Witness Name: Duncan Burton

Statement No.: 1

Dated: 26 March 2025

LAMPARD INQUIRY

FIRST WITNESS STATEMENT OF DUNCAN BURTON

Contents

I, Duncan Burton, will say as follows: -

1. NHS England welcomes the Lampard Inquiry, fully supports its work and is grateful for the opportunity to participate. We are committed to assisting the Inquiry and learning from the evidence provided to it, as well as its findings.

2. I would like to emphasise that my thoughts remain focused on the families, friends and carers of those who have lost loved ones or have been affected in any way by the issues the Inquiry is exploring. I want to acknowledge the pain and anguish that they have suffered and continue to suffer and assure them that we will listen to families so that we can make sure we are hearing and acting where improvements can be made.

3. NHS England recognises how important this Inquiry is for those who have lost loved ones, or who are affected in any way by the issues it is exploring. We welcome and support the Chair's intention to ensure that those affected remain at the heart of the Inquiry's work. We will continue to listen to families so that we can make sure we are hearing where improvements can be made.

4. This is NHS England's first formal witness statement to this Inquiry. It provides contextual information, requested by the Inquiry, including an explanation of the statutory and policy framework within which NHS England operates and the various 'moving parts' of the NHS ecosystem. It attempts to trace changes to that framework and ecosystem over the course of time. As a result, this first statement is somewhat removed from the individuals and events at the heart of this Inquiry. We will provide further evidence in due course which will engage more directly with those individuals and events. I am aware that recent announcements about the future of NHS England may be of concern but I can assure families and the Inquiry that we will continue to work hard to support our mental health providers and to ensure that any identified improvements are implemented.

5. NHS England (and its legacy bodies) has four broad responsibilities relevant to the Inquiry:

    a. First as commissioner: Since its operational establishment in 2013, NHS England has been the commissioner of certain mental health services commissioned in Essex (the "Specialised MH Services"). The Specialised MH Services include children and young people's mental health service units

("CYPMHS") (acute and PICU), mother and baby mental health units, eating disorder and forensic/secure units.

b. Second as regulator: NHS England is the statutory regulator of local commissioners, and (previously through Monitor and the Trust Development Authority, together known as NHS Improvement) and Trusts.

c. Third, in its overall leadership role: NHS England is responsible for the co-ordination of the provision of healthcare services in England and provides leadership to all NHS bodies to drive high quality NHS services across England, including through leading national transformation programmes.

d. And finally, a patient safety role: NHS England sets the patient Safety Strategy and supports the NHS to achieve the strategy aims. This work relates to the strategy's foundations of 'patient safety culture' and 'patient safety systems', and the three strategic aims 'insight', 'involvement' and 'improvement'.

6. NHS England recognises the incredibly important role for this Inquiry in identifying lessons that can be learned from the events that led to these tragic deaths, in order to improve NHS mental health services both in Essex and nationally.

7. We recognise that there will be areas where NHS England and the organisations that came before us could have done better. We know there is still work to do to provide high quality and timely mental health care for everyone who needs it, and to tackle inequalities in access, experience and outcomes. NHS England will value all the learning that will come out of this Inquiry to help us with this work.

(1) Background

8. I am the Chief Nursing Officer for England. I trained as a nurse at Swansea University between 1995-1998 and registered with the Nursing and Midwifery Council ("NMC") as a Registered Nurse (Adult) in September 1998. I also have a Bachelor of Nursing (Hons) degree from the University of Wales, Swansea (1998) and an MSc in Healthcare Practice from Bath Spa University College (2001-2004). I am a member of the Royal College of Nursing.

9. From September 2019 to April 2021, I was the Regional Chief Nurse — South East England. I am employed by NHS England and before the merger I was jointly employed by NHS England and NHS Improvement. From April 2021 until July 2024, I

was the Deputy Chief Nursing Officer for England — Clinical Delivery, employed full-time by NHS England.

10. Since July 2024, I have been the Chief Nursing Officer ("CNO") for England. The CNO role has existed in some form in England since 1941, pre-dating the creation of the NHS. The CNO post resided in the Department of Health and Social Care ("DHSC") until 2012 when, as part of the Health and Social Care Act 2012 reforms, it was moved to NHS England (although remains the most senior adviser to DHSC as set out below).

11. The role of the CNO is broad: I am employed by NHS England, but I am also the most senior adviser to DHSC, Government and the wider NHS on nursing and midwifery related issues. The CNO is the professional lead for the nursing and midwifery professions - there are over 372,000 nurses and midwives working for the NHS in England, who make up the largest group of the total NHS workforce. I am accountable for providing clinical and professional leadership for all nurses and midwives in England.

12. Within NHS England, I am an executive director and I lead the Nursing Directorate. This means that I am responsible for the delivery of national programmes and policy areas that typically have a strong focus on nursing and midwifery. I also provide the nursing perspective and input into a wide range of clinical and operational issues that are the responsibility of other senior colleagues.

13. I work closely with NHS England's seven regional teams through their regional Chief Nurses. Typically, one of the roles of Regional Chief Nurses is to manage relationships with lead nurses in Integrated Care Boards ("ICBs"), which include Trusts, who are responsible for the leadership of nurses and midwives within their own organisations.

14. Before September 2019, when I joined NHS England, I held the following roles:

Organisation	**Role**	**Dates**
Frimley Health NHS Foundation Trust	Director of Nursing and Quality	September 2017 - September 2019
	Director of Operations	July 2019 - September 2019
Kingston Hospital NHS Foundation Trust	Director of Nursing and Patient Experience	February 2013 - September 2017
	Chief Operating Officer	July 2015 – September 2015
University College	Deputy Chief Nurse	September 2010 - February

Organisation	Role	Dates
Hospitals NHS Foundation Trust ("UCLH")	Specialist Hospitals Board	2013
	Deputy Chief Nurse – Medicine Board	May 2009 – August 2010
	Divisional Senior Nurse – Emergency Services	2007 - 2009
	Matron - Infection and Pathology	2004 - 2007
	Deputy Charge Nurse then Charge Nurse Acute Admissions ward	2002 -2004
Royal United Hospitals, Bath	Junior Charge Nurse – Neurology Unit	2001-2002
	Staff Nurse – Respiratory Unit	1998-2001

(2) Approach to the NHSE/1 Rule 9 Request

15. This witness statement was drafted on my behalf by the external solicitors acting for NHS England in respect of the Inquiry, with my oversight and input. The request received by NHS England on 17 January 2025 pursuant to Rule 9 of the Inquiry Rules ("the NHSE/1 Rule 9 Request") is broad in scope and goes beyond matters which are within my own personal knowledge. As such, this statement is the product of drafting after communications between those external solicitors and a number of senior individuals in writing, by telephone and video conference. This includes both current and former NHS England employees, and former employees of the legacy regulatory bodies, particularly Monitor and the NHS Trust Development Authority (each a "Legacy Body" and referred to together, along with NHS Improvement, in this statement as the "Legacy Bodies"). I do not, therefore, have personal knowledge of all the matters of fact addressed within this statement. However, given the process here described, I can confirm that all the facts set out in this statement are true to the best of my knowledge and belief.

16. The statement has been produced following a targeted review of documents collated to date and with the intention of providing any information which may assist the inquiry. However, in the time available, it has not been possible to review every potentially relevant document, and it is highly likely that relevant documents exist that have not been reviewed. NHS England will, of course, notify the Inquiry as soon as practicable if information comes to light that would have been included in this statement if it was

known to us before the deadline for its production and is happy to expand on any of the areas if it would assist the inquiry.

17. The Term of Reference for the Lampard Inquiry relate to a 24 year period of time from 1 January 2000 and 31 December 2023 (the “Inquiry Period”). During this time, and as described in this statement, there have been a number of important changes. This includes but is not limited to structural changes as a result of legislative and policy developments.

18. NHS England, formerly the NHS Commissioning Board for England, is an executive non-departmental public body of the DHSC. It was established in shadow form in October 2012, becoming fully operational on 1 April 2013. This statement therefore focuses on the period from 2013 onwards (the “Relevant Period”), providing background context from before this where it is relevant and in our knowledge. We cover NHS England’s role as a commissioner of specialised mental health services, as well as its role in provider and national strategic oversight and leadership.

19. This statement includes evidence from a range of sources, including those relating to legacy statutory bodies that are now, by virtue of statutory transfer, part of NHS England. Although we have sought to be clear about what role and responsibilities each Legacy Body had during the period that the Inquiry is considering, the evidence has been combined to represent the evidence and voice of NHS England. This recognises that the functions, staff and liabilities of the Legacy Bodies (Monitor, the NHS Trust Development Authority, Health Education England, NHS Digital and NHS Improvement) have transferred to NHS England. Accordingly, references throughout to ‘NHS England’, and ‘we’ represent the voice of the organisation at the present day, unless it is obvious from the context that the statement is describing the actions of NHS England before the Legacy Bodies merged into it. I have referred to all individuals (including myself) in the third person, by job title.

20. In order to ensure that the statement is focused on the list of issues, some material which is primarily required for contextual or reference purposes, including relating to NHS England’s legal duties and functions as well as those of the most relevant Legacy Bodies it is now responsible for, is contained within annexes at the end of the statement.

21. The Relevant Period contains a programme of significant legislative reform of the NHS. In addition, a policy programme for joint working led to a number of national NHS

regulatory bodies coming together to work in an aligned way, but without any formal legal changes to each body's underlying legal status: first as NHS Improvement (in the case of Monitor and the NHS Trust Development Authority), then as NHS Improvement and NHS England (in the case of those two bodies). A summary of legislative changes with respect to NHS England and its Legacy Bodies over the Inquiry Period is set out in **Annex 1 (Further details on Legislative changes to the NHS).** Briefly, these changes can be summarised as follows:

Date	Event
1991	• NHS Trusts were introduced as separate statutory bodies.
2004	• Monitor was established as the independent regulator of NHS Foundation Trusts (legally the Independent Regulator of Foundation Trusts until 2012). • NHS Foundation Trusts became operational.
2012	• The NHS Leadership Academy was set up as an independent organisation.
June 2012	• Health Education England was established as a special health authority. • The NHS Trust Development Authority was established to formally regulate and monitor NHS Trusts (becoming fully operational from 1 April 2013). • Monitor's role was expanded to reflect its role as the system regulator in relation to providers of NHS services (other than NHS Trusts).
October 2012	• The NHS Commissioning Board was established (becoming fully operational on 1 April 2013). • Clinical Commissioning Groups were established (becoming fully operational on 1 April 2013).

Date	Event
1 April 2013	• NHS Digital (legally the Health and Social Care Information Centre) was established. • The NHS Commissioning Board becomes fully operational, under the name “NHS England”. • The NHS Trust Development Authority becomes fully operational. • The National Institute for Health and Clinical Excellence, originally set up in 1999 as the National Institute for Clinical Excellence, was renamed the National Institute for Health and Care Excellence ("NICE") to mark its expansion into social care. • Clinical Commissioning Groups were established.
1 April 2015	• Health Education England became a non-departmental public body under the provisions of the Care Act 2014.
1 April 2016	• Monitor and the NHS Trust Development Authority start to work together under the operational name NHS Improvement.
February 2019	• NHS England and NHS Improvement come together. • NHSX, a joint unit between NHS England, NHS Improvement and the Department of Health and Social Care, became operational.
1 July 2022	• The NHS Trust Development Authority was abolished. • NHS Improvement and NHS England merged with the effect that the functions formerly performed by Monitor and the Trust Development Authority (then NHS Improvement) were legally conferred on NHS England.

Date	Event

	• Integrated Care Systems were placed on a statutory footing:
	  • Integrated Care Boards were established to replace Clinical Commissioning Groups which were abolished.
	  • Local Authorities and Integrated Care Boards were required to establish Integrated Care Partnerships.

1 February 2023	• NHS England legally merged with NHS Digital.
1 April 2023	• NHS England merged with Health Education England.

22. The title of the Secretary of State has also changed during the Relevant Period, being the Secretary of State for Health until 8 January 2018 and the Secretary of State for Health and Social Care from 8 January 2018 to date. For ease, we have referred throughout to the "Secretary of State" or “SSHSC”.

(3) Outline of this corporate witness statement

23. This statement contains responses to topics and questions set out in the NHSE/1 Rule 9 Request. The statement adopts its own structure and deals with the Inquiry’s questions and topics in a different order to the way they appear in the NHSE/1 Rule 9 Request. As agreed with the Inquiry, NHS England has split its response to the NHSE/1 Rule 9 Request into two statements (this being the first statement).

24. This first statement responds primarily to the contextual questions regarding NHS England's role in the NHS. It is separated into three parts:

    a. Part A ("*NHS England in Context*") aims to help the Inquiry to understand contextual matters such as NHS England’s structure and role in the wider healthcare system, its role specifically as a commissioner of specialised services and, latterly, as the regulator of NHS Trusts and NHS Foundation Trusts. This part explains the role of ‘commissioners’ and ‘providers’, the NHS provider

landscape, regulation and how arrangements have changed during the Relevant Period.

b. Part B ("*Quality and Patient Safety*") sets out NHS England's role in patient safety and provides a high-level overview of what is meant by patient safety, as one of the core components of quality, as defined in Part A of this statement. Key patient safety structures and frameworks in place at a national level are described. This includes an explanation as to how we work with partner bodies and other regulators.

c. Part C ("*Current NHS England Policies and Procedures*") describes NHS England's current procedures and policies and sets out the latest developments in mental health policy. Whilst some of the material strays beyond the Relevant Period, it is submitted to be helpful to the Inquiry when considering recommendations for future actions.

PART A: NHS ENGLAND IN CONTEXT

25. This Part A explains the role of NHS England and its relationship with other key NHS statutory bodies in relation to matters of oversight and regulation. This part is structured as follows:

    (1) The NHS, providers, commissioners and regulation;

    (2) The role of NHS England;

    (3) NHS England's commissioning role;

    (4) NHS England's role in provider oversight and regulation;

    (5) Changes to NHS Trust Development Authority, Monitor and NHS Improvement (the Legacy Bodies).

(1) The NHS, providers, commissioners and regulation

(a) The NHS

26. Statutory NHS bodies, including NHS England, must act within their legal frameworks and in accordance with their public law duties. They perform the functions which Parliament sets for them under the direction of the government of the day.

27. The NHS in England is an ecosystem of commissioners of services, regulators and providers, each with their own distinct role. The publicly funded health service (excluding public health) in England comprises primary care, secondary care, tertiary care, mental health and community care, as more particularly described below. It is important to note that NHS England is not the same as 'the NHS in England', with the latter being the phrase often used to refer to all bodies which collectively make up the publicly funded health service in England (again, excluding public health, except as below).

28. Public health functions are, for the most part, carried out by the DHSC (including the Office for Health Improvement and Disparities which sits within it), and its executive agencies, including Public Health England (now the UK Health Security Agency) and Local Authorities. However, the Secretary of State for Health and Social Care routinely delegates some specific public health functions to NHS England on an annual basis. These functions are known as 'section 7A functions' and includes public health services for people in prison and other places of detention.

29. For the most part, the term ‘NHS’ is used as an umbrella term to mean all those performing their services with NHS monies and contracts.

30. Many bodies hold contracts with the NHS and are part of the publicly funded health service, such as GP practices, dentists, independent hospitals and community rehabilitation providers, but not all will be NHS bodies[1]. The term ‘NHS body’ is defined in section 275 of the National Health Service Act 2006 (the "2006 Act") to mean certain specific entities.

(b) Providers

31. Patients in England receive their services from ‘providers’ (for example, an NHS Trust) who have an arrangement to deliver these services with one or more commissioners (described in further detail below). Depending on the type of services and the nature of the provider, these arrangements will take the form either of an NHS contract (which is a non-legally binding contract at law); a legally binding contract; or a primary care contract (such as a General Medical Services Contract).

32. Providers are accountable to commissioners through their contracts for the services commissioned and through associated service specifications.

33. It is the responsibility of the provider to ensure that services are carried out in accordance with specifications, allocated budgets and taking into account appropriate clinical guidance and nationally determined healthcare standards, such as those set by the Care Quality Commission ("CQC"). In order to properly understand the comprehensive statutory framework for regulation of providers, it is important to consider both the role performed by Monitor (and latterly NHS England) and the CQC, and the way that these bodies interact. This is described in more detail at various points in this statement, in particular in Section 2 of this Part A and in Part B.

34. Providers employ their own staff, procure their own supplies, and oversee the day-to-day running of the services at the point of patient care. There is no centrally employed

[1] In March 2014, there were: 160 NHS Trusts, 130 Foundation Trusts, 7,613 GP practices, 11,674 community pharmacies in England. On 31 March 2020, there were: 74 NHS Trusts,149 Foundation Trusts, 6,771 GP practices in England. In 2019/20, there were approximately 11,800 community pharmacies in England. As of 31 March 2022, there were 69 NHS Trusts, 144 NHS Foundation Trusts, 6,499 GP practices, and approximately 11,500 community pharmacies in England. In February 2025 there were 75 NHS Trusts, 154 NHS Foundation trusts, 6,925 GP practices and approximately 12,000 community pharmacies in England.

'NHS workforce'. NHS Foundation Trust staff are not employed or managed by NHS England. The position is the same for NHS Trusts, except that NHS England today exercises an appointment role in relation to certain senior roles within NHS Trusts.

35. Since 2003, a Trust can be an NHS Trust or an NHS Foundation Trust. Foundation Trusts have more autonomy than NHS Trusts to decide how to organise their services to best meet local needs. Further details are set out at **Annex 5 (NHS Providers (NHS Trusts and NHS Foundation Trusts)**.

36. Each NHS Trust and NHS Foundation Trust is responsible as a statutory body for ensuring compliance with all applicable statutory and regulatory requirements for the delivery of safe, effective, efficient, high-quality services, both now and in the longer term. NHS Providers are also responsible for meeting the financial and performance requirements set out in the NHS priorities and operational planning guidance **[Exhibit DB/001],** for complying with their Provider Licence Standard Conditions **[Exhibit DB/002]** (more detail on the Provider Licence is provided in Part A Section 4) and for complying with CQC fundamental standards.

37. Governance is the means by which those NHS Trusts and NHS Foundation Trusts direct and control their organisations so that decision-making is effective, risk is managed, and care is delivered safely and effectively in a caring and compassionate environment. It is ultimately the role of the Board of each individual NHS Trust and NHS Foundation Trust to assure itself as to the organisation's compliance with these various requirements and as to the organisation's effectiveness.

38. The day-to-day care and management of patients is the responsibility of the relevant provider and their leadership teams, Board, CEO and accountable officers. In hospitals, for example, clinicians use their professional judgement and appropriate clinical guidelines to determine the treatment that a patient should be offered and receive. This judgement includes the patient's suitability for treatment options (assuming those are NHS-funded and commissioned services/treatments), as well as whether a patient should be admitted.

39. Clinical treatment decisions are made in accordance with operational policies and procedures set by the relevant provider and reflecting appropriate clinical guidance (including guidance issued by the National Institute of Health and Care Excellence) and service specifications set by the relevant commissioner.

40. Most clinical staff operating within a provider will also be subject to professional regulatory requirements, such as, in the case of medical staff, the General Medical Council ("GMC") or, in the case of nurses and midwives, the NMC. The Health & Care Professions Council also provides regulation of 15 health and care professions in the UK. Further information about professional regulation is set out in **Annex 10 (Professional Regulation)**.

(c) Commissioners

41. 'Commissioning' is the term given to the role of planning and securing the provision of healthcare services (including by contracting). It involves the ongoing process needs assessment, planning, agreeing and monitoring to ensure that appropriate healthcare services are provided and that these services are being delivered to the required quality standard. Commissioning includes, but is not limited to, entering into contracts with providers of NHS services and monitoring the performance of such contracts **[Exhibit DB/003].** Commissioners of health services therefore hold providers to account formally through contract management, which will include various touchpoints, including contract monitoring review meetings, case management oversight of units/patients, visiting the patients/services and carrying out annual service reviews.

42. Commissioning mental health services can be the responsibility of NHS England (through its Specialised Commissioning team for prescribed specialised services, as set out in the specialised services manual), or Integrated Care Boards ("ICBs") - formerly Primary Care Trusts, then Clinical Commissioning Groups ("CCGs") - for non-specialised mental health services. Lead Providers as part of the Mental Health Provider Collaborative programme play an important role in ensuring pathways of care are joined up. As part of their responsibilities, they hold contracts with providers of local services to deliver joined up care to meet the needs of their population.

43. The long-term and continuing ambition is to put decision-making at as local a level as possible.

(d) Regulation

44. Regulation is distinct from contract management by commissioners. Whilst there are some commonalities, such as performance management and assurance, these tasks are performed for different purposes. This distinction between provider regulation and contract management is important when considering the different roles of the Legacy

Bodies and NHS England during the Relevant Period. NHS England's role with regards to provider oversight and regulation is set out in detail below.

45. Other organisations, for example the CQC, play a role in regulation too. Regulatory bodies like NHS England are integral in providing guidance, oversight and support to NHS Trust and NHS Foundation Trust boards, but they are necessarily removed from day-to-day operation and there is a level of presumed autonomy.

46. Mental health services are delivered by a range of professionals working in multidisciplinary teams. This includes psychiatrists, psychologists, mental health nurses, support staff and peer support workers. The majority of mental health professionals will be regulated by the NMC or the GMC. These regulators will set the professional standard of practice and behaviours for mental health professionals. The Health & Care Professions council also provides regulation of 15 specific health care professions in the UK (further detail is set out in **Annex 10 (Professional Regulation)**).

47. There are requirements upon certain individuals nominated or appointed as Responsible Officers by designated bodies pursuant to the Medical Profession (Responsible Officers) Regulations 2010. Designated bodies include NHS England, ICBs, NHS Trusts and NHS Foundation Trusts. Every designated body must nominate a Responsible Officer. The responsibilities of Responsible Officers are, in summary:

    a. to ensure that the designated body carries out regular appraisals on medical practitioners;

    b. to establish and implement procedures to investigate concerns about a medical practitioner's fitness to practice raised by patients or staff of the designated body or arising from any other source;

    c. where appropriate, to refer concerns about the medical practitioner to the GMC;

    d. where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the GMC, to monitor compliance with those conditions or undertakings;

    e. to make recommendations to the GMC about medical practitioners' fitness to practise;

f. to maintain records of practitioners' fitness to practice evaluations, including appraisals and any other investigations or assessments.

48. These obligations are not imposed upon provider bodies but on individual practitioners nominated or appointed to the role of Responsible Officer.

49. The above regulations relating to Responsible Officers apply only in relation to professionals registered with the GMC. There are no equivalent regulations relating to other registered professionals. However, NHS England has a general expectation that where concerns arise in relation to an individual who is a member of a regulated profession, an appropriate reference would be made to their regulatory body.

(2) The role of NHS England

(a) Introduction to NHS England

50. NHS England is an executive non-departmental public body sponsored by the DHSC. It is called an 'arms-length body' as it is a public body established with autonomy from the Secretary of State. It was established on 1 October 2012 and is operationally distinct from the DHSC.

51. Up until 1 July 2022, when changed by the Health and Care Act 2022 ("2022 Act"), NHS England's legal name was the National Health Service Commissioning Board. It adopted the operational name NHS England for almost all of this time.

52. NHS England's core legal function and purpose is to promote a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical and mental illness. It owes this duty concurrently with the Secretary of State (except that NHS England's duty excludes that part of the health service that is provided in pursuance of statutory public health functions, and the Secretary of State's duty excludes the commissioning responsibilities given to NHS England).

53. For the purpose of discharging this core legal function and purpose, NHS England has statutory responsibility for commissioning certain services (including specialised mental health services) and for overseeing certain NHS bodies.

54. NHS England's role in respect of oversight has changed in recent years. Today, NHS England is responsible for the oversight of local commissioners and providers of those healthcare services. By contrast, up until 1 July 2022, NHS England was only

legally responsible for the oversight CCGs. Its role in relation to providers of healthcare services was primarily confined to interactions with them as a commissioner of services on its own behalf, although this did include contract management. Regulation of providers was the legal responsibility of the Legacy Bodies (as described in detail in **Annex 2 (Legacy Bodies)**, which worked together as NHS Improvement from 1 April 2016, and then together with NHS England as 'NHSE/I' from 1 April 2019), as well as the CQC (whose role has remained broadly consistent throughout the Relevant Period).

55. NHS England has taken on the responsibilities of legacy organisations, including Health Education England, NHS Digital and NHS Improvement. Further information on the role of these organisations is set out in **Annex 2 (Legacy Bodies)**.

56. The Secretary of State had a power under section 13Z2 of the 2006 Act to give directions to NHS England if, in the Secretary of State's opinion, it was failing to discharge one or more of its functions, properly or at all, but this power was never exercised. NHS England had a similar power with respect to CCGs (section 14Z21 of the 2006 Act), which it did exercise when necessary.

57. The DHSC is responsible for setting policies that deliver the Government's strategic health objectives and, in turn, for making sure the legislative, financial and administrative frameworks are in place to deliver those policies, including the NHS Mandate. NHS England works with the DHSC to contribute to the development of policy and to support the government of the day to understand the operational implications of their priorities. NHS England will involve and engage with other people and organisations across the healthcare sector, including service users as necessary, before providing input. Further information is set out in **Annex 3 (Relationship between NHS England and DHSC**).

58. In summary, NHS England is a commissioner, a regulator and a system leader. It is not a political or governmental decision-making body, responsible for setting national health or public health policy, nor a provider of patient services.

(b) Governance arrangements

59. NHS England is governed by its Board which provides strategic leadership and accountability to Government, Parliament and the public. The role of the NHS England Chair is appointed by the Secretary of State for Health and Social Care, as set out in paragraph 3 of Schedule A1 to the NHS Act 2006. The Chief Executive is appointed by

the non-executive members, but cannot be appointed without the consent of the SSHSC.

60. Since establishment, NHS England has been able to determine its own operating structure under the legislation. It has always operated with a mix of clinical and non-clinical national directors and teams, and separate regional directorates and teams.

(c) NHS England's Regional Teams

61. The NHS England regional teams are responsible for the quality, financial and operational performance of all NHS organisations in their region. They have responsibility for much of the oversight of and interactions with local CCGs, as well as responsibility for NHS England's commissioning functions in the region (noting that some specialised commissioning is undertaken nationally).

62. The size and function of the regional teams has varied as NHS England has developed. When NHS England was first established, there were four regional teams - North of England, London, Midlands and the East and South of England. In April 2018, the South of England region split into two (South East of England and South West of England) resulting in five regions. The Midlands was then split into two regions (Midlands and East of England). Since September 2018, there have been seven regional teams: East of England, London, Midlands, North East and Yorkshire, North West, South East and South West.

63. Until 2015, regional teams were supported by area teams. In the period 2013 to 2015, there were 27 area teams. Each area team was led by a Director of Commissioning Operations and supported by a full management team. By 2016, area teams had been consolidated into regional teams and the term was no longer used from that time.

64. Today, each regional team has an executive team led by the Regional Director, who is part of the NHS England Executive and reports to the NHS England Chief Operating Officer, which typically includes the following roles:

    a. Regional Medical Director;

    b. Regional Chief Nurse;

    c. Regional Director of Finance;

    d. Regional Director of Workforce Training and Education;

e. Regional Commissioning Director; and

f. Regional Director of Public Health.

65. There is some variation in specific roles within Regional Executive teams across different regions. Some teams include Directors of Performance and Strategy, Chief Operating Officers, Clinical Information Officers, and Directors of Communications, either as distinct roles or combined responsibilities.

66. Despite these variations, each region provides the following functions in relation to Mental Health services:

a. Strategic Oversight – Offering strategic leadership to ensure mental health services are effectively integrated and aligned with national policies and local needs.

b. Quality and Patient Safety Oversight – Monitoring the quality of mental health care providers, implementing oversight processes for inpatient care, and responding to concerns about service quality.

c. Policy Implementation – Executing national mental health policies, supporting transformation initiatives, and ensuring compliance by local Providers.

67. Regional teams align with national transformation programmes to ensure quality and safety are integrated through programme management, commissioning, and clinical quality improvement teams.

68. Within Regional Executive teams, the Regional Medical Director and the Regional Chief Nurse hold specific quality improvement and clinical leadership roles that are particularly relevant to this Inquiry. These roles are detailed below.

69. Both the Regional Medical Director and Chief Nurse provide expert professional and clinical leadership, working alongside or reporting to the Regional Director. Their responsibilities include ensuring high-quality care within the regional health system, fostering a culture of continuous service improvement, and driving system-wide enhancements.

70. The Regional Chief Nurse and Medical Director support ICBs and providers through the clinical leadership infrastructure, including the Clinical Senates Council Forum, Clinical Networks, Operational Delivery Networks, and Health Innovation Networks

("HINs"). They also provide professional leadership and supervision to directly employed regional staff.

71. Regional teams hold responsibility for quality duties under regulatory frameworks, including:

    a. Licensing NHS service providers and enforcing compliance with quality conditions (Health & Social Care Act 2012, Chapter 3 of Part 3);

    b. Monitoring NHS trusts, offering advice, guidance, and support as needed; and

    c. Issuing directives to NHS trusts regarding the execution of their functions (NHS Act 2006, as amended).

72. The Regional Medical Director and Chief Nurse lead regional quality teams to ensure robust clinical governance and quality assurance. Their responsibilities include:

    a. Overseeing systems that identify significant variations in clinical practice and patient care quality, enabling timely interventions and service improvements;

    b. Conducting Higher Level Responsible Officer quality review visits for all designated bodies to ensure doctors operate within robust clinical governance structures;

    c. Monitoring trust-level quality issues through relevant quality meetings, including chairing or co-chairing regional quality assurance groups or engaging in ICB quality assurance efforts;

    d. Supporting the implementation of CQC quality improvement plans by providing professional advice and direct support where needed;

    e. Ensuring the NHS England Accountability Framework is applied, particularly regarding quality aspects, leveraging expertise and senior leadership, to influence executive decision-making;

    f. Providing leadership and challenge in the Regional Quality Surveillance Group and Risk Summit processes, ensuring appropriate escalation and oversight;

    g. Chairing or managing the NHS England Regional Investigations Assurance Group, which provides quality assurance oversight for high-profile or complex quality investigations;

h. Chairing the Regional Quality Committee ("RQC"), which oversees quality improvement, patient safety, and service excellence across healthcare providers. The RQC's key functions include:

   a) Monitoring performance data and identifying risks to patient safety and service quality;

   b) Reviewing serious incidents, complaints, and CQC reports;

   c) Offering guidance to System Quality Groups ("SQGs") at the ICS level;

   d) Supporting NHS Trusts and providers in addressing quality concerns and implementing best practices;

   e) Escalating major quality concerns to national NHS England teams when necessary;

   f) Facilitating cross-system learning and quality improvement programmes; and

   g) Aligning regional quality efforts with national NHS priorities.

73. Regional teams participate in or support ICB Executive Quality Groups ("EQGs"), which oversee strategic quality, safety, and improvement efforts within ICBs. They also engage with SQGs, which drive quality improvement across the health and care system.

74. When necessary, the Regional Chief Nurse or Medical Director may commission system or service reviews through appropriate agencies.

75. In cases of provider or ICB-level failures, the regional team assesses the implications, provides leadership, and supports providers with performance challenges.

76. If a provider receives a CQC Warning Notice (section 31 Health and Social Care Act 2008), the regional team supports the provider in implementing the National Quality Board guidance for a Rapid Quality Review. The Regional Medical Director and/or Chief Nurse may offer additional support to provider directors and participate as stakeholders in the review process.

77. For providers in the Recovery Support Programme ("RSP") – which replaced the previous Special Measures Programme in July 2021 – regional teams support the

central NHS England team in managing providers undergoing recovery. Organisations enter the RSP when they meet at least one of the following criteria:

a. Longstanding and/or complex issues preventing agreed levels of improvement;

b. A catastrophic safety failure;

c. A catastrophic failure in leadership or governance that risks damaging the NHS's reputation;

d. A significant underlying financial deficit or an actual/forecasted financial gap; or

e. A CQC recommendation (applicable to NHS trusts).

78. The regional team provides oversight and challenge through Regional Support Groups ("RSGs"), which review and monitor improvement plans while ensuring national-level oversight by NHS England.

79. In the Relevant Period, the Legacy Bodies had similar regional arrangements, described in further detail below at **Annex 2 (Legacy Bodies)**. In the period 2017-2019, the Legacy Bodies' regional arrangements changed to reflect the establishment and operation of NHS Improvement. However, NHS England's regional teams remained separate from NHS Improvement's regional teams (whilst having working relationships) until 2019. From 2019, the NHS England and NHS Improvement regional teams were integrated. Each regional team was led by one Regional Director, who was a member of the Executive Group, and who worked for both organisations, with a move to seven regional teams to underpin this new approach: East of England, London, Midlands, North East and Yorkshire, North West, South East and South West.

