As part of the oversight of ICBs and trusts, NHS England will monitor and gather insights about performance across each of the themes of the framework (Figure 1). The information collected and reviewed will include both quantitative data, including, but not limited to, the published Oversight Framework metrics, and qualitative information derived from oversight, quality, improvement and performance conversations with ICBs and their formal reporting documents, as well as other routine information including that from relevant third parties.

26. Depending on the type of information, the collection and review of data may be:

    a. **in year:** using monthly or quarterly collections and forums as appropriate

    b. **annual:** using annual submissions, surveys or other annually published information. In these cases, we expect that systems and regional teams will agree how they monitor progress on a timely basis linked to locally agreed plans and milestones

    c. **by exception:** where material events occur or we receive information that triggers our concern outside the regular monitoring cycle.

27. This information will be used to support ongoing monitoring at ICB and provider level of:

    a. **current performance** and service quality (based on the most recent data and insight available), including onward trajectories where available

b. the **historical performance trend** to identify patterns and changes, including evidence of improvement in reducing clinical variation.

28. A key outcome of the successful implementation of the framework will be the early identification of emerging issues and concerns, so that they can be addressed before they have a material impact or performance deteriorates further. ICBs and trusts are expected to maintain relationships with NHS England so that actual or prospective changes in performance are shared in a timely manner. Where quality risks are material to the delivery of safe and sustainable services, these should be managed and escalated in line with the National Quality Board quality risk response and escalation guidance.

29. NHS England regional teams will work with ICBs to ensure that oversight arrangements at ICB, place (including delegated commissioning arrangements) and organisation level incorporate regular review meetings as appropriate. Meetings will be informed by a shared set of information and regional teams will draw on national and other expertise as necessary (Table 1). Oversight conversations should reflect a balanced approach across the six oversight themes.

30. Ongoing oversight meetings will be complemented by focused engagement with the ICB and the relevant organisations where specific issues emerge.

Table 1: Ongoing monitoring process – review meetings

	ICB	Individual organisations/collaboratives
Scope	• Performance against national requirements including the NHS Long Term Plan deliverables at ICB level across the five national themes of the NHS Oversight Framework • Delivery against key 'local priorities' agreed with system partners • Effectiveness of current support arrangements and the extent to which these may need to be refined • Extent to which system partners are working effectively together to deliver and improve	• Oversight of and support to: – individual organisations, including those that span multiple ICSs, or have significant funding flows from outside an ICS, e.g. ambulance trusts and specialist trusts – collaboratives that span multiple places, including for the delivery of specialised services – place-based partnerships • By exception with scope determined by the specific issues identified in discussion between the NHS England regional team and ICB leadership
Roles and participation	• Led by NHS England regional team with: – ICB leadership team – senior leaders from system providers/ organisations (if not part of the ICB)	• Led by ICB with: – senior leaders from relevant providers/collaboratives – NHS England, where appropriate and by mutual agreement
Frequency of review meetings	• The default frequency for these meetings will vary according to the governance arrangements agreed between the regional team and ICB, but should be at least quarterly • Regional team will engage more frequently where there are material concerns • Annual meeting linked to ICB assessment process	• The default arrangements should be agreed between the ICB and partner organisation, and set out within the MoU

Identifying the scale and nature of support needs

31. To provide an overview of the level and nature of support required across systems, inform oversight arrangements and target support capacity as effectively as possible, regional teams have allocated all ICBs and trusts to one of four 'segments' as described in Table 2. Primary care providers and primary care networks (PCNs) will not be allocated to segments; however, the overall quality of primary care will inform ICB segmentation decisions.

32. Segmentation decisions are determined by assessing the level of support required based on a combination of objective criteria and judgement and are regularly reviewed to ensure they remain an accurate reflection of the level of support required. For individual trusts, NHS England and the relevant ICB will together discuss segmentation and any support required. NHS England will be responsible for making the final segmentation decision and taking any necessary formal enforcement action.

33. Segmentation decisions indicate the scale and nature of support needs, from no specific needs (segment 1) to a requirement for mandated intensive support (segment 4). A segment does not determine the specific support requirements. These will be identified as set out in the section 'Identifying specific support needs'

34. The principles and approach to oversight will apply across all segments. These criteria have two components which are set out in detail in Table 3:

    a. objective, measurable eligibility criteria based on performance against the six oversight themes using appropriate oversight metrics

    b. additional considerations focused on the assessment of system leadership and behaviours, and improvement capability and capacity.

35. Where the objective, measurable eligibility criteria are met this will trigger consideration of the additional factors that will determine the overall segmentation decision.

36. Autonomy will be the default position with the expectation that ICBs and trusts will be allocated to segment 2 unless specific mandated support is required. Those ICBs and trusts allocated to segment 1 will benefit from the lightest oversight arrangements, and may be encouraged to provide peer-to-peer support and spread good practice to other systems and providers.

Table 2: Support segments: description and nature of support needs

	Segment description		Scale and nature of support needs
	ICB	Trust	
1	Consistently high performing across the six oversight themes Capability and capacity required to deliver on the statutory and wider responsibilities of an ICB are well developed	Consistently high performing across the five national oversight themes and playing an active leadership role in supporting and driving key local place based and overall ICB priorities	No specific support needs identified. Trusts encouraged to offer peer support Systems are empowered to direct improvement resources to support places and organisations, or invited to partner in the co-design of support packages for more challenged organisations
2	On a development journey, but demonstrate many of the characteristics of an effective ICB Plans that have the support of system partners are in place to address areas of challenge	Plans that have the support of system partners in place to address areas of challenge Targeted support may be required to address specific identified issues	Flexible support delivered through peer support, clinical networks, the NHS England universal support offer (e.g. GIRFT, Right Care, pathway redesign, NHS Retention Programme) or a bespoke support package via one of the regional improvement hubs
3	Significant support needs against one or more of the six oversight themes Significant gaps in the capability and capacity required to deliver on the statutory and wider responsibilities of an ICB	Significant support needs against one or more of the five national oversight themes and in actual or suspected breach of the NHS provider licence (or equivalent for NHS trusts)	Bespoke mandated support, potentially through a regional improvement hub, drawing on system and national expertise as required (see Annex A)
4	Very serious, complex issues manifesting as critical quality and/or finance concerns that require intensive support	In actual or suspected breach of the NHS provider licence (or equivalent for NHS trusts) with very serious, complex issues manifesting as critical quality and/or finance concerns that require intensive support	Mandated intensive support delivered through the Recovery Support Programme (see Annex A)

Table 3: Support segments: segmentation approach

	Eligibility criteria	Additional considerations
1	• Performance against the oversight themes typically in the top quartile nationally based on the relevant oversight metrics and • Balanced plan, actual/forecast breakeven or better and • CQC 'Good' or 'Outstanding' overall and for well-led (trusts)	**For ICBs:** • Success in tackling variation across the system and reducing health inequalities • Whether the ICB consistently demonstrates that it has built the capability and capacity required to deliver on its statutory and wider responsibilities **For trusts:** • Evidence of established improvement capability and capacity • The degree to which the trust plays a strong, active leadership role in supporting and driving place-based priorities, provider collaboration and overall ICB priorities
2	This is the default segment that all ICBs and trusts will be allocated to unless the criteria for moving into another segment are met	
3	• Performance against multiple oversight themes in the bottom quartile nationally based on the relevant oversight metrics or • A dramatic drop in performance, or sustained very poor (bottom decile) performance against one or more areas or • Plan not balanced and/or a material actual/forecast deficit or • A CQC rating of 'Requires Improvement' overall and for well-led (trusts)	**For all:** • Existence of other material concerns about a system's and/or organisation's governance, leadership, performance and improvement capability arising from intelligence gathered by or provided to NHS England (e.g. delivery against the national and local transformation agenda) • A material concern with regard to the quality or safety of services being provided or a failure to escalate such risks • Evidence of capability and capacity to address the issues without additional support, e.g. where there is clarity on key issues with

	Eligibility criteria	Additional considerations
		an existing improvement plan and a recent track record of delivery against plan and/or of agreed recovery actions • There are other exceptional mitigating circumstances **For ICBs:** • Evidence of collaborative and inclusive system leadership across the ICB, e.g. where the system is not in financial balance, whether it has been able to collectively agree credible plans for meeting the system envelope • Clarity and coherence of system ways of working and governance arrangements **For trusts:** • Whether the trust is working effectively with system partners to address the problems
4	In addition to the segment 3 criteria: • Longstanding and/or complex issues that are preventing agreed levels of improvement for ICBs or trusts or • A catastrophic safety failure or • A catastrophic failure in leadership or governance that risks damaging the reputation of the NHS or • A significant underlying deficit and/or significant actual or forecast gap to the financial plan or • CQC recommendation (trust)	

37. Where ICBs and trusts have significant support needs that may require formal intervention and mandated support, they will be placed into segment 3 or 4. They will be subject to enhanced direct oversight by NHS England (in the case of individual trusts this will happen in partnership with the ICB) and, depending on the nature of the problem(s) identified, additional reporting requirements and financial controls. Full details are set out in Annex A.

    a. Mandated support consists of a set of interventions designed to remedy the identified problems within a reasonable timeframe. There are two levels of support depending on the severity and complexity of the issues:

        i. Mandated support that is led and co-ordinated by NHS England regional teams with input from the national intensive support team where requested. This level of support means automatic entry to segment 3.

        ii. Mandated intensive support that is agreed with NHS England regional teams and delivered through the nationally co-ordinated Recovery Support Programme (see Section 6: Recovery Support Programme). This level of support means automatic entry to segment 4.

    b. While the eligibility criteria for mandated support will be assessed at ICB and individual trust level, mandated support packages will always be designed and delivered within the relevant system context (e.g. place-based or provider collaboratives). Where the support need is triggered by an individual organisation, this means that local system partners will be expected to play their role in addressing system-related causes or supporting system solutions to the problem(s).