(3) NHS England's commissioning role

(a) Introduction to NHS England's commissioning responsibilities

80. NHS England mandates the use of the NHS Standard Contract by commissioners when commissioning NHS-funded healthcare services (excluding primary care), including the commissioning of specialised services by NHS England. It is the key mechanism for ensuring that providers of NHS services are subject to consistent contractual conditions.

81. NHS England's responsibilities as a commissioner are often referred to as its 'direct commissioning' responsibilities. When exercising its direct commissioning

responsibilities, NHS England enters into contracts with both independent and NHS providers. As part of the Mental Health Provider Collaborative programme, the nominated Lead Providers are then able to sub-contract with other mental health providers for adult secure, CYPMH, adult eating disorders and Perinatal inpatient mother and baby services.

82. From 2013, NHS England has had statutory responsibility for commissioning the following:

    a. Primary care services. From February 2015, NHS England started to formally delegate this role to CCGs for GP services, and from July 2022 all ICBs assumed delegated responsibility with NHS England retaining overall accountability for the discharge of these delegated functions. NHS England, particularly through its regional teams, retained responsibility for commissioning dental, optometry and community pharmacy services up until July 2022, when responsibility for commissioning these additional primary care services was delegated to some ICBs and to the remainder of the ICBs in 2023;

    b. Prescribed specialised services (”Specialised Services”). These services, which are defined in statute, support patients with rare and complex conditions and include services for high consequence infectious diseases and specialist acute dental care. Some mental health services are identified as prescribed specialised services. Delegation of Specialised Services to ICBs has taken a staged approach since April 2023 with some mental health Specialised Services due to be delegated in April 2025. See **Annex 4 (Specialised commissioning governance arrangements)** for more detail.

    c. Certain military and veteran health services;

    d. Health services that support children and adults throughout the youth justice and criminal justice systems in England; and

    e. A limited number of public health services (working closely with Public Health England/UK Health Security Agency and as delegated to it by the Secretary of State).

83. Since 2013, NHS England has directly commissioned specialised services for mental health. NHS England publishes national service specifications and standards for the specialised services, with which all providers are expected to comply. Directly

commissioned mental health services are set out in the prescribed specialised services manual. They include:

a. Adult Secure – low, medium and high secure;

b. Children and Young People Mental Health Services - General Adolescent (GAU); Psychiatric Intensive Care (PICU); Low Secure; Medium Secure, Eating Disorder; Children's (under 13s); Deaf; Forensic Child and Adolescent Mental Health Services (FCAMHS);

c. Specialist autism spectrum disorder;

d. Adult Eating Disorder;

e. Obsessive Compulsive Disorder and Body Dysmorphic Disorder;

f. Adult Secure and Non-secure Deaf;

g. Mother and Baby In-patient Units (Perinatal);

h. Deaf children, adolescents and adults;

i. Tier 4 Personality Disorder; and

j. Offender Personality Disorder services (delivered in prisons only).

84. The first Direct Commissioning Assurance Framework, published in 2013/14, explained that the Board had delegated assurance of direct commissioning to regional officers **[Exhibit DB/004]**. This Assurance Framework recognised the interdependencies between NHS England assurance of the services it commissioned, and its assurance of CCGs as commissioners themselves. By using common themes, assurance discussions for both NHS England's direct commissioning responsibilities and CCG responsibilities could be supported by similar processes (such as national guidance, data collection and analysis). This recognised that commissioners needed to be able to work "in unison to address any concerns around the quality of care across the whole health economy" **[page 10, Exhibit DB/004]**.

(b) Specialised commissioning national programmes of care & Clinical Reference groups

85. Specialised services commissioned by NHS England are currently grouped into six National Programmes of Care ("NPoC"), as follows:

a. Cancer;

b. Mental Health;

c. Blood and Infection;

d. Internal medicine;

e. Trauma; and

f. Women and Children.

86. These NPoCs bring together clinical and commissioning leadership, as well as stakeholders, and principally operate through a network of affiliated Clinical Reference Groups ("CRG"). CRGs develop national service specifications[2] and associated commissioning products, such as guidance.

87. There are different models of CRGs, aligned to the programme of work within each service area. Services which are major NHS England priority areas, usually with a national transformation programme in place, are led by a fully constituted CRG, led by either a National Clinical Director (NCD) or National Speciality Advisor (NSA), which is actively engaged with and advises the national change programme.

88. Other CRGs range from having a full work programme, which might include policy development and service specification development, to others that are not fully constituted but have a named lead who will draw on a network of specialist advice, which can be responsive to requests for expert advice from national or regional teams or Integrated Care Systems ("ICSs"). These are able to set up ad hoc groups for specific tasks as needed.

89. For the mental health programme of care, the current CRGs are for:

a. adult secure services;

b. all-age eating disorders;

c. children and young people mental health, learning disability and autism services ("MHLDA");

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[2] The service specifications are listed at https://www.england.nhs.uk/specialised-commissioning-document-library/service-specifications/

d. perinatal mental health;

e. mental health services for Deaf people;

f. obsessive compulsive and body dysmorphic disorders; and

g. tier 4 personality disorder.

90. Details of NHS England's CRGs are published online and include details of how to register as a stakeholder[3]. One aim of the CRGs is to integrate insights from individuals with lived inpatient experience, including carers, in order to enhance mental health services. This is done through a range of approaches, including:

a. Active Participation: Patients and carers engaged as equal partners in discussions, ensuring their experiences directly inform service specifications and commissioning policies.

b. Decision-Making Roles: Individuals with lived experience are involved in decision-making processes, contributing to the development of policies and practices that affect care delivery.

c. Policy Development: Insights from lived experiences shape policies to ensure they address real-world challenges and improve patient outcomes.

d. Service Design: Services are tailored based on feedback from those with lived experience, leading to more effective and compassionate care models.

91. Further information on national governance of specialised commissioned services is set out in **Annex 4 (Specialised commissioning governance arrangements)**.

(c) Developments in commissioning arrangements for specialised services

(i) NHS-led Provider Collaboratives

92. NHS-led Provider Collaboratives started to go-live for mental health services from October 2020. An NHS-led Provider Collaborative is a group of providers of specialised mental health, learning disability and autism services who have agreed to

[3]Available here: NHS commissioning » Mental health
https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-c/

work together to improve the care pathways for their local population. They do this by taking responsibility for the budget and pathway for in-scope specialised services they deliver to their local population.

93. NHS-led Provider Collaboratives are not separate legal entities. Instead, an individual NHS provider within the collaborative takes on the responsibility as the "Lead Provider" for a particular service/facility or set of services/facilities. Members of the collaborative enter into a partnership agreement which provides a framework for their joint working.

94. NHS-led Provider Collaboratives are intended to:

    a. reduce unwarranted variation and inequality in health outcomes, access to services and experience;

    b. improve resilience by, for example, providing mutual aid; and

    c. ensure that specialisation and consolidation occur where this will provide better outcomes and value.

95. NHS England's regional specialised commissioning teams agree a contract with each Lead Provider. The Lead Providers then enter into sub-contracts with other providers in the collaborative to provide services to patients. The Lead Provider manages the budget for the services for which it is responsible and assumes responsibility for the oversight and assurance of the delivery of the services sub-contracted from its partner(s). The Lead Provider remains accountable to NHS England for the commissioning and provision of the services[4].

96. NHS-Led Provider Collaboratives currently deliver the following Specialised services: CYPMHS, Adult Low and Medium Secure Services and, Adult Eating Disorder Services. The Long-Term plan ambition is for NHS-led Provider Collaboratives to manage the majority of specialised mental health services in 100% of the country[5].

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[4] A full list of provider collaboratives is available here: NHS England » Live NHS-Led Provider Collaboratives across the country https://www.england.nhs.uk/mental-health/nhs-led-provider-collaboratives/live-provider-collaboratives/

[5] See NHS Mental Health Implementation plan 2019 –_2023/24_https://www.longtermplan.nhs.uk/wp-content/uploads/2019/07/nhs-mental-health-implementation-plan-2019-20-2023-24.pdf

(ii) Integrated care systems

97. ICSs are partnerships that bring together NHS organisations, local authorities and others to take collective responsibility for planning services, improving health and reducing inequalities across geographical areas. There are currently 42 ICSs in England.

98. ICSs comprise of two key components; ICBs, which are statutory bodies that are responsible for planning and funding most NHS services in the area; and Integrated Care Partnerships ("ICPs"), which are statutory committees that bring together a broad set of system partners (including local government, the voluntary, community and social enterprise sector (VCSE), NHS organisations and others) to develop a health and care strategy for the area.

99. ICBs are responsible for commissioning certain mental health, learning disability and autism services ("MHLDA"). Non-specialised MHLDA services are directly commissioned by the local ICB, with contracts held directly with the provider of the services.

100. Since 1 April 2023, joint working agreements between NHS England and each ICB have been in place for the commissioning of specialised services that have been identified as suitable and ready for further integration, which does not include mental health services[6]. Under these agreements, the commissioning assurance and oversight of the delegated services are delegated to a joint committee of NHS England and each ICB. NHS England retain control of certain aspects of arranging the provision of specialised services, including responsibility for drafting the Service Specifications.

101. The role of ICBs is evolving as NHS England builds on the current scope of delegations to ICBs. NHS England's "Roadmap for integrating specialised services with Integrated Care Systems" (31 May 2022) **[Exhibit DB/005]** sets out the case for delegation. Since April 2024, all ICBs in the East of England, Midlands and the North West regions have taken on full delegated commissioning responsibility for all suitable and ready specialised services. The intention of delegation is to enable ICBs, who hold the budget for their specific population's needs, to oversee and commission services in

[6] The most recent list of services determined as suitable for delegation are available here https://www.england.nhs.uk/long-read/annex-1-services-suitable-for-delegation-in-2024-25/

an integrated way so that the ‘care pathway’ is joined up and provides the best care for the patient.

102. Delegation is accomplished by a formal delegation agreement (made under the powers set out in section 65Z5 of the 2006 Act) with additional agreements in relation to the transfer of staff to ensure continuity and transfer of corporate memory as part of the delegation. A new assurance framework, co-developed by NHS England and a number of ICBs, will also be implemented. Key requirements of this include:

    a. That specialised services must continue to be commissioned using national standards;

    b. 10 core commissioning requirements, which include ensuring provider adherence to national standards (or that appropriate improvement plans are in place);

    c. Full alignment with the Oversight Framework and the NHS ‘system by default’ operating model.

(iii) Clinical Commissioning Groups

103. Clinical Commissioning Groups (CCGs) were established on 1 April 2013 following the Health and Social Care Act 2012 (the "2012 Act"). CCGs were responsible for planning and commissioning healthcare services within their local areas and were clinically led statutory NHS bodies.

104. As co-commissioners, CCGs worked with NHS England regional teams to ensure joined up care. Before being replaced by ICBs in 2022, CCGs were responsible for:

    a. Financial Management & Budget Control - CCGs managed a large portion of the NHS budget, ensuring that funds were allocated efficiently to meet the healthcare needs of their local population. They were required to operate within financial constraints and avoid deficits.

    b. Commissioning & Contract Oversight - CCGs commissioned services from providers (such as hospitals, GPs, and community services) and monitored contract performance to ensure quality, efficiency, and value for money.

c. Performance Monitoring & Accountability - They assessed the effectiveness of commissioned services using national standards and key performance indicators (KPIs), such as waiting times, patient outcomes, and service accessibility.

d. Regulatory Compliance & Reporting - CCGs were accountable to NHS England and had to demonstrate financial sustainability, service effectiveness, and compliance with NHS priorities.

e. Intervention & Improvement Planning - If providers underperformed or financial risks emerged, CCGs intervened by implementing recovery plans, negotiating with providers, or adjusting commissioning decisions to ensure sustainable healthcare delivery.

(iv) Primary Care Networks

105. Since 2019, as part of the NHS Long Term Plan, GP practices have been working together with community, mental health, social care, pharmacy, hospital and voluntary services in their local areas in groups of practices known as primary care networks ("PCNs").

106. PCNs build on existing primary care services and enable greater provision of proactive, personalised, coordinated and more integrated health and social care for people close to home. Each of the 1,250 PCNs across England are based on GP registered patient lists, typically serving natural communities of between 30,000 to 50,000 people (with some flexibility). PCNs are led by clinical directors, who may be a GP, general practice nurse, clinical pharmacist or other clinical professional working in general practice.

107. Primary care services are often the first point of contact for people experiencing mental health problems, including people with high levels of need and complexity. The PCNs ensure that mental health services are closely linked to community healthcare and provide an opportunity to develop more comprehensive approaches to primary mental health care. New models of integrated primary and community care for people with severe mental health (including psychosis, bipolar disorder, 'personality disorder' diagnosis, eating disorders and severe depression) are being developed, which will span both core community provision and dedicated services, where the evidence supports them, built around PCNs.

(4) NHS England's role in provider oversight and regulation

(a) Introduction to provider oversight

108. All providers of NHS services are subject to different types and degrees of oversight, monitoring and assurance. These primarily consist of the following:

    a. Registration and regulation by the CQC, which is responsible for ensuring that the services provided by registered providers of health and social care in England are safe, effective, caring, responsive and well-led. The CQC carries out regular planned inspections of registered providers, as well as unplanned ones (which can include when it becomes aware of potential issues). It has intervention powers, including powers to prosecute providers for failings in care. The CQC also monitors reporting data from providers. The CQC, as the regulator, has oversight of all registered MHLDA services (both specialised and ICB commissioned services).

    b. Contractual controls via the commissioning contracts entered into between the relevant commissioner(s) and the provider. These are described in more detail below.

    c. In the case of Foundation Trusts, NHS Trusts and certain types of independent provider of NHS services, the NHS Provider Licence **[Exhibit DB/002],** which all providers of NHS services are required to hold and comply with (unless exempt under regulations made by the Secretary of State **[Exhibit DB/006]**). Although the same NHS Provider Licence is used for each category of licensed provider, there are specific conditions that apply only to NHS Trusts and NHS Foundation Trusts (currently contained within Section 4 of the Provider Licence). There are also specific conditions for licensed NHS-controlled providers (currently these are contained within Section 5 of the Provider Licence) **[Exhibit DB/002]**. NHS-controlled providers are entities ultimately controlled by one or more NHS Trust or NHS Foundation Trust, but this category does not apply to the Trust or Foundation Trust itself.

109. At the beginning of the Relevant Period, NHS Trusts were not directly subject to the NHS Provider Licence. However, the National Health Service Trust Development Authority Directions 2013 required that the NHS Trust Development Authority ensured that NHS Trusts complied with "such conditions which are equivalent to the conditions of any licence issued by Monitor…as the Authority deems appropriate to apply to

English NHS Trusts". This position was repeated in 2016 Directions issued by the Secretary of State and remained the position until 1 July 2022.

(b) Trust oversight

110. Trusts are subject to requirements set out in statute. For the Relevant Period these frameworks were found primarily in the 2006 Act and in the 2012 Act.

111. A provider's compliance with these requirements is overseen by statutory regulators. This means that one of the core purposes of a statutory regulator is to monitor, oversee and account for the way in which providers are meeting the requirements they are subject to.

112. The key statutory regulators prior to July 2022 were:

    a. the CQC;

    b. the NHS Trust Development Authority; and

    c. Monitor.

113. In the period from 1 April 2016 to 2022, Monitor and the NHS Trust Development Authority worked together as NHS Improvement, with a stated policy intention of working consistently and with a greater focus on supporting trusts rather than just 'regulation', but their respective regulatory roles continued within this joint working structure.

114. Understanding the policy intentions underpinning the establishment of both the NHS Trust Development Authority and Monitor is central when considering how providers were regulated during this period. Very broadly, and as expanded on below, Monitor was intended to operate in a way that was modelled on the way the financial services sector was regulated. The idea was to distance NHS providers from a system of 'top-down' management. Instead, both NHS providers and other providers would compete in a market governed by a rules-based system of regulation and patient choice — this was designed to stimulate innovation and improvements in both quality and productivity. NHS services would be provided on the basis of fixed national prices set out in a "National Tariff", so competition would be on the basis of quality of services and patient choice rather than price.

115. In the period from 2004 to at least 2016, there was a sustained focus on NHS Trusts becoming Foundation Trusts. This was often referred to as the "Foundation Trust pipeline". The 2010 White Paper included the ambition that all NHS Trusts would become Foundation Trusts and that it would "not be an option for organisations to decide to remain as an NHS Trust rather than become or be part of a Foundation Trust". This policy was reflected in the 2012 Act provisions for the abolition of NHS Trusts, although these were never in fact enacted and were ultimately repealed by the 2022 Act.

116. The flexibilities and freedoms that Foundation Trusts were granted were similarly reflected in the way that they were regulated. This was in contrast to the more hands-on oversight of NHS Trusts, which is better characterised as performance management and intensive support (rather than regulation in the broader sense). In terms of the key differences between the role of Monitor and that of the NHS Trust Development Authority, these included that Monitor did not have the power to direct Foundation Trusts and that it did not have a formal role in relation to board-level appointments, except where it had decided to exercise its enforcement powers.

(i) The Provider Licence

117. In the period up to 1 April 2023, providers of secondary care services in England who were not NHS Trusts were required to hold a licence, the Provider Licence. Since 1 April 2023, this requirement has extended to include NHS Trusts as well. The Provider Licence comes with standard conditions **[Exhibit DB/009]**. The standard conditions of the Provider Licence included the following, and these remained constant throughout the period 2013-2023:

    a. General conditions: covering areas such as the provision and publication of information; fit and proper persons requirements (reflecting the requirements in Schedule 7 of the 2006 Act[7]); requirements for the providers to be registered with the CQC.

    b. Pricing conditions: including those relating to the National Tariff and associated reporting requirements about compliance with the Tariff;

[7] It should be noted that these requirements do not include the distinct fit and proper persons requirements introduced under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. These are described in more detail below, and compliance with which is regulated by the Care Quality Commission.

c. Choice and competition conditions: incorporating the key policy requirement around providing information for patients to enable them to exercise choice around the provider they access and not to engage in anti-competitive behaviour;

d. Integrated care condition: requiring licence holders not to do anything which could be regarded as detrimental to the integration with other NHS health services, which included for this purpose social care and other health-related services;

e. Continuity of services conditions: these conditions were designed to assist Monitor to ensure the continuity of NHS services, in the event that a provider became financially distressed or insolvent;

f. Governance conditions: applying only to Foundation Trusts (i.e. not to other providers regulated by Monitor who were subject to the provider licence framework). The key governance condition was FT4, which contained detailed requirements as to the governance arrangements required of Foundation Trusts. This included requirements to implement effective board and committee structures and systems and/or processes relating to oversight and leadership of, and accountability for, the collection and use of information relating to quality of care. It also required Foundation Trusts to establish and effectively implement systems and/or processes for the following:

- ensuring compliance with the Foundation Trust's statutory duty to operate efficiently, economically and effectively;
- timely and effective scrutiny by the Board;
- compliance with healthcare standards, including those specified by the CQC and legal requirements (for example, those arising directly under statutory framework governing Foundation Trusts or the more general statutory obligations applying to public bodies, such as equality law);
- effective financial decision-making, management and control.

118. Foundation Trusts were also expected to follow The NHS Foundation Trust Code of Governance **[Exhibit DB/008]** (which reflects the requirements of the UK Corporate Governance Code) and to report on this in their Annual Report. The Code replicated the Provider Licence requirement for Foundation Trusts to ensure adequate systems

and processes were maintained to measure and monitor its economy, efficiency and effectiveness, as well as the quality of the healthcare delivery. Reviews had to be conducted at least annually into the effectiveness of internal control systems and this review had to be reported to members.

(ii) Fit and proper persons

119. Many sectors have requirements that stipulate what basic standards are expected of leaders of the bodies in that sector. These are often referred to as what constitutes ‘fit and proper' people. In the NHS secondary care sector, ‘fit and proper’ can apply to both bodies and individuals.

120. In 2012 and 2014, two separate statutory requirements imposed fit and proper persons requirements in relation to director and non-executive director appointments to NHS Foundation Trust boards. Only one of these also applied to Foundation Trust Governors. This position remained unchanged until 31 March 2023, when the new Provider Licence was issued.

121. The first of these were the requirements under Schedule 7 of the 2012 Act, which were incorporated into, and extended by, the Provider Licence Condition G4. These requirements also applied to governors, whereas the CQC requirements did not.

122. Condition G4 defined an unfit person by reference to both individuals and bodies corporate. The criteria included are essentially objective, i.e. the fact of a conviction.

123. In the case of an individual, an unfit person included an individual who:

    a. had been adjudged bankrupt or whose estate had been sequestered and (in either case) had not been discharged;

    b. had been convicted in the British Islands of any offence in the preceding five years and a sentence of imprisonment (whether suspended or not) was imposed on him for a period of less than three months (without the option of a fine); or

    c. was subject to an unexpired disqualification order made under the Company Directors’ Disqualification Act 1986.

124. The definition for bodies corporate focused on similar categories, including bodies corporate where, for instance, an administrator or receiver had been appointed.

125. The full requirements of Condition G4 (as they were up until 31 March 2023, when a new version of the Provider Licence was implemented) are exhibited to this statement **[Exhibit DB/009]**.

126. The second set of requirements applying to Trusts were, from November 2014, the requirements in regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (known as the "Fit and Proper Person Regulation"). These were part of the regulations setting fundamental standards and other requirements for providers of health and social care registered with the CQC, including Trusts.

127. Enforcing compliance with the Fit and Proper Person Regulation was the responsibility of the CQC. Although a healthcare standard set by the CQC, Foundation Trusts had a duty under the conditions of their licence (and NHS Trusts under their NHS Trust Development Authority equivalent conditions) to establish and effectively implement systems and processes to secure compliance with the Fit and Proper Person Regulation requirements, breach of which could potentially lead to Monitor investigation/enforcement.

128. The fit and proper persons requirements under the Fit and Proper Person Regulation were much broader than the Condition G4 requirements and incorporated subjective elements alongside the accepted objective ones (e.g., not being excluded by virtue of a previous conviction). The Fit and Proper Person Regulation required that trusts do not appoint or have in place a person as an executive director (which included associate director roles) or a non-executive director unless the individual could satisfy the following:

    a. being of good character (assessed by reference to the matters to be considered listed in Part 2 of Schedule 4 to the Fit and Proper Person Regulation);

    b. having the necessary qualifications, skills and experience;

    c. being able to perform the work they are employed for, after reasonable adjustments have been made;

    d. having not been responsible for, or privy to, contributed to or facilitated any serious misconduct or mismanagement in the course of carrying on a regulated activity (or which, if provided in England, would be a regulated activity);

e. none of the grounds for unfitness specified in Part 1 of Schedule 4 to the Fit and Proper Person Regulation applying.

129. Each Trust needed to hold information relating to each director (to be supplied on request to the CQC), as specified in Schedule 3 to the Fit and Proper Person Regulation.

130. As with the 2012 Act and Condition G4, the Fit and Proper Person Regulation listed the criteria that automatically meant an individual was unfit and therefore ineligible for appointment. Many of these were the same as the criteria contained within the 2012 Act and Condition G4, but there were some important additions, including:

a. the specific inclusion of safeguarding offences and associated inclusion on the children's or adults' barred lists; and

b. individuals who "have been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity, or discharging any functions relating to any office or employment with a service provider".

131. Individuals also had to meet the "good character" and "not responsible for serious misconduct or mismanagement" requirements. The Fit and Proper Person Regulation included certain aspects that had to be considered as part of the "good character" assessment. This required consideration of whether a person had been convicted of any offence or whether the person had been erased, removed or struck off a register of professionals maintained by a regulator of healthcare or social work professionals.

132. The CQC assessed Trusts' compliance with the Fit and Proper Person Regulation during its inspections and reported on this aspect as part of the well-led sections of the inspection report. However, day to day, the onus was on the provider organisation to ensure that it had complied with the fit and proper persons requirements, at initial appointment and at other key points during an individual's employment/appointment to the organisation, or on receipt of information or an allegation that a director is not 'fit and proper'. The provider's assessment of an individual's fitness would be recorded on the individual's personnel file or in other provider-based systems.

133. Although compliance with the Fit and Proper Person Regulation was primarily managed by the CQC, both aspects were directly incorporated into the Provider Licence framework by virtue of the general requirement in Condition G7 to be and

remain registered with the CQC (and thereby satisfy the requirements of registration) and the specific requirements in Provider Licence Condition FT4, including ensuring compliance with healthcare standards (including those of the CQC) and complying with all applicable legal requirements. Condition FT4 also included a requirement on Foundation Trusts to establish and effectively implement systems and/or processes to ensure compliance with a range of matters, including that there was sufficient capability at Board level.

134. In practice, therefore, Monitor's oversight and assurance of Foundation Trust governance included assuring compliance with the requirements around fit and proper persons, both under the 2012 Act and licence Condition G4, and in terms of requiring ongoing compliance with the CQC's regulatory framework.

135. The same two-part structure applied in relation to NHS Trusts, except that the general fit and proper requirements (e.g. around bankruptcy and criminal convictions) were contained in the National Health Service Trust (Membership and Procedure) Regulations 1990, not the 2012 Act.

136. The NHS Leadership Academy played a key role in supporting the development of individuals in leadership roles, as described below at **Annex 7 (How the NHS works with other partners)**.

(iii) Single Oversight Framework

137. Prior to September 2016, when the Single Oversight Framework was introduced, there was an oversight framework which applied to NHS Foundation Trusts and a separate accountability framework which applied to NHS Trusts boards. These are described above.

138. The Single Oversight Framework was introduced in September 2016 **[Exhibit DB/010]** and was deliberately closely aligned with the CQCs regulatory structure and approach, with the aim of supporting more Trusts to achieve 'good' or 'outstanding' ratings. It replaced the two pre-existing frameworks above and applied to the oversight of both NHS Trusts and NHS Foundation Trusts. This move to a Single Oversight Framework reflected Monitor and the NHS Trust Development Authority coming together under the operational name NHS Improvement on 1 April 2016.

139. The Single Oversight Framework initially had five themes or areas of focus: quality of care; finance and use of resources; operational performance; strategic change;

leadership and improvement capability. Each contained a number of metrics or indicators, based on which NHS Improvement would assign trusts to one of four segments, depending on the assessed level of support they required. These segments were as follows:

a. Segment 1: trusts with no support needs;

b. Segment 2: trusts with some support needs who would be offered targeted support;

c. Segment 3: trusts with significant concerns, who would be given 'mandated support'; and

d. Segment 4: trusts with major or complex concerns and who would be subject to 'special measures'.

140. Trusts were assessed against NHS Improvement's definition of success, which incorporated:

a. finance and use of resources;

b. quality;

c. operational performance;

d. strategic change; and

e. leadership and improvement capability.

141. Those trusts who were assessed as being in segments three and four were generally subject to formal enforcement action. In the case of Foundation Trusts, this still required a formal assessment to determine that they were in breach, or suspected of being in breach, of their Provider Licence.

142. Although the Provider Licence provisions continued not to formally apply to NHS Trusts during this period, they were applied "in effect", as NHS Trusts had to comply with equivalent conditions. NHS Improvement would also accept undertakings from NHS Trusts to take action (similar to the statutory enforcement undertakings for Foundation Trusts) and requirements could be imposed in a similar way to those for Foundation Trusts.

143. The creation of NHS Improvement and the development of the Single Oversight Framework marked a shift away from more traditional performance management and arms-length regulation to a regulatory and oversight role, underpinned by a comprehensive development and support offering for Foundation Trusts, as well as Trusts.

144. This change in approach was the basis for much of NHS Improvement's work from 2016, which included providing Trusts with the tools to enable them to develop and improve the quality of care they were providing.

145. During 2016 to 2019, the oversight of CCGs was subject to a separate framework – the Clinical Commissioning Group Improvement and Assessment Framework. The framework aligned with NHS England's Mandate and planning guidance, with the aim of unlocking change and improvement in a number of key areas. Each CCG received a performance rating based on the following four indicators:

    a. Better health: how the CCG is contributing to improving the health of its population;

    b. Better care: focussing on care re-design, performance of constitutional standards, and outcomes, including in important clinical areas;

    c. Sustainability: focussing on financial sustainability;

    d. Leadership: assessing the quality of the CCG's leadership, planning, partnership working and governance.

146. With the joining of NHS England and NHS Improvement in 2019, alongside the move to system working through (non-statutory) ICSs, the two frameworks were replaced by a single NHS Oversight Framework which applied to both commissioners and providers. There have been iterations of this system-based oversight approach since August 2019, reflecting a greater emphasis on system performance alongside the contribution of individual healthcare providers and commissioners to system goals.

147. The current version of the oversight framework is the NHS Oversight Framework [**Exhibit DB/011**], which was first published very shortly before 1 July 2022 to reflect the 2022 Act putting ICSs on a statutory footing (in particular, establishing statutory ICBs) and effecting the merger of NHS Improvement and NHS England.

148. The current Oversight Framework is characterised by five key principles, one of which is “autonomy for Integrated Care Boards and NHS providers as a default position”. This is, in turn, underpinned by the statutory duties that NHS England has, including those around efficiency and effectiveness, but also the ‘new’ duties introduced as a result of the 2022 Reforms (such as the Triple Aim).

149. This reflects the evolution of the commissioner/provider relationship during the Relevant Period, which is now based on a more collaborative, mutually-supportive relationship with a greater emphasis on system performance. In addition to the principle of autonomy, there is “a greater emphasis on system performance and quality of care outcomes, alongside the contributions of individual healthcare providers and commissioners to system goals” and “matching accountability for results with improvement support”.

150. In addition, the delivery of good quality healthcare services and a focus on continuous improvement is underpinned by associated legal and contractual duties on those regulating, commissioning and providing NHS healthcare services.

151. In particular, NHS Trusts and NHS Foundation Trusts are subject in their own right to legal duties around health and safety, patient safety, complaints and raising concerns, data protection, medicines management and safeguarding. Compliance with these duties informs the oversight of providers by NHS England, the CQC and others, but legal enforcement can also occur outside the health sphere, such as through health and safety prosecutions, judicial reviews, claims for clinical negligence and other civil and criminal liability, all of which would arise directly against the provider in question.

152. NHS England’s fundamental expectation in terms of policies and procedures relating to areas such as safeguarding and raising concerns is that each provider will ensure it complies with its statutory, regulatory and contractual obligations. This principle applies whether NHS England is acting as the regulator with responsibility for provider oversight or as the commissioner of mental health services.

153. The way in which NHS England seeks this assurance is through the Oversight Framework and the associated oversight metrics (the current version of which is the NHS oversight metrics for 2022/23). The metrics are used to indicate potential issues and prompt further investigation. The metrics align with the five national themes of the Oversight Framework:

    a. Quality of care, access and outcomes;

b. Preventing ill health and reducing inequalities;

c. People;

d. Finance and use of resources; and

e. Leadership and capability.

154. The metrics (aligned with these themes) are reviewed and organisations are put into segments according to their performance against the metrics. For example, to be in the top segment, organisations typically demonstrate:

a. Performance against the oversight themes, typically in the top quartile nationally based on the relevant oversight metrics;

b. Balanced plan, actual/forecast breakeven or better; and

c. CQC ‘Good’ or ‘Outstanding’ overall and well-led (Trusts).

155. There are four segments, with 1 relating to having no specific support needs and 4 requiring mandated intensive support. Importantly, the CQC's view on the organisation is taken into account as part of the oversight framework, with a rating of 'Requires improvement overall' triggering segment 3. In addition, our oversight framework also highlights the following concerns as additional considerations for triggering segment 3:

a. 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);

b. A material concern with regard to the quality or safety of services being provided or a failure to escalate such risks; and

c. Evidence of capability and capacity to address the issues without additional support.

156. Importantly, while the Oversight Framework provides a common structure through which oversight is delivered, it recognises that oversight needs to be informed by “the unique local delivery and governance arrangements specifically tailored to the needs of different communities”. The purpose of the Oversight Framework is stated as being 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; and

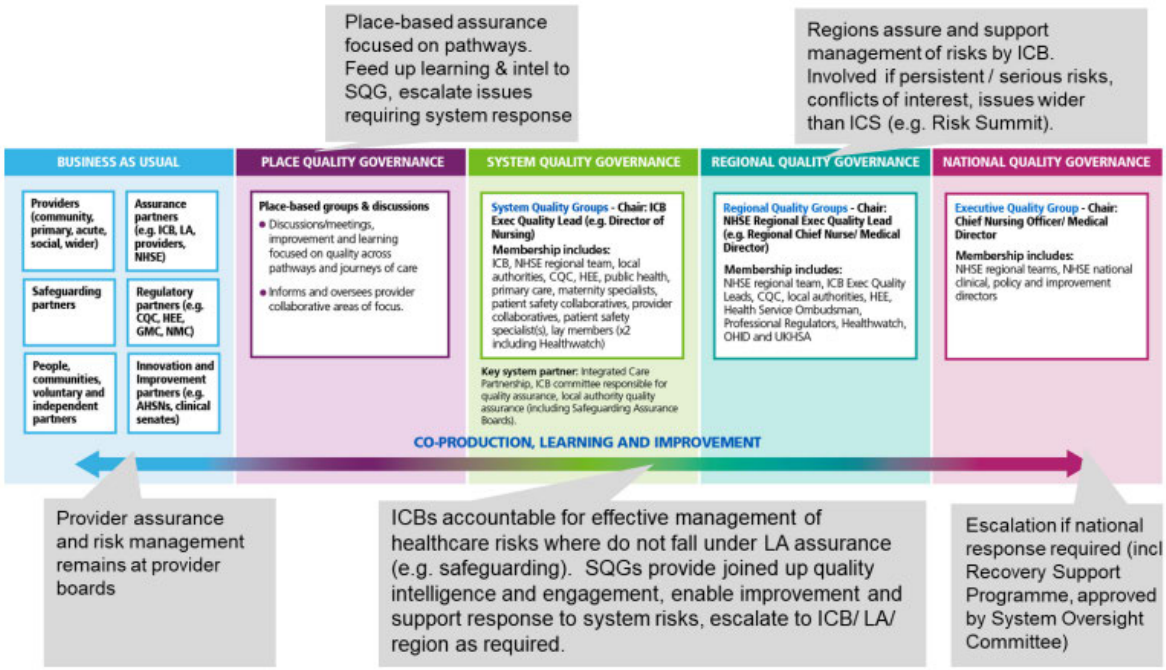
c. provide an objective basis for decisions about when and how NHS England will intervene.

157. NHS England is updating the framework to include more metrics which cover different provider types and ICBs providing more detail on delivery performance and system working.

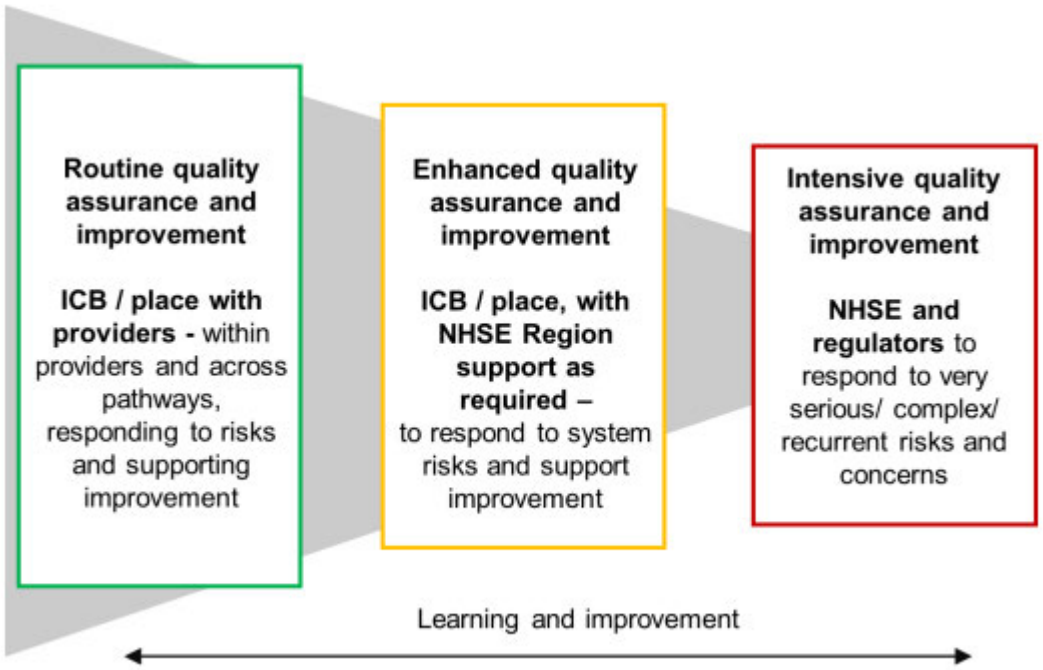
(iv) National Guidance on Quality Risk Response and Escalation in Integrated Care Systems

158. In addition to the Oversight Framework, the management of quality is enhanced through the National Guidance on Quality Risk Response and Escalation in ICSs **[Exhibit DB/012].** This guidance supports commissioners (whether an ICB or NHS England as a specialised commissioner) to manage risk, which includes escalation of risk with associated increased oversight and increased intervention.

159. The below diagram sets out an overview of how quality governance is managed:



160. There are also three levels of quality assurance and improvement that apply to the different geographies, as below:



(5) Changes to NHS Trust Development Authority, Monitor and NHS Improvement

161. This section briefly describes how the NHS Trust Development Authority, Monitor and NHS Improvement performed their performance management, regulatory and oversight functions. It describes how, following the 2022 Act, NHS England formally merged with NHS Improvement and that this saw the integration of NHS Improvement's regulatory duties into NHS England.

(a) Monitor and the Regulation of NHS Foundation Trusts 2013-2016

162. This section describes what Monitor's role was as an arms-length regulatory body.

163. NHS Foundation Trusts were originally regulated by an independent regulatory body, the Independent Regulator of Foundation Trusts, which was established in 2004. It operated under the name Monitor, with its name being formally changed under the 2012 Act reforms. At the same time, its role was expanded, reflecting its position as the system regulator in relation to providers of NHS services (the exception being NHS Trusts).

164. Monitor's expanded role was a key part of the 2012 Act reforms, particularly in terms of its role to licence providers of NHS healthcare services and ability to enforce the conditions of the licence, using the enforcement powers it was given in Chapter 3 of Part 3 of the 2012 Act. However, Monitor was established as an arms-length regulatory body and it was intended that it would operate as such, i.e. without the more directive performance management role of the NHS Trust Development Authority.

165. From the outset, Monitor worked closely alongside the CQC, other national partner regulatory organisations, including the NHS Trust Development Authority, and commissioners (both NHS England and CCGs) to discharge its regulatory responsibilities, assess whether any intervention was required and, ultimately, to take enforcement action.

166. Monitor had a range of intervention and enforcement actions that it could take, as well as its role in supporting Foundation Trusts who were failing or at risk of failing. These intervention and enforcement powers included:

    a. the ability to impose additional Provider Licence conditions (see below for detail on the Licence) (section 111 of the 2012 Act). This power was specific to Foundation Trusts. This could include, for instance, requiring the licensee to have in place sufficient board and management capacity and capability to address failures, such as implementing a required plan;

    b. as part of its licence enforcement powers, which apply to all licensees;

    c. impose discretionary requirements on the licensee where it had breached the conditions of its licence (section 105 of the 2012 Act); and

    d. seek/accept statutory enforcement undertakings from any licensed provider who is reasonably suspected of breach of the conditions of their licence (section 106 of the 2012 Act).

167. Monitor did not have a direct role in making or approving appointments to Foundation Trust boards (in contrast to the NHS Trust Development Authority's role in relation to NHS trusts). However, it could (and did) exercise its intervention powers to effect leadership change, where it was assessed that the current leadership arrangements were insufficient (either in capacity or capability, or both).

168. More broadly, however, Monitor had a role to play in relation to supporting the development of senior leaders within Foundation Trusts. This included board induction

days for chairs and chief executives, as well as training for non-executive directors through targeted developmental programmes, such as the NHS Trust Non-Executive Directors' programme run in conjunction with the Cass Business School. The NHS Leadership Academy also played a key role in this development support.

169. Similarly, Monitor and the NHS Trust Development Authority carried out a joint survey of medical directors in NHS Trusts and NHS Foundation Trusts in the period December 2013 to January 2014 and targeted support was developed as a result.

(b) How Monitor exercised its regulatory powers

170. During the period 2013-2016, Monitor operated with a combination of national and regional governance structures. Regionally, it was organised into four regions: London, Midlands and East, North, and South. Each of these regions was responsible for regulating healthcare providers within its jurisdiction and, as with NHS England's commissioning responsibilities, day-to-day oversight by Monitor was carried out at a regional level. This included assessing and enforcing each NHS Foundation Trust's compliance with its licence conditions, including consideration of risks to financial sustainability and good governance, based on information on performance, quality of care and financial health, and taking appropriate regulatory action.

171. At this regional level, Monitor operated as part of a collaborative regional structure that included close working with the equivalent structures in operation by the NHS Trust Development Authority, the CQC, commissioners (both NHS England and CCGs) and other partners. Monitor regulated NHS Foundation Trusts via the NHS Provider Licence and in accordance with its statutory enforcement powers, as described in its Enforcement guidance. Foundation Trust compliance with the Provider Licence was monitored in accordance with Monitor's Risk Assessment Framework **[Exhibit DB/013]**.

172. Monitor could become aware of an issue relating to patient safety or quality as a result of:

    a. submissions made by the provider (whether regular or 'by exception');

    b. other information, such as plans, reports and forecasts, shared by the provider. This would include Quality Accounts, which providers of NHS services have been required to complete since 2009;

c. information shared with it by a commissioner of services, which could include the commissioner making Monitor aware of recent CQC activity or concerns;

d. information shared with it directly by the CQC;

e. information shared with it by another third party, such as one of the medical Royal Colleges; and

f. safeguarding concerns, including those raised via regional and local safeguarding board arrangements.

173. For example, in its Annual Report and Accounts for 2015/16, Monitor set out in table form **[Exhibit DB/014]** a list of Foundation Trusts it had found in breach of their Provider Licence during the 2015/16 period. 17 Foundation Trusts were listed, with a short form explanation of the breach and the regulatory action taken by Monitor as a result. In several cases, the breach included governance breaches, and the key information relied on in more than one case was CQC issues and/or inspection findings. A further table within the same document listed those Foundation Trusts that were under investigation.

174. For the most part, this information sharing took place at a regional level and was coordinated through the structures and processes in place regionally to facilitate information sharing between the regulatory bodies, commissioners and providers. If a serious concern was raised through one of these mechanisms, an initial screening teleconference would take place, to decide whether or not to convene a risk summit.

175. In tandem with this risk summit, Monitor would conduct its own assessment (against the Risk Assessment Framework) to decide whether a formal investigation was required and to establish what, if any, enforcement action was appropriate. Monitor followed a formal approach to intervening with individual Foundation Trusts and would only consider using its statutory enforcement powers if it felt that the outcome of its formal investigation warranted this, consistent with the prioritisation criteria set out in its Enforcement Guidance.

176. Although Monitor was not directly responsible for assessing or regulating the safety or quality of the care a Foundation Trust was providing (this being the role of the CQC), evidence of poor-quality care or safety issues could potentially indicate a failure of governance. For instance, it could suggest that the Foundation Trust was not complying with its licence conditions to have in place systems to secure the quality of

care provided to patients (as per Condition FT4). Using its Risk Assessment Framework, Monitor would assign a risk rating to the two key elements that it assessed in relation to Foundation Trusts. This risk rating was a number rating from 1 to 4 for financial sustainability, whereas a red/green/under review rating was used for governance. These ratings indicated where there was a cause for concern and would inform whether a formal investigation was commenced, so as to enable a detailed assessment of the scale and scope of the risk and ultimately whether any enforcement action was appropriate.

177. Foundation Trusts were required to carry out an external review of their governance every three years, under the 'Well Led' framework. Monitor explicitly aligned this with the CQC's characteristics of 'good' under their well led domain when the Well Led Framework for governance reviews was updated in 2015 **[Exhibit DB/015]**. However, although these reviews were aligned, they were separate reviews, in order to enable Monitor and the CQC to perform their separate, respective regulatory responsibilities.

178. Monitor's remit focused on board and committee level effectiveness, covering strategy, planning, capability and culture, process and structures and measurement. In contrast, the CQC looked at the patient experience at ward and service level to see whether the outcomes being delivered demonstrated that the board's policies were operating effectively. The CQC's approach was known as 'ward to board' inspection. In carrying out that inspection, the CQC could (and did) ask Foundation Trusts how they assured their governance arrangements, including asking for information about any independent reviews and whether/how they had been acted on.

179. Monitor's Well Led Framework had four main domains for review and involved a comprehensive assessment of how well the Foundation Trust was run. Reviews, which were commissioned externally by Foundation Trusts, needed to be carried out using the Framework guidance. The four domains were: strategy and planning; capability and culture; process and structures; and measurement. Within those domains, the Framework included considering whether:

    a. the board was sufficiently aware of potential risks to the quality of current services;

    b. the board shaped an open, transparent and quality-focused culture;

    c. there were clear roles and accountabilities in relation to board governance (including quality governance);

d. processes for escalating and resolving issues and managing performance were clearly defined and well-understood; and

e. the board actively engages patients, staff, governors and other key stakeholders on quality and operational performance (including whether staff actively raise concerns and those who do, including external whistleblowers, are supported).

180. At the end of the Well Led Review process, the Foundation Trust Chair was required to write to Monitor to advise them that the review had taken place, set out any material issues that had been identified and explain what the proposed action plan was to address these.

181. Recognising the inter-dependencies between their regulatory roles, Monitor and the CQC (along with the NHS Trust Development Authority) worked closely together throughout this period. This is reflected in the memorandum of understanding that the CQC and Monitor entered into in 2015 **[Exhibit DB/016**] and in the tri-partite special measures guidance published in February 2015 by Monitor, the CQC and the NHS Trust Development Authority **[Exhibit DB/017]**. This tri-partite guidance was issued in light of the findings of the 2013 Keogh Review, discussed below.

182. Under the approach described in this guidance, special measures would apply to both NHS Trusts and Foundation Trusts that had serious failures in quality of care and where there were concerns that existing management could not make the necessary improvements with support. The CQC would focus on identifying failures in the quality of care, judging whether improvements had been made and, where necessary, using its enforcement powers. The NHS Trust Development Authority and Monitor would use their powers to support improvement in the quality of care provided, including appointing an improvement director to support the board of the Trust concerned, and reviewing (and, if necessary, making changes to) the Trust's leadership.

(c) NHS Improvement (2016-2019)

183. On 1 April 2016, Monitor and the NHS Trust Development Authority started to work together under the operational name NHS Improvement. NHS Improvement was responsible for overseeing NHS hospitals in England, as well as independent providers providing NHS-funded care.

184. In 2018, it was announced that, while maintaining its statutory independence, NHS England would be merged with NHS Improvement and establish seven integrated regional teams.

185. Further information on NHS Improvement can be found at **Annex 2 (Legacy Bodies)**.

(d) Regulation following NHS England merger with NHS Improvement (2019)

186. In statutory terms, NHS England's role did not change in 2019, as there was no formal merger at this point. What changed was how NHS England and NHS Improvement operated. From 2019, the two organisations came together to operate as a single organisation, with a shared leadership model. In particular:

    a. The boards of NHS England and NHS Improvement remained separate but would meet 'in common' – i.e. hold meetings at the same time to discuss issues and make aligned decisions, to a large degree operating as if they had a single board;

    b. NHS England and NHS Improvement retained separate chairs and chief executives, but NHS Improvement's chief executive was chief executive of both its constituent statutory bodies (Monitor and the Trust Development Authority) and also joint chief operating officer of both NHS England and NHS Improvement;

    c. For the senior executives below chief executive officer, there was a shared executive group – i.e. all posts were joint between NHS England and NHS Improvement, with each executive being an officer/employee of both NHS England and NHS Improvement;

    d. Those joint executives managed combined directorates and teams – i.e. there would be a single directorate (e.g. finance) consisting of staff from both organisations, exercising the functions of both NHS England and NHS Improvement in relation to the relevant area.

    e. Similarly, the regional teams of NHS England and NHS Improvement came together to operate as single regional teams, each headed by a jointly appointed Regional Director.

187. NHS England continued to have responsibility as respects the commissioning of services (e.g. oversight of CCGs and direct responsibility for commissioning certain

services, such as specialised services and primary care). NHS Improvement continued to be responsible, through the statutory functions of Monitor and the Trust Development Authority, for the regulation of the provision of NHS services (e.g., licensing of providers of NHS care and use of enforcement powers to intervene in cases of licence breach, including cases which involved failure of financial or quality governance).

188. Arrangements were in place to manage any potential conflicts between the functions of the different bodies. For example, some NHS Improvement regulatory functions, which potentially involved the regulation of NHS England activity, had a decision-making structure which escalated decisions to a senior manager employed by NHS Improvement only. In some cases, NHS England and NHS Improvement issued new guidance as a combined organisation, but in other cases, the guidance issued by each separate body simply remained in place unless amended or replaced.

189. To take some specific examples:
    a. Monitor's guidance on the use of its enforcement powers issued under section 108 of the 2012 Act (the "Enforcement Guidance") remained in place and continued to be the basis for how the powers were used.
    b. NHS Improvement's NHS Single Oversight Framework, which set out how it oversaw providers of NHS services, continued in effect until replaced by the NHS Oversight Framework 2019/20 in August 2019. This was an NHS England and NHS Improvement document covering oversight of both providers (for which NHS Improvement was responsible) and CCGs (for which NHS England was responsible).

190. On 1 July 2022, NHS England and NHS Improvement formally merged. At that point, NHS England formally took on the functions of NHS Improvement (as modified by the 2022 Act) and all acts, decisions and documents issued by Monitor and the Trust Development Authority in relation to the shared functions transferred to NHS England. Guidance and other documents issued by NHS Improvement before 1 July 2022 therefore remained in force until amended or replaced by NHS England. All of NHS Improvement's staff, property and liabilities were transferred by statutory schemes from Monitor or the Trust Development Authority to NHS England.

191. To avoid any conflicts of interest between functions, section 34 of the 2022 Act places a duty on NHS England to minimise the risk of conflict or manage any conflicts that

arise between their regulatory functions. As part of this duty, NHS England is required to include in its annual report a statement explaining how it has complied with its duty.

PART B: QUALITY INCLUDING PATIENT SAFETY

(1) Introduction

192. The statutory and regulatory landscape described in Part A is important context for understanding the shared responsibilities of those working within the NHS to ensure safe patient care. Without wishing to repeat that content here, we emphasise the following points:

    a. All provider organisations are independent, responsible corporate entities;

    b. NHS Trusts and NHS Foundation Trusts are statutory bodies in their own right;

    c. All providers of NHS services are subject to statutory, regulatory and contractual duties, including those relating to patient safety and governance;

    d. Each NHS Trust and NHS Foundation Trust is governed by a Board, which includes executive and non-executive directors (Foundation Trusts additionally have a Council of Governors). Provider Boards are ultimately accountable for the performance of the organisation, which includes assuring itself as to effectiveness and regulatory compliance;

    e. NHS England operates as one of several arms-length bodies that have a shared responsibility to oversee patient safety.

193. In this part, we explain what is meant in the NHS by the terms ‘quality’ and ‘patient safety’, and cover in high level the key structures and processes for quality and patient safety outside of the regulatory oversight role performed by Monitor and the NHS Trust Development Authority (which is described above in Part A).

194. We do not address how the safety or wider quality of patient care is considered at the day-to-day ward, clinician and treatment level in the NHS, but at the more senior, accountable board levels.

(2) Overview

195. The current definition of 'quality', as set out by the National Quality Board **[Exhibit DB/018]**, refers to the extent to which healthcare is safe, effective, delivers a positive experience, is well led, sustainably resourced and is equitable.
    Patient safety specifically, as a core component of this wider concept of quality, is about maximising success in healthcare. It is the avoidance of unintended or

unexpected harm to people during the provision of healthcare and the reduction of risk of unintended of unexpected harm to an acceptable minimum.
The delivery of good quality healthcare services and a focus on continuous improvement is underpinned by associated legal and contractual duties on those regulating, commissioning and providing NHS healthcare services, some of which have already been drawn out in Part A.

196. The following examples establish an expectation that NHS bodies will deliver and/or oversee quality services, including services that continuously improve patient safety:

    a. Legal duties, including those set in the form of national healthcare standards by the CQC and enforced by the CQC exercising its inspection duties, as well as by virtue of the Provider Licence, provider/system oversight frameworks, and the commissioner/provider relationship.

    b. Observance of clinical standards set by national regulatory bodies, such as NICE, the professional regulatory bodies and Royal Colleges.

    c. Clinical governance requirements, ordinarily described as being based on the 'seven pillars' of clinical governance, which are: audit, risk management, clinical effectiveness, training and education, patient and public involvement, information systems, and staff management. The effectiveness of the structures and processes providers have in place to enable clinical governance are regulated by provider regulatory bodies (the role of commissioners is noted separately, below at e).

    d. Wider reporting requirements, including reporting certain events to external bodies or independent systems. This includes notification of certain deaths to the Coroner and review of all deaths not referred to the Coroner by the Medical Examiner, the routine recording of patient safety incidents via local risk management systems and the collation of those incident records by the Learn from Patient Safety Events service, occasional referral to and involvement of the Health Services Safety Investigation Body (as it is currently named), statutory requirements to notify certain events to the CQC, and various other confidential enquiries and clinical outcome review programmes.

    e. Commissioner Requirements: National frameworks, including the NHS Standard Contract (in particular, NHS Standard Contract condition 37 and 38), incorporate standard requirements around quality, ensuring that all commissioned providers

of NHS services are operating to the same overall expectations. As part of the overall commissioner/provider relationship and the ongoing assurance process this relies on, providers will report to commissioners about issues relating to quality, including patient safety, and provide assurance around clinical governance processes and structures to manage such issues.

f. Governance Requirements: as set out in Part A of this statement, a Foundation Trust is required under the Provider Licence to meet specific governance conditions, which include requirements around compliance with healthcare standards.

197. Each provider of NHS services will have its own patient safety and wider quality planning, assurance and improvement mechanisms. This includes the reporting arrangements each provider has in terms of national systems and processes, but also their own internal processes and structures for the identification, examination, management and improvement of patient safety and wider quality matters. Hospitals, general practices and other providers are responsible for the safety of their patients and sharing local information about risks and best practice.

198. Trusts, as separate bodies, make their own polices for risk management and health and safety. This will generally be informed by guidance from organisations such as the Health and Safety Executive and CQC. For example, the CQC has provided guidance on reducing harm from ligatures in mental health wards and wards for people with learning disabilities [**Exhibit DB/019**].

199. Most NHS bodies ensure they meet the various requirements and maintain a focus on quality by having an identified board committee that focuses on quality of care, including patient safety. That board committee will in turn receive information from and oversee the management of quality, including patient safety, by subsidiary groups and individuals.

200. Quality is also enshrined in the NHS Constitution, which provides that the NHS aspires to the highest standards of excellence and professionalism and to provide high quality care that is safe, effective and focused on patient experience. The NHS Constitution contains pledges that the NHS is committed to achieve, which go above and beyond legal rights. This includes the right for patients to be treated with a professional standard of care by appropriately qualified and experienced staff that meets required levels of safety and quality. The commitment to quality of care means that the NHS

welcomes feedback from patients, families, carers, staff and the public. The NHS Constitution is covered in more detail in **Annex 3 (Relationship between NHS England and DHSC)**.

(3) NHS England and Quality, including Patient Safety

(a) Policy development

201. In 2015, the Government published the policy paper "2010 to 2015 government policy: patient safety" **[Exhibit DB/020]**. This policy referenced Domain 5 of the NHS Outcomes Framework, which contained indicators intended to measure patient safety and which were how NHS England was held to account by the Government for the way in which it delivered on patient safety.

202. In the period following this policy paper, NHS England was established and was given relevant statutory duties under section 13R of the 2006 Act to deliver key statutory patient safety duties across the NHS. These are:

    a. collecting information about what goes wrong in the health service, in part by maintaining and operating the National Reporting and Learning System ("NRLS") and its replacement, the Learn from patient safety events ("LFPSE") service: and

    b. using that information to provide advice and guidance "for the purposes of maintaining and improving the safety of the services provided by the health service".

203. To deliver these functions, NHS England was given responsibility for the NRLS as part of the 2012 Act Reforms, with this transferring from the National Patient Safety Agency.

204. In the period 2012-2018, a significant number of patient safety initiatives were directed by the Government and in particular by the Secretary of State at the time, who made patient safety an explicit priority for his leadership. For example, in 2016, the Secretary of State announced three new initiatives regarding patient safety: the Healthcare Safety Investigation Branch to carry out around thirty 'no-blame' theme based investigations a year; the introduction of Medical Examiners to provide independent scrutiny of the causes of non-coronial deaths, allowing them to identify cases for further review under local mortality arrangements and contribute to other clinical governance processes; and a "Learning from Mistakes" league table of NHS trusts,

drawing on data from the staff survey and rates of reporting incidents. These were supported/implemented as appropriate by NHS England and/or NHS Improvement.

205. In 2016, with the advent of NHS Improvement, the Secretary of State directed the NHS Trust Development Authority to exercise NHS England's patient safety functions. In practice, this resulted in the transfer of the National Patient Safety Team from NHS England to NHS Improvement. This direction was set out in the NHS Trust Development Authority (Directions and Miscellaneous Amendments etc.) Regulations 2016.

206. The transfer of the responsibility for these patient safety functions from NHS England to NHS Improvement was accompanied by a transfer of the NRLS from Imperial College Healthcare NHS Trust to the NHS Trust Development Authority. The NRLS team moved to sit with the National Patient Safety Team, as part of NHS Improvement. This enabled improved alignment between the patient safety duties related to collecting information about what goes wrong in healthcare and using that information

207. The Patient Safety Strategy incorporated and refreshed National Patient Safety Improvement Programmes, which began as a result of the Berwick Report in 2013 and collectively form the largest safety initiative in the history of the NHS. The programmes are led by the NHS England National Patient Safety Team and aim to support a culture of safety, continuous learning and sustainable improvement across the healthcare system. Programme Implementation is ongoing.

208. The NHS Patient Safety Strategy 2019 **[Exhibit DB/021]**, which was updated in 2021 **[Exhibit DB/022]** and again in 2023 **[Exhibit DB/023]**, set a vision for the NHS to improve patient safety continuously. However, the Strategy did not (and, in its current iteration, does not) seek to direct the whole of the NHS. Elements of the NHS, such as workforce and financial planning, clinical training/education and guidance and estates and facilities maintenance, remain subject to each provider's own strategic leadership and implementation and to wider support and guidance provided by other parts of NHS England and beyond.

209. The NHS Patient Safety Strategy aims to:

    a. improve the way the NHS learns about patient safety — termed 'insight';

    b. build capability and capacity to address safety challenges — termed 'involvement'; and

c. focus on key improvement priorities where additional national activity can add value — termed ‘improvement’.

210. To do this, the NHS Patient Safety Strategy builds on two foundations: a patient safety culture and patient safety systems.

211. The NHS Patient Safety Strategy is in its sixth year of operation and has demonstrated success in implementing initiatives, hitting milestones and improving outcomes.

212. Since 1 July 2022, the NHS National Patient Safety team has formally been in the new NHS England, following transition back from NHS Improvement.

(b) NHS England’s statutory role

213. NHS England has explicit statutory responsibilities in relation to quality. Section 13E of the 2006 Act requires that NHS England “exercise its functions with a view to securing continuous improvement in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, or the protection or improvement of public health”. Section 13E(2) further specifies that NHS England must “act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services”. The outcomes that are relevant for the purposes of section 13E(2) are as follows:

a. the effectiveness of the services;

b. the safety of the services; and

c. the quality of the experience undergone by patients.

214. When discharging this duty, NHS England must have regard to any document published by the Secretary of State for the purposes of section 13E and the quality standards prepared by NICE (under its own duty, found in section 234 of the 2012 Act).

215. These duties are general and are intended to be incorporated into everything that NHS England does. This means that they do not relate to the work of any single team but are discharged (on both national and regional footprints) through NHS England’s wider system of quality governance.

216. As part of the 2012 Reforms, the National Patient Safety Agency (a Special Health Authority established in 2001) was abolished on 1 June 2012. Prior to that, it had been

responsible for certain patient safety related functions, the key aspect of which was the function of improving the safety of NHS care by promoting a culture of reporting and learning from adverse events. NHS England inherited some of the functions of the National Patient Safety Agency. This transfer took effect in the period prior to NHS England's full operational establishment on 1 April 2013, as part of the transition arrangements incorporated within NHS England's status as a Special Health Authority for the period October 2011 to 1 April 2013.

217. The specific functions that NHS England inherited from the National Patient Safety Agency took the form of two key statutory duties, which are contained within section 13R of the 2006 Act, requiring that NHS England:

    a. establish and operate systems for collecting and analysing information relating to the safety of services provided by the health service (section 13R(1));

    b. give advice and guidance for the purposes of maintaining and improving the safety of the services provided by the health service (section 13R(4)).

218. NHS England's governance facilitates a focus on quality as follows:

    a. As explained in Part A, NHS England was (and remains) governed by its Board, which provides strategic leadership and accountability to Government, Parliament and the public. Board members bring a wide range of experience, skills and perspectives to the Board. Together, they set the strategic direction of the organisation and ensure there is robust and open debate during Board deliberations.

    b. Matters relating to quality and specifically patient safety are reported to the Board (through the structures described below at d) and discussed as appropriate at each Board meeting).

    c. The NHS England Board is supported in its operation by committees which undertake detailed scrutiny in their respective areas of responsibility and provide the Board with regular reporting and assurance. They are led by non-executive directors (as Chairs) and include a dedicated quality committee, which is currently constituted as the Quality Committee. Further committees and groups report to this, notably the Quality and Performance Committee and the Executive Quality Group.

d. NHS England's Regional (and previously, Area) structures support this focus on quality, with equivalent governance processes and structures in place and reporting arrangements to enable appropriate escalation to the national structures, principally via the Executive Quality Group. This is covered further in Part A Section 2.

219. For a period between 1 April 2016[8] and 1 July 2022, the NHS Trust Development Authority was directed to perform part of NHS England's statutory role in relation to the NRLS. Following the disestablishment of the Trust Development Authority and transfer of its functions to NHS England, these duties reverted back to NHS England and are performed by the National Patient Safety Team, which is overseen by the National Director of Patient Safety.

(c) Patient safety incident investigation and management policies

220. There were two principal systems setting out expectations for how the NHS should identify and manage certain significant patient safety incidents and other defined 'serious incidents', and some changes to their underlying guidance:

a. 2010-2013: the "National Framework for Reporting and Learning from Serious Incidents Requiring Investigation", published in 2010 by the National Patient Safety Agency [**Exhibit DB/024**]; and

b. the "Serious Incident Framework", first published in 2013 by NHS England (2013–2015) [**Exhibit DB/025**] and refreshed in 2015 (2015–2023) [**Exhibit DB/026**].

221. In 2022, a new policy for incident management was announced when NHS England published the Patient Safety Incident Response Framework ("PSIRF") **[Exhibit DB/027]**. Some "early adopters" across the country had implemented requirements of this policy beforehand in order that their experience would assist to inform the national roll out in 2022 **[Exhibit DB/028]**.

222. The PSIRF replaced the 2015 Serious Incident Framework. The PSIRF is one of the key initiatives under the Patient Safety Strategy. It sets out the NHS's approach to

[8] See paragraph 2 of The National Health Service Trust Development Authority (Directions and Miscellaneous Amendments etc.) Regulations 2016.

developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

223. Compliance with the PSIRF is a contractual requirement under the NHS Standard Contract. As such, it is mandatory for all services provided under that contract. The rationale for incorporating PSIRF as a contractual requirement is to emphasise and support the development and maintenance of an effective patient safety incident response system. PSIRF is described in further detail below.

(d) Patient safety incident reporting

224. Patient Safety Incidents are defined as ‘’any unexpected or unintended event occurring in healthcare that could have, or did, lead to harm to one or more patients’’. It is worth noting that this definition effectively excludes deliberate or intended harmful actions, wilful or malicious neglect and similar. These issues are the concern of the police and safeguarding leads and policies.

225. ‘Seven Steps to Patient Safety’, first published by the National Patient Safety Agency in 2004, highlighted as one of its seven steps the importance of ‘promoting reporting’ by providers. This coincided with the launch of the NRLS as a single national database to collect patient safety incident records from organisations across the NHS.

226. When introduced, national patient safety incident reporting was entirely voluntary, recognising that patient safety incident reporting is an inherently human activity that is influenced by a range of factors within the complex sociotechnical system that is healthcare (see discussion below). That position has changed over time and now providers have a statutory responsibility to notify CQC about a specified set of patient safety incidents (amongst other things).

227. Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 requires providers to notify CQC of the deaths of service users where the death ‘’cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care and treatment’’. This is the equivalent of a patient safety incident that has led to a patient’s death.

228. Regulation 18 of the Care Quality Commission (Registration) Regulations 2009 requires providers to notify CQC of ‘injuries’ to service users that are permanent, cause prolonged pain or prolonged psychological harm, or require action to be taken to

prevent death of the service user. This is the equivalent of a patient safety incident that has led to 'severe' (i.e. permanent) harm.