38. For ICBs and trusts in segments 1 and 2, overall support needs will be formally reviewed on a quarterly basis, likely as part of the routine meeting detailed in Table 1 (in the case of individual trusts this will happen in partnership with the ICB). Where ongoing monitoring suggests that the support needs may have changed, this will trigger a review of the segment allocation (see 'Identifying specific support needs' below).

39. For ICBs and trusts in segments 3 and 4, the agreed exit criteria will need to be met to exit mandated support and move to a lower segment (see Annex A).

Identifying specific support needs

40. Where an ICB or trust is triggering a specific concern, the NHS England regional team will work with the ICB to understand why the trigger has arisen and if a support need exists. The regional team will, as appropriate, involve system leaders and appropriate subject matter experts in this process – both to identify the factors behind the issues and determine whether local support is available and appropriate.

41. Regional teams will assess the seriousness, scale and complexity of the issues that the ICB, or trust where a need for support or intervention is evident, is facing. This will be done using information gathered through quality oversight, existing relationship knowledge and discussions with system members, and information from partners and evidence from formal or informal investigations. As part of this, regional teams will draw on the expertise and advice of national colleagues as required.

42. Regional teams, working with the ICB and system leaders (as appropriate), will consider the:

    a. degree of risk and potential impact
    b. degree to which the driver of the issue is understood
    c. views of leadership, governance and maturity of improvement approach
    d. inherent capability and credibility of plans to address the issue
    e. previous steps taken to support the resolution of the issue
    f. extent to which delivery against a recovery trajectory is being achieved.

43. Based on this assessment, regional teams will identify whether an ICB or trust has a specific support need and the subsequent level of support that is required. Support decisions will be taken having regard to the views of the system leadership.

44. This assessment may lead to a re-evaluation of the current allocated support needs segment, although this will not necessarily precipitate a change of segment.

45. Specific support needs will be reviewed through regular ICB oversight meetings, detailed in Table 1, or enhanced oversight arrangements, where these are required to:

a. track improvement and understand the effectiveness of the various support measures
b. ensure support is targeted where it has the greatest impact.

Co-ordinating support activity

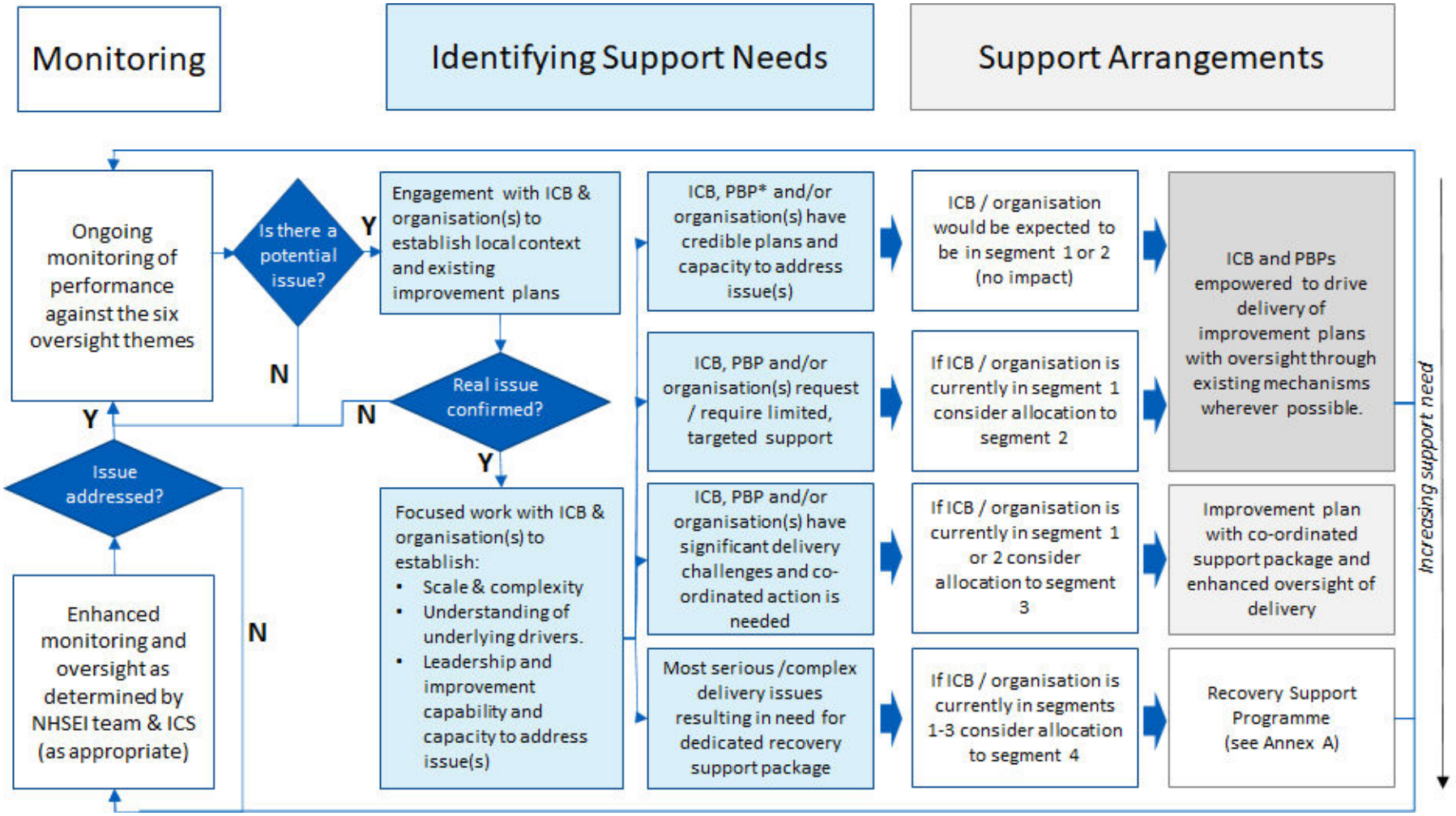
46. NHS England will work flexibly with ICBs to deploy the right support through this ongoing cycle, drawing on the expertise and advice of national colleagues as appropriate. During 2022/23 we will explore with ICBs the role peer review could play in the oversight model in future.

47. In line with the principles governing the framework, NHS England will work with and through ICB leaders, wherever possible, to tackle problems and ensure that the oversight process is both proportionate and co-ordinated across ICBs.

48. Expertise, advice and support from wider NHS England colleagues will be drawn on as appropriate, including clinical quality teams. NHS England colleagues will work to ensure that a co-ordinated support offer is provided and reflected in a co-ordinated action plan. Support requirements will be considered in parallel so that any support activities (and where necessary interventions) are mutually reinforcing and can be deployed at the right level, e.g. where concerns affect multiple organisations a system-wide approach may be needed.

49. Where the operation of the ICB itself is deemed to be a causal part of the identified issue(s), this could result in a change to the oversight approach normally associated with that system's previously assessed maturity level.

Figure 2: Oversight, diagnosis and support and intervention process



6. Recovery Support Programme

50. For ICBs and trusts allocated to segment 4, the national Recovery Support Programme (RSP) provides focused and integrated support, working in a co-ordinated way with the ICB, regional and national NHS England teams.

51. The RSP has replaced the separate quality and finance special measures programmes that were in place between 2013 and 2021 and is:

    a. available to support ICBs and trusts with increasing, complex challenges, helping to embed improvement upstream to prevent further deterioration and enable stabilisation

    b. focused at system level, while still providing tailored, intensive support to individual organisations

    c. focused on the underlying drivers of the problems that need to be addressed and those parts of the system that hold the key to improvement

    d. in the case of ICBs, nationally led by a credible, experienced system improvement director (SID) jointly appointed by the system, region and national intensive support team

    e. able to draw in support from an expert multidisciplinary team co-ordinated by the SID, or improvement director (ID) in the case of trusts

    f. time limited with clear exit criteria

    g. focused on building resilience within trusts and systems with knowledge and skills transfer providing sustainable capability within the system, such that they exit the programme with the knowledge and skills they need to achieve sustainable improvement

    h. designed to place an expectation on systems to build the capacity required to maintain improvement.