229. For both Regulation 16 and 18, NHS trusts are able to comply with the requirement to notify the CQC by reporting the incident to the NRLS or LFPSE, because all this information is shared with the CQC. This removes potential duplication of reporting, but also effectively mandates the reporting of patient safety incidents causing severe harm and death in NHS Trusts and Foundation Trusts to NRLS or LFPSE.

230. While the PSIRF no longer distinguishes between serious incidents and other patient safety incidents, the 'threshold' for reporting in the Care Quality Commission (Registration) Regulations do not require incidents to be reported which do not meet the thresholds of Regulation 16 or 18 (as above).

231. Patient Safety Incidents thought to have led to lower levels of harm (no harm, low harm or moderate harm) do not have to be reported to any national body, but each represents an opportunity for learning and improvement, locally and nationally, so reporting is always encouraged.

232. In the case of both Regulation 16 and 18, the test involves the "reasonable opinion of the registered person" in deciding whether or not a report should be made. Determining when an incident has occurred, the extent to which that incident has caused harm, and the level of harm caused, are all judgements.

(e) Patient safety incident reporting tools

233. The following three patient safety incident reporting tools have been used during the Relevant Period to record patient safety incidents. Each tool is reliant on individuals reporting information onto it and this then informs the analysis and monitoring each tool enables.

    a. **The National Reporting and Learning System** (NRLS), which was created in 2003 to identify themes and support patient safety, with both mandatory and voluntary elements. Patient safety incidents are defined as "any unexpected or unintended event occurring in healthcare that could have, or did, lead to harm to one or more patients". The aim of the tool is to identify rare, unusual and emerging risks that might happen multiple times a year across the whole of the NHS, and to share learning across the system via patient safety alerts. It is not

intended as an oversight tool for regulation or as a means of identifying local safety issues.

b. **The Strategic Executive Information System**, which was primarily used as a mechanism for NHS provider Trusts to notify regional and national health bodies about incidents that met the definition of a 'Serious Incident'. Serious Incidents include "Never Events", which are a specific type of serious incident and which are listed by NHS England in guidance that is regularly updated (the list for 2015/2016 is at **[Exhibit DB/029]**).

c. **Learn From Patient Safety Events Service.** This is a new national NHS service for the recording and analysis of patient safety events that occur in healthcare, to replace both the NRLS and Strategic Executive Information System.

234. Both the NRLS and LFPSE services operate as 'secondary use' services, as both collate information already recorded on Trusts' 'local risk management systems'. These are IT systems supplied by and purchased from commercial vendors and include brand names such as 'Datix' and 'Ulysses'. Patient safety incidents are recorded on local risk management systems, which are then used by Trusts to manage the response to those incidents. LFPSE and NRLS collate those records into a national database.

(f) Benefits and challenges of incident reporting

235. Recording patient safety incidents is critical for identifying opportunities to improve the safety of healthcare. It is a core foundation of patient safety work and described by the World Health Organisation as 'key to improving patient safety'. The NHS's national approach to patient safety incident reporting and learning has saved thousands of lives, prevented tens of thousands of incidents leading to severe harm and saved hundreds of millions of pounds in care costs.

236. The commonly held mental model of a patient safety incident is that of a single identifiable event where healthcare deviated from what was expected or intended and led directly to a detrimental outcome for a patient. These events do happen, but they are not the most common mechanism of harm.

237. The majority of harm in healthcare is caused by multiple, lower-level instances of suboptimal care that accumulate, particularly in the case of individuals with complex conditions or multiple co-morbidities, which contribute to outcomes that are worse than

might have been expected if care was optimal. These complex ‘incidents’ present challenges in terms of incident identification, classification, analysis and risk reduction.

238. Determining when an incident has occurred, the extent to which that incident has caused harm, and the level of harm caused, are all judgements. While some cases are clearly incidents meeting the definition provided earlier, many will sit in the grey areas where it is possible for two or more people to have sincerely held but different opinions about an incident or its outcome.

239. As well as what is reported, there will be variation in how something is reported and the amount of, and veracity of, the detail provided in an incident report. Some of this will relate to opinion, but beyond this, there are a variety of other influences on incident reporting. These include beliefs and culture, with different groups of people having been taught, or having grown to believe that, certain events are, or are not, patient safety incidents. This will influence what they report and in what detail. Similarly, the culture of an organisation or team will also impact on what people report and how. Where reporters see that improvement action is taken in response to an incident and where openness is encouraged, reporting will be more effective and detailed. Conversely, a culture that disincentivises reporting, perhaps by not welcoming challenge, will lead to fewer incident reports. While all incident records received nationally are anonymised, local records will include information that identifies staff and patients. While this is important for local risk management, it does create the requirement for much more careful handling to avoid risks to the psychological safety of those involved.

240. These and other factors mean that while patient safety incident reporting can provide critical information about risks and how to mitigate them, incident reporting alone cannot be used to measure the safety of healthcare or as a perfect record of everything that has happened, or at a national level, to determine exactly who was involved.

(g) Patient safety incident response

241. The above parts have addressed the reporting of concerns raised by NHS workers and by service users. We now describe the PSIRF and the expected improvements this will enable in patient safety response and learning.

242. By way of brief background, concerns about the effectiveness of the previous Serious Incident frameworks have been raised by previous inquiries, investigations and

reviews into the NHS or specific NHS organisations, including the Government response to the Freedom to Speak Up Consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation.

243. In the period 2015-2016 a number of specific reports brought this issue to the fore. These reports included:

    a. the Public Administration Select Committee report in March 2015 on investigating clinical incidents in the NHS;

    b. the Government of the time's response "Learning not Blaming" to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation in July 2015;

    c. the Parliamentary and Health Service Ombudsman's report on complaints investigations related to harm in December 2015;

    d. the CQC's report on learning from Serious Incidents in acute hospitals in June 2016; and

    e. the CQC's Learning, Candour and Accountability report in December 2016.

244. In response to these reports, in March 2018 NHS Improvement launched an engagement programme around the future of NHS patient safety investigation to gather thoughts and feedback to support the development of a new approach **[Exhibit DB/030]**. A summary of that work was published in November 2018 **[Exhibit DB/031]**.

245. At the same time the National Patient Safety Team launched a consultation on developing the NHS's first overarching Patient Safety Strategy **[Exhibit DB/032]**. This work, in combination with the engagement exercise on the future of NHS patient safety investigation, led to the commitment in the new NHS Patient Safety Strategy published in July 2019 to create a new 'Patient Safety Incident Response Framework' (the PSIRF).

246. A draft 'introductory' version of the PSIRF was published in March 2020 and tested by 24 'early adopters', including 17 provider organisations alongside their commissioning bodies. The early adopter programme was independently evaluated, with the learning

from this process informing the development of the PSIRF published in 2022 alongside a 12-month preparation guide.

247. Implementation of the PSIRF is required by the NHS Standard Contract and organisations were expected to implement the PSIRF in the Autumn of 2023.

248. The new PSIRF has four key aims:

    a. Compassionate engagement and involvement of those affected by patient safety incidents;

    b. Application of a range of system-based approaches to learning from patient safety incidents;

    c. Considered and proportionate responses to patient safety incidents; and

    d. Supportive oversight focused on strengthening response system functioning and improvement.

249. Unlike the predecessor Serious Incident Framework 2015, the PSIRF makes no distinction between 'patient safety incidents' and 'Serious Incidents'. Instead, the PSIRF promotes a proportionate approach to responding to patient safety incidents.

250. Organisations are required to develop a thorough understanding of their patient safety incident profile, ongoing safety actions (in response to recommendations from investigations and elsewhere, for example) and established improvement programmes, and to use that information to inform what the organisation's proportionate response to patient safety incidents should be.

251. The organisation's understanding of their patient safety incident profile should then be used alongside effective stakeholder engagement, including with patients and the public, to create a Patient Safety Incident Response Plan. This Plan is then used to guide how the organisation responds to individual incidents. NHS England has published a template Incident Response Plan as part of the core materials to support the PSIRF. This suite of guidance documents relating to the PSIRF is provided with this statement **[Exhibit DB/033] [Exhibit DB/034] [Exhibit DB/035] [Exhibit DB/036] [Exhibit DB/037] [Exhibit DB/038] [Exhibit DB/039]**.

252. The PSIRF emphasises the central importance of engagement and involvement with families. Under the PSIRF, there is greater engagement with those affected by an

incident, including patients, families and staff, ensuring they are treated with compassion and are able to be part of any investigation.

253. The ‘Guide to engaging and involving patients, families and staff following a patient safety incident’, **[Exhibit DB/033]** published alongside the PSIRF, sets out expectations for how organisations should engage with all those affected by patient safety incidents. Organisations should work hard to answer any questions and to involve those affected in patient safety incident investigations. Put simply, involvement should begin from the point at which an incident is identified and throughout any investigation, in so far as the patient/family wish to be involved. It should also extend beyond the close of any investigation if the patient/family wish to be involved in ongoing improvement work.

254. Work is underway to explore how to support patients’ ability to input their experiences of safety events to support learning. At present, this may come through local or national complaints, online feedback, Patient Advice Liaison Services, or direct to the national safety team. A discovery phase has been completed to explore the best way for patients to record their experiences, the output from which was published in October 2023 **[Exhibit DB/040]**. This report recommends that future additions to the Learn From Patient Safety Event service should be designed to enable local response to, and management of, any safety issues raised, alongside feeding relevant data into the national team as part of their surveillance work and the continuation of the ability for anonymous reporting by patients and families if they so choose.

(4) National Quality Board and System Quality Groups

255. The National Quality Board was established in 2009 as the single forum where national bodies with some responsibility for quality of care came together to provide strategic oversight and leadership on quality across the whole system.

256. It acts as an important forum to align and develop quality policy and governance as well as providing advice, recommendations and endorsements on matters relating to quality, aiming to support delivery of the NHS Long Term Plan's ambition for quality in the NHS. Recently this has included publishing a set of key principles to support assessment and management of risks across integrated care systems. It organises discussions around six themes:

    a. supporting system transformation;

b. digital transformation;

c. research and innovation;

d. support for the health and social care workforce;

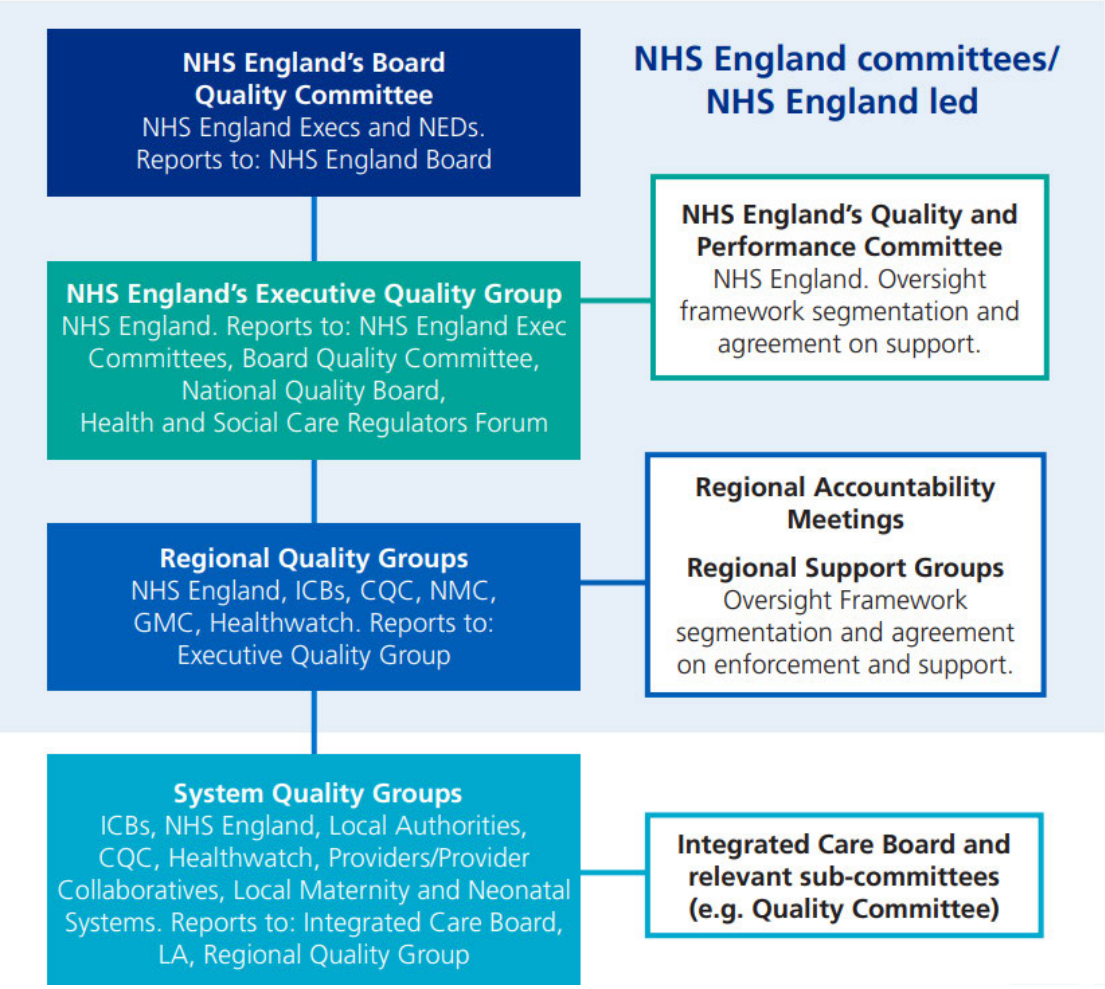
e. patient safety; and

f. improving population health and health inequalities.

257. The National Quality Board is jointly chaired by NHS England's National Medical Director and the CQC's Chief Inspector of Hospitals. Membership is made up of senior clinical and professional leaders from the NHS and partner organisations, alongside patient and public representatives **[Exhibit DB/041]**.

258. Since its establishment, the National Quality Board has played an important role in publishing advice and guidance on key quality areas and quality governance structures affecting the wider health and care system. Some examples include, guidance System Quality Groups (previously known as Quality Surveillance Groups), Risk escalation and response for ICS, safe staffing guides, guidance on learning from death and principles for patient recall framework. These structures and some of the key guidance documents are described in more detail below from paragraph 272.

259. The diagram below provides a simplified overview of the quality governance structure within NHS England following the implementation of the 2022 Act.



(5) The Care Quality Commission

260. Under section 290 of the 2012 Act, the CQC and NHS England were given duties to cooperate with each other in the exercise of their respective functions.

261. In January 2013, following the 2012 reforms taking effect, NHS England and the CQC signed a Partnership Agreement **[Exhibit DB/042]** to set an initial framework for the strategic working relationship between the two organisations.

262. The Partnership Agreement recognised the respective roles of the two organisations; the CQC being the independent regulator of health and social care providers in England, which protects and promotes the health, safety and welfare of people who use health and social care service, and the NHS Commissioning Board in its role of ensuring that the NHS delivers continuous improvements in outcomes for patients within resources available.

263. The Partnership Agreement reflected the shared fundamental goal of the two organisations of working in a way which supported and promoted the delivery of safe and good quality care for the public. It set out three initial priorities with a view to achieving that goal:

    a. Establishing information sharing arrangements, to ensure proactive sharing of information and intelligence about the quality of care in order to spot potential problems early and manage risk;

    b. Implementing the mechanisms which had been proposed by the National Quality Board in its document "Quality in the new health system: Maintaining and improving quality from April 2013" (January 2013) **[Exhibit DB/043**], on how the healthcare system should prevent, identify and respond to serious failures in quality; and

    c. Establishing ways for the two organisations to work together at a local and regional level, with wider stakeholders, and in light of the National Quality Board's proposals to establish regional Quality Surveillance Groups.

264. The Partnership Agreement established that there would be an annual meeting of the boards of both organisations, including Chairs and Chief Executives, in order to set joint strategic priorities. More frequent (e.g. quarterly) meetings of lead officials were then held with a focus on delivery and allocation of respective resources.

265. Alongside the Partnership Agreement, there are other particular arrangements for the two organisations to work together.

266. NHS England and the CQC have a longstanding shared commitment to establish and refine an operating model for quality governance. One of the key aspects of this model was the establishment of Quality Surveillance Groups, which have (as of 1 July 2022) been replaced by System Quality Groups. Both structures are described further below.

(a) The inspections conducted by the Care Quality Commission

267. The context around the role of the CQC is important because it is the body within the regulatory system that has primary statutory responsibility for carrying out regular site visits and on-the-ground inspections of care delivery. These inspections look at, amongst other things: whether regulated providers have appropriate staffing arrangements in place, both in terms of capacity and capability; whether clinical governance systems and processes are appropriate and effective; whether patients

feel well cared for; and how incidents (including but not limited to patient safety incidents) are identified and learned from.

268. As a result of the on-the-ground nature of the CQC's inspections, other regulatory bodies such as NHS England and its Legacy Bodies placed — and continue to place — considerable reliance on its assessments. Whilst NHS England and NHS Improvement had inspection rights under the Standard Contract and Provider Licence, these were rarely exercised unless there were significant concerns about the quality and safety of the services commissioned (for example, where there were concerns around staffing levels or the cleanliness of the facilities).

(6) Joint Strategic Oversight Group

269. The Joint Strategic Oversight Group was established in May 2017 and continues in operation at the present day. It provides a national forum for intelligence sharing among national partners, including the GMC, the NMC and the CQC.

270. In the period prior to July 2022, the Joint Strategic Oversight Group ("JSOG") also included representatives from the Legacy Bodies, including NHS Improvement (Monitor and the NHS Trust Development Authority) and Health Education England.

271. The JSOG meets on a bi-monthly basis and its purpose is to:

    a. develop and agree an aligned and consistent approach to joint working to ensure timely and appropriate intervention and support for trusts in special measures for quality reasons and for challenged trusts; and

    b. exchange learning, intelligence and information to aid future improvement, particularly in providing support and interventions for trusts with significant quality issues.

(7) Quality Surveillance Groups

272. Quality Surveillance Groups were a crucial means of facilitating NHS England's engagement with the CQC and other regulators, including the GMC and the NMC.

273. The background to Quality Surveillance Groups was published in the report 'Quality in the new health systems — maintaining and improving quality from April 2013' (published January 2013) **[Exhibit DB/043]**. The report recognised the need for collaboration across commissioning, regulation and performance monitoring in pursuit

of a shared commitment to quality, whilst confirming that individual organisations should retain their distinct responsibilities.

274. The report introduced Quality Surveillance Groups as “a new approach for supporting collaboration across the system and facilitating the sharing of information and intelligence on quality” and sought to ensure “a clear and agreed approach to taking swift and coordinated system-wide action in the event of a serious quality failure being identified, in order to rapidly protect patients and service users”.

275. The model for Quality Surveillance Groups was to operate at both regional and area team footprint. Detailed guidance on the establishment of Quality Surveillance Groups was published alongside the report in January 2013 **[Exhibit DB/044]** and there have been various iterations since.

276. Local Quality Surveillance Groups were described in these documents as the “backbone of the network” of bodies concerned with quality matters. This is because they were closest to the detail and most aware of concerns, and because they facilitated taking coordinated action to mitigate quality failures. These local groups were facilitated and chaired by the NHS England area leads, but their membership included representatives from the CQC and wider stakeholders (CCGs, Healthwatch, Local Authorities and others).

277. The regional Quality Surveillance Groups were then a point of escalation for the local groups to “assimilate risks and concerns from local QSGs, identifying common or recurring issues that would merit a regional or national response”. Again, regional Quality Surveillance Groups were chaired by relevant regional NHS England directors and had representation from the CQC. At the regional level, Quality Surveillance Groups were required to include representation from the GMC and the NMC to secure their routine involvement.

278. The role of Quality Surveillance Groups was described from the outset as being proactive forums for collaboration, providing the health economy with:

    a. a shared view of risks to quality through sharing intelligence;

    b. an early warning mechanism of risk about poor quality; and

    c. opportunities to coordinate actions to drive improvement, respecting statutory responsibilities of and ongoing operational liaison between organisations.

279. Once a concern was identified by a Quality Surveillance Group, it was for organisations to take relevant actions depending on their statutory functions, such as: contractual action (by commissioners), regulatory/enforcement action, or improvement support.

280. As described in the National Quality Board's report which established these groups, NHS England in its role as commissioner of certain services could raise matters with the CQC through these groups. It would do so where it had concerns about whether providers were meeting the essential standards of quality, including safety. Similarly, NHS England could raise matters with the professional regulators (the GMC and the NMC) through the groups if there were issues relating to regulated professionals.

281. In turn, the CQC was able to share information and intelligence about providers through these groups with other parts of the system, including NHS England, as relevant to its role around quality. The professional regulators would also use Quality Surveillance Groups to share information and intelligence they had that related to wider system or organisational problems. This would include, for example, information arising from investigations of individual practitioners, or in relation to the regulator's roles relating to education and training of practitioners.

(8) System Quality Groups

282. In January 2022, the National Quality Board replaced the guidance on Quality Surveillance Groups and Risk Summits with a new operating model for quality governance **[Exhibit DB/045]**. This was part of preparing for the 2022 reforms to take effect, and for the transition to formal ICS working. Further guidance was issued in June 2022 by the National Quality Board on Quality Risk Response and Escalation in ICSs **[Exhibit DB/046]**.

283. As a result, all ICSs are expected to have a System Quality Group, with the National Quality Board setting the expectations for quality governance in ICSs. As was the case with Quality Surveillance Groups, System Quality Groups are not statutory bodies and do not act as a substitute for each statutory body's own internal quality arrangements to ensure compliance with their statutory duties.

284. The updated model retains the regional quality structures (now known as Regional Quality Groups), which are chaired and facilitated by NHS England's regional teams. The regional groups continue to include representation from the CQC and the

professional regulators (and others, such as local authorities and the Health Service Ombudsman). They have two principal objectives:

a. maintaining and safeguarding quality; and

b. supporting and enabling improvement.

285. NHS guidance states that the minimum requirements for System Quality Group members include: the ICB; local authorities; provider collaboratives; regional NHS England and NHS Improvement teams; regulators (CQC and Health Education England); primary care; local maternity systems; patient safety specialists; and at least two lay members with lived experience. System Quality Groups must meet at least quarterly and are chaired by ICB executive quality leads.

286. System Quality Groups will have the full range of health and care services and providers of the ICS within their remit, including services commissioned by the NHS jointly with local authorities or by local authorities. System Quality Groups should provide a forum for engagement, intelligence sharing, learning and quality improvement across the ICS. The actions System Quality Groups take will vary, depending on the individual statutory responsibilities of the members. They may include, for example, improvement support, performance management, contractual action, regulatory or enforcement action.

(9) Emerging Concerns Protocol

287. Importantly, in relation to emerging concerns and the involvement of professional regulators, it should also be noted that the CQC, and others concerned with quality and safety and public protection, have developed an Emerging Concerns Protocol (the "Protocol").

288. The Protocol was first published in 2018, having arisen as an action following a forum convened by a meeting of system regulators and professional regulators in October 2016. Professional regulators (such as the GMC and the NMC), the Local Government and Social Care Ombudsman, Health Education England, and the Parliamentary Health Standards Ombudsman) are signatories to the Protocol.

289. The Protocol sits alongside other specific arrangements which the CQC has with individual signatories, such as the GMC/CQC Joint Working Group, NMC/CQC Joint Working Group and memoranda of understanding. Its purpose is to provide a clearly

defined mechanism “for organisations which have a role in the quality and safety of care provision, to share information that may indicate risks to people who use services, their carers, families or professionals”. It aims to facilitate earlier sharing of concerns and identifies three categories that such concerns may fall into:

a. concerns about individual or groups of professionals;

b. concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); and

c. concerns that might have an impact on trust and confidence in professionals or the professions overall.

290. The Protocol sets out underpinning principles and a process for how concerns should be raised with respective bodies, and what information should be shared between them and when. For example, it explains the nature of concerns that the respective professional regulators would like to be informed about (including concerns about individual professionals' fitness to practise) and summarises their key activities and responsibilities.

291. Where an organisation initiates a concern under the Protocol, it contacts other relevant partners (which may be some or all of the signatories) and arranges for a Regulatory Review Panel to be convened to facilitate shared consideration of the concern and coordinated intervention.

292. A Regulatory Review Panel is an opportunity for regulatory partners to collaborate and discuss how best to use their respective regulatory powers. Meetings of a Regulatory Review Panel are to be attended by individuals within organisations who have the delegated authority to take relevant decisions. It will be decided during the meetings whether no action needs to be taken, whether further investigation is needed and/or whether regulatory action is required. In the latter case, the organisations will decide which body or bodies should take such action and when, including whether coordinated action is needed.

293. As explained in the protocol, NHS England is not a signatory, but it expressly supports its use, agrees strongly with its principles and it has sought to align the National Quality Board guidance on quality surveillance with it.

294. As noted in the Protocol, and in practice, a Regulatory Review Panel may decide that matters relevant to such emerging concerns need to be referred to the Quality

Surveillance Groups (which would now be understood as the equivalent structures under the post-July 2022 landscape, e.g. System Quality Groups). Model terms of reference for the current System Quality Groups require these groups to work in close partnership with professional and system regulators, including sharing and considering intelligence gathered through the Emerging Concerns Protocol processes.

(10) Healthcare Safety Investigation Branch/The Health Services Safety Investigations Body

295. The House of Commons Public Administration Select Committee, in its March 2015 report "Investigating Clinical Incidents in the NHS", recommended the establishment of a new body to conduct some patient safety investigations.

296. In response, the Department of Health report "Learning not blaming…" (July 2015) committed to establishing an independent patient safety investigation function. An Expert Advisory Group was tasked by the Secretary of State to advise on the establishment of the function and provide advice on the purpose, role and operation of a new body, which it did in its Report of the Expert Advisory Group: Healthcare Safety Investigation Branch (May 2016) **[Exhibit DB/047]**. The Chair of the Expert Advisory Group was Dr Mike Durkin, who at the time was Director of Patient Safety at NHS England.

297. Following the above, the Healthcare Safety Investigation Branch was established pursuant to the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 ("the Healthcare Safety Investigation Branch Directions"). These directions required the NHS Trust Development Authority to establish the Healthcare Safety Investigation Branch as an independent division responsible for investigating patient safety incidents in the NHS in England. The Healthcare Safety Investigation Branch became operational in April 2017.

298. Although the Healthcare Safety Investigation Branch was hosted by the NHS Trust Development Authority, it was operationally independent for funding and employment purposes. The NHS Trust Development Authority had specific obligations under the Healthcare Safety Investigation Branch Directions to take reasonable steps to protect the independence of the Healthcare Safety Investigation Branch from the other activities of the NHS Trust Development Authority. As part of discharging this duty, the NHS Trust Development Authority established an independent advisory group. This independent advisory group provided external input and advice to the investigations

carried out by the Chief Investigator and their staff. Its independence was emphasised by its reporting and accountability obligations, with the Healthcare Safety Investigation Branch reporting directly to the Secretary of State and being accountable to Parliament through the DHSC.

299. The purpose of the Healthcare Safety Investigation Branch was to conduct independent investigations into patient safety incidents in the NHS in England. The Healthcare Safety Investigation Branch was responsible for investigating incidents or accidents, which in the view of the Chief Investigator evidenced (or likely evidenced) risks affecting patient safety, and for making recommendations to improve patient safety across the NHS. 'Risks affecting patient safety' included, but were not limited to risks:

    a. resulting in repeated, preventable or common occurrences of safety risks or harm to patients;

    b. indicating a systemic problem with significant impact in more than one setting; or

    c. involving new or novel forms of harm, or new or novel risks of harm.

300. The Healthcare Safety Investigation Branch was also responsible for promoting a culture of learning and improvement within the NHS, and for sharing best practice and lessons learned from its investigations.

301. The Healthcare Safety Investigation Branch was run operationally by a Chief Investigator. The Chief Investigator was appointed by the NHS Trust Development Authority, but only with the approval of the Secretary of State. The role of the Chief Investigator was to develop and publish investigation principles to govern investigations carried out by the Healthcare Safety Investigation Branch, identify incidents or accidents for investigation, oversee those investigations and ensure that the Healthcare Safety Investigation Branch was meeting its objectives. The Chief Investigator was supported by a team of investigators and other staff members.

302. During 2015, it was recommended[9] that the Healthcare Safety Investigation Branch should be established in primary legislation to secure its independence and safeguard the principles protecting information from its investigations from disclosure. In

[9] By the Public Administration Select Committee, in their report 'Investigating Clinical Incidents in the NHS', published on 24 March 2015.

response, the Government published a draft Bill[10] in September 2017, which was scrutinised by Parliament in 2018 and 2019. The Bill proposed the establishment of the Health Services Safety Investigation Body, which would be named to distinguish it from the Healthcare Safety Investigation Branch that it would replace.

303. Ultimately, rather than the Bill, the vehicle for establishing the new Health Services Safety Investigation Body was the 2022 Act, and the Health Services Safety Investigation Branch was established on 1 October 2023. As described in the DHSC Policy Paper on the Health Services Safety Investigation Branch (March 2022), the Health Services Safety Investigation Branch was to be established on an independent statutory footing, with independence as a "crucial way of ensuring that patients, families and staff have trust in its processes and judgements".

304. In the intervening period between the NHS Trust Development Authority being abolished on 1 July 2022, with its functions transferring to NHS England, and 1 October 2023 when the Health Services Safety Investigation Branch was established, transitional arrangements were implemented to enable the Healthcare Safety Investigation Branch to continue its investigations and activities. To cover this transitional period, the Secretary of State made directions on 1 July 2022, which established the Healthcare Safety Investigation Branch as a division of NHS England.

305. As was the case in the earlier 2016 Healthcare Safety Investigation Branch Directions, the 2022 Healthcare Safety Investigation Branch Directions required NHS England to maintain and protect the Healthcare Safety Investigation Branch's independence and, to support this, further required NHS England to establish a group of independent advisors to meet with the Chief Investigator to ensure the independence of reports. The 2022 Healthcare Safety Investigation Branch Directions also placed a duty on the Chief Investigator to report to NHS England on matters relating to budget, staffing and administrative efficiency, but report to the Secretary of State in relation to the performance of functions by the Healthcare Safety Investigation Branch. NHS England was responsible for paying the Healthcare Safety Investigation Branch its annual budget allocation, after providing these figures to the Secretary of State.

306. As noted above, the Health Services Safety Investigation Branch was established on 1 October 2023 and, as a result, the transitional arrangements relating to the

[10] Health Service Safety Investigations Bill.

Healthcare Safety Investigation Branch came to an end. The Health Services Safety Investigation Branch is a fully independent arm's-length body of the DHSC and is no longer hosted in any way by NHS England.

307. Part 4 of the 2022 Act is now in force and makes provision for the new body, its constitution and its procedures. I would note the following, in particular:

a. The Health Services Safety Investigation Branch has the function of investigating "qualifying incidents," which are incidents that occur during the provision of healthcare services and have, or may have, implications for the safety of patients.

b. The Health Services Safety Investigation Branch must determine and publish the criteria it will use to determine the incidents it will investigate, the principles that will govern investigations, the processes that will be followed in carrying out investigations, and the processes for ensuring that, so far as reasonable and practicable, patients and their families are involved in investigations.

c. The purpose of the Health Services Safety Investigation Branch's investigations is to identify risks to the safety of patients and address those risks, by facilitating the improvement of systems and practices in the provision of healthcare services.

d. The Health Services Safety Investigation Branch may investigate such incidents that occur during the provision of healthcare services in any setting in England, including in the NHS or in the independent sector.

308. It should be noted that HSIB/HSSIB undertake a very small number of patient safety investigations each year in the context of wider NHS activity. Depending on the period, HSIB/HSSIB has conducted up to 30 investigations per year. By contrast there are around 80 NHS England commissioned patient safety incident investigations ongoing at any one time. ICBs will commission or conduct 100-200 investigations per year. Providers undertake up to an estimated 3000 investigations per year under the PSIRF. Overall, there are more than 2.5 million patient safety incidents recorded each year in the NHS. The vast majority involve no harm and are not investigated. Patient safety incident investigations are discussed in more detail below.

(11) NHS England investigations into patient safety

309. Investigations are one of the patient safety learning response methods endorsed in the PSIRF **[Exhibit DB/048]**.

310. NHS England's policy is that investigations are best led as close to the care being investigated as possible, while ensuring appropriate objectivity and independence. This means the vast majority of patient safety incident investigations are conducted by providers.

311. NHS England has the power to undertake patient safety incident investigations directly, although to the best of our knowledge it has not exercised this power to date. NHS England typically commissions investigations rather than conducting its own. It will normally do this at regional level, and more rarely at national level, and only when it is considered more appropriate for NHS England to do this than the investigation being commissioned/conducted at ICB or provider level.