52. Where entry to segment 4 and the RSP is triggered by an individual organisation, local system partners will be expected to play their role in addressing system-related causes or supporting system solutions to the problem(s).

53. On entering the RSP a diagnostic stocktake, involving all relevant trust, system, regional and national partners, will:

    a. identify the root cause(s) of the problem(s) and the structural and strategic issues that must be addressed

    b. recommend the criteria that must be met for the system or organisation to exit mandated intensive support (exit criteria)

    c. review the capability of the ICB's or trust's leadership.

54. At the same time as helping to address the specific issues that have triggered mandated intensive support, NHS England will also consider whether long-term solutions are needed to any structural issues affecting the ICB's or trust's ability to ensure high quality, sustainable services for the public.

55. The SID will be jointly appointed by the ICB and NHS England's national and regional intensive support teams and will normally report to the chief executive of the ICB with a reporting line to the Director of National Intensive Support to ensure sufficient independence. Specific arrangements will need to be agreed in each situation to ensure appropriate governance and independence.

56. The SID will support the ICB or relevant organisations to develop the improvement plan, which will include a target timeline for exit from the RSP and segment 4.

57. Where a trust is in the RSP, an ID, reporting to the Director of National Intensive Support, will support the trust and its system partners to develop an improvement plan which will include a target timeline for exit from the RSP and segment 4.

58. NHS England must sign off the improvement plan for both ICBs and trusts placed in segment 4.

59. The SID or ID will work with the ICB, and trust if appropriate, to co-ordinate the necessary support from the system, NHS England teams, the broader NHS or, where appropriate, an external third party. This support could include:

    - intensive support for emergency and elective care
    - intensive support to deliver the national programmes focused on reducing clinical variation across clinical pathways
    - intensive support for workforce and people practices

- financial recovery support including specialist support, eg to reduce agency use, implement cost controls
- drivers of deficit review
- governance review
- governance and leadership programme for improvement in challenged organisations and systems
- tailored delivery of a range of improvement programmes such as 'well led', 'better tomorrow' and 'making data count'.

60. NHS England will make a decision on exit from the RSP on the basis that the agreed exit criteria have been met in a sustainable way and any required transitional intensive support is in place as an ICB or trust moves to segment 3. As support is also mandated in segment 3, the improvement plan should remain in place and will continue to be reviewed at a regional level to ensure improvement is being achieved. Where the objective eligibility criteria for entry into the RSP included a recommendation from the CQC, the decision to exit segment 4 will consider the evidence underpinning the CQC recommendation.

61. In addition to the process described above, further RSP review meetings may be held between the NHS England Board and the trust and its system or the ICB. These meetings can take place:

- on entry to segment 4 and the RSP, to gain assurance that the improvement plan is robust to achieve exit in a sustainable way to the agreed timescale
- on exit to segment 3 from the RSP, to gain assurance that, with an agreed package of support, improvement can be sustained, and any lessons learnt are shared as appropriate
- where there has been a national escalation of concerns regarding a lack of progress either by regional or national executives.

62. Further details on the operation of mandated support, including how decisions are made and how support is applied, is included as Annex A.

7. ICB assessment

63. NHS England has a legal duty to annually assess the performance of each ICB in each financial year and publish a summary of its findings.

64. In conducting this performance assessment, NHS England will consult each relevant health and wellbeing board as to its views on the ICB's implementation of any joint local health and wellbeing strategy.

65. The NHS England regional team will conduct the annual assessment, drawing on national expertise as required and having regard to relevant guidance. We will, in particular, consider how successfully the ICB has:

    a. contributed to the wider local strategic priorities of the ICS

    b. performed its statutory functions, including in particular how it has discharged its legal duties under the National Health Service Act 2006 (as amended by the Health and Care Act 2022) and the Local Government and Public Involvement in Health Act 2007, in relation to:

        i. improving the quality of services

        ii. reducing inequalities

        iii. obtaining appropriate advice

        iv. the effect of decisions (The "triple aim")

        v. public involvement and consultation

        vi. financial duties

        vii. having regard to local assessments and strategies

        viii. promoting and using evidence from research.

    c. delivered on any guidance set out by NHS England or the Secretary of State regarding the functions of the ICB

66. For 2022/23 the assessment will be in narrative form and will identify areas of good and/or outstanding performance, areas for improvement and any areas that are particularly challenged.

67. As this will be the first year in which ICBs operate, NHS England will work with them during the first half of the year to develop further detailed guidance to support annual assessments for 2022/23. We expect to review and develop this approach for future years.

8. Alignment with partner organisations

68. The National Health Service Act 2006, as amended by the Health and Care Act 2022, places a duty on NHS bodies to co-operate with each other in the exercise of their functions. NHS bodies including, but not limited to, NHS England, ICBs and NHS providers must, therefore, work in close partnership to deliver their duties. The Secretary of State may also publish guidance on the duty to co-operate between NHS bodies and between NHS bodies and local authorities, which must be taken into account. A failure to collaborate may lead to formal enforcement action being considered.

69. Alongside the duty of NHS bodies to co-operate with one another, it is essential that all members within ICSs, whether NHS bodies or not, also work together across boundaries to deliver services and outcomes for their population. To achieve this, each integrated care partnership must prepare an integrated care strategy setting out how the assessed needs of its area are to be met by the exercise of functions of:

    a. the ICB
    b. NHS England or
    c. responsible local authorities.

70. The integrated care strategy will have regard for best practice and the need for a joined-up approach and increased partnership with other organisations. The NQB's A shared commitment to quality and National guidance on system quality groups emphasise the importance of prioritising quality in decision-making, having a shared understanding of quality across partner organisations, a set of agreed quality improvement priorities for the system and common quality structures in

place to support intelligence-sharing, improvement and assurance (Including system quality groups).

71. Systems will also continue to benefit from the health and wellbeing boards and local authority health overview and scrutiny committees reviewing and scrutinising their work.

72. At a regional and national level, NHS England will continue to work alongside key regulators, CQC, Health and Care Professions Council, General Medical Council and the Nursing & Midwifery Council through the Joint Strategic Oversight Group (JSOG) function to provide a dedicated space for regulators to share intelligence and develop aligned approaches to support organisations.

73. The Health and Care Act 2022 places new duties on CQC to conduct reviews of the provision of health and adult social care in each ICS and assess the functioning of the ICS, including how its ICB, local authorities and registered service providers work together. NHS England and CQC will continue to work together to ensure synergy between the ICS reviews undertaken by CQC and the ICB assessments undertaken by NHS England.

Annex A: Intervention and mandated support

Introduction

1. Mandated support applies when integrated care boards (ICBs), NHS trusts and foundation trusts ('trusts'), have serious problems and where there are concerns that the existing leadership cannot make the necessary improvements without support.

2. Mandated support consists of a set of interventions designed to remedy the problems within a reasonable timeframe. There are two levels depending on the severity and complexity of the issues:

    - Mandated support that is led and co-ordinated by NHS England regional teams with input from the national intensive support team where requested. This level of support means automatic entry to segment 3 of the NHS Oversight Framework.
    - Mandated intensive support that is agreed with NHS England regional teams and delivered through the nationally co-ordinated Recovery Support Programme (RSP). This level of support means automatic entry to segment 4 of the NHS Oversight Framework.

3. While the eligibility criteria for mandated support will be assessed at ICB and trust level, mandated support packages will always be designed and delivered within the relevant system context (e.g. place-based or provider collaboratives). Where the support need is triggered by an individual organisation, this means that local system partners will be expected to play their role in addressing system-related causes or supporting system solutions to the problem(s).

4. Mandated support may involve the use of NHS England's statutory enforcement powers. A decision by NHS England to take such action must comply with the relevant statutory threshold and conditions. A trust considered to be in need of mandated support may be subject to enforcement action that requires it to carry out specific actions as part of the intervention.

5. This annex explains:

- how NHS England determines the requirement for mandated support and the level of support
- what happens to an ICB or organisation when mandated support applies
- the roles and responsibilities of other key organisations involved, specifically the Care Quality Commission (CQC)
- how an ICB or trust exits from mandated support
- what Recovery Support Programme (RSP) review meetings are.

6. This annex supersedes the previously published policy described as 'special measures' and should be read in conjunction with the 2022/23 NHS Oversight Framework.

7. While regulatory action arising from this framework at NHS foundation trusts will utilise the NHS provider licence, NHS England will, from July 1, use the legacy NHS Trust Development Authority powers it will inherit on that date to underpin any enforcement/mandated actions at NHS trusts until they receive a licence as per section 49 of the Health and Care Act 2022.

How NHS England determines the need for mandated support

8. NHS England determines which ICBs and trusts require mandated support with reference to a set of objective criteria, but also by considering other appropriate considerations. Any ICB or trust meeting the objective criteria set out below is eligible to be considered for the relevant level of mandated support but may also be excluded from this in light of other relevant considerations.

Mandated support (segment 3)

9. An ICB or trust is eligible to be considered for mandated support and entry to segment 3 if:

- performance against multiple oversight themes is in the bottom quartile nationally based on the relevant oversight metrics

  or

- there has been a dramatic drop in performance, or sustained very poor (bottom decile) performance against one or more areas

  or

- it has an underlying deficit that is in the bottom quartile nationally and/or is reporting a negative variance against the delivery of the agreed financial plan and/or it is not forecasting to meet plan at year end

  or

- for trusts, there is a CQC rating of 'Requires Improvement' overall and for well-led.

10. Where there are material concerns about an ICB's and/or trust's governance, leadership, performance and improvement capability arising from intelligence gathered by or provided to NHS England (eg delivery against the national and local transformation agenda), this may also trigger consideration of mandated support. In these circumstances regional teams will also consider the extent to which the above objective eligibility criteria are met.

11. Meeting one of the objective eligibility criteria does not automatically lead to entry to segment 3. In considering whether an ICB or trust that has met the eligibility criteria would benefit from mandated support, regional teams will consider whether:

    For all:

    - there is the capability and capacity to address the issues without additional support, eg where there is clarity on key issues with an existing improvement plan and a recent track record of delivery against plan and/or of agreed recovery actions
    - there are other exceptional mitigating circumstances.

    For ICBs:

    - there is evidence of collaborative and inclusive system leadership across the ICS, e.g. where the system is not in financial balance, whether it has been able to collectively agree credible plans for meeting the system envelope
    - there is clarity and coherence in ways of working and governance arrangements across the system.

For trusts:

- whether the trust is working effectively with other system partners to address the problems.

12. NHS foundation trusts will only be placed in segment 3 where there is evidence that they are in actual/suspected breach of their NHS provider licence conditions (or equivalent for NHS trusts).

Mandated intensive support (segment 4)

13. An ICB or trust is eligible to be considered for mandated intensive support and entry to segment 4 if, in addition to the considerations for mandated support above, any of the following criteria are met:

- longstanding and/or complex issues that are preventing agreed levels of improvement for ICBs or trusts

  or

- a significant underlying deficit and/or a significant actual or forecast gap to the agreed financial plan

  or

- a catastrophic failure in leadership or governance that risks damaging the reputation of the NHS

  or for trusts only:

- a recommendation is made by the CQC.

14. The CQC, through the Chief Inspector of Hospitals, will normally recommend to NHS England that a trust is mandated to receive intensive support when it is rated 'Inadequate' at the single trust rating level.

15. The evidence provided by the CQC will include the reasons why it is recommending the trust is mandated to receive intensive support, the specific areas of improvement where actions need to be taken and what improvements in quality need to be achieved.

16. Based on the full range of information and judgement, NHS England will decide, following national moderation, whether the trust will be placed in segment 4 and receive intensive support through the RSP.

What happens when NHS England mandates support for an ICB or trust

Mandated support (segment 3)

17. NHS England will communicate its decision to the ICB or trust, and work with it to develop and deliver a bespoke mandatory support package through the relevant regional improvement hub, drawing on system and national expertise as required.

18. The relevant NHS England regional leadership will sign off the criteria that the ICB or trust must meet to exit mandated support (exit criteria) and the ICB or trust will develop an improvement plan with a target timeline for meeting the exit criteria.

19. Typically, the following additional interventions will be put in place:

    - enhanced monitoring and oversight of the ICB or trust by the NHS England regional team
    - NHS England advisory role for senior appointments, including shortlisting and as external assessor on interview panels.

20. The interventions listed above may be supported or implemented using formal statutory enforcement action

21. Depending on the nature of the problem(s) identified and the support need, further interventions may include enhanced:

    - scrutiny/assurance of plans
    - reporting requirements
    - financial controls including lower capital approval limits.

Mandated intensive support (segment 4)

22. NHS England will communicate its decision to the ICB or trust and then make a formal public announcement.

23. Mandated intensive support will be agreed with the region and delivered through the nationally co-ordinated RSP. The RSP has been developed to provide intensive support either at organisation level (with system support) or across a whole health and social care system.

24. A diagnostic stocktake involving all relevant system partners will:

- identify the root cause(s) of the problem(s) and the structural and strategic issues that must be addressed
- recommend the criteria that must be met for the ICB or trust to exit mandated intensive support (exit criteria) and an indicative exit timeline. These must be agreed by NHS England.

25. NHS England will review the capability of the ICB's or trust's leadership. This may lead, if necessary, to changes to the management of the ICB/trust to make sure the board and executive team can make the required improvements. Where changes are required, this will happen as soon as is practical and the necessary support will be provided to facilitate this.

26. At the same time as helping to address the specific issues that triggered mandated intensive support, NHS England will consider whether long-term solutions are needed to address any structural issues affecting the ICB's or trust's ability to ensure high quality, sustainable services for the public.

27. NHS England will appoint a system improvement director (SID) or an improvement director (ID) who will act on its behalf to provide assurance of the ICB's or trust's approach to improving performance. The SID or ID will support the ICB or trust to develop an improvement plan with an indicative timescale for meeting the exit criteria (typically within 12 months).

28. The ID will work with the trust and/or ICB to co-ordinate the necessary support from the system, NHS England teams, the broader NHS or, where appropriate, an external third party. This could include:

- intensive support for emergency and elective care
- intensive support to deliver the national programmes focused on reducing clinical variation across clinical pathways
- intensive support for workforce and people practices
- financial turnaround/recovery support including specialist support, eg to reduce agency use, implement cost controls
- drivers of deficit review

- governance review
- governance and leadership programme for improvement in challenged organisations and systems
- tailored delivery of a range of improvement programmes such as 'well led', 'better tomorrow' and 'making data count'.

29. Typically, the following additional interventions will be put in place:

    - regular formal progress and challenge meetings with national-level NHS England oversight
    - board vacancies filled on the direction of NHS England (trusts).

30. Depending on the nature of the problem(s) identified and the support need, further interventions may include:

    - NHS England-appointed board adviser
    - enhanced reporting requirements
    - enhanced financial controls including:
        - NHS England control of applications for Department of Health and Social Care financing (trusts)
        - peer review of expenditure controls
        - reduced capital approval limits (trusts)
        - rapid roll out of extra controls and other measures to immediately strengthen financial control, including those set out in NHS England guidance (including the 'Grip and Control' checklist).

31. The interventions listed above may be supported or implemented using formal statutory enforcement action

32. Where a trust is deemed to require mandated intensive support on the recommendation of the CQC, there will be close dialogue between the CQC, NHS England, the trust and ICB, which will include what improvements in quality would give assurance of progress being made. These improvements form the basis of joint reviews of progress during the mandated intensive support period, as well as the existing regular information exchange between the CQC and NHS England regional leads.

33. This process of information exchange and review will enable extra support or intervention to be considered as needed. These decisions need not wait until the next re-inspection.

34. NHS England will ensure that the trust addresses any urgent patient safety and quality issues identified as a priority. The CQC will continue to monitor quality at the trust. If at any time patients are at immediate serious risk of harm, the CQC can use its urgent powers to safeguard them.

35. The expectation is that the CQC will re-inspect the trust within 12 months of the start of mandated intensive support. It will judge if the quality of patient care and the trust's leadership have improved.

How ICBs and trusts exit from mandated support

36. Exit from mandated support will ordinarily occur when it can be demonstrated that exit criteria have been met in a way that is sustainable. Over time it may be necessary to review or revise these exit criteria. Any change to exit criteria must be approved by NHS England.

Mandated support (segment 3)

37. To be considered for removal from mandated support, an ICB or trust must demonstrate that the exit criteria have been met in a sustainable way. When deciding on a recommendation to exit, the NHS England regional team will also consider whether a targeted and time-limited post-exit support package is needed to ensure the improvement is sustained.

Mandated intensive support (segment 4)

38. To be considered for removal from mandated intensive support, an ICB or trust must demonstrate that the exit criteria have been met in a sustainable way. When making a decision on a recommendation to approve exit, NHS England will also consider the proposed transitional support package that will be needed when an ICB or trust enters segment 3 to ensure the improvement is sustained.

39. Where a trust is in segment 4 and so in receipt of mandated intensive support as a result of a recommendation of the CQC, NHS England will take account of any recommendation by the Chief Inspector of Hospitals before deciding the trust should exit that segment. The Chief Inspector will usually recommend this where

there is no reason on grounds of quality why a trust should remain in receipt of mandated intensive support – that is, if the quality of care is showing sufficient signs of improvement, even if it is not yet 'good', and if the trust leadership is robust enough to ensure that the trust will sustain current improvements and make further improvements. NHS England must also be confident that improvements will be sustained.