312. NHS England can be made aware of patient safety incident investigations at local level in different ways. If the investigation is undertaken in NHS-funded secondary care, then the mechanism by which providers should record that they are undertaking a patient safety incident investigation will depend on whether the provider in question is using a local risk management system (LRMS) compatible with the latest version of the Learn from Patient Safety Events (LFPSE) service. If they are working with an LRMS only compatible with version 5 of LFPSE, they should use StEIS to record those incidents selected for patient safety incident investigation. If they are working with an LRMS compatible with version 6 of LFPSE, they should use the PSIRF fields within their LRMS to capture incident responses. Any provider using the LFPSE online service should use the PSIRF fields within the LFPSE online service to record their incident responses.

313. NHS England regional teams and the national patient safety team have access to information recorded in StEIS and LFPSE. However, that does not mean NHS England regional teams would be 'aware' of every incident subject to investigation. As noted earlier, there are millions of incidents reported every year and thousands of NHS-led investigations, and there is no expectation that NHS England is involved in, oversees, or reviews the investigations conducted by NHS providers.

314. Regional teams may set local policies or expectations that they are notified directly (e.g. via email or telephone call) about certain events that may be subject to patient

safety incident investigation. There are national expectations set out in PSIRF that describe a small number of circumstances where we would expect NHS England regional teams to be informed about incidents, principally in relation to mental health related homicides. When those occur, we expect the regional team to be notified so that the NHS England regional independent investigation team can consider if an independent patient safety incident investigation is required. Regional independent investigation teams can support/be involved in the response to other incidents as well.

315. In some circumstances it may be necessary for incidents to be escalated, firstly to ICBs and then, if still necessary, to NHS England. Typically, this escalation may be appropriate when:

    a. an organisation is too small (i.e. does not have the workforce) to provide an objective response and analysis;

    b. an investigation independent of the provider is deemed necessary to ensure public confidence in the investigation integrity;

    c. a multi-agency incident occurs, and no single provider is the clear lead for an investigation; or

    d. the incident(s) represent significant learning potential for the wider system (regional or national).

(a) Investigations into homicides

316. In April 2013, NHS England became responsible for commissioning independent investigations into homicides that are committed by patients being treated for mental illness (sometimes referred to as mental health homicide reviews). As noted earlier, independent investigations are the exception rather than the rule. Most investigations are provider led, but in some circumstances, including with many mental health homicides, it is considered appropriate for NHS England to commission an independent patient safety investigation. Previously, these were commissioned by Strategic Health Authorities, which were abolished in 2013. NHS England oversees the commissioning of independent investigations via its Regional Independent Investigation Teams.

317. The purpose of an independent patient safety investigation is to capture insight to inform improvement through investigation and exploration of the care, treatment and

healthcare systems and processes for one or more patients at any level of the healthcare system. They support the NHS to:

a. Be open and transparent about what happened and how it happened;

b. Identify areas for improvement to reduce the possibility of a reoccurrence of similar events; and

c. Make recommendations for the improved delivery of health services in the future which can then be acted upon by relevant organisations with the power to make appropriate changes.

(12) Independent scrutiny

(a) The Medical Examiner System

318. In June 2018, the DHSC published its response to a consultation on plans for reform of the death certification system in England and Wales and the approach to introduce a medical examiner system nationally, and initially on a non-statutory basis, from April 2019.

319. In June 2022, the government announced that it intended to implement the statutory medical examiner plan from April 2023, using the relevant provisions from the Coroners and Justice Act 2009 (as amended by the 2022 Act). NHS England sent another letter to NHS healthcare providers and ICBs in July 2022, setting out what local health systems needed to do to prepare for the statutory system. Acute Trusts were asked to ensure that medical examiner offices based at their Trusts had adequate workforce and support in processing patient records from other healthcare providers.

320. Specialist, mental health and community trusts and GP practices were asked to work with established medical examiner offices to make plans for how deaths of their patients could be scrutinised, with each organisation being required to work with one established medical examiner office. ICSs and CCGs were asked to facilitate partnership working across systems **[Exhibit DB/049]**.

321. The role of the national medical examiner is to provide professional and strategic leadership to regional and trust-based medical examiners. The role supports medical examiners in providing better safeguards for the public, patient safety monitoring, and informs the wider learning from deaths agenda.

322. Each NHS region has a regional medical examiner and a regional medical examiner officer to support medical examiner offices. Regional medical examiners oversee the provision of services and provide an independent line of advice and accountability for medical examiners at trusts in their region.

323. The purpose of the medical examiner system is to:

    a. provide greater safeguards for the public by ensuring independent scrutiny of all non-coronial deaths;

    b. ensure the appropriate direction of deaths to the coroner;

    c. provide a better service for the bereaved and an opportunity for them to raise any concerns to a doctor not involved in the care of the deceased;

    d. improve the quality of death certification; and

    e. improve the quality of mortality data.

324. Specifically, in scrutinising deaths, medical examiners:

    a. seek to confirm the proposed cause of death by the medical doctor and the overall accuracy of the medical certificate of cause of death;

    b. discuss the proposed cause of death with bereaved people and establish if they have questions or any concerns relating to the death;

    c. support appropriate referrals to senior coroners; and

    d. identify cases for further review under local mortality arrangements and contribute to other clinical governance processes.

325. Each medical examiner office in England is required to provide regular submissions to the National Medical Examiner. This includes important information for quality assurance of the medical examiner office, such as the number of cases referred for clinical governance review due to concerns, including deaths in hospitals of people with learning disabilities or severe mental illness, and the number of cases notified to coroners.

326. Since September 2024, all deaths in any health setting that are not investigated by a coroner will be reviewed by NHS medical examiners. This change was part of the

DHSC's Death Certification Reforms under which medical practitioners are now able to complete a medical certificate of cause of death (MCCD) if they attended the deceased in their lifetime. This was a simplification of the previous rules, when cases had to be referred to a coroner if the practitioner had not seen the patient within the 28 days prior to death or had not seen in person the patient after death.

(b) Office of the Chief Coroner

327. In 2019, the Chief Coroner produced guidance around death referrals and Medical Examiners. This guidance confirms that if coroners, based on reports of death, have cause for concern about any possible issues in a hospital (and in due course, in the community), they should raise this with their local medical examiner, or the regional medical examiners (or the National Medical Examiner and the Chief Coroner as appropriate) and agree any action.

328. NHS England and the coronial service also work together in relation to Coronial "Prevention of Future Deaths" ("PFD") reports made under paragraph 7, Schedule 5, Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. A coroner has a duty to issue such a report where they believe that action needs to be taken to prevent future deaths. Whilst the majority of PFD reports are addressed directly to individual organisations (healthcare or otherwise), on occasions where the coroner is concerned that there is a national healthcare issue which needs to be addressed, they will address their PFD report to NHS England or to DHSC (or the Secretary of State for Health), who will often share it with NHS England so that NHS England can input pertinent information into the DHSC's response to the Chief Coroner. Reports concerning national healthcare related issues may also be sent to national organisations such as CQC, NICE, one of the Royal Colleges, or national charities, as well as or instead of NHS England, depending on the issues covered. NHS England may also receive PFD reports in its direct commissioning role.

329. PFD reports relating to deaths in health and social care settings can help to identity what went wrong and the actions needed to prevent a similar incident reoccurring. They also may provide points of learning that are applicable beyond the organisation in which this took place which can inform wider system learning.

PART C: NHS ENGLAND POLICIES AND PROCEDURES

330. This part discusses the guidance NHS England provides NHS Trusts and NHS Foundation Trusts on their policies relating to, amongst other matters, safeguarding, raising concerns, and mental health.

331. The Inquiry has asked about NHS England's expectations around the processes and procedures in place in relation to Trusts investigating concerns or complaints (whether raised by staff or parents) regarding mental health care and for reporting concerns to external bodies.

332. The Inquiry has also asked about the data collected in relation to mental health and the arrangements in place relating to the monitoring and analysis of data and data trends at a local and national level, as well as how systems operate for reporting concerns.

(1) NHS England Policies and Guidance

333. We have been asked to explain how NHS England guidance and policy is made available to providers and commissioners and if notification is given of the publications on the NHS website.

334. NHS England will usually direct guidance and policies to the relevant audience, for example to the ICBs or providers. This is done in conjunction with our national and regional operations centres. Where appropriate, it will be sent direct to the CEOs and/or chairs of the ICB. It may also be cascaded to specific roles within the ICB or provider (for example, chief finance officers, medical directors, chief nurses, chief people officers, etc.), depending on the subject matter.

335. Guidance and policies will usually be cascaded to the relevant audience on the day they are published on the NHS website. However, some guidance may be shared via bulletins instead, for example, in the weekly healthcare leaders bulletin or the mental health, learning disability and autism bulletin.

(2) Addressing concerns raised by patients, carers and others

336. There is a detailed statutory framework that applies in relation to patient and carer complaints. This is supplemented by regulatory and contractual requirements, and by guidance, which includes guidance published by NHS England. All providers of NHS

services and all commissioners, including NHS England in its direct commissioning role, are subject to these requirements. They apply to all complaints, whether or not they are related specifically to mental health services.

337. This framework provides for various stages in relation to complaints, progressing through internal consideration and investigation of complaints to external scrutiny and review. It also requires that each body subject to this framework ensures appropriate governance and oversight of the processes and structures put in place to comply with the requirements. Concerns that do not take the form of a complaint will generally be dealt with informally and many NHS Trusts and NHS Foundation Trusts will have a Patient Advice and Liaison Service ("PALS"), who assist with this more informal aspect.

338. The same fundamental requirements in relation to concerns and complaints apply in relation to all NHS services. These are:

    a. the statutory duties that all providers and commissioners of NHS services are subject to, by virtue of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 ("the 2009 Complaints Regulations");

    b. the rights and pledges contained within the NHS Constitution;

    c. the Parliamentary and Health Service Ombudsman complaints standards; and

    d. the contractual obligations contained within the NHS Standard Contract.

(a) Statutory complaints requirements

339. All providers and commissioners of NHS services are subject to a statutory duty to handle complaints in accordance with the requirements of the 2009 Complaints Regulations. This includes primary care providers and independent sector providers.

340. The 2009 Complaints Regulations place a number of requirements on providers in relation to the handling and consideration of complaints. In summary, by virtue of the 2009 Complaints Regulations, providers must have arrangements in place to ensure the following:

a. Complaints are dealt with efficiently, properly investigated, and that appropriate action is taken in light of the outcome of a complaint[11];

b. The Chief Executive Officer is designated as the Responsible Person (i.e. the person responsible for ensuring compliance with the requirements of the Complaints Regulations and ensuring action is taken in light of a complaint outcome)[12];

c. There is a complaints manager designated, who is responsible for managing the procedures for handling and considering complaints;

d. Complainants are treated with respect and courtesy, receive appropriate assistance to help them make a complaint, receive a timely and appropriate response (including progress updates) and are informed in writing of the outcome of the investigation of their complaint;

e. Written complaint investigation reports must be signed by the Responsible Person and explain how the complaint has been considered, the conclusions reached, any remedial action required, as well as the Trust's view on what action it has taken/it intends to take. The written report must also set out the complainant's right to complain to the Parliamentary and Health Service Ombudsman;

f. Records are maintained of each complaint received, its subject matter and outcome; and

g. An annual report is prepared, which provides an overview of all complaints received in the preceding year, the subject matter and outcomes (with a focus on thematic issues arising).

(b) NHS Constitution

341. These statutory requirements are reflected in the NHS Constitution, which provides as follows in relation to complaints and redress:

"Complaint and redress

[11] Regulation 3(1) and (2) of the 2009 Complaints Regulations.

[12] Regulation 4(2) of the 2009 Complaints Regulations.

Your rights

You have the right to have any complaint you make about NHS services acknowledged within three working days and to have it properly investigated.

You have the right to discuss the manner in which the complaint is to be handled, and to know the period within which the investigation is likely to be completed and the response sent.

You have the right to be kept informed of progress and to know the outcome of any investigation into your complaint, including an explanation of the conclusions and confirmation that any action needed in consequence of the complaint has been taken or is proposed to be taken.

You have the right to take your complaint to the independent Parliamentary and Health Service Ombudsman or Local Government Ombudsman, if you are not satisfied with the way your complaint has been dealt with by the NHS.

You have the right to make a claim for judicial review if you think you have been directly affected by an unlawful act or decision of an NHS body or local authority. You have the right to compensation where you have been harmed by negligent treatment."

342. The NHS also pledges to:

a. "ensure that you are treated with courtesy and you receive appropriate support throughout the handling of a complaint; and that the fact that you have complained will not adversely affect your future treatment;

b. ensure that when mistakes happen or if you are harmed while receiving healthcare you receive an appropriate explanation and apology, delivered with sensitivity and recognition of the trauma you have experienced, and know that lessons will be learned to help avoid a similar incident occurring again;

c. ensure that the organisation learns lessons from complaints and claims and uses these to improve NHS services".

(c) The Parliamentary and Health Service Ombudsman Complaints Standards

343. In December 2022, the Parliamentary and Health Service Ombudsman issued Complaints Standards[13]. These standards include details of the Parliamentary and Health Service Ombudsman's expectations on how providers and commissioners will handle complaints, together with a model complaint handling procedure and detailed guidance on how the Complaint Standards can be applied in practice.

344. Prior to these standards being issued, the Parliamentary and Health Service Ombudsman ("PHSO") published a document "My expectations for raising concerns and complaints in 2014". This was published in response to the government's response to the Inquiry into the failings at Mid Staffordshire NHS Foundation Trust, Hard Truths. NHS England had no role in relation to that document. The PHSO's role in respect of mental health care in Essex specifically is outside the scope of this witness statement.

345. NHS England expects providers to comply with the above, as part of their overall statutory and regulatory compliance.

(d) Contractual requirements

346. Providers of NHS services are also subject to contractual requirements around complaints and concerns, by virtue of the NHS Standard Contract.

347. As the commissioner of specialist mental health services, NHS England requires the providers it enters into arrangements with for the delivery of these services to comply with the terms of the NHS Standard Contract, which in turn requires that the provider complies with its statutory obligations around complaints.

348. The NHS Standard Contract has previously included provisions equivalent to the current Service Condition 16.2.1, which requires that the contracted party complies with the following:

    a. publish, maintain, and operate a complaints procedure in compliance with the fundamental standards of care and other applicable law and guidance;

[13] See NHS Complaints Standards, Summary of expectations (December 2022)

b. provide clear information to service users, their carers and representatives, and to the public, displayed prominently in the services environment as appropriate, on how to make a complaint or to provide other feedback and on how to contact Local Healthwatch;

c. ensure that this information informs service users, their carers and representatives, of their legal rights under the NHS Constitution, how they can access independent support to help make a complaint, and how they can take their complaint to the PHSO should they remain unsatisfied with the handling of their complaint by the provider[14];

d. continually review and evaluate the services they provide, act on insight derived from those reviews and evaluations, from feedback, complaints, audits, clinical outcome review programmes, patient safety incidents, and from the involvement of service users, staff, GPs and the public (including the outcomes of surveys), and must demonstrate at review meetings the extent to which service improvements have been made as a result and how these improvements have been communicated to service users, their carers, GPs and the public[15].

349. The fundamental standards of care (incorporated as above into the NHS Standard Contract), require, in respect of complaints, that:

a. any complaint received by an NHS Trust must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation[16];

b. every NHS Trust must establish and operate effectively an accessible system for identifying, receiving, recording, handling, and responding to complaints by service users and other persons in relation to the carrying on of the Trust's regulated activities (which include, inter alia, treatment of disease, disorder or injury, personal care, surgical procedures, diagnostic and screening procedures, maternity and midwifery services, nursing care, and ancillary activities[17/18]);

[14] NHS Standard Contract Condition 16.2.2
[15] NHS Standard Contract Condition 3.4
[16] Regulation 16(1) of the 2014 Regulations
[17] Regulation 16(2) of the 2014 Regulations
[18] Schedule 1 of the 2014 Regulations

c. an NHS Trust must provide to the CQC, when requested to do so and within 28 days of receiving such a request, a summary of:

a) complaints made to the NHS Trust under the Trust's complaint system;

b) responses made by the NHS Trust to such complaints (and any further correspondence with the complainants in relation to such complaints); and

c) any other relevant information in relation to such complaints as the CQC may request[19].

(e) Patient Advice and Liaison Service

350. In terms of how Trusts operationalise these statutory, regulatory and contractual requirements, most will have a Patient Advice and Liaison Service (PALS), which provides a point of contact for patients, families and carers. PALS assists with resolving concerns or problems and signposts to the complaint process.

(f) NHS England recording and monitoring of complaints

351. NHS England has a role in relation to complaints handling by NHS Trusts and NHS Foundation Trusts:

a. as commissioner, when monitoring and managing performance of the NHS Standard Contract requirements (but noting that the CQC is the designated body to whom complaints data must primarily be reported to and who would be the key regulatory body that assesses complaints compliance and effectiveness, as part of its regulation of compliance with the assessed standards);

b. NHS England maintains records of complaints made to it in that context. These records are kept for a minimum of 10 years, in accordance with NHS England's retention of records schedule **[Exhibit DB/050]**;

c. in its assurance and oversight role as the recipient of NHS Trust and NHS Foundation Trust annual reports.

352. Beyond this, however, where a complaint is made directly to a provider, that provider would maintain its own records and NHS England does not have access to this

[19] Regulation 16(3)(c) of the 2014 Regulations

information. Each NHS Trust and NHS Foundation Trust is required to provide aggregated data on their complaint statistics. Prior to the COVID-19 pandemic, this data needed to be submitted quarterly. However, this has subsequently been reduced to an annual return in order to minimise the burden on providers. The data is published online **[Exhibit DB/051]**.

353. NHS England monitors trends and themes in relation to complaints (using a range of data sources, including the annual reports submitted by NHS Trusts and NHS Foundation Trusts). This is carried out as part of the Freedom to Speak Up.

354. NHS England will sometimes also actively support providers through carrying out targeted reviews of provider complaints processes.

(3) Patient Engagement and Involvement

355. At a service delivery level, NHS England and ICBs have a statutory duty to promote the involvement of patients in their care. NHS England and ICBs also have a duty to involve patients and representatives in the planning and development of proposals in respect of services. There is statutory guidance published by NHS England setting out how all NHS bodies should work with people and communities.

356. There are a number of different ways NHS England carries out patient engagement and involvement and enables individuals to ask questions and to provide feedback. This includes service user representation on many different policy development groups and listening to the feedback from service user involvement and engagement groups in order to drive improvement.

357. In 2023, following pilot work with four mental health trusts, NHS England nationally rolled out launched its first ever anti-racism framework: the Patient and carer race equality framework ("PCREF"), for all NHS mental health trusts and mental health service providers across England to embed. This mandatory framework is intended to ensure trusts and providers are responsible for co-producing and implementing concrete actions to reduce racial inequalities within their services. The PCREF framework includes an element about patient and carer feedback from ethnic minority groups:

    a. Ensure patient experience data is used, monitored and flowed to national data-sets to enable benchmarking, lesson-sharing and service improvement;

b. Ensure outcome measures are routinely used and monitored locally, and flowed to national datasets to enable benchmarking, lesson-sharing and improvement of services;

c. Agree approaches for implementing a 'real time' and transparent feedback loop for racialised and ethnically and culturally diverse communities.

358. Patients are able to share their experience of their GP practice via the GP Patient survey, an independent survey run by Ipsos on behalf of NHS England. The survey is sent out to over two million people across England. Questions included in the survey provide statistics on multiple topics, including:

a. How well people felt clinicians considered their mental well being at their last appointment;

b. How confident people who reported they had a mental health condition were in managing issues caused by their condition (62.5% with a mental health condition said "confident");

c. Whether people who reported they had a mental health condition felt they had had enough support from local services in managing that condition in the last 12 months (59.5% of those with a mental health condition said "yes").

359. The percentage of respondents saying they had a mental health condition was 13.5% of a base of 645,007 respondents – the 3rd highest answer after joint problems (17.9%) and high blood pressure (17.8%).

360. In addition, in surveys such as the inpatient survey (surveying people who have had an overnight stay), the results can be analysed by self-reported conditions; from this we learn information such as:

a. Respondents with a mental health condition also reported less confidence and trust in doctors;

b. People with a mental health condition were more likely to feel they were not treated with sufficient respect and dignity;

c. People with a mental health condition were less likely to report that hospital staff discussed whether they would need further care after leaving hospital;

d. As with other areas of care explored within this survey, respondents with a mental health condition were also more likely to report more negatively overall.

361. Patient-reported outcome measures ("PROMs") are used to assess the quality of healthcare experiences, focusing on the patient experience. These measures help healthcare providers, commissioners and other stakeholders to make informed changes to their services. Patient-reported outcomes and experiences are commonly collected using questionnaires. For example, a PROM was implemented to assess people with serve mental illness in community mental health settings **[Exhibit DB/052]**.

362. The Friends and Family Test ("FFT") is an important feedback tool that Provider Trusts use and that supports the fundamental principle that people who use NHS services should have the opportunity to provide feedback on their experience. It asks people if they would recommend the services they have used and offers a range of responses. When combined with supplementary follow-up questions, the FFT provides a mechanism to highlight both good and poor patient experience. This kind of feedback is vital in transforming NHS services and supporting patient choice.

363. The CQC publishes patient experience surveys in secondary care under their National Patient Survey Programme. This includes a survey specifically on community mental health. The last survey was published in April 2024 **[Exhibit DB/053]**.

364. The Medical Examiner system, described above, critically provides families an immediate option to discuss and ask questions of an independent clinician where there has been a death that has not been referred to the Coroner.

(4) Safeguarding

365. Safeguarding means protecting a citizen's health, wellbeing and human rights, enabling them to live free from harm, abuse and neglect. It is an integral part of providing high-quality healthcare. Safeguarding children, young people and adults is a collective responsibility. Those most in need of protection include:

a. Children and young people;

b. Adults at risk, such as those receiving care in their own home, people with physical, sensory and mental impairments, and those with learning disabilities.

366. All staff, whether they work in a hospital, a care home, in general practice, or in providing community care, and whether they are employed by a public sector, private sector or not-for-profit organisation, have a responsibility to safeguard children and adults at risk of abuse or neglect in the NHS. Appropriate safeguarding must be in place across all vulnerable patient and service user groups.

367. During the Relevant Period, safeguarding has advanced as a result of identified learnings and reforms. This part of the statement explains the role of NHS England in relation to safeguarding.

(a) Statutory framework for safeguarding

368. Safeguarding responsibilities arise from duties to adults at risk of abuse and neglect (e.g., under the Care Act 2014 and the Care Act statutory guidance), and in respect of children (e.g., under the Children Act 2004 and the national "Working Together to Safeguard Children" guidance, which is published by the Secretary of State for Education, "Working Together"). However, safeguarding, to NHS England, is broader that the specific statutory duties it and others are subject to. For NHS England, safeguarding means "protecting a citizen's health, wellbeing and human rights; enabling them to live free from harm, abuse and neglect. It is an integral part of providing high-quality health care."

369. The Working Together guidance is published under section 11 of the Children Act 2004 Act as statutory guidance, which means that all those who have safeguarding duties in respect of children must have regard to the guidance when performing their duties and good reasons would be needed to lawfully depart from it. The Care and support statutory guidance, which sets out guidance regarding the safeguarding of adults, is also statutory guidance and relevant public bodies must therefore have regard to this guidance also.

370. Safeguarding also forms part of the NHS standard contract (service condition 32) and commissioners need to agree with their providers, through local negotiation, what contract monitoring processes are used to demonstrate compliance with safeguarding duties.

371. NHS England's role and the documents it publishes within the wider framework of the national Working Together guidance are discussed below. However, the full statutory framework that applies to safeguarding is not set out in this statement. In summary, we consider the following aspects to be key in the context of the Inquiry:

a. NHS partners, including NHS England (in both its national and regional capacity) and providers of NHS services, play a key role in relation to safeguarding. This is alongside representatives from the police, local authorities and others;

b. To be effective, safeguarding relies on strong partnership working. As Working Together emphasises, this means “strong partnership working between parents/carers and the practitioners working with them”;

c. Safeguarding is closely connected with other areas described below, including raising concerns and external scrutiny.

372. In discharging their duties under section 11 of the Children Act 2004, the bodies must have regard to guidance given by the Secretary of State for Education, namely the Working Together Guidance. Chapter 4 of the current version of Working Together, published in December 2023, describes the role of different bodies as relevant to safeguarding. Equally, when discharging duties under sections 42-46 of the Care Act 2014 in respect of safeguarding adults, relevant bodies must have regard to the Care and Support Statutory Guidance. Chapter 14 of the guidance includes further detail on adult safeguarding procedures, the roles of public bodies and multi-agency working, and further information on Safeguarding Adult Boards and Reviews.

373. In terms of the role of NHS organisations, the roles of NHS England and ICBs (formerly CCGs) in respect of the safeguarding of children are described as follows in the Working Together guidance:

> “*NHS England is responsible for ensuring that the health commissioning system as a whole is working effectively to safeguard and promote the welfare of children. It is accountable for the services it directly commissions or delegates, including healthcare services in the under 18 secure estate (for police custody settings see below in the policing section). NHS England also leads and defines improvement in safeguarding practice and outcomes and should also ensure that there are effective mechanisms for safeguarding partners to raise concerns about the engagement and leadership of the local NHS. Each NHSE region should have a safeguarding lead to ensure regional collaboration and assurance through convening safeguarding forums*.”
>
> With regards adult safeguarding, the Care Act statutory guidance confirms that NHS England and CCGs (now ICBs) are 'Relevant Partners' for the purposes of the Act and guidance and notes:

"Safeguarding requires collaboration between partners in order to create a framework of inter-agency arrangements. Local authorities and their relevant partners must collaborate and work together as set out in the co-operation duties in the Care Act and, in doing so, must, where appropriate, also consider the wishes and feelings of the adult on whose behalf they are working."

374. NHS Trusts and NHS Foundation Trusts must also have regard to this key piece of guidance. Responsibilities for safeguarding form part of the organisations' statutory functions, and each organisation's executive board is responsible for effectively discharging those statutory functions. Providers' safeguarding duties are reflected within the wider contractual and regulatory framework within which NHS services are commissioned and provided.

375. The Working Together guidance in particular recognises that "Local safeguarding arrangements will need to reflect health and care infrastructure such as Integrated Care Boards, Integrated Care Systems, collaboratives, primary care networks and NHS specialised commissioning arrangements". Similarly, the Care and Support guidance notes that "A local authority must promote integration between care and support provision, health and health related services, with the aim of joining up services."

376. Additionally, as the Working Together guidance sets out, professionals operating within health and care settings have certain roles and are expected to meet certain competencies to protect children from harm. These are described in an "Intercollegiate Document", which is published by the Royal College of Nursing but developed by over twenty other organisations. There is an equivalent intercollegiate document, produced by the Royal College of Nursing in conjunction with a number of other organisations, for adult safeguarding. Although these are not NHS England documents, they are helpful context in understanding the responsibilities which professionals operating within health and care settings have and the expectations around how these roles operate.

(b) Intercollegiate Safeguarding Guidelines

377. Mental health services are delivered by a range of professionals in a multidisciplinary team. The majority of mental health professionals will be regulated by the NMC or the GMC and are required to comply with the standards of their profession (see **Annex 10 (Professional Regulation)**). Intercollegiate Documents are sets of guidelines

developed collaboratively by Royal Colleges and professional bodies within the NHS to define roles, responsibilities, and competencies for specific healthcare professionals.

378. There are numerous Intercollegiate Documents covering different areas. With regard to children and young people safeguarding, "Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff" outlines the levels of safeguarding training and competency expected of healthcare professionals in protecting vulnerable individuals. Likewise the "Adult Safeguarding: Roles and Competencies for Health Care Staff" provides the same information but with a focus on adult safeguarding.

379. The above Intercollegiate Documents apply across the UK. The Children's Intercollegiate Document was first published in 2006 and was revised in 2010, 2014 and 2019 to respond to relevant policy development, as mentioned in its foreword. The Adults Intercollegiate Document was originally published in 2018 and was reviewed in 2023.

380. These Intercollegiate Documents are not intended to replace contractual arrangements between NHS commissioners and providers, or between NHS organisations and their staff, but they aim to set out a consistent framework of indicative minimum training requirements and competencies. The frameworks identify five levels of competence, ranging from Level 1 to 5. In summary and by way of example, for the Children's safeguarding Intercollegiate Document the Levels are as follows:

    a. Level 1: All staff including non-clinical managers and staff working in healthcare services.

    b. Level 2: Minimum level required for non-clinical and clinical staff who, within their role, have contact (however small) with children and young people, parents/carers, or adults who may pose a risk to children.

    c. Level 3: All clinical staff working with children, young people and/or their parents/carers and/or any adult who could pose a risk to children who could potentially contribute to assessing, planning, intervening and/or evaluating the needs of a child or young person and/or parenting capacity (regardless of whether there have been previously identified child protection/safeguarding concerns or not).

d. Level 4: Named professionals. These are professionals which all providers of NHS funded health services must have. There should be a dedicated named nurse, named doctor and a named midwife (if the organisation provides maternity services). Named practitioners have a key role in promoting good professional practice within their organisation, providing advice and expertise for fellow practitioners, ensuring safeguarding training is in place, and working closely with others with responsibilities for safeguarding across the organisation and wider system. Appendix 2 of the Intercollegiate Document provides a template role description for named professionals.

e. Level 5: Designated professionals. ICBs (formerly CCGs) are required to employ, or have in place a contractual arrangement, to secure the expertise of designated safeguarding practitioners whose role is to provide advice and expertise to organisations and agencies across the local health economy (including, in particular, the ICB, NHS England, and local authorities). Appendix 3 of the Intercollegiate Document provides a template role description for designated professionals.

381. These Intercollegiate documents sit alongside other documents relevant to safeguarding. For Children's safeguarding in particular, other documents include:

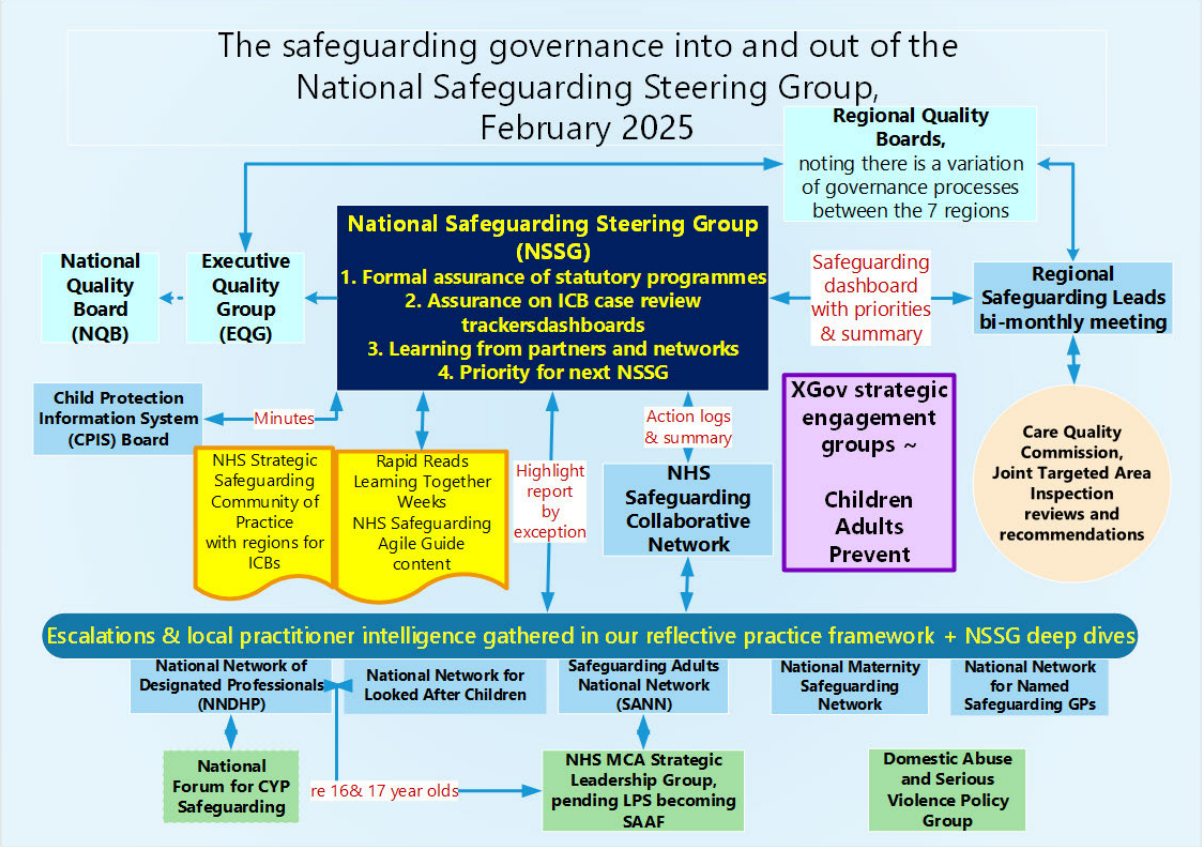
a. "Adult Safeguarding: Roles and Competencies for Health Care Staff", as referred to above, which outlines competencies and roles for healthcare staff in safeguarding adults, ensuring they can effectively protect vulnerable individuals from abuse, harm, or neglect.

b. "Looked After Children: Roles and Competencies of Healthcare Staff": This guideline specifies the roles and required competencies for healthcare professionals working with children in care, ensuring their health needs are met and promoting their well-being; and

c. "Preventing Harm, Promoting Justice: Responding to the Needs of Children and Young People with Learning Disabilities Who Experience, or Are at Risk of, Child Sexual Exploitation": This document provides guidance on recognising and responding to the specific needs of children and young people with learning disabilities who are at risk of or experiencing sexual exploitation.