40. Where NHS England is not satisfied that the exit criteria have been met, mandated intensive support will be extended for a short period to allow the ICB or trust to make the improvements needed. This might occur, for example, where there have been changes to the leadership team and more time is needed for the new team to bring about change. In the case of an extension, the ICB or trust will prepare a revised improvement plan that lists actions to address any outstanding or new concerns.

41. NHS England will inform the ICB or trust in question of its exit decision once it has completed its formal decision-making processes. NHS England will then make a formal public announcement

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This publication can be made available in a number of other formats on request.

Publication approval reference: PAR1378

Classification: Official

Publication approval reference: PAR1497

National Guidance on Quality Risk Response and Escalation in Integrated Care Systems

National Quality Board

6 June 2022

Contents

Introduction, purpose, and aims

This guidance builds on the National Quality Board's (NQB) Guidance on System Quality Groups (SQGs) and sets out how quality concerns and risks should be managed within Integrated Care Systems (ICSs) in collaboration with NHS England (NHSE) and wider partners. It supersedes and brings together the NQB Guidance on Risk Summits and NHSE Quality Escalation Framework and Trigger Tool, and aligns with the NHS Oversight Framework (NHSOF), Perinatal Quality Surveillance Model and Patient Safety Incident Response Framework[1].

The document is for system leaders as they develop their approach to quality management, providing clarity on:

- The expected approach to managing system-level concerns and risks – including categorising concerns, reporting, escalating, de-escalating and monitoring
- The expected role of Integrated Care Systems (namely Integrated Care Boards (ICBs) and local authorities), working with NHS England (NHSE) and wider partners in managing quality concerns and risks - this includes expected roles when there are multiple commissioners (e.g. Integrated Care Boards (ICBs) and Local Authorities; NHSE and ICBs; multiple ICBs)
- What should happen when there are quality concerns that justify escalation to a regional or national response due to the consequences or potential for learning, including complex, significant or recurrent concerns that may require regulatory action and service closures. Examples: significant quality failings across a pathway, material concerns about the leadership or culture within a provider or ICB, lack of timely and sustained traction to address regulatory non-compliance.

Quality care is understood in the guidance according to the NQB Shared Commitment's definition, as care that is **safe, effective**, provides a **personalised experience,** is **well-led** and **sustainably resourced**. The NQB is also clear that quality care must be **equitable,** focused on reducing inequalities and addressing wider determinants. Based on this definition, **this guidance considers the full range of health and care services and providers**, including services commissioned by the NHS (either ICB or NHSE), jointly commissioned by the NHS and local authorities, and commissioned by local authorities from NHS providers and non-NHS providers (e.g. under public health grant).

[1] The PSIRF is the framework for responding to patient safety incidents in providers.

As per the Guidance on System Quality Groups, this document will be updated as the new operating model evolves. Three annexes are included: a) Glossary of Key Terms; b) TORs for Rapid Quality Review Meetings; c) TORs for Quality Improvement Groups.

Key principles for effective quality management

In the Guidance on System Quality Groups, the NQB emphasised the importance of all ICSs having effective structures and infrastructure in place to support quality management, combining quality planning, quality assurance/ control and quality improvement functions. The NQB set out the role that System Quality Groups and wider forums (e.g. ICB Quality Committees) would play in quality management (see Figure 2), providing model Terms of Reference and clarifying the expected relationships between Integrated Care Boards (ICBs), Local Authorities and other partners (e.g. NHSE). It also highlighted the significant opportunity that ICBs now have to **improve quality structures in order to reduce bureaucracy and support integration.**

These same principles, responsibilities, governance arrangements and relationships are the basis for this document and must be taken on board by system leaders as they develop their approach to managing quality risks within ICSs[2]. Figure 2 provides an overview of the expected responsibilities for quality risk management at different geographies.

To work effectively, there is a need for strong partnership working and intelligence-sharing across organisations, including shared ownership of risk. Clear reporting and governance arrangements must be in place within and beyond ICSs, including alignment with Regional Quality Groups[3].

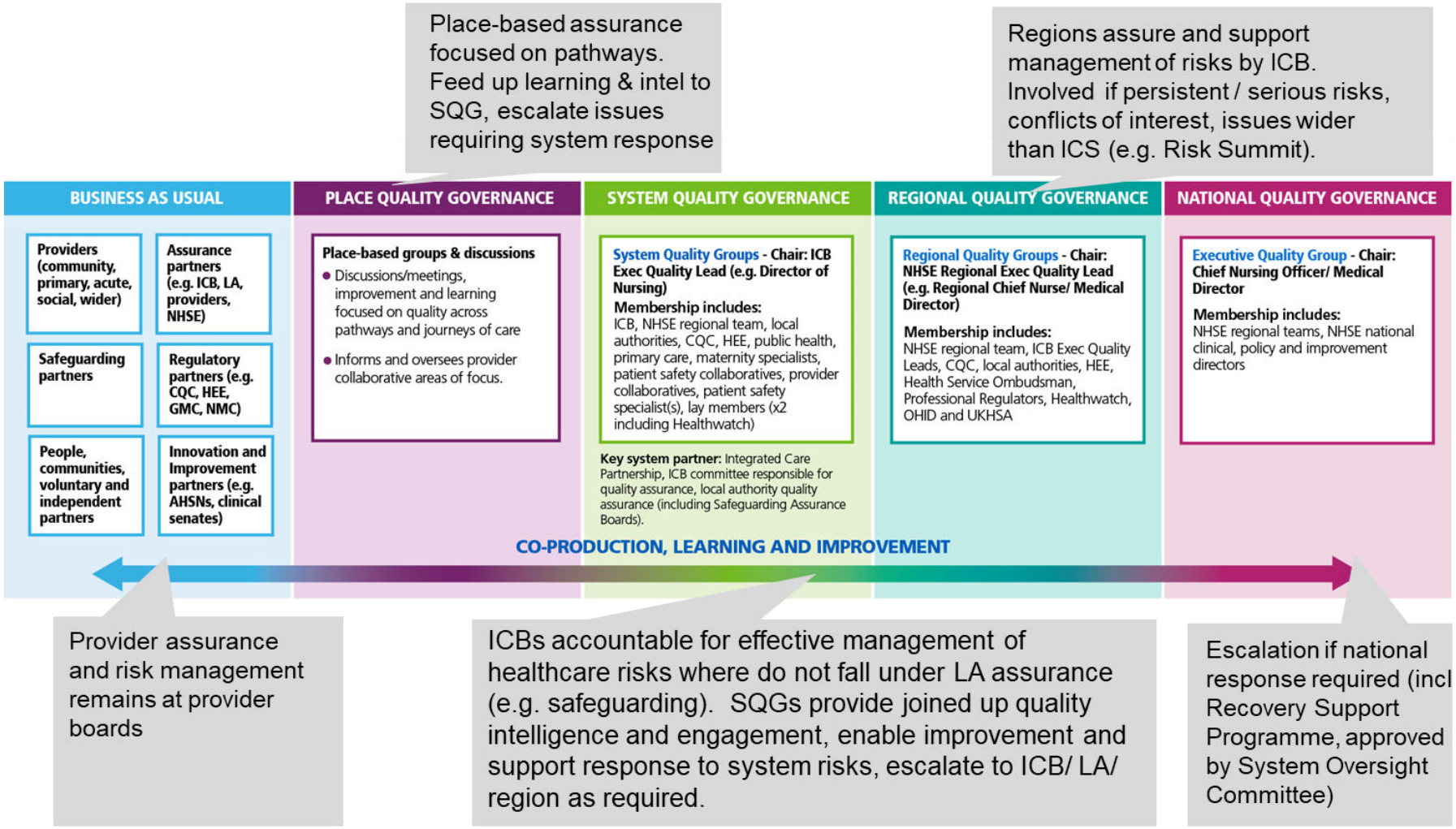
Below we set out the expected approach to management of system-level quality concerns and risks. This aligns with the forthcoming **NHSE Guidance on System Quality Risk Management**, which will set out key principles and examples of good practice for risk management, including: agreed system risk appetite statements; common language and scoring; and risk frameworks which clearly link to associated accountability and governance frameworks, and which cover quality alongside wider risk frameworks (e.g. performance, operational, financial).

[2] Key principles include: having a clear line of sight, including concerns and risks; investing in building an improvement culture; having streamlined, agile and lean quality structures which are standardised where possible and support partnership working and intelligence sharing; and working closely with staff and people drawing on services to support effective quality management.
[3] Regional Quality Groups have replaced Regional QSGs to align with changes at system level. We expect these to include discussion about independent providers with a view to use existing contractual levers to bring about improvement.

It is crucial that NHSE regional and national teams adopt a system-first approach wherever possible when managing risks. Risks should be managed as close to the point of care as possible, where successful mitigation is not possible then escalation and management at the next level occurs as linked to the designated risk framework and overseen by the ICS. However, as the Guidance on System Quality Groups made clear, there will be situations in which **NHSE and other regulators have the right to intervene,** particularly if there are complex, significant and/or recurrent risks. Further details on triggers for NHSE involvement are provided below.

Note that for independent sector providers as there is no NHSE regulatory remit for oversight of quality or quality governance, other regulators and commissioners must use their contractual levers to influence place, ICS and regional quality governance.

Figure 2: Overview of Quality Governance, NQB Guidance on SQGs



Overarching approach to quality risk response and escalation

The refreshed approach to quality risk management is based on three main levels of assurance and support from the NHSE regions with the ICS partners:

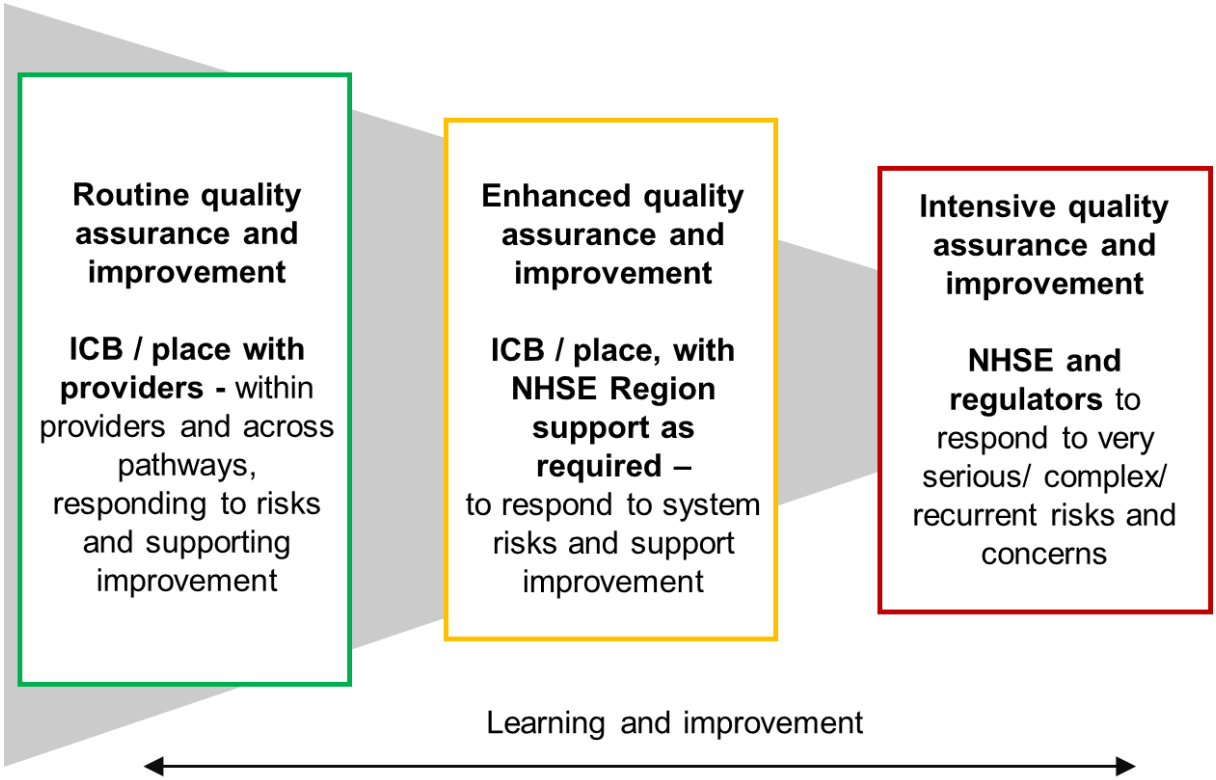
1. **Routine quality assurance and improvement** – activity when there are no risks or minor risks which are being addressed effectively. Includes standard monitoring and reporting, due diligence and contract management

2. **Enhanced quality assurance and improvement** – undertaken when there are quality risks that are complex, significant and/ or recurrent and require action/ improvement plans and support

3. **Intensive quality assurance and improvement** – a last resort, when there are very complex, significant or recurrent risks, which require mandated intensive support led by NHSE and regulators. For health services, this includes mandated support from NHSE for recovery and improvement (e.g. Intensive Support Team, maternity support).

The three levels apply to different geographies – places, ICSs, pathways and journeys of care. Figure 4 provides an overview of the three levels.

Figure 4: Overview of main levels of quality assurance and improvement



Decisions on how to move through the escalation process must be taken as close to the point of care as possible, reflecting effective risk profiling and accountability arrangements. Generally, it is expected that for health services the move into enhanced assurance will be authorised by the ICB, and the move into intensive assurance by NHSE. However, the decision will need to reflect the risk profile and regulatory and accountability arrangements.

The approach is based on the following core components:

Component	Description
Effective risk profiling	• To determine the approach and actions required. Timely, triangulated data, aligned with the Patient Safety Strategy for healthcare concerns/ risks • Each ICS must have commonly agreed metrics to measure quality and an active list of quality risks at each level. These may be agreed through the SQG, with risks relating to health services integrated in the main risk register for the ICB. • The Quality Risk Profiling Tool is an analytical tool which triangulates key data to profile risks. The tool is currently being updated to support ICSs.
Rapid Quality Review Meetings (See TORs in Annex B).	• Meetings to rapidly share intelligence, diagnose, profile risks and develop action/improvement plans • May be stood up at short notice by ICBs or wider partners (e.g. Local Authority, NHSE, other regulators), where there is deemed to be a significant or immediate risk to quality, including safety, which is not being addressed in wider discussions (e.g. oversight) • Replace former Single Item QSGs and Risk Summits.
Action/ improvement plans	• Set out the required actions for mitigation and actions. Must include KPIs, action owners, timescales and success criteria, and reflect contractual processes and requirements and regulatory frameworks • Where multiple commissioners (e.g. ICB / local authorities or multiple ICBs), must include coordinated actions for improvement • For healthcare risks, plans should align with any existing improvement plans or support offers to prevent duplication or misalignment of effort. Where the system or trust is already in receipt of mandated national support via the NHS Recovery Support Programme the relevant System Improvement Director (system) or Improvement Director (trust) must be consulted.
Quality Improvement Groups (See TORs in Annex C).	• Set up to plan, co-ordinate and facilitate the delivery of the required changes / improvement. May be standalone groups or integrated into wider improvement /assurance processes (e.g. NHS Oversight Framework).

Below we provide further information on expected roles/ responsibilities of the different partners. This is primarily for services by ICBs and of course will need to be adapted to reflect different commissioning and accountability arrangements (e.g. local authority commissioned services, NHSE commissioned services).

Routine Quality Assurance and Improvement – Led by provider/ ICB
Business as usual activity and reporting within providers (including independent sector providers), provider collaboratives/ networks for service delivery, place-based structures, ICB/ICSs, including independent providers, provider collaboratives and networks.

Overview	ICB-led action, with providers, at place level	ICB-led action, with providers, at system level	Regional NHSE action	National NHSE/ other regulatory action
Category of risk: • **No risks**: The quality of care is meeting expected standards • **Minor risks:** There are one or more areas where care is not meeting the required standards. However, these concerns can be managed at place level (e.g. GP practice assurance) and there are active action/ improvement plans to meet the required standards which are consistently delivered against.	**Activity:** • Integrated quality review meetings, specific meetings (e.g. Local Safeguarding Children Partnerships, Safeguarding Adult Boards, case management reviews), oversight meetings, contract management • Dynamic monitoring of quality. Focus on trajectories, variation and inequalities • Effective assurance processes in place that align with consistent indicators used at different geographies • Contractual actions to improve quality **Reporting:** • Minor and moderate concerns reported to place-based structure and ICB/ICS. Shared through SQGs and wider discussions.	**Activity:** • Integrated quality review meetings, specific meetings, SQG meetings, ICB Quality Committee meetings, oversight meetings, (sub-) contract management • Dynamic monitoring of quality. Focus on trajectories, variation in quality and outcomes, and inequalities • Liaison with ICB/ICS to agree/ accept contractual actions to improve quality • Advice and suggestions for quality improvement may be made by the organisations within the ICS with a view to preventing low-level risks developing into more significant concerns **Reporting:** • Minor and moderate concerns may be included on ICB risk registers.	**Activity:** • Limited involvement from NHSE regions where NHSE is not commissioner. Focused on supporting cross-ICB/ICS learning and intelligence • Where NHSE is commissioner (or joint commissioner), quality meetings dynamic monitoring, contractual actions and improvement actions must be undertaken **Reporting:** • Minor concerns in NHSE-commissioned services may be on regional or national risk registers (not the case for non-NHSE commissioned services).	**Activity:** N/A **Reporting:** • Minor concerns in NHSE-commissioned services may be on national risk registers where nationally commissioned (not the case for non-NHSE commissioned services) • The Emerging Concerns Protocol, used by regulators to share intelligence and information when there are emerging concerns, may provide a source of intelligence for enhanced assurance discussions. It is important that this intelligence is shared in a timely manner with all relevant partners.