(c) Governance structures for fulfilling NHS England's statutory safeguarding responsibilities

382. The Chief Nursing Officer for NHS England has executive lead responsibility to ensure the effective discharge of NHS England's statutory safeguarding responsibilities and has a number of forums through which oversight is sought. These include the National Safeguarding Steering Group and its sub-groups and networks. The following diagram shows these safeguarding governance structures:



383. The Chief Nursing Officer is responsible for providing overall assurance to the NHS England Board, and assurance is secured through the annual review process assisted by NHS England's Regional teams. Each NHS England Region provides an annual safeguarding assurance report to the National Safeguarding Steering Group for assurance purposes, and to enable common issues, emerging trends and learning to be identified from across the health system.

384. The National Safeguarding Steering Group plays a key role in bringing together regional safeguarding reports, assuring the system overall, and identifying and disseminating common issues, emerging trends and learning. The National Safeguarding Steering Group is a permanent structure, chaired by the Deputy Chief Nursing Officer for England – Professional and System Leadership. Its work is supported by a number of working groups, national networks and implementation

groups. These vary, reflecting safeguarding priorities, new legislation and specific projects.

385. NHS England also facilitates national sharing of best practice and safeguarding improvements with a view to ensuring the health system as a whole is working effectively. There are various way in which this is done. For example, through ensuring that the NHS Standard Contract has standard conditions for providers relating to safeguarding. Namely, Standard Condition 32, which requires providers to, in brief summary:

    a. ensure service users are protected and to take appropriate action to respond to allegations and disclosures of contrary behaviour;

    b. nominate lead professionals and ensure the relevant commissioner is informed of those professionals;

    c. comply with relevant specified law and policies relating to safeguarding;

    d. implement comprehensive programmes for safeguarding;

    e. evidence that it is addressing safeguarding concerns, when reasonably requested by the commissioner;

    f. include in relevant policies a comprehensive programme to raise awareness of the Intercollegiate Guidance in relation to Safeguarding Training (for example, see the Safeguarding accountability and assurance framework **[Exhibit DB/054]**).

386. In addition, NHS England promotes best practice through making available the NHS Safeguarding App as a resource for healthcare professionals, carers and the public; establishing the NHS Safeguarding Accountability and Assurance Framework; and ensuring, through statutory guidance, that ICBs appoint senior executives at Board level who have responsibility for safeguarding.

(i) NHS Safeguarding Accountability and Assurance Framework

387. Consistent with its national leadership role in relation to safeguarding in the NHS, NHS England has developed and published a “Safeguarding children, young people and adults at risk in the NHS Safeguarding Accountability and Assurance Framework” (“the NHS Safeguarding Accountability and Assurance Framework”) alongside a number of associated protocols. The 4th edition of the NHS Safeguarding Accountability and

Assurance Framework was published in July 2024 **[Exhibit DB/104].** Prior versions were published in 2022 **[Exhibit DB/054];** March 2013 **[Exhibit DB/055]**; July 2015 (to address relevant duties coming into force under the Care Act 2014 in April 2015) **[Exhibit DB/056]**; and in May 2019 **[Exhibit DB/057]**.

388. As stated in the NHS Safeguarding Accountability and Assurance Framework, the document is intended to provide the minimum standards that all those working in NHS funded care settings should work to, but it is not intended to constrain the development of other effective local safeguarding practice and arrangements (e.g., those developed by local safeguarding partners).

389. The current NHS Safeguarding Accountability and Assurance Framework aims to draw together and describe the safeguarding roles and responsibilities of NHS organisations, regulators and individuals working in NHS funded care settings (e.g., NHS Trusts and NHS Foundation Trusts) and NHS commissioning organisations. It seeks to clarify the relevant legal framework and cross refers to relevant statutory guidance.

390. The NHS Safeguarding Accountability and Assurance Framework describes NHS England's role in relation to safeguarding, in terms of: (a) its system leadership role and facilitating peer support between safeguarding professionals; (b) its role as a direct commissioner of certain services (e.g., primary care, and specialised services); and (c) its role in assuring ICBs in their commissioning role.

391. The latter involves formal quarterly assurance reviews of ICBs, which regional chief nurses are accountable for. This has involved developing the safeguarding commissioning assurance toolkit, to assist local commissioners to optimise their commissioner role under the NHS Standard Contract which they hold with providers.

392. As set out in the NHS Safeguarding Accountability and Assurance Framework, NHS providers are required to demonstrate that safeguarding is embedded at every level in their organisation and they must be able to assure themselves, regulators and commissioners that safeguarding arrangements are robust and are working. The framework states that robust arrangements include the following:

    a. Identification of a named nurse and named doctor for safeguarding children; Identification of a named nurse and named doctor for children in care; Identification of a named lead for adult safeguarding and a Mental Capacity Act (MCA) lead – this role should include the management of adult safeguarding

allegations against staff. This could be a named professional from any relevant professional background;

b. Safe recruitment practices and arrangements for dealing with allegations against staff;

c. Provision of an executive lead for safeguarding children, adults at risk and prevent;

d. An annual report for safeguarding children, adults and children in care to be submitted to the provider's board;

e. A suite of safeguarding policies and procedures that support local multiagency safeguarding procedures;

f. Effective training of all staff commensurate with their role and in accordance with the Intercollegiate Document (and equivalent document, intercollegiate document for adult safeguarding), the Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff 2019, Looked After Children: Roles and Competencies of Healthcare Staff 2020 and the Adult Safeguarding: Roles and Competencies for Health Care Staff 2018;

g. Safeguarding must be included in induction programmes for all staff and volunteers;

h. Providing effective safeguarding supervision arrangements for staff, commensurate to their role and function (including for named professionals);

i. Developing an organisational culture where all staff are aware of their personal responsibilities for safeguarding and information sharing;

j. Developing and promoting a learning culture to ensure continuous improvement; and

k. Policies, arrangements and records to ensure consent to care and treatment is obtained in line with legislation and guidance.

393. NHS providers demonstrate compliance with the NHS Safeguarding Accountability and Assurance Framework by way of the annual assurance process.

(ii) Integrated Care Board Executive Leads

394. In relation to safeguarding, NHS England anticipates that, for most ICBs, the Executive Lead will be the ICB's Chief Nurse. This reflects at the local level the national position that NHS England's Chief Nursing Officer is responsible for providing overall assurance to the NHS England Board on the effectiveness and quality of safeguarding arrangements across England. The role of the Executive Lead for safeguarding is to lead on supporting the chief executive and the ICB to ensure the ICB performs its functions effectively, as relevant to safeguarding. This would also include ensuring compliance with the Safeguarding Accountability and Assurance Framework, referred to above.

395. Although the guidance is aimed at ICBs, its intentions are to secure visible and effective board-level leadership within ICSs for addressing issues faced by these population groups. The implementation of the roles is intended to provide key contact points at a senior level between the ICB, wider ICS partners, and NHS England's regional and national teams. It is expected that appointed executive leads will have a good understanding of the law, policy, guidance and best practice and that they work closely with wider ICS partners to promote integrated working for the benefit of these population groups.

(5) Whistleblowing and Freedom to Speak Up

(a) The Role of NHS England

396. In this part, we describe the processes and procedures in relation to concerns raised by an NHS worker (which includes an employee, secondee, contractor, student, volunteer, agency or temporary staff member, locum or governor delivering NHS care). These concerns will be raised in the context of the role of that individual as an NHS worker, and the processes and policies in relation to whistleblowing and freedom to speak up will apply. This is distinct from complaints raised by service users, which we deal with separately.

397. It should be noted that the area of Freedom to Speak Up and Whistleblowing is distinct from other policy areas, as NHS England does itself publish guidance to providers in the form of national guidance which is intended to set a minimum standard to which providers should comply.

398. Prior to 2016, there was no national whistleblowing guidance published by NHS England or NHS Improvement, Monitor or the NHS Trust Development Authority, though each would have had their own policies and associated processes for receiving and responding to whistleblowing.

399. Delivering one of the recommendations from the Freedom To Speak Up (FTSU) Review by Sir Robert Francis, NHS Improvement published the first 'National Policy for Raising Concerns (whistleblowing)' on 1 April 2016 **[Exhibit DB/058]**, which all NHS organisations were expected to adopt as a minimum standard. That followed a public consultation exercise with feedback received from over 100 stakeholders.

400. The policy was designed to cover 'whistleblowing' and other types of concerns from staff that might not meet the legal definition of a public interest disclosure, but which were still potentially relevant to the effective running of an NHS organisation (e.g. poor team culture).

401. The national policy has always provided for the raising of concerns externally, specifically to NHS England and its Legacy Bodies and/or the CQC.

402. In 2016, NHS England also published sector specific guidance on whistleblowing for primary care organisations, which included a version for the national policy in its annex.

403. NHS England is aware from case reviews by the National Guardian's Office that not all organisations adopted the national policy. In 2016, it was not considered to be the role of NHS Improvement to enforce this.

404. NHS England has since published a Freedom to Speak Up policy for the NHS **[Exhibit DB/059]** (the "Freedom to Speak Up Policy") which provides the minimum standard for local Freedom to Speak Up policies across the NHS. All NHS organisations and others providing NHS healthcare services in primary and secondary care in England are required to adopt the Freedom to Speak Up Policy as a minimum standard to normalise speaking up for the benefit of patients and workers.

405. Through general condition 5.10 of the NHS Standard Contract, NHS England requires providers of NHS services to:

    a. appoint and at all times have in place one or more Freedom to Speak Up Guardians to fulfil the role set out in, and otherwise comply with, the requirements of the National Guardian's Office guidance;

b. ensure that the commissioner of those services and the National Guardian's Office are kept informed at all times of the identity of the Freedom to Speak Up Guardian(s);

c. co-operate with the National Guardian's Office in relation to any speaking up reviews and take appropriate and timely action in response to the findings of such reviews;

d. have in place, promote and operate (and ensure that all sub-contractors have in place, promote and operate) a policy and effective procedures, in accordance with Freedom to Speak Up policy and guidance, to ensure that staff have appropriate means through which they may speak up about any concerns they may have in relation to the services provided under the contract and how they can be improved;

e. ensure that nothing in any contract of employment, or contract for services, settlement agreement or any other agreement entered into by the provider (or any sub-contractor) with any member of staff will prevent or inhibit, or purport to prevent or inhibit, that member of staff from speaking up about any concerns they may have in relation to the quality and/or safety of care, nor from speaking up to any regulatory or supervisory body or professional body in accordance with their professional and ethical obligations, nor prejudice any right of that member of staff to blow the whistle; and

f. include a mandatory provision in any settlement agreement or other agreement entered into by the provider (or any sub-contractor) with any member of staff in relation to the termination of their employment or engagement setting out the matters referred to in e. above.

406. NHS England also requires NHS organisations and those providing NHS healthcare services in primary and secondary care in England to appoint a senior lead responsible for Freedom to Speak Up. The senior lead responsible for Freedom to Speak Up provides senior support for the Freedom to Speak Up Champion and is responsible for reviewing the effectiveness of their organisation's Freedom to Speak Up arrangements. NHS organisations with boards are also required to appoint a non-executive director responsible for Freedom to Speak Up. The non-executive director responsible for Freedom to Speak Up provides more independent support for the Freedom to Speak Up Guardian, providing a fresh pair of eyes to ensure that

investigations are conducted with rigour and helping to escalate issues, where needed **[Exhibit DB/059]**.

407. NHS England and the National Guardian's Office have published a reflection and planning tool **[Exhibit DB/060]** for use by senior leads for Freedom to Speak Up to identify strengths in themselves, their leadership teams and their organisations, and any gaps (the "Freedom to Speak Up Improvement Tool").

408. In partnership with the National Guardian's Office, NHS England has published a guide for leaders in the NHS and organisations delivering NHS services (the "Freedom to Speak Up Guide") **[Exhibit DB/061]**. This was most recently updated in June 2022 and is now called the FTSU Guide. It is aimed at leaders because smaller organisations do not have boards. This guidance is supplemented by a self-review tool, most recently called a self-reflection tool. The purpose of this guidance was to expand the focus of FTSU beyond FTSU Guardians and ensure that boards and senior leaders were aware of their responsibilities in ensuring FTSU arrangements they put in place are effective. NHS England also provides a range of resources to help NHS organisations and those providing NHS healthcare services to develop their Freedom to Speak Up arrangements, including videos, podcasts, and case studies.

409. NHS England expected all NHS Trusts to have adopted the Freedom to Speak Up Policy, applied the Freedom to Speak Up Guide and Freedom to Speak Up Improvement Tool, and provided assurance to their public boards by January 2024. ICBs are expected to ensure that their own staff have access to routes for speaking up, including Freedom to Speak Up Guardian(s), to have used the Freedom to Speak Up Guide and Freedom to Speak Up Improvement Tool to map the plan for the next three years. They are also expected to put systems in place to capture and measure speaking up data.

410. NHS England expects all NHS organisations to ensure:

    a. their relevant departments, such as human resources, and their freedom to speak up guardians are aware of the national Speaking Up Support Scheme offer;

    b. their policies and processes reflect the principles in the guide for leaders in the NHS and organisations delivering NHS services;

c. workers have easy access to information on how to speak up and the Speaking Up Support Scheme, and actively refer individuals to the scheme;

d. they are mindful of those workers who may have cultural barriers to speaking up or who are in lower paid roles and less confident to do so, and also those who work unsociable hours and may not always be aware of or have access to the policy or processes supporting speaking up;

e. they communicate with all their workers by identifying the best channels to do so; and

f. they reflect on any learning to build healthy cultures in which every worker feels safe to speak up.

(b) Speaking Up to NHS England and other bodies

411. NHS England expects staff to speak up externally if they do not want to speak up within their organisation. Anyone who works in NHS healthcare, including pharmacy, optometry and dentistry, can speak up to NHS England. This encompasses any healthcare professionals, clinical and non-clinical workers, receptionists, directors, managers, contractors, volunteers, students, trainees, junior doctors, locum, bank and agency workers, and former workers. Staff working in NHS healthcare can speak up to NHS England about:

a. GP surgeries;

b. dental practices;

c. optometrists;

d. pharmacies;

e. how NHS trusts and NHS Foundation Trusts (including ambulance trusts and community and mental health trusts) are being run;

f. NHS procurement and patient choice; and

g. the national tariff.

412. NHS England has a webpage dedicated to “Speaking up to NHS England” which provides detail as to how concerns can be raised, including providing an address, telephone number and dedicated email address for doing so.

413. As a prescribed person[20], NHS England publishes an annual report which sets out the number of whistleblowing cases it received that it considered to be qualifying disclosures[21], and how they were taken forward **[Exhibit DB/062]**.

414. The Freedom to Speak Up Policy also signposts staff to the CQC (if they wish to raise quality and safety concerns about the services the CQC regulates) and the NHS Counter Fraud Authority (if they wish to raise concerns about fraud or corruption in the NHS).

415. The DHSC has partnered with Social Enterprise Direct to deliver ‘Speak Up’, which provides free, independent, confidential advice about the speaking up process in the NHS.

(c) Support for those who speak up

416. NHS England has developed a Freedom to Speak Up in Healthcare in England programme, in partnership with the National Guardian’s Office and Health Education England. This programme is delivered in three parts:

    a. Speak Up: Core training for all workers (including volunteers, students, and those in training) on what speaking up is and why it matters.

    b. Listen Up: Training for all line and middle managers focused on listening up and the barriers that can get in the way of speaking up.

    c. Follow Up: Training aimed at senior leaders (including executive board members and their equivalents, non-executive directors and governors) to help them understand their role in setting the tone for a good speaking up culture and how speaking up can promote organisational learning and improvement.

417. NHS England also provides support for past and present NHS workers who have experienced a significant adverse impact on both their professional and personal lives,

[20] Public Interest Disclosure (Prescribed Persons) Order 2014.

[21] A disclosure of information which, in the reasonable belief of the worker making the disclosure, is made in the public interest and tends to show one or more of the types of wrongdoing or failure listed in section 43B(1)(a)-(f) of the Employment Rights Act 1996.

to move forward, following a formal speak up process through the Speaking Up Support Scheme. The Speaking Up Support Scheme was introduced in 2019 (known then as the Whistleblowers Support Scheme) as a response to the recommendations from the Freedom to Speak Up Review. The Speaking Up Support Scheme provides a structured programme of support which includes:

a. health and wellbeing sessions;

b. one-to-one psychological wellbeing support;

c. career coaching;

d. personal development workshops; and

e. a range of practical support through group sessions.

418. We are exploring with the National Guardians Office whether it can include a notification of national policy adoption in the quarterly data return it gets from all organisations with a FTSU Guardian.

(d) Recent work in relation to speaking up

419. In November 2023, NHS England established a Task and Finish Group to bring together a group of subject matter experts to explore the effectiveness of escalation routes in cases of speaking-up in the context of complex cases, such as those involving a combination of suspected criminal conduct and patient safety concerns **[Exhibit DB/063]**.

420. With CQC, we have made progress on an updated process for sharing escalated concerns and aim to agree with them a proposed approach for ensuring consistency and robustness in sharing information about escalated concerns that also protects confidentiality of whistleblowers.

421. NHS England has in the last year sought to assure itself that all Trusts and ICBs have either adopted the national policy and guide for leaders or that they are close to completing this work.

422. We are also working to improve clinical confidence and awareness of escalation routes among clinicians.

(6) Mental health policy

423. This section sets out developments in mental health policy of relevance to this Inquiry. Some of what is set out in this section goes beyond the Inquiry's Relevant Period, but is included here to support the Inquiry in its considerations of future recommendations.

(a) The Five Year Forward View

424. The 'Five Year Forward View' published in October 2014 **[Exhibit DB/064]** set out a vision to transform the NHS by 2020. This argued for a radical upgrade in prevention and public health, for patients to gain greater control of their own care, and for the NHS to take decisive steps to break down barriers in how care was being provided. It recognised a need for national leadership of the NHS to act coherently together, but to provide meaningful local flexibility.

425. The Five Year Forward View was a joint publication by NHS England, the CQC, Health Education England, Monitor, Public Health England and the NHS Trust Development Authority. The Five Year Forward View focused on addressing three identified gaps:

    a. The health and wellbeing gap: the need to reduce demand on the NHS by shifting focus towards prevention and addressing health inequalities;

    b. The care and quality gap: to harness technology and innovation to reduce variations in the quality of care, including in relation to safety and outcomes in care; and

    c. The funding and efficiency gap: to ensure that additional funding for the NHS is used to improve efficiencies, transform services and achieve financial sustainability.

426. 'Implementing The Five Year Forward View for Mental Health' **[Exhibit DB/102]** was published by NHS England in 2016, setting out a plan for developing mental health services across the health system for all ages, following recommendations made in the independent report of the Mental Health Taskforce commissioned by NHS England. It was directed at commissioners and providers to support and influence the development and implementation of their own local plans. Delivery of the Five Year Forward View was underpinned by an additional £1 billion in funding for mental health.

(b) Mental Health Waiting Time Targets

427. In 2015, NHS England introduced specific waiting times standards for three mental health service areas:

    a. Talking therapy services;

    b. Early intervention in psychosis services; and

    c. Eating disorder services for children and young people.

428. The access and waiting time standard for mental health was an important step towards parity of esteem with physical health services.

429. Since 2015, the NHS has met the standard for Talking Therapy services and early intervention in psychosis services. Whilst a standard was defined in 2015 for Eating Disorder services for children and young people, tolerance levels were not set until 2016, when a specific target of 95% of referrals to be seen within the standard by 2020/21 was set. This target has not been met and demand for services for eating disorders rose significantly during the Covid 19 pandemic.

430. The current standards only cover a limited number of service areas. Between July and September 2021, as part of the Mental Health Clinically-led Review of Standards (CRS), NHS England held a public consultation on a range of proposed waiting time standards for urgent and non-urgent mental health services, for both children and young people, as well as adults and older adults. NHS England's response to the consultation was published in February 2022, setting out the broad agreement of stakeholders with the proposed range of waiting time standards.

431. NHS England routinely publishes waiting times data for mental health services[22].

(c) Transforming Care Programme

432. In 2015, the Transforming Care Programme committed to providing support and care in the right place for people with a learning disability and autistic people, including discharge from inpatient care if it is no longer required.

[22] https://digital.nhs.uk/data-and-information/publications/statistical/mental-health-services-monthly-statistics

433. In October 2015, NHS England published guidance to NHS and local authority commissioners setting out a national plan for developing community services and inpatient facilities close to home for people with a learning disability and autistic people, including those with a mental health condition. NHS England also published a national service model, developed with the help of people with lived experience setting out a range of support.

434. NHS England's current Learning Disability and Autism Programme is focused on making health and care services better so that more people with a learning disability, autism or both can live in the community, with the right support, and close to home.

(d) NHS Long Term Plan

435. In 2019, the NHS Long Term Plan was published, which set out an ambitious plan to transform mental health services and build on progress from the Five Year Forward View for Mental Health.

436. The NHS Long Term Plan made a renewed commitment that mental health services would grow faster than the overall budget, with a ringfenced investment worth at least £2.3 billion a year by 2023/24. It also committed to growing Children and Young People's mental health services faster than both the overall NHS funding and total mental health spend.

(e) NHS Mental Health Implementation Plan 2019/20 – 2023/24

437. The NHS Mental Health Implementation Plan 2019/20 – 2023/24 **[Exhibit DB/103]** focused on implementing the commitments of the Five Year Forward View for Mental Health and the Long Term Plan, setting out planning and delivery requirements over 5 years.

438. The NHS Mental Health Implementation Plan 2019/20 – 2023/24 committed to:

    a. expanding talking therapy services by 380,000 to a total of 1.9 million adults and older adults;

    b. maintaining the waiting time and recovery standards (see section 2.1 of this Statement);

c. maintaining the requirement in the Five Year Forward View for Mental Health for all areas to commission talking therapy services for people with long term conditions;

d. eliminate of out of area placements (still expected at that time to end by 2020/21); and

e. reduce length of stay, and improve patient experience and outcomes.

439. The policy ambition has been to provide more integrated services for people with mental health needs in the community. This involves new care models with better coordination between the range of different NHS mental and physical health services and other services (for example, social care) that an individual may need.

(f) The Mental Health Safety Improvement Programme

440. The Mental Health Safety Improvement Programme (“MHSIP”) was a national patient safety programme commissioned by NHS England and NHS Improvement. It was developed following a pilot programme which saw a significant reduction in recorded restrictive practice. Its aim was to improve safety and experience in mental health, learning disability and autism inpatient services, and specifically to reduce restrictive practices in mental health inpatient settings. It started in 2021 and concluded in September 2023. The Mental Health Safety Improvement Programme worked with the 54 NHS Trusts providing mental health services in England and closely with the CQC and regional NHS Improvement teams. It also involved the National Collaborating Centre for Mental Health ("NCCMH") and the Mental Health Patient Safety Networks (which are supported by Patient Safety Collaboratives).

441. The learning from the Mental Health Safety Improvement Programme was used as part of the co-production of the Culture of Care Standards for Mental Health Inpatient Services (see below) and the associated national implementation support offer, which saw a new Culture Change Programme delivered across all NHS-commissioned providers of inpatient services.

(g) Mental Health, Learning Disability and Autism Inpatient Quality Transformation Programme

442. In 2022, NHS England launched a three-year Mental Health, Learning Disability and Autism Inpatient Quality Transformation Programme to support cultural change and

develop a new model of care across all NHS-funded mental health, learning disability and autism inpatient settings. The programme subsumed elements of the MHSIP and looked at the root causes of poor-quality care and safety in inpatient mental health settings and to support cultural change. The programme has the following objectives:

a. Localising and realigning inpatient services, harnessing the potential of people and communities;

b. Improving culture and supporting staff;

c. Supporting systems and providers facing immediate challenges; and

d. Reducing restrictive practice through least coercive care.

443. Since it was created, the programme has published commissioning guidance to support ICBs. This has included the "Commissioning framework for mental health inpatient services" [**Exhibit DB/065**] and the "Commissioner guidance for adult mental health rehabilitation inpatient services" [**Exhibit DB/066**].

444. The programme has also published the Culture of care standards for mental health inpatient services. This guidance provides support to all providers to achieve the culture of care that patients, families and staff want to experience. The standards are co-produced with people with lived experience of inpatient services and their families, health professionals working in mental heath and various organisations, including voluntary sector organisations, royal colleges and academic experts [**Exhibit DB/067**].

445. In February 2024, NHS England launched a culture change improvement programme as part of the quality transformation programme. It has been established as a universal support offer for 60 NHS commissioned mental health, learning disability and autism providers. It will be delivered over two years up to March 2026.

(h) NHS Priorities and planning guidance

446. The annual planning guidance sets out NHS England's priorities for the coming year and provides guidance on how they will be achieved.

447. The latest guidance published for 2025/26 prioritises improving patient flow through mental health crisis and acute pathways, reducing average length of stay in adult acute beds, and improving access to Children and Young People's mental health services, to achieve the national ambition for 345,000 additional Children and Young

People aged 0 to 25 compared to 2019. It sets out support that will be provided to providers to achieve these aims.

(i) Investment in mental health services

448. The Mental Health Investment Standard ("MHIS" or "the Standard") was introduced by NHS England in 2016/17 and requires local commissioners (previously CCGs, now ICBs) to increase their spend on mental health services by at least as much as their overall programme allocations, maintaining mental health as a proportion of total local spending on health services. In the Long Term Plan , NHS England made an additional commitment to increase the share of the total recurrent NHS budget which is spent on mental health services. This includes MHIS spend, as well as specialised commissioning spend on mental health and national spending on mental health transformation ("Service Development Funding" or "SDF"). The 2022 Act also requires an annual statement to Parliament by ministers on mental health funding and share of spend. The most recent statement confirms that in the financial year 2023-24, mental health spending is forecast to make up 9% of all recurrent NHS spending. For the financial year 2024-25, mental health spending is forecast to make up 9.01% of all recurrent NHS spending [[**Exhibit DB/068**].

449. Between 2017/18 and 2022/23, total spending on mental health services went up by an average of 2.7% a year (in real terms). In the same period, spending on Children and Young People's mental health increased by an average of 7% a year. Mental health spend as a proportion of total recurrent NHS spend increased from 8.9% in 2022/23 to 9% in 2023/24.

450. In 2023/24, ICBs spent £15.1 billion on mental health, learning disability and dementia services in England. This is 14.5% of the total funding allocated to ICBs for health services. NHS England spent a further £2.5 billion on specialised commissioning for mental health services, for a total of £17.6 billion. This figure has risen from £12 billion in 2017/18 (in cash terms).

(j) NHS Long term workforce plan

451. NHS England recognises that staff shortages remain a major constraint to improving and expanding mental health services. There are also concerns about increasing pressures, as evidenced by the rising number of staff sick days due to poor mental health and the number of staff leaving.

452. In 2017, NHS England and Health Education England published estimates of how many additional staff would be needed to deliver improved and expanded mental health services. NHS England published updated estimates in 2019. Overall, the NHS mental health workforce has increased in line with these sets of estimates. Between 2016-17 and 2021-22, NHS staff numbers grew by 22%, compared with the estimated requirement of 17%.

453. However, the rate of increase varies by discipline. Mental health services are delivered by a range of professionals in a multidisciplinary team. This includes psychiatrists, psychologists, mental health nurses, support staff and peer support workers. Between 2016/17 and 2021/22, nursing numbers grew by less than the estimated requirement (9%, compared to an estimate of 16%), while numbers of therapists and support staff for therapists grew by substantially more (for example, a 41% growth in therapists compared to 25%). The latest figures (from November 2024) show that mental health nursing numbers were 45,135 - this is an increase of 26% on the figures from April 2016. The workforce numbers for Children and Young People's mental health services (including non-NHS staff) grew by 70% between 2016 and 2021, higher than the estimated requirement of 55%.

454. On 30 June 2023, NHS England published the NHS Long Term Workforce Plan. The plan anticipated that demand for mental health services will grow faster than other NHS services and set out plans for addressing these challenges. The government have backed NHS England's commitment to refreshing the Long Term Workforce Plan, and an update aligned to the governments priorities is planned for summer 2025.

(k) Reducing inequalities

455. Tackling mental health inequalities is an important policy objective for NHS England. In 2019, it set out its expectations for local systems to reduce mental health inequalities by 2023-24. In 2020, NHS England published its 'Advancing Mental Health Equalities Strategy' [**Exhibit DB/069**], which prioritised a number of actions, including supporting local health systems to adopt population health approaches, improving data and information, and developing a more diverse workforce. A taskforce (the Advancing Mental Health Equality Taskforce) was set up to oversee the strategy.

456. In 2022-23, NHS England provided funding of around £695 million to ICBs, on the condition that they had clear plans in place to address inequalities in their area. In 2023, NHS England published the 'Patient and Carers Race Equality Framework'

[Exhibit DB/070] for all NHS mental health trusts and mental health service providers to embed across England. The mandatory framework provides support to Trust and providers to become 'actively anti-racist organisations' and provides guidance on how to reduce racial inequalities within their services. The Framework supports improvements in three domains:

a. Leadership and governance: Trusts' boards will be leading on establishing and monitoring concrete plans of action to reduce health inequalities;

b. Data: new data set on improvements in reducing health inequalities will need to be published, as well as details on ethnicity in all existing core data sets;

c. Feedback mechanisms: visible and effective ways for patients and carers to provide feedback will be established, as well as clear processes to act and report on that feedback.

(l) Mental health suicides

457. Suicide prevention is a complex system-wide challenge which requires close working between the NHS, public health and its partner organisations.

458. The Five Year Forward View for Mental Health made a commitment to reduce suicides by 10% nationally by 2020/21. This was confirmed in the Implementing the Mental Health Forward View which included as an objective that all CCGs fully contribute to the development and delivery of local multi-agency suicide prevention plans by 2017. NHS England committed £25 million for suicide prevention from 2018 – 2021, with £5 million in 2018/19 and £10 million in each of the following two years. This was supported by the government's 'National Suicide Prevention Strategy' **[Exhibit DB/071]**, which was refreshed in 2017. The strategy included making sure there were clear local multi-agency suicide prevention plans at a local level. It was also accompanied by additional funding for suicide prevention and reduction schemes.

459. NHS England commissions (via the Healthcare Quality Improvement Partnership ("HQIP")) the National Confidential Inquiry into Suicide and Homicide ("NCISH") to develop research from national data collections and comparisons regarding suicides. This information is broken down to provide comparisons and learning, which includes a focus on inpatient suicides, different marginalised communities and other themes.

NCISH provide annual and special reports to inform NHS England's specific policy work on mental health suicide.

460. For example, NCISH published a toolkit to improve safety for mental health services, which identifies 10 priorities for improving safety to reduce suicide. NHS England policy reflects a number of these evidence-based priorities, including:

    a. Early Follow up on Discharge - in 2019/20, NHS England introduced a Commissioning of Quality and Innovation Framework ("CQUIN") to reduce the amount of time people wait for follow up upon discharge from hospital from 7 days to 72 hours. This is now the national standard.

    b. NHS England increased provision of 24/7 Crisis Response and Home Treatment teams from 47% of CCGs having services in place in 2016 to 100% in 2020.

461. In September 2023, the government published a policy paper on suicide prevention in England: 5 year cross-sector strategy **[Exhibit DB/072]**, its fourth progress report of the cross-government outcomes strategy to save lives through suicide prevention. The report recognised that between 2010-2020, efforts to improve patient safety led to a 35% fall in suicides in mental health inpatient settings, which is likely due to safer physical environments (including the removal of ligature points), staff vigilance, and wider improvements in mental health inpatient settings.

(m) Mental Health Data and Benchmarking

462. The Mental Health Services Data Set ("MHSDS") is a patient level, output based, anonymized, secondary uses data set collected monthly, which aims to deliver robust, comprehensive, nationally consistent and comparable person-based information for children, young people and adults who are in contact with services for mental health and wellbeing, learning disability, autism or other neurodevelopmental conditions. It is mandatory for all providers of NHS-funded specialist mental health services to submit relevant data to the MHSDS, including the voluntary and independent sector[23].

463. The MHSDS data is published in various formats, including Excel reports, CSV files or interactive dashboards, and can be accessed through different platforms. This data is

[23] Further information is available on the MHSDS website www.digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/mental-health-services-data-set/about

regularly released on a monthly and annual basis via the (legacy) NHS Digital website. Additional analysis and dashboards are available via the FutureNHS Collaboration Platform which is available to users with a *nhs.net* email address. These dashboards are customised to address specific policy needs for each team, focusing on monitoring progress against future NHS planning commitments. The reports and dashboards allow users to filter the data at various levels, from national down to provider level, to narrow the information to the desired level of detail required for analysis and decision-making. For more granular and complex analysis, users access the raw data via Excel or CSV files. The data is generally used to support systems planning, benchmarking, performance management, or service delivery monitoring.

464. MHSDS statistics offer a comprehensive national picture of the use of specialist mental health, learning disabilities or autism services in England and can be used by policy makers, commissioners, mental health service users and members of the public. At a national level, the data is used to inform national performance management and benchmarking, in particular against the priorities and targets set for the mental health system relating to areas such as inappropriate out of area placements, length of stay, access to community services and addressing health inequalities. For example, this happens via national reporting at NHS England board level, to Ministers, and/or in national-regional forums.

465. In 2016, as part of the Five Year Forward View for Mental Health, NHS England introduced the Mental Health Dashboard to bring together key data from across mental health services and to provide transparency in assessing how NHS mental health services are performing. It also provides technical details explaining how mental health services are funded and delivered. The dashboard is primarily populated by data collated as part of the MHSDS.

466. The dashboard provides NHS England and the Trusts with insight on mental health service performance, allowing them to review and benchmark providers. It also measures the performance of the NHS against the ambitions of the Five Year Forward View for Mental Health and NHS Long Term Plan, and presents activity and implementation data for specific ambitions, with a view on the progress that has been made in the latest quarter.

467. The most recent version is available up to and including quarter 2 of the 2024/25 financial year **[Exhibit DB/073]**.

468. NHS England also expects that services will utilise data from their systems at a local level, alongside that referred to above, in order to obtain assurance and monitor data trends.

469. In addition, NHS England may commission specific analyses on mental health data. For example, HQIP on behalf of NHS England jointly commissioned the National Clinical Audit and Outcomes Programme. This includes the Mental Health Clinical Outcome Review Programme, which examined suicide and homicide committed by people who had been in contact with secondary and specialist mental health services.

(7) Concluding Remarks

470. NHS England has sought through this first statement to provide a high-level summary of how the matters under investigation by the Inquiry should be considered within the broader context of statutory functions, regulatory responsibilities, and the wider structure of the NHS.

471. As noted above, NHS England operates within a complex statutory and regulatory framework, working alongside other NHS bodies, which remain independent statutory entities responsible for their own performance and regulatory compliance, all under the direction of the government of the day.

472. As a commissioner, NHS England has been responsible for commissioning specialised mental health services in Essex since 2013. This includes children and young people's mental health units, mother and baby units, eating disorder services, and forensic/secure units. As a regulator, NHS England oversees local commissioners and NHS Trusts, a function previously carried out by Monitor and the Trust Development Authority, collectively known as NHS Improvement. In its leadership role, NHS England coordinates healthcare services across England, providing direction and leading national transformation programmes to drive improvements in service quality. Additionally, NHS England plays a critical role in patient safety, setting and implementing the NHS Patient Safety Strategy to strengthen safety culture, systems, and improvements across the NHS.

473. We are cognisant that this statement provides a high-level summary, particularly in relation to the extensive Mental Health policy, and we expect to provide the Inquiry with further statements that cover these areas in greater detail.

474. NHS England will continue to work closely and transparently with the Inquiry as it takes forward consideration of these important issues.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: _____ [I/S] _____

Dated: _____26 March 2025_____

Annexes

- Annex 1 Further detail on legislative changes to the NHS
- Annex 2 Legacy Bodies
- Annex 3 Relationship between NHS England and DHSC
- Annex 4 Specialised commissioning governance arrangements
- Annex 5 NHS Providers (NHS Trusts and NHS Foundation Trusts)
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ANNEX 1: Further detail on legislative changes to the NHS

1. In the Relevant Period, the NHS in England underwent four major legislative reforms:

    a. The Health and Social Care (Community Health and Standards) Act 2003 ("the 2003 Act") provided for the establishment of NHS foundation trusts, semi-autonomous acute trusts with greater freedoms. Further details are provided below from paragraph 4.

    b. The National Health Service Act 2006 ("the 2006 Act") made a number of changes intended to protect the health of the public and to improve the running of the NHS. As a result of the reforms, the number of Strategic Health Authorities ("SHAs") were reduced from 32 to 10 on 1 July 2006 and the number of Primary Care Trusts ("PCTs") were reduced from 303 to 152 on 1 October 2006.

    c. The Health and Social Care Act 2012 (“the 2012 Act”) significantly re-organised the NHS, with many of the changes coming into effect on 1 April 2013. The 2012 Act amended the 2006 Act, which remains the main piece of primary legislation governing the NHS. These 2012 changes were known as the ‘Lansley Reforms’.

    d. The Health and Care Act 2022 (“the 2022 Act”) came into effect on 1 July 2022. The 2022 Act again amended the 2006 Act and re-organised the NHS (we have also referred to this as the 2022 Reforms). This is covered in paragraph 22 onwards, below.

2. As a result of these reforms, the NHS today is very different, both in structure and in the way it operates, to how it was at the beginning of the Relevant Period. These differences are important background, particularly when considering the responsibilities that the various statutory bodies (including NHS England) have had during this period and how these responsibilities have changed over time.

3. A brief explanation about how these pieces of legislation changed the structure of the health system are set out below.

(1) The Health and Social Care (Community Health and Standards) Act 2003

4. Statutory responsibility for providing or securing the provision of services for the purpose of the health service lay on the Secretary of State, rather than directly on

national, regional or local NHS bodies (although Trusts had the general function of providing services). At a national level, the DHSC discharged the Secretary of State's functions in relation to the NHS through part of the DHSC known as "the NHS Executive", headed by a civil servant known as the NHS Chief Executive.

5. At the regional level, Strategic Health Authorities ("SHAs") were responsible for overseeing and managing the health service. At a local level, NHS services were commissioned by PCTs, in exercise of functions directed by the Secretary of State. These commissioned services were provided by a combination of statutory NHS providers (Trusts) and independent or third sector providers. PCTs also provided some services, such as community health services, using their own staff and facilities.

(2) The National Health Service Act 2006

6. The 2006 Act consolidated existing legislation related to the health service. The 2006 Act also set out the importance of individuals being involved in their own care and treatment and placed duties on commissioners to promote such involvement.

7. The 2006 Act also places duties on commissioners to promote integration.

(3) The Health and Social Care Act 2012

8. Following the general election in 2010, the Government proposed extensive NHS reforms, known as the 'Lansley Reforms' after the then Secretary of State for Health, Andrew Lansley. These reforms were intended to bring about a "culture of open information, active responsibility and challenge" and "ensure that patient safety is put above all else, and that failings such as those in Mid-Staffordshire cannot go undetected".

9. The proposals were set out in the White Paper "Equity and Excellence: Liberating the NHS" published 12 July 2010 ("2010 White Paper") and formed the basis of the Health and Social Care Bill introduced in the subsequent year, which became, on enactment, the 2012 Act. The proposals included an "independent and accountable" and "autonomous" NHS Commissioning Board supporting local "GP commissioning consortia" (later to be called CCGs) who would be responsible for commissioning NHS services in local areas.

10. The establishment of NHS England and CCGs extended and completed the 'commissioner provider split', with neither NHS England nor CCGs being able to

provide healthcare services themselves. The Lansley Reforms also saw the establishment of the NHS Trust Development Authority and an updated and extended role for Monitor, reflecting the policy objectives underpinning the reforms.

11. A focus on outcomes and the quality standards that delivered them was emphasised throughout the 2010 White Paper. This built on the work of Lord Darzi, whose report "High Quality Care For All: Next Stage Review Final Report" (published on 30 June 2008) set out a three-domain definition of quality. This definition was incorporated into the 2010 White Paper and remains the accepted core definition of 'quality' within the NHS:

    a. the effectiveness of the treatment and care provided to patients — measured by both clinical outcomes and patient-reported outcomes;

    b. the safety of the treatment and care provided to patients; and

    c. the broader experience patients have of the treatment and care they receive.

12. To help deliver these quality-led improvements, the Lansley Reforms placed patient choice and provider competition at the forefront of how the NHS was intended to operate. Competition was understood to be focused on quality, rather than in a financial sense, with pricing nationally controlled through the National Tariff pricing structure. That said, the incentives to drive competition did include financial ones, such as contractual penalties for poor quality performance.

13. The core policy objectives underpinning the reforms legislated for in the 2012 Act were:

    a. a patient-centred health system, with more choice and control by patients, helped by easy access to information about the best providers;

    b. a focus on clinical outcomes, with success measured by improved outcomes; and

    c. empowered health professionals, including through healthcare being run from the bottom up and clinically led commissioning.

14. Commissioning was reformed in the following ways:

a. Establishment of the NHS Commissioning Board (known as “NHS England”) under section 9 of the 2012 Act by inserting a new section 1H to the 2006 Act. The Board was legally established on 1 October 2012, albeit without its full functions at that stage, following only partial commencement of section 9. The Board became fully operational on 1 April 2013 and adopted its operational name “NHS England” shortly after, with the agreement of the Secretary of State.

b. Establishment of local commissioning bodies, known as CCGs. A key feature of the Clinical Commissioning Group framework was that their members were the providers of primary medical services for the area of the CCG — i.e. the GP practices which served the CCG's population. CCGs were therefore intended to deliver a ‘clinically-led’ approach to the commissioning of local NHS services. The intention was that most NHS services would be commissioned by CCGs, supporting this clinically led approach.

15. From 2013 to 2022, the commissioning of most NHS healthcare services, including hospital, ambulance and community health services as listed in section 3 of the 2006 Act, was the responsibility of CCGs (excluding those services that NHS England had a duty to commission, as listed in Part A Section 3 above).

16. NHS England was responsible for establishing and assuring the performance of CCGs and setting their annual funding allocation. NHS England’s principal oversight tools were:

a. designating the Accounting Officer and removing the designation;

b. limited intervention powers that could only be exercised when a CCG was failing or at risk of failing; and

c. issuing guidance, the majority of which did not have binding statutory force. Instead, CCGs were required to have regard to it.

17. Powers of oversight were limited because CCGs were autonomous entities and NHS England had a statutory duty to promote the autonomy of CCGs[24]. This necessarily informed how NHS England exercised its assurance and performance functions.

[24] See Section 13F of the 2006 Act which was added by the 2012 Act and repealed by 2022 Act.

18. NHS England was responsible for making funding allocations to CCGs for the purpose of commissioning local health services from providers. Annual funding allocations to the system by year are available online and a diagram of how healthcare sums are spent is exhibited to this statement **[Exhibit DB/074]**.

19. Commissioning Support Units were established to provide support services to CCGs. They were created on the abolition of PCTs and they operate across the whole country. Commissioning Support Units deliver a range of support services that have been independently assessed to ensure that the NHS receives the benefits of scale, including clinical procurement services, business intelligence services and human resources. Commissioning Support Unit group staff are employed by the NHS Business Services Authority. Commissioning Support Units are hosted by (and are legally part of) NHS England, but have always been operationally distinct. Commissioning Support Unit activities are included in NHS England's Annual Report and Accounts, except where otherwise indicated. They continue in operation today, servicing a wide range of organisations, including ICSs, ICBs, local authorities and non-NHS bodies. The 2010 White Paper described NHS England as having five main functions, one of which was to provide national leadership on commissioning for quality improvement. This role was reflected in the statutory duties NHS England had, including the duty in section 13E of the 2006 Act to improve the quality of services.

20. The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("The Standing Rules Regulations") placed further specific responsibilities on NHS England in relation to its commissioning role. For instance, the Standing Rules Regulations required that NHS England draft model commissioning contracts, which CCGs were required to incorporate in commissioning arrangements (per Regulation 17). They also included a requirement (at Regulation 34) that commissioning decisions made by NHS England and CCGs complied with relevant recommendations made by the NICE[25].

21. In addition to these commissioning-specific reforms, there were other structural changes made in relation to previous arms-length bodies, including their abolition. This included changes to the role of the Independent Regulator of NHS Foundation Trusts and a statutory name change to Monitor, reflecting its operational name, and the

[25] And from 1 April 2013, the National Institute for Health and Care Excellence.

National Patient Safety Agency, which was abolished and whose functions were transferred to NHS England.

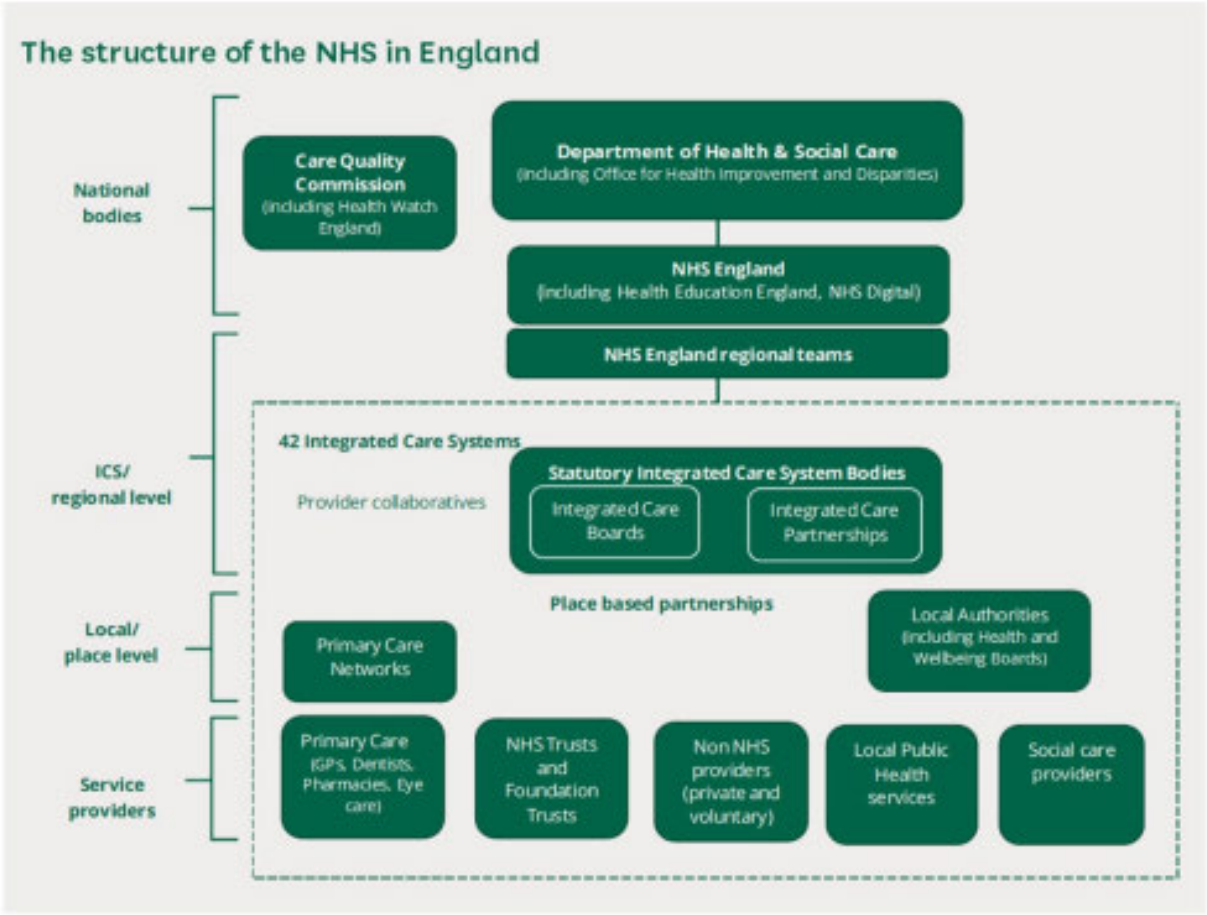
(4) The Health and Care Act 2022

22. The 2022 Act contained the biggest reforms to the NHS in nearly a decade, laying the foundations to improve health outcomes by joining up NHS, social care and public health services at a local level and tacking health inequalities.

23. The 2022 Act focused on developing system working, with ICSs being put on a statutory footing through the creation of ICBs. The Act provides simpler mechanisms for NHS England to delegate commissioning (and other functions) to ICBs, where appropriate. These provisions have been used to enable local commissioning of some specialised mental health services (with NHS England remaining accountable overall).

24. The Act formally merges NHS England and NHS Improvement and gives the Secretary of State a range of powers of direction over the national NHS bodies and local systems and trusts. Other provisions include putting the Healthcare Safety Investigation Branch ("HSIB") on a statutory footing; a new legal power to make payments directly to social care providers; the development of a new procurement regime for the NHS, and a new duty on the SSHSC to report on the system for assessing and meeting the workforce needs of the health service in England.

25. The below diagram sets out how the 2022 reforms discussed below are designed to bring about more integrated ways of working across the NHS:



Source: *'The Structure of the NHS in England,'* House of Commons Research Briefing, 10 July 2023 (Tom Powell)

ANNEX 2: Legacy bodies

1. The 2022 Act created the legal framework for Health Education England, NHS Digital and NHS Improvement (i.e. Monitor and the NHS Trust Development Authority) to merge with NHS England.

(1) Monitor

2. Monitor was established in 2004 as the independent regulator of NHS Foundation Trusts — a category of healthcare provider with greater freedoms and 'independence' from central administration than NHS Trusts.

3. Under the 2012 Act, Monitor's role was expanded and it became an independent regulator for NHS Healthcare services in England. This meant, in practice, that it regulated both Foundation Trusts and other independent sector providers of health services. However, NHS Trusts continued to be regulated separately by the NHS Trust Development Authority — essentially, on the basis that the NHS Trust Development Authority was preparing (i.e. developing) NHS Trusts for Foundation Trust status. In exercising its functions, Monitor was required to protect and promote the interests of patients by promoting the provision of healthcare services which are economic, efficient and effective, and which maintain or improve the quality of the services.

4. Monitor was established as an executive non-departmental public body operating under statutory provisions contained within both the 2006 Act and the 2012 Act. It operated within the same overall accountability structure and policy context as that described for NHS England. Monitor was directly accountable to Parliament as well as the Secretary of State and was required to submit annual reports and annual accounts. Like NHS England, Monitor was able to determine its own operating structure under the legislation and, throughout its operation, this included a mix of national directors and teams, and separate regional directorates and teams.

5. As an arms-length body, Monitor also entered into a Framework Agreement with the DHSC **[Exhibit DB/075]**. The 2014 Framework Agreement set out the principles that Monitor and the DHSC had agreed to operate under, as follows:

    a. working together in the interests of patients, people who use services and the public;

    b. respect for the importance of autonomy throughout the system;

c. working together openly and positively; and

d. mutual recognition of the Secretary of State's ultimate accountability to Parliament and the public.

6. In terms of its governance, Monitor had:

a. a Board, which included a non-executive chair and at least four other non-executive members, all of whom were appointed by the Secretary of State;

b. a chief executive appointed by the non-executive members of the Board, subject to the consent of the Secretary of State; and

c. other executive members, all appointed by the non-executives and subject to the requirement that the executives had to be fewer in number than non-executives.

7. Monitor's Board was required to operate in accordance with the corporate governance code for Central Government departments. Essentially, this meant that the role of its Board was to establish and take forward Monitor's strategic aims and objectives; hold the executive team to account; and enable Monitor to meet its accountability responsibilities. In order to perform this role, the Board was required to ensure that effective arrangements for assurance were in place (including assurance around risk management and governance).

8. Monitor set its own objectives. To ensure that these aligned with the DHSC's overall objectives for the health sector, Monitor was required to produce an organisational strategy every three years, with the aims of the strategy subject to DHSC agreement. In order to operationalise this strategy, and formalise the objectives that Monitor would work to, it was also required to develop a business plan. As with the strategy, the business plan was subject to agreement with the DHSC. DHSC Ministers met with Monitor on a quarterly basis to discuss strategic and topical issues. Agenda items for these meetings could be suggested by either party. The Chair and Chief Executive of Monitor attended these meetings, one of which was generally chaired by the Secretary of State. The Framework Agreement makes clear the expectation that Monitor and the DHSC operated in an 'open book' way, i.e. that there was a mutual flow of information and appropriate onward third-party sharing.

9. The Secretary of State also had the power (under section 63 of the 2012 Act) to issue guidance to Monitor on the objectives specified in NHS England's Mandate that were relevant to Monitor. We are not aware that this power was ever used.

10. A key part of its regulatory role was to licence providers of NHS healthcare services, and to enforce the conditions of the licence, under Chapter 3 of Part 3 of the 2012 Act. In this role, Monitor worked alongside the CQC to take action, using its licence enforcement powers when the CQC reported that a hospital Trust was failing to provide good quality care.

11. Monitor's regulatory powers and responsibilities are set out paragraphs 170-182 of this Statement. It operated alongside the NHS Trust Development Authority as NHS Improvement from 1 April 2016 until 1 July 2022.

(2) NHS Trust Development Authority (2012–2016)

12. Since their creation, NHS Trusts have been subject to a significant degree of control over key aspects of their operation, including their finances, appointments and removal of trust chairs and non-executive directors. In the period prior to 1 April 2013, this oversight was carried out by Strategic Health Authorities, exercising the functions of the Secretary of State pursuant to directions. Strategic Health Authorities operated under the oversight of the NHS Executive (an executive agency, part of the Department of Health) and the Chief Executive of the NHS.

13. A targeted transition period (which included establishing the NHS Trust Development Authority) was developed to enable a smooth changeover from Strategic Health Authority oversight to the formal establishment of the NHS Trust Development Authority.

14. The NHS Trust Development Authority was a Special Health Authority established by the Secretary of State by Order under section 28 of the 2006 Act. The Order took effect on 1 June 2022, and the NHS Trust Development Authority became fully operational from 1 April 2013. The NHS Trust Development Authority was established primarily to exercise such functions as the Secretary of State directed in connection with the management of the performance and development of NHS Trusts, in particular with a view to those NHS Trusts becoming NHS Foundation Trusts. These were the functions that had previously been exercised by Strategic Health Authorities.

15. Like Monitor, the NHS Trust Development Authority was party to a Framework Agreement **[Exhibit DB/076]** with the DHSC, through which it was accountable for the performance of its functions. This Framework Agreement was underpinned by annual objectives and business plans, subject to the same approval mechanisms as those described above at paragraph 5 for Monitor. The NHS Trust Development Authority, like NHS England and Monitor, had the ability to determine its operational structure under the legislation (and directions made by the Secretary of State). Throughout its operation, this included a mix of national directors and teams, and separate regional directorates and teams. Unlike Monitor, however, the NHS Trust Development Authority was subject to the Secretary of State's power to direct the body about how it exercised its functions (section 8 of the 2006 Act).

16. At the time of the NHS Trust Development Authority being established (and reflecting the policy objectives underpinning the 2012 reforms), the intention was that all NHS Trusts would over time become Foundation Trusts, either through applying in their own right to become one, or through being acquired by a Foundation Trust. An NHS Trust could be acquired either by application under Section 56A of the 2006 Act (as amended by the 2012 Act) or by the Secretary of State dissolving the Trust and transferring its staff and property to a Foundation Trust (paragraphs 29 to 30 and 44 of Schedule 4 to the 2006 Act). Section 179 of the 2012 Act provided for the abolition of NHS Trusts — the policy intention being this would be enacted once all NHS Trusts had become or had been acquired by Foundation Trusts.

17. With this in mind, the NHS Trust Development Authority's functions, as set out in the National Health Service Trust Development Authority Directions 2013, were to:

    a. performance manage NHS Trusts;

    b. manage the Foundation Trust pipeline;

    c. assure the adequacy of each NHS Trust's clinical quality, governance and risk management, as well as their compliance with relevant standards (this included monitoring their performance in terms of meeting the CQC's requirements) and support them where it considered improvements could be made; and

    d. make key appointments to NHS Trusts, including those of chairs and non-executive directors (pursuant to paragraph 3 of the 2013 Trust Development Authority Directions) and exercise the associated functions of the Secretary of State as contained in the National Health Service Trusts (Membership and

Procedure) Regulations 1990. This included suspension and termination of the chairs and non-executive directors. This role meant that representatives from the NHS Trust Development Authority sat on appointments panels for NHS Trusts.

18. In addition, because the NHS Trust Development Authority exercised the Secretary of State's powers to direct NHS Trusts, it could take more formal intervention measures if necessary.

19. The NHS Trust Development Authority's role in managing the 'Foundation Trust pipeline' necessarily meant that it needed to play a direct role in supporting the development of NHS Trusts. This included robustly assessing the effectiveness of NHS Trust boards and senior leaders. Standardised support and development tools, such as the Board Governance Assurance Framework **[Exhibit DB/077]**, were utilised to enable the NHS Trust Development Authority to perform this role.

20. In performing this supportive and developmental role, the NHS Trust Development Authority needed to work closely with commissioners (both NHS England and local CCGs), as well as with Monitor and the CQC. Given the focus in this statement on Foundation Trusts, we have not included detail about how the NHS Trust Development Authority operated in its NHS Foundation Trust pipeline/Trust development role.

21. In the period from 1 April 2016, the NHS Trust Development Authority operated as part of NHS Improvement. This is described in detail at paragraphs 36 to 41 of this Annex.

(3) Health Education England

22. Health Education England was established as an Executive Non-Departmental Public Body pursuant to section 96 of the Care Act 2014 on 1 October 2014 and the Special Health Authority, known by the same name, established in 2012[26] was abolished.

23. Education England's function was to provide national leadership and coordination for the training and development of the workforce. Health Education England was responsible for the planning, education and training of the future workforce, and development of the existing workforce working alongside commissioners and service providers.

[26] Pursuant to the Health Education England (Establishment and Constitution) Order 2012

24. Health Education England served the wider healthcare system (including private and third sector providers), but had no remit over social care.

25. Health Education England had six levers to achieve its purpose of improving the quality of patient care:

    a. Workforce planning: Each year they identified the numbers, skills, values and behaviours that employers told them were needed for future. Ensuring that the shape and skills of workforce evolve with demographic and technological change;

    b. Attracting and recruiting the right people to the education and training programmes they plan to commission;

    c. Workforce Transformation: Supporting the work of Local Workforce Action Boards in workforce transformation activities;

    d. Commissioning education and training programmes for medical students: Using commissioning levers to best effect so that medical students can learn to provide safe, high-quality care for patients;

    e. Lifelong investment in people: Encouraging employers to continue to provide high-quality care for patients through ongoing training;

    f. Leadership Academy: Developing better leaders, delivering better care: To develop outstanding leadership in health, in order to improve people's health and their experiences of the NHS.

26. Additionally, Health Education England supported healthcare providers and clinicians to take greater responsibility for planning and commissioning education and training through the development of Local Education and Training Boards, which were statutory committees of Health Education England.

27. Local Education and Training Boards were responsible for education and training at regional level. Their main role was to:

    a. plan and commission high-quality education and training in order to secure future workforce supply with the right numbers and right skills to improve health outcomes;

b. identify the local education and training needs of health and public health staff required to build skills and meet future service needs; and

c. bring providers and relevant stakeholders together to develop the workforce in line with local health needs and the service transformation agenda.

28. NHS England assumed responsibility for the activities previously undertaken by Health Education England following the merger.

(4) NHS Digital

29. NHS Digital was the operational name used by the 'Health and Social Care Information Centre', established under section 252 of the 2012 Act.

30. That name reflects what NHS Digital did: designing, developing, deploying and operating national digital products, platforms and information technology systems for the NHS; and collecting, analysing, curating, publishing and sharing health data and, to a lesser extent, adult social care data. This was for the direct care of patients (e.g. through the national digital products and systems we provided) and for secondary use purposes (such as for planning and commissioning health and adult social care services, and for research). NHS Digital was, therefore, a delivery organisation.

31. NHS Digital's statutory functions were principally set out in Chapters 2 and 3 of Part 9 of the 2012 Act. Its core statutory functions were summarised as:

a. establishing and operating information systems for the collection and analysis of data, where directed by the Secretary of State or NHS England under section 254 or requested by other eligible bodies under section 255 of the 2012 Act;

b. publishing data under section 260 of the 2012 Act and in accordance with the Code of Practice for Statistics;

c. disseminating data under section 261 of the 2012 Act and other relevant legislation, including in relation to the COVID-19 pandemic, under Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 ("COPI Regulations"); and

d. exercising IT system delivery functions of the Secretary of State or NHS England when directed to do so under Regulation 32 of the National Institute for Health

and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013/259 ("the NICE Regulations"); and supplying digital, data and technology services under section 270(1)(d) of the 2012 Act.

32. In relation to its role as a national statistics provider, NHS Digital was a large independent producer of statistical publications across health and care in England, producing around 80 series of publications, comprising around 300 individual publications a year. Publications were drawn from record level administrative datasets, surveys, clinical datasets and collections and covered the health of the population, patients' interactions with different care settings (including primary, secondary, mental health and social care), and cross-cutting areas, such as workforce.

33. NHS Digital was not the only producer of health and care statistics across England, with a number of other organisations producing statistics including NHS England, Office for National Statistics, the DHSC and UK Health Security Agency. These organisations worked closely together where statistics were on similar themes.

34. NHS Digital was accountable to the Secretary of State. The DHSC set out the Government's objectives for NHS Digital via remits which also outlined the operating context for NHS Digital, its accountability and funding flows.

35. As part of the 2022 reforms, NHS Digital's functions and staff transferred to NHS England and now operate as part of NHS England's Transformation Directorate.

(5) NHS Improvement

36. The move to a joint way of working between Monitor and the NHS Trust Development Authority was announced in June 2015 by the Secretary of State. This reflected the understanding that had become clear in the period from 2012 that many NHS Foundation Trusts had similar developmental and support needs to NHS Trusts and that, in order to drive improvements in operational performance and quality of care, a consistent approach was required; one that applied regardless of organisational form.

37. On 1 April 2016, the NHS Trust Development Authority and Monitor were brought together to create "NHS Improvement", under a formal joint working arrangement. (Legally, Monitor and the NHS Trust Development Authority remained in existence until they were merged with NHS England on 1 July 2022).

38. A number of NHS England teams moved to operate as part of NHS Improvement. This included:

    a. the National Patient Safety Team, which transferred from NHS England;

    b. the Advancing Change Team;

    c. the National Reporting and Learning System team; and

    d. Intensive Support teams from NHS Interim Management and Support.

39. Acting together as NHS Improvement, Monitor and the NHS Trust Development Authority were therefore responsible for regulation of Foundation Trusts and performance management of NHS Trusts, collectively referred to as provider oversight and governed by the Single Oversight Framework. This Single Oversight Framework replaced the separate frameworks that had been in place previously (namely Monitor's Risk Assessment Framework **[DB/013]** for NHS Foundation Trusts and the NHS Trust Development Authority's Accountability Framework for NHS Trust Boards **[DB/079]**). The Single Oversight Framework is described in more detail below.

40. No changes to primary legislation were implemented at this point to enable the establishment and operation of NHS Improvement, although 2016 Directions issued by the Secretary of State required the NHS Trust Development Authority to work collaboratively with Monitor, under a single leadership and operating model, to ensure "quality of care, patient safety and financial sustainability across the health service."

41. Although each body remained legally separate, with its own board and committees, a shared leadership model was facilitated by joint appointments of board members (i.e. individuals appointed as directors of both Monitor and the NHS Trust Development Authority), including the chairs and chief executives, and the practice of the boards and committees "meeting in common" (i.e. a Monitor and the NHS Trust Development Authority board meeting held at the same time and with a common agenda, in effect meeting as a single board).

(6) NHSX

42. In February 2019, the Secretary of State announced a new joint unit between NHS England, NHS Improvement and the DHSC called NHSX. Its aim was to focus on technology, data, innovation and digital capability. This new unit brought together

policy, strategic skills and expertise across these organisations to support the delivery of the Secretary of State's technology vision, launched in 2018 and to support the NHS Long Term Plan published in January 2019.

43. NHSX was not a legal body, but a working unit of the two teams, under the leadership of one Chief Executive (with dual appointments). It was responsible for coordination and consistency, setting national policy and developing and agreeing clear standards for the use of technology in the NHS. It was designed to be the single point for accountability for national digital transformation programmes and have oversight over NHS Digital.

ANNEX 3: Relationship between NHS England and DHSC

(1) NHS England's relationship with the Department of Health and Social Care

1. In general, and as described above, it is the responsibility of Ministers to direct national strategy and set funding levels.