Enhanced Quality Assurance and Improvement – Led by provider/ ICB in most circumstances

Implemented when concerns/ risks are identified that require more frequent and intensive oversight to gain confidence that care is of sufficient and consistent quality, that action/ improvement plans are leading to the desired outcome and that the improvements in care are sustained. May include regulatory action, including enforcement action (aligned with NHSOF segment 3) and contractual actions (e.g. service development and improvement plans, suspension of service, termination of contract). The enhanced approach will be agreed and supported by Regional NHSE teams, based on the risk profile and support needs. See triggers for regional involvement in Overview column.

Overview	ICB-led action, with providers, at place level	ICB-led action, with providers, at system level	Regional NHSE action	National NHSE/ other regulatory action
Category of risk: • **System concerns:** there are a number of areas where the quality of care does not meet the required standards, plans (e.g. PSIR policy and plans) in place are not delivering sustainable improvement at the pace required and /or there are recurrent quality issues that are not being addressed • **Triggers include:** quality concerns across pathways of care, PSIR policy and plans not in place, significant safety concerns, significant contract breaches/ contractual notices, issues outside of the providers' / ICBs' control, lack of confidence in improvement, conflicts of interest, recurrent failure to meet CQC standards **Triggers for NHSE regional involvement:**	**Activity:** • Rapid Quality Review meetings, replacing Single Item QSGs. Providers, ICBs/ ICSs (including local authorities) and regulators (including NHSE regions) may be at these discussions, with reporting linkages to System Quality Groups and ICB Quality Committees. Rapid Quality Reviews may be stood up rapidly at the request of partner organisations (e.g. NHSE, CQC) and may result in links to NHSOF processes where regulatory action may be being considered. • Action/ Improvement Plans must be developed to address risks/ issues. Providers/ provider collaboratives are expected to develop these plans collaboratively with commissioners (e.g. ICB/ NHSE). Should align with wider improvement plans as required • Quality Improvement Groups may be set up to	**Activity:** • Enhanced approach is place or system-led unless there is a conflict of interest or rationale why this should not be the case. See triggers for regional involvement in Overview column. • Rapid Quality Review meetings • Action/ Improvement Plans • Quality Improvement Groups **Reporting:** • System concerns must be shared with System Quality Groups and be included on system and ICB/ICS risk registers and shared with affected NHSE regions.	**Activity:** • For services commissioned by ICB, Regional NHSE involvement agreed with ICBs. Trigger to review of NHSOF segment allocation. May also include a 'check and challenge' function through the Regional Quality Groups and wider discussions (e.g. oversight). • Where NHSE is commissioner (or joint commissioner), arrangements again agreed with ICB based on accountabilities. • Rapid Quality Review meetings, Action/ Improvement Plans, Quality Improvement Groups (or equivalent oversight). **Reporting:** • Significant concerns must be shared with Regional Quality Groups (or	**Activity:** • Risks/ concerns requiring national attention / involvement reported regional and national NHSE governance (as appropriate) • Regional Support Groups/ System Oversight Committee will decide on NHSE regulatory action. Other regulators may also act. **Triggers for NHSE national involvement:** • Requires national action - e.g. outdated policy, national commissioning issue • NB: if national regulatory action is required, would move into level 3 intensive, aligned with NHSOF segment 4.

• Lack of assurance that the material issue/ concern is being addressed or managed in a timely and effective manner by the ICB/ ICS • Material concerns regarding the structure, leadership, and culture of an ICB • System tensions or conflicts of interest, e.g. significant whistleblowing report about ICB exec lead • Significant failings representing a threat to service users/ staff and requiring immediate response, including within independent providers • Same risk recurs in close proximity (6-12 months)/ programmes not led to sustainable improvement, including within independent providers • Issues outside of ICB control. Or service is commissioned by NHSE.	oversee delivery of action/ improvement plans, with clear success criteria. For healthcare risks, these should be integrated into wider improvement and assurance groups where they are in place • Contractual actions to improve quality • Additional activity: inspection visits, walk arounds, targeted quality assurance visits • For providers spanning ICS boundaries (e.g. ambulance trusts, specialist services) or with multiple commissioners, must be agreement as to who leads the process (e.g. coordinating commissioner under relevant contract, or one ICB on behalf of all where multiple affected contracts) and to agreed actions being applied across boundaries.	equivalent) and may be escalated nationally. • System concerns may be on regional or national risk registers.

Intensive Quality Assurance and Improvement – Led by NHSE and other regulators

Implemented as a last resort, when there are very significant, complex or recurrent risks, which require mandated or immediate support from NHSE for recovery and improvement, including support through the Recovery Support Programme, or from wider regulators. The intensive approach must be agreed based on the risk profile and support needs within the ICB. This assurance level covers previous **NHSE Risk Summits**.

Overview	ICB-led action, with providers, at place level	ICB-led action, with providers, at system level	Regional NHSE action	National NHSE/ other regulatory action
Categories of risk: • **Very significant, complex of recurrent risks:** care quality has fallen, or is at risk of falling, well below the standards expected. All options are exhausted to respond to recurrent/ significant quality risks, conflicts of interest, or risks / concerns. The provider/ group or providers has not delivered on the improvement trajectory agreed; there is a significant risk to, or significant impact on, the quality of care **Triggers include:** • Very significant failings, representing a threat to service users/ staff and requiring immediate response, including within independent providers • A need to act rapidly to protect service users and / or staff.	**Activity:** • Rapid Quality Review meetings • Action/ Improvement Plan, with clear objectives and success/ success criteria • Quality Improvement Groups For healthcare risks, these may be incorporated in wider oversight forums set up by ICBs e.g. linked to a broader set of mandated support measures.	**Activity:** • Rapid Quality Review meetings • Action/ Improvement Plan • Quality Improvement Groups For healthcare risks, these may be incorporated in wider oversight forums set up by ICBs e.g. linked to a broader set of mandated support measures.	**Activity:** • Includes commissioner action (e.g. suspension or termination of contract), regulatory action (e.g. CQC enforcement action) • Support via regions, for trusts/ ICBs in NHSOF 3. Recovery plans must be in place. **Reporting:** • Very significant, complex or recurrent concerns shared with Regional Quality Groups for inclusion on regional risk registers and escalated nationally. • Concerns relating to challenged providers/ ICSs reported to Regional Support Groups/ System Oversight Committee. ICBs and provider chairs must be notified and kept informed.	**Activity:** • Risks/ concerns requiring national attention / involvement reported through regional and national NHSE governance (as appropriate) • System Oversight Committee will decide on NHSE regulatory action in consultation with Regional Support Groups. Other regulators may also act. **Triggers for NHSE national involvement:** • Very significant, complex or recurrent risks in challenged providers/ ICBs (NHSOF segment 4) • Requires national action, e.g. outdated policy, national commissioning issue

Annex A: Glossary of Key Terms

Rapid Quality Review Meeting	Multi-stakeholder meetings set up to give specific, focused consideration to quality concerns/ risks, facilitate rapid diagnostic work and agree action and improvement plans. The meetings can be called at short notice by ICBs or wider partners (e.g. Local Authorities, NHSE, CQC). The meetings may inform regulatory action. **These meetings replace Single Item QSGs and Risk Summits**.
Emerging Concerns Protocol	A protocol through which a wide range of health and care regulators can share intelligence on emerging/ existing quality concerns. This includes setting up a Regulatory Review Panel to share and assess information and inform next steps.
NHS Oversight Framework	NHS England's Oversight framework applying to Integrated Care Boards (ICBs), NHS trusts and foundation trusts. The framework is based on a single set of oversight metrics, used to flag potential issues and prompt further investigation of support needs. The metrics align with five national themes: quality of care, access and outcomes; preventing ill health and reducing inequalities; people; finance and use of resources; and leadership and capability.
Recovery Support Programme	NHS England's mandatory support provided when there are significant quality concerns or risks within a Trust or ICB, as defined by the NHS Oversight Framework.
Quality Improvement Group	Multi-stakeholder group set up to plan, coordinate and facilitate the effective and sustained delivery of action/ improvement plans to mitigate and address quality concerns and risks. Quality Improvement Groups are organised by ICSs with system partners (e.g. NHSE, CQC, HEE, GMC, NMC).
Quality	The NQB defines of quality according to five elements: safe, effective, positive experience, well-led and sustainable, plus equitable.
Risk Appetite	The Institute of Risk Management defines the risk appetite as "The amount of risk that an organisation is willing to seek or accept in the pursuit of its long-term objectives". Normally set against categories of risk rather than individuals of risk.
System Quality Group	A forum at ICS level that brings together system partners to engage, share intelligence on learning, opportunities for improvement and concerns/risks, and develop system responses to deliver and mitigate them. This replaces existing Quality Surveillance Groups (QSGs) See the NQB's Guidance on System Quality Groups.

Annex B: TORs for Rapid Quality Review Meetings

Purpose:

Rapid Quality Review Meetings are multi-stakeholder meetings set up to facilitate rapid diagnosis of quality concerns/ issues and to agree next steps, including action/ improvement plans.

Their purpose is to:

- Give specific and focused consideration to quality concerns/risks raised, sharing intelligence, including with providers where quality risks have been identified
- Facilitate rapid, collective judgements to be taken about quality within the provider / sector/ pathway in question
- Identify actions needed as a result of the risk(s) identified, summarised in an Action/ Improvement Plan, which may be taken forward by a **Quality Improvement Group**. This may include actions at provider, sector or pathway level. Clear success criteria must also be agreed in the Action/ Improvement Plan, which align with NHSOF criteria for health as appropriate.

The role of attendee organisations:

Rapid Quality Review Meetings should be ICB-led where possible, subject to accountability arrangements (e.g. NHSE commissioned services) and regional involvement considerations (e.g. conflicts of interest).

Participants in Rapid Quality Review meetings will have sufficient authority to take the necessary decisions on behalf of their respective organisations and actions to help drive actions at pace. Where decisions are required to be approved by additional bodies / structures, the participants must drive this decision making at pace so as not to become the time-limiting factor in making necessary changes.

Minimum members:

- Relevant provider(s) (including independent providers) / provider collaboratives
- ICB/ place - Executive Lead for Quality, contract managers, System Improvement Director
- Local Authorities

- NHSE Regional Clinical Director
- CQC
- HEE
- Lay members with relevant lived experience

Other system partners will be invited depending on the issue, e.g. regulators (e.g. NMC, GMC, OFSTED, PHSO), public health, police, primary care, maternity and neonatal, specialised or direct commissioning, deaneries.

There may be some circumstances in which system partners may wish to meet without providers.

Chair:

Rapid Quality Review meetings should be chaired by the ICS (ICB Exec Lead for Quality and/or Local Authority representative). NHSE Regional teams may co-chair or chair where the agreed triggers for regional involvement have been met. Conflicts of Interest must also be considered when deciding chairing arrangements (e.g. the ICB cannot chair if the ICB is the subject of the quality concern).

Reporting:

- Agreed actions made in Rapid Quality Review meetings must be summarised in an action/ improvement plan and reported to System Quality Groups and ICBs/ Local Authority assurance (as appropriate).
- The actions may be incorporated into wider processes or taken forward by a Quality Improvement Group as relevant.
- The key themes and outcomes should also be reported to the Regional Quality Group (RQG).

Annex C: TORs for Quality Improvement Groups

The establishment of a Quality Improvement Group may be instigated by the ICB, a local authority, NHSE or wider regulators; or a provider or group of providers may request that the ICB establish a Quality Improvement Group. The group should usually be convened by the ICB, but may be convened by the NHSE region if necessary (e.g. where services are commissioned/ jointly commissioned by NHSE).

Purpose:

The key purpose of the Quality Improvement Group is to support planning, coordination and facilitate the sustained delivery of actions to mitigate and address the quality risks/ concerns within an individual provider or across the providers in the local system more generally. It will do this by:

- Providing advice and support to the provider(s)/ ICB to address quality risks/ concerns, including identifying required responses and planning for mitigation of risks
- Providing a mechanism for facilitating direct assurance of the achievement of milestones within the action/ improvement plan, including ensuring that there are clear arrangements for confirming that the action / improvement plan has been successfully delivered
- Reviewing and challenging outstanding actions, ensuring that the most robust approaches are being considered
- Escalating to System Quality Group, ICB, Regional Quality Group and wider partners (e.g. NHSE, local Authority, CQC) where appropriate.
- Ensuring that learning is embedded in ongoing continuous improvement.

The Group will meet monthly until most or all of the following conditions are met:

- Achievement of the milestones in the Action/ Improvement Plan and assurance that these have been embedded in a sustainable way

- All members, and the ICS/B/ Regional Quality Group, agree that the relevant milestones have been achieved and there is a clear plan and capacity to deliver any outstanding milestones.

The role of member organisations:

Members of the group will have sufficient delegated authority to take the necessary decisions and actions on behalf of their respective organisations to help drive actions at pace. Where decisions are required to be approved by additional bodies / structures, the role of the group members is to drive this decision making at pace so as not to become the time-limiting factor in making necessary changes.

Minimum members:

- Relevant providers (including independent sector providers)/ provider collaboratives
- ICB/ place-based Executive Lead for Quality, senior contract manager, System Improvement Director
- Local Authorities – adult and children's services
- NHSE Regional Clinical Director
- CQC
- HEE
- Healthwatch/ lay members with relevant lived experience

Other partners will be invited depending on the issue, e.g. public health, primary care, maternity and neonatal, OFSTED, police other professional regulators, deaneries.

Responsibilities of members:

Providers/ provider collaboratives May include: Chief executive; Medical Director; Director of Nursing and Midwifery;	• Work with the ICS/B, NHSE and partners to agree the action / improvement plan • Share progress and provide assurance against key milestones relating to quality and performance • Update the group if there are concerns that key milestones may not be achieved • Escalate any new quality or performance concerns to the group including information on steps taken by the provider to manage and mitigate risk.

Director of Midwifery; Director of Quality Governance; Director of Finance; Chief Operating Officer, or each provider	• Work with partners to deliver, enable and support quality and performance improvement • Ensure that learning is embedded in ongoing improvement.
ICB/ Place-based Executive Lead for Quality (or nominated deputy)	• Chair the group as appropriate. Where the service is jointly commissioned with the Local Authority, the Local Authority may chair or co-chair • Regional NHSE teams may co-chair or chair where regional triggers for involvement have been agreed (e.g. conflicts of interest) or the service is commissioned/ jointly commissioned by NHSE • Ensure that services commissioned from providers meet the quality and performance requirements of contracts • Manage risks and mitigations within the contractual arrangements and ensure pace in quality and performance actions • Where there are multiple commissioners (e.g. health commissioners and local authorities), ensure that action/ improvement plans include coordinated actions and take account for the different contractual and regulatory frameworks • Lead commissioner engagement in respect to provider issues and outcomes on behalf of the local population • Work with the providers and partners to develop action/ improvement plans, track progress against milestones relating to quality and performance • Work with the providers and partners to agree direct assurance processes for relevant milestones • Engage and communicate with relevant stakeholders. • Work with partners to establish and sustain processes to deliver quality and performance improvement • Ensure that learning is embedded in ongoing improvement.
Local Authorities	• Co-chair the group where services are commissioned by the Local Authority • Work with health commissioners to ensure that services commissioned from providers meet the quality and performance requirements of contracts • Manage risks and mitigations within the contractual arrangements and ensure pace in quality and performance actions • Where there are multiple commissioners (e.g. health and local authorities), ensure that action/ improvement plans include coordinated actions and take account for the different contractual and regulatory frameworks • Lead commissioner engagement in respect to provider issues and outcomes on behalf of the local population • Work with the provider and partners to develop action/ improvement plans, track progress against milestones relating to quality and performance. • Work with the provider and partners to agree direct assurance processes for relevant milestones • Engage and communicate with relevant stakeholders. • Work with partners to establish and sustain processes to deliver quality and performance improvement • Ensure that there are effective information flows between co-opted Local Authorities and other relevant stakeholders • Ensure that learning is embedded in ongoing improvement.
NHSE Regional Clinical Quality May include Regional Chief Nurse; Regional	• May co-chair or chair the group (as above) • Work with the provider(s), ICB and partners to track progress against milestones relating to quality and performance • Work with the provider(s), ICB and partners to agree direct assurance processes for relevant milestones • Provide subject matter expertise • Engage and communicate with relevant stakeholders • Escalate where national involvement / action is required

Medical Director; Regional Chief Midwife and Lead Obstetrician	• Work with partners to ensure systems and processes are in place to deliver quality and performance improvement • Ensure that systems and processes are in place to continually review changes and that they are embedded in practice
Care Quality Commission	• Ensure that the necessary actions are taken, and timely progress is being made against milestones relating to quality and performance, in line with the CQC inspection methodology • Engage and communicate with relevant stakeholders. • Where appropriate to share information/flag concerns identified as part of CQCs routine monitoring to support quality and performance improvement • Consider need for a regulatory response, engaging with all key partners in process
Health Education England	• To report on progress in assuring the milestones within the action/ improvement plan related to relevant workforce education and training elements. • To report on progress in trainee educational issues that impact on the delivery of services within the provider or ICS.
Healthwatch/ lay members with relevant lived experience	• Work with partners to ensure patient voices are heard and included as part of the meeting and progress.

It is the responsibility of each member representative to ensure that information and reporting on progress and outcomes is disseminated to appropriate individuals within their own organisations and back into the group. All parties will ensure relevant wider stakeholder engagement is in place.

Chair:

The Group should normally be chaired by the ICB Exec Lead for Quality or Local Authority representative. NHSE Regional teams may co-chair or chair, where the triggers for regional involvement have been met.

Reporting:

The Quality Improvement Group is accountable to the System Quality Group/ ICB (or ICB Quality Committee) and the Regional Quality Group.

Contact details TBC