2. The DHSC is responsible for setting policies that deliver the Government's strategic health objectives and, in turn, for making sure the legislative, financial and administrative frameworks are in place to deliver those policies, including the NHS Mandate (as described in paragraphs 4 to 10 below).

3. NHS England works with the DHSC to contribute to the development of policy and to support the government of the day to understand the operational implications of their priorities. NHS England will involve and engage with other people and organisations across the healthcare sector, including service users, as necessary, before providing input. Central government is then responsible for selecting from the policy options and ensuring any policy selected is appropriately financed.

4. NHS England is responsible for determining how to operationalise those policies to ensure effective delivery, and also for evaluating their impact. This is reported to government via the DHSC. NHS England's role in relation to Central Government decision making and policy development has remained broadly the same since 2013, with few notable exceptions (such as certain NHS-led changes introduced through the 2022 Act). Up until the 2022 Act came into effect, the Secretary of State would issue an annual 'Mandate' for NHS England. This set out the objectives which NHS England must seek to achieve and its budget, which established limits on the use of capital and revenue resources (in effect, this sets NHS England's financial allocation). This Mandate would be issued before the start of each financial year. Certain resources were ringfenced by the Mandate meaning that those sums could not be used for any other purpose, even if there was an underspend.

5. The Mandate and NHS England's financial allocation and associated resource limits have changed since 1 July 2022. The Mandate no longer needs to be issued annually and resource limits are now set in directions, not in the Mandate itself. As a result, the current Mandate **[Exhibit DB/080]** applies "until a new mandate is published".

6. Despite these changes, the accountability framework that the Mandate supports remains the same. NHS England is accountable to the Secretary of State for the

delivery of the Mandate. NHS England's Chair and Chief Executive Officer met the Secretary of State periodically to provide assurance on progress against Mandate objectives. The Mandate is reviewed annually by Government and an assessment is laid before Parliament.

7. The current mandate includes various mental health objectives, including supporting the NHS to reduce waiting times, improving patient flow through mental health crisis and acute pathways by providing new infrastructure for mental health support and to avoid unnecessary A&E attendance.

8. NHS England is required to produce a business plan that sets out how NHS England will deliver the objectives set out in the Mandate and reports on progress against this. It also produces an Annual Report on how it has exercised its functions during the year. NHS England's financial position is reported on annually through its Annual Accounts. I am providing NHS England's Business Plans for the years 2012 to 2023 to the Inquiry by way of general disclosure **[Exhibit DB/081] [Exhibit DB/082] [Exhibit DB/083] [Exhibit DB/084] [Exhibit DB/085] [Exhibit DB/086] [Exhibit DB/087] [Exhibit DB/088] [Exhibit DB/089]**.

9. The first Mandate was issued for the period April 2013 to March 2015 (the "First Mandate") **[Exhibit DB/090]]**. This First Mandate specifically referenced NHS England's responsibilities as a commissioner, including those in relation to specialised care, noting the opportunity that this provided for improved standards and national consistency **[§92 Exhibit DB/090].**

10. **The** First Mandate also emphasised the importance of NHS England working with CCGs and others to ensure that — whether NHS care is commissioned nationally or locally — the quality and value of the services should be measured and published in a similar way. The NHS Outcomes Framework was one aspect of supporting this objective. The emphasis on consistent measurement and publication of these metrics reflected the focus on reducing health inequalities and unjustified variation.

(2) The NHS Constitution

11. The NHS Constitution **[Exhibit DB/091]**, which is the responsibility of the DHSC, establishes the principles and values of the NHS in England. It sets out the rights to which patients, public and staff are entitled. It includes a specific section on the responsibilities that staff have to the public, patients and colleagues. These

responsibilities, which combine legal duties to which staff are subject and aims they should work to, include the following:

a. To accept professional accountability and maintain standards of professional practice as set by the appropriate regulatory body;

b. Raise any genuine concern about a risk, malpractice or wrongdoing; and

c. Be open with patients and families if anything goes wrong; welcome and listen to feedback and address concerns promptly.

12. In addition, the NHS Constitution and the associated Handbook summarises the legal rights that staff have. This includes the right to “raise any concern with their employer, whether it is about safety, malpractice or other risk, in the public interest”.

13. In addition to the fundamental standards contained within the NHS Constitution, many staff working within the NHS will be subject to professional regulation and required, as a result, to operate in accordance with the standards of their profession.

ANNEX 4: Specialised commissioning governance arrangements

1. Details of NHS England's commissioning role is described above in Part A Section 3. This annex provides further details on specialised commissioning governance arrangements at a national level.

2. Under the 2006 Act and secondary legislation made under it (specifically the Standing Rules Regulations), the Secretary of State has required NHS England to arrange for certain specified services or facilities. This approach has been used from the outset of NHS England's establishment. The Standing Rules Regulations contain the list of services that are "Prescribed Specialised Services". This is the basis of NHS England's duties to commission specified services for rare and very rare conditions. Some mental health services are identified as Prescribed Specialised Services.

3. The Prescribed Specialised Services Manual sets out a description of each of the 143 Specialised Services and how they are commissioned. It also contains the identification rules which describe how commissioners identify specialised services within the data flows that support the commissioning process.

4. NHS England's governance arrangements in relation to specialised services commissioning have evolved and developed over time. These arrangements continue to evolve as the commissioning of more specialised services are delegated to ICBs, supported by Provider Collaboratives (see Part A, Section 3 above).

5. The role of the national teams, and associated governance structures supporting specialised commissioning, is to identify learnings and disseminate these to develop, review and modify national standards and specifications and to manage the overall budget for specialised services. The national governance arrangements have developed over time, as described below.

6. Part of the way through 2013, NHS England established a Directly Commissioned Services Committee to oversee the delivery of directly commissioned services within the overall strategy set by NHS England. This Committee's remit was not specific to specialised services and included within its scope all services for which NHS England has direct commissioning responsibility (as set out at paragraph 85). The Directly Commissioned Services Committee's responsibilities included the following:

a. ensuring quality standards were defined and that services were delivered to those standards; and

b. agreeing commissioning priorities and allocation of resources, and assuring appropriate service planning was in place.

7. This Directly Commissioned Services Committee was supported by the Specialised Commissioning Oversight Group, which had operational oversight and responsibility to take operational decisions specific to specialised commissioning. The Terms of Reference for the Specialised Commissioning Oversight Group describe the shared responsibility of national and regional teams in discharging the specialised services commissioning responsibilities, with the Group holding these teams to account for delivering high-quality specialised services within budget. In addition, the Group's role was to provide leadership and direction to the overall operating model, acting as a single voice for specialised commissioning within NHS England.

8. From the outset, specialised services commissioning was supported by a number of Clinical Reference Groups, which were established on a service-specific basis. These Groups were the primary forum in which issues relating to the service specification and design were considered.

9. With the move to a national commissioning approach for specialised services, there was a focus during this initial post-establishment period on developing and implementing national data collection systems. This was done alongside a structured quality assurance framework for specialised services and included the development of a number of quality dashboards, against which providers of specialised services could be measured and, crucially, which would enable benchmarking between providers. These quality dashboards enabled collation of data relating to patient outcomes and experiences and supported assurance of provider delivery against national service specifications for specialised services. The development and implementation of these dashboards were also intended to enable a move away from service audits as the primary way of measuring service delivery against specified standards. The dashboards were designed to be dynamic; able to measure performance against a smaller set of metrics and enable benchmarking.

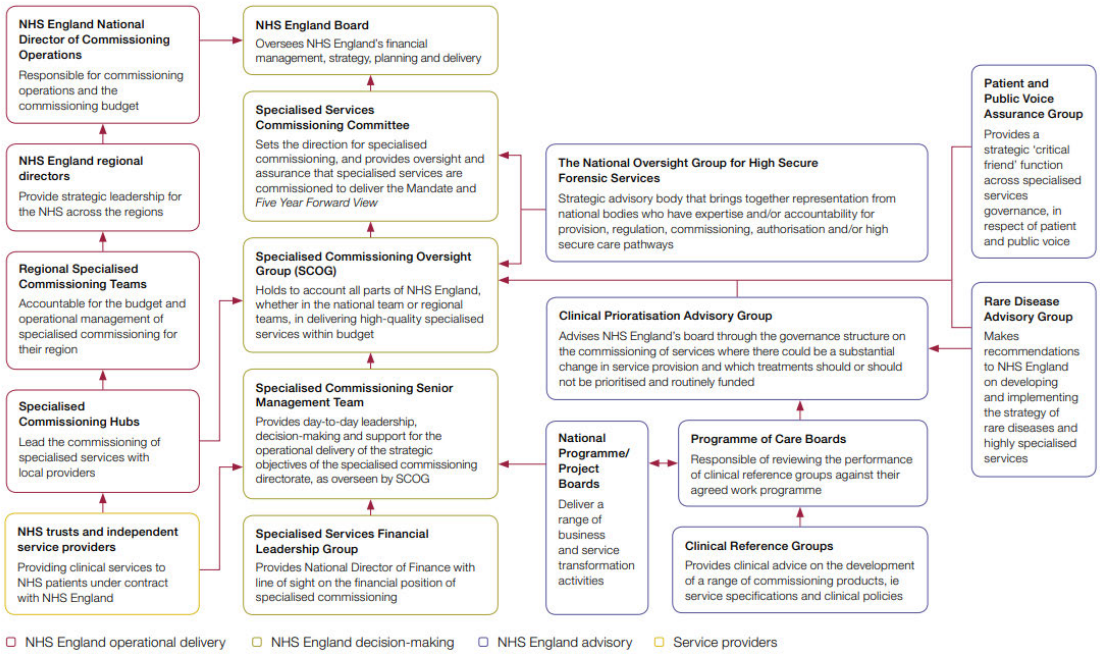
10. Following an internal review of the governance arrangements for specialised services, the national governance arrangements changed in mid-2015, with the establishment of a standalone Specialised Services Commissioning Committee reporting directly to

NHS England's Board. The purpose of establishing this Committee was to create a strategic agenda and focus for the governance of specialised services commissioning separate to the wider direct commissioning agenda.

11. The Specialised Commissioning Oversight Group continued in existence, but its reporting arrangements were updated, reflecting the establishment of the Committee. The Group remained focused on operational oversight and operational decision making.

12. The national specialised services governance arrangements in place in the period 2015/16 are set out below:

NHS England's management and governance structure for the commissioning of specialised services, 2015-16



Notes

1 The National Director of Specialised Commissioning is the chair of SCOG, a member of the Specialised Services Commissioning Committee and reports directly to the NHS England Board.

2 Regional specialised commissioning teams and hubs are supported by the Specialised Commissioning Senior Management Team in their day-to-day operations. They report to SCOG on their performance commissioning specialised services, but are held accountable by their regional directors for their specialised commissioning budgets.

Source: National Audit Office review of NHS England documents and interviews

13. There were further changes to the governance of specialised services as a result of the more integrated working arrangements put in place between NHS England and NHS Improvement in 2018. As part of these changes, the Specialised Services Commissioning Committee was disbanded, with the majority of its remit being transitioned to the new Delivery, Quality and Performance Committee and associated subcommittees.

14. There was also a separation of strategy and delivery, with the Specialised Commissioning Oversight Group being replaced by the Specialised Commissioning and Health and Justice Strategy Group and the Specialised Commissioning and Health and Justice Delivery Group. These arrangements remained in place until 2022. However, while these structural changes took place, the underlying principles around the role of the National Specialised Services Directorate and the reporting and accountability lines described above remained consistent throughout this period.

15. Finally, in 2022, NHS England set up a Delegated Commissioning Group for Specialised Services. This was to support the move towards delegation of some Specialised Services to ICBs. This Group acts as the advisory forum in respect of delegated Specialised Services. In parallel, a National Commissioning Group was established to act as the advisory forum in respect of the Specialised Services that will continue to be commissioned by NHS England. These Groups will be responsible for approving national standards for the services within their respective remits, as well as for assuring and overseeing specialised services as set out in the Specialised Commissioning Assurance Framework.

ANNEX 5: NHS Providers (NHS Trusts and NHS Foundation Trusts)

1. As explained above, there are two types of provider trusts in England: NHS Trusts and NHS Foundation Trusts. The key differences are the degree of autonomy they enjoy from central control by NHS England and the Secretary of State, and up until July 2022 they had different regulators. Together, we refer to them as ‘Trusts’ or 'NHS providers' in this statement.

(1) NHS Trusts

2. NHS Trusts as a type of provider organisation have existed since 1991. They are independent organisations, with their own budgets and management structures. As a statutory NHS body, they are subject to a range of legislative provisions, and there was an oversight regime that was specific to them.

3. From 1 April 2013, NHS Trusts were formally monitored and regulated by the NHS Trust Development Authority, which exercised many of the Secretary of State’s functions in relation to NHS Trusts, pursuant to Secretary of State directions. In addition, and in the same way as NHS Foundation Trusts, NHS Trusts were regulated by the CQC.

4. When considering the regulation of NHS Trusts, it is helpful to understand briefly the history of how NHS Trusts came into being:

    a. Before 1991, hospitals and hospital services were directly managed by the health authorities responsible for securing the provision of services to their population. Health authorities would arrange for some services to be provided by independent providers or voluntary organisations but, otherwise, there was no separation between NHS bodies responsible for arranging hospital services (commissioners) and those providing them (providers).

    b. This position first began to change with the National Health Service and Community Care Act 1990 and the ‘internal market’ reforms of the government of the day. These reforms introduced NHS Trusts as separate statutory corporate bodies, responsible for managing and administering hospitals and providing both hospital and community health services for the purposes of the NHS.

    c. NHS Trusts were independent, in that they were separate statutory bodies managed by a board of directors. They provided services under agreements with

health authorities. These agreements took the form of NHS contracts and, as is the case now, they were not enforceable as contracts in law (see section 9 of the 2006 Act).

d. However, NHS Trusts at this time were subject to a significant degree of control over their finances. For example, the Secretary of State set financial objectives, supplied the capital for NHS Trusts and imposed spending limits. The Secretary of State also had powers to appoint and remove trust chairs and non-executive directors, intervene in the event of failure, and dissolve or merge trusts.

e. NHS Trusts were also subject to the Secretary of State's powers of direction. Originally, this power of direction applied only in certain limited areas (such as the terms and conditions of staff and powers to generate income) but, following the changes introduced by the Health Act 1999, NHS Trusts were subject to a general power for the Secretary of State to direct them about the exercise of any of their functions.

5. From 1 April 2013, as described above, these powers over NHS Trusts were exercised by the NHS Trust Development Authority.

6. The legal position today essentially remains the same in terms of the status and oversight of NHS Trusts, with the exception that the oversight role in relation to trusts is now performed by NHS England. Over time and particularly since 2016 when NHS Improvement became operational, there has been a move towards the use of a common oversight process and structure for both NHS Trusts and NHS Foundation Trusts.

(2) NHS Foundation Trusts

7. NHS Foundation Trusts were introduced in 2003, in line with the NHS Plan published in 2000. The overall aims of the 2000 Plan were to enhance services, provide more choices to patients and reduce the central control of the NHS. The policy was detailed in the White Paper "Delivering the NHS Plan: Next Steps on Investment, Next Steps on Reform" (April 2002) **[Exhibit DB/092]**. It was envisaged in that White Paper that existing high-performing trusts would become Foundation Trusts with greater freedoms than existing trusts, including "the freedom to develop their board and governance structures to ensure more effective involvement of patients, staff, the local community and other key stakeholders". Foundation Trusts would have more financial control over

their assets but would “operate to NHS standards, be subject to NHS inspection and abide by NHS principles”.

8. The Health and Social Care (Community Health and Standards) Act 2003 was the legislation that first enabled NHS Foundation Trusts. It established the Independent Regulator of NHS Foundation Trusts (which was known operationally at the time as ‘Monitor’) and enabled NHS Trusts to apply to Monitor to become authorised as an NHS Foundation Trust. Details of the new arrangements were set out in “A Guide to NHS Foundation Trusts” (December 2002) **[Exhibit DB/093].**

9. The first NHS Foundation Trusts became operational in April 2004, and by 2012 there were around 140 NHS Foundation Trusts across the country. Today there are 154.

10. In 2006, the Health and Social Care (Community Health and Standards) Act 2003 was, in a large part, repealed, but with the legal provision which enabled the establishment of NHS Foundation Trusts re-enacted in Chapter 5 of Part 2 of the 2006 Act (being the key piece of legislation which continues to govern the NHS in England).

11. Like NHS Trusts, Foundation Trusts are statutory corporate bodies with a board of directors. However, NHS Foundation Trusts are a particular type of corporate body, namely ‘public benefit corporations’, and they have greater freedoms than NHS Trusts. In particular, NHS Foundation Trusts are not subject to the Secretary of State power of direction and they have financial freedom to manage their own budgets, decide on capital investment, borrow from third parties and retain surpluses.

12. Whereas NHS Trusts are established in accordance with Establishment Orders issued by the Secretary of State and their governance structure (including Board membership) is determined by the Order, regulations made by the Secretary of State and provisions of the 2006 Act, the governance structure of NHS Foundation Trusts is set out in their constitutions. These must be consistent with Schedule 7 of the 2006 Act and they are expected to follow a form which is consistent with a model published by Monitor (which remains current as of the present day).

13. One key distinguishing feature of NHS Foundation Trusts, in terms of their governance and constitution, is that they are membership organisations with a membership comprised of local people, patients, carers, and staff. They are also required to have a Council of Governors, elected from amongst the membership.

14. At least half of the governors on the Council of Governors must be elected by public or patient members; at least three governors must be elected by staff; and at least one governor must be elected by one or more qualifying local authorities. Governors are elected for a period of up to three years and are then subject to re-election.

15. Foundation Trust chairs and non-executives are appointed by the organisation's own Council of Governors rather than the Secretary of State (or an arms-length body exercising this power, as in the case of the NHS Trust Development Authority). Additionally, the 2012 Act introduced new duties and powers for Governors, including:

    a. a general duty to hold the NHS Foundation Trust non-executive directors individually to account for the performance of the Board of Directors;

    b. a general duty to represent the interests of the members of the NHS Foundation Trust as a whole, and the interests of the public;

    c. a power to require one or more of the Directors to attend a meeting for the purpose of the governors obtaining information about the NHS Foundation Trust's performance of its functions or the directors' performance of their duties.

16. Foundation Trusts are required to take steps to secure that their governors are equipped with the skills and knowledge they require in their capacity as governors. During the Relevant Period, this has included the following national learning and development offers:

    a. GovernWell **[Exhibit DB/094]**, which was jointly commissioned from 2013 by NHS Providers and the NHS Leadership Academy, and which has evolved since then to include other support tools, such as an induction toolkit.

    b. guidance and information for governors published by Monitor (and, in some cases, as joint publications between Monitor and the DHSC), an example being the August 2013 publication **[Exhibit DB/095]** "Your statutory duties: A reference guide for NHS foundation trust governors" (which remains in use as of the present date, but which was updated by NHS England in 2022 through the publication of an addendum **[Exhibit DB/096]**.

    c. products and publications issued by NHS Providers (the membership organisation for all NHS Trusts and NHS Foundation Trusts).

17. In addition, NHS Trusts and NHS Foundation Trusts are able to independently commission training and other organisational development support.

18. Further information about training and development for those in leadership roles in NHS Trusts and NHS Foundation Trusts, including the role of the NHS Leadership Academy, is set out below.

19. There are also differences in the way that NHS Foundation Trusts contract. Unlike NHS Trusts, the arrangements that NHS Foundation Trusts enter into with commissioning bodies to provide services are contracts in law not NHS contracts (subject to section 9 of the 2006 Act). However, although this has a theoretical impact on how any contractual dispute is dealt with[27], NHS Foundation Trusts are still (like NHS Trusts) required to use the NHS Standard Contract and, in reality, this distinction does not otherwise have a practical impact on how commissioning contracting works in a NHS Foundation Trust context.

20. To obtain NHS foundation trust status, an NHS trust must make an application to NHS England (Monitor before July 2022) (section 33 of the NHS Act 2006). The application must be accompanied by the proposed constitution of the Foundation Trust and provide any information required. Before July 2022, an NHS trust could only make an application if it was supported by the Secretary of State. From 1 July 2022, when NHS England took on the Foundation Trust authorisation function, the position is that NHS England can only authorise the trust as an Foundation Trust if the Secretary of State approves the decision.

21. In addition to the SSHSC's authorisation, in order to grant an application NHS England (previously Monitor) must be satisfied as to the matters specified in section 35 (2) of the NHS Act 2006:

    - the proposed constitution is in accordance with the Schedule 7 to the Act, which specifies requirements for FT constitutions;

    - the applicant has taken steps to secure that (taken as a whole) the actual membership of any public constituency of the FT, and (if there is one) of the

[27] NHS Contracts are not enforceable in the usual way through the courts, whereas the contracts that NHS Foundation Trusts enter into (even commissioning ones, using the NHS Standard Contract) have ‘regular’ contract status and as such can be enforced in court, in the usual way.

patients' constituency, will be representative of those eligible for such membership;

- there will be a council of governors and a board of directors constituted in accordance with the constitution;
- the steps necessary to prepare for NHS foundation trust status have been taken;
- the applicant will be able to provide goods and services for the purposes of the health service in England (and in doing so may consider any CQC reports or recommendations in respect of the trust, and the trust's financial position); and
- any other requirements which NHS England considers appropriate are met.

22. NHS England must also be satisfied that the applicant trust has sought the views of;

- those who live in the area of the proposed public constituency;
- any local authority who would be authorised by the constitution to appoint a member of the council of governors;
- if the proposed constitution includes a patient constituency, the individuals who would be able to apply to become members of that constituency.

23. Applications would be considered in accordance with guidance issued by NHS England (or before July 2022, Monitor). The latest guidance is that issued by Monitor and updated in 2015, which remains in force (although has not been applied in practice since the last Foundation Trust authorisation in 2016). Trust applications to become an NHS Foundation Trust were assessed to test whether the trust was financially sustainable, well led (in terms of governance processes and quality of leadership), locally accountable, and ready to take on the greater freedoms that NHS Foundation Trust status allows. In 2010, Monitor also introduced new criteria for testing Trusts' governance arrangements for ensuring quality care (in light of the lessons from the failings in patient care at Mid Staffordshire NHS Foundation Trust and the resulting inquiry into this, as discussed in Section 3A below).

24. Once authorised, the NHS Foundation Trust was subject to standard 'terms of authorisation'. These covered things such as a description of the services it was

authorised to provide, a requirement to operate in accordance with national standards for healthcare, a list of assets designated as protected (and therefore subject to limits on disposal etc.), limits on amount of private work the NHS Foundation Trust could carry out, and a total borrowing limit. From 1 April 2013, the terms of authorisation were replaced by the Provider Licence (described in detail below).

25. A Foundation Trust is automatically issued an NHS Provider Licence, and the Foundation Trust is regulated in accordance with the licence and related enforcement powers. In addition, each Foundation Trust is subject to the power of Monitor (now NHS England) under section 111 of the Health & Social Care Act 2012, which enables NHS England to impose additional licence conditions;
    - Where NHS England is satisfied that the governance of the Foundation Trust is such that the trust will fail to comply with the conditions of its licence, and the licence condition is appropriate for the purpose of reducing that risk; and
    - Where the CQC has issued a warning notice under s.29A of the Health and Social Care Act relating to the quality of the Foundation Trust's services.

26. If a Foundation Trust breaches an additional condition, NHS England may require it to suspend or remove the board of directors or governors and replace them with interims.

27. There is no process for re-assessing or removing Foundation Trust status. However, the use of enforcement powers may limit the freedoms of individual Foundation Trust's. In addition, since the Health & Care Act 2022, NHS England has the power to impose a limit on the capital expenditure of an individual Foundation Trust (section 42B of the NHS Act 2006).

28. Although there is no process to remove Foundation Trust status, a Foundation Trust can be subject to “trust special administration” where the Foundation Trust is, or is likely to become, unable to pay its debts, or there is a serious failure of an Foundation Trust to provide services of sufficient quality. In this process, the Foundation Trust is administered by an administrator appointed by NHS England, who makes recommendations as to the future of the trust. At the end of the process, the Foundation Trust may be dissolved and its services, staff and property transferred to another trust.

ANNEX 6: Role of the Care Quality Commission in regulating providers

1. As noted above at paragraph 117, all NHS providers must be registered with the CQC. The various interdependencies between the CQC and Monitor/the NHS Trust Development Authority and latterly NHS Improvement have been set out above, in describing the way that Monitor, the NHS Trust Development Authority and NHS Improvement regulated NHS Trusts and NHS Foundation Trusts during the Relevant Period.

2. We note particularly the following points:

    a. The CQC is (and has been since it was established in 2009) the primary body responsible for regulating the quality of care being provided by regulated providers of healthcare services.

    b. It assesses regulated providers against fundamental standards of care. The wording of these has changed during the Relevant Period, but the underpinning concepts that inform these fundamental standards have remained largely constant.

    c. Unlike other regulatory bodies, including Monitor/NHS Improvement, the CQC carries out “live”, “on-site” inspections of providers, including NHS Foundation Trusts. While the NHS Standard Contract and the Provider Licence provide for the right of inspection, these powers are rarely used, with both commissioners and other regulators seeking to derive efficiencies and reduce regulatory burden by utilising the information obtained by the CQC during its inspections.

    d. The CQC shared access to the key systems that were also used by Monitor/NHS Improvement and NHS England to perform their regulatory, oversight and commissioning functions. In particular, all of these bodies used the National Reporting and Learning System, which was the primary reporting system during the Relevant Period that NHS Foundation Trusts would use to report serious incidents. The CQC's notification requirements reflected this common reporting system for NHS Foundation Trusts (and NHS Trusts), as distinct from other non-NHS regulated providers who had to report incidents directly.

e. In addition to its inspections, the CQC monitored provider performance using intelligence gathered in a number of ways. This was known as “Intelligent Monitoring”. These shared national programmes of data collection and analysis are part of the National Clinical Audit and Patient Outcomes Programme, which is a programme of clinical audits commissioned on behalf of NHS England by the Healthcare Quality Improvement Partnership.

f. Monitor/NHS Improvement, NHS England and the CQC all operated at both national and regional levels and had both national and regional structures that facilitated multi-agency working and information sharing.

(1) Inspections of regulated providers

3. During a routine comprehensive inspection, the CQC will assess how well a provider is meeting all the inspected standards. Whilst these standards have changed slightly over the last 15 years, they have always focused on matters of safety and quality. Part of the routine inspection may include an unannounced inspection.

4. A focused inspection is, as the name suggests, a more targeted assessment and will involve focusing on relevant aspects of the inspected standards, but will not always involve looking at all of them.

5. Following an inspection, each provider will receive an overall rating of either: outstanding, good, requires improvement or inadequate. In addition to this overall rating, providers will also be given service-by-service ratings.

(2) Intelligent Monitoring

6. Alongside its inspection programme, the CQC also monitors regulated provider performance. As discussed, it used a tool called “Intelligent Monitoring” to highlight specific areas of care that the CQC would then follow up through inspections and other activity with regulated providers. The indicators used in Intelligent Monitoring were related to the five key questions used during inspections (as above).

7. NHS England understands that the CQC would also take the results of their intelligent monitoring analysis and group the 160 acute and specialist NHS trusts into six priority bands for inspection. These bands were intended to provide an indicator as to the overall risk that a provider might not meet one or more of the regulatory standards.

8. At the time that NHS Improvement was established, there was a desire to enhance the effectiveness and timeliness of how the CQC's monitoring information about providers was shared with NHS Improvement, in order to ensure that there were “sufficient early warning of quality issues at providers” **[Exhibit DB/097]**.

9. Although the term “Intelligent Monitoring” is no longer used, the CQC continues to monitor a range of data sources to inform its regulation of providers.

10. The CQC's approach to regulation has evolved over time, with its remit expanding to incorporate assurance of ICSs (including ICBs and Local Authorities). From 18 July 2022, the CQC has used its new single assessment framework, with an early adopter programme commencing from 21 November 2022. Well led assessments for all NHS Trusts and NHS Foundation Trusts were due to begin from 6 February 2023.

11. In addition to the above routine regulatory processes, the CQC carries out service-specific programmes of inspection.

ANNEX 7: How the NHS works with other partners

(1) NICE

1. The National Institute of Health and Care Excellence (NICE) was established as a body corporate under the 2012 Act. Previously, it existed as a Special Health Authority known as the National Institute for Clinical Excellence, using the same acronym.

2. The National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Information Functions) Regulations 2013 ("the 2013 NICE Regulations"), made under the 2012 Act, conferred on NICE the power to make three categories of recommendation:

    a. a general power to give advice or guidance, provide information or make recommendations about any matter concerning its core activity;

    b. NICE Technology appraisal recommendations; and

    c. NICE highly specialised technology recommendations.

3. NHS England and ICBs should have regard to NICE recommendations, but they are not mandatory. This is in contrast to "technology appraisal recommendations" and "highly specialised technology appraisal recommendations", with which commissioners must comply under the 2013 NICE Regulations.

4. NICE and NHS England work together to manage access to new drugs and medical technologies. As per section 234(1)(a) of the 2012 Act, NHS England can also direct NICE to prepare a quality standard in relation to the provision of NHS Services.

5. In 2016, NHS England and NICE agreed a Memorandum of Understanding covering the period 2016 – 2019, in relation to the "innovative activities in the fields of medical technologies and observational data" that NHS England had commissioned NICE to carry out. This is the main document setting out the overarching relationship between NICE and NHS England. It covers the following fields:

    a. Cancer Drugs Fund;

    b. Commissioning Support Documents / Evidence Summaries;

    c. Rapid Evidence Summaries;

d. Medical Technology Innovation Briefings; and

e. Commissioning Through Evaluation Projects.

6. Further information on the activities within each of those fields is set out in Schedule 3 of the Memorandum of Understanding **[Exhibit DB/098]**.

7. A key area of NICE's work is clinical guidelines, quality standards, and indicators, all of which are publicly available on NICE's website.

   a. Clinical guidelines are evidence-based recommendations, developed by independent committees and consulted on by stakeholders.

   b. Quality standards set out priority areas for quality improvement. They highlight areas with identified variation in current practice.

   c. Indicators measure outcomes that reflect the quality of care, or processes linked by evidence to improved outcomes.

8. A focus of NHS England's working with NICE has been on the development of quality standards. The topics for quality standards are considered and determined through cross-organisation input, including NICE, NHS England, and the DHSC. Previously "The Three Sectors Meeting Terms of Reference" **[Exhibit DB/099]** set out those key partners and a decision-making tree for how clinical guidelines and quality standards would be initiated. The Three Sectors Meeting then became the "Cross Agency Topic Prioritisation Group" ("CATPG"), also including representatives of NICE, NHS England and the DHSC. CATPG determines the priority of new and updated NICE guideline topics, and the coordination and alignment with other guidance and policy. Further information is set out in the Terms of Reference for the CATPG **[Exhibit DB/100].**

9. The initial library of Clinical Guidelines and Quality Standards had to be selected for development each year as new topics were developed. The development stage is now completed, and NICE have moved into systematic review and product maintenance stage.

10. The NICE CGQS Development Process sets out the processes for topics to be developed to publication as a Clinical Guideline, Quality Standard, or Indicator.

11. NICE have published 10 guidance documents on different aspects of mental health and wellbeing. It has also published 10 quality standards setting out priority areas for

quality improvement. This includes 'promoting health and preventing premature mortality in black, Asian and other minority ethnic groups' and 'mental health of adults in contact with the criminal justice system'. NICE is currently developing a quality standard for 'school-based interventions: physical and mental health and wellbeing promotion'.

(2) NHS Leadership Academy

12. The NHS Leadership Academy was set up as an independent organisation in April 2012, following an announcement by the Secretary of State in May 2011. Its principal purpose is the stewardship of the leadership agenda, including developing outstanding leadership in health with a continual focus on improving the experiences and health outcomes of patients. The Academy continued the pre-existing NHS graduate management training scheme and Top Leaders programmes, as well as delivering a suite of leadership development programmes through partners. In order to broaden its reach, the NHS Leadership Academy became part of Health Education England in 2017.

13. In April 2019, the NHS Leadership Academy transferred to the NHS Trust Development Authority and so became part of NHS Improvement, and through joint working within the body known as ‘NHSEI’. However, it was not legally or formally part of NHS England.

14. By the National Health Service Trust Development Authority (Leadership Academy) Directions 2019, the Secretary of State directed the NHS Trust Development Authority to maintain and provide for the operation of the Leadership Academy as a unit of the Trust Development Authority, and to work collaboratively with Monitor and NHS England in carrying out those activities. The Academy was based in NHS England’s People Directorate, but from 2019 to 1 July 2022 it was required to be operated as a separate unit.

15. On 1 July 2022, the NHS Leadership Academy’s staff and activity transferred to NHS England upon the abolition of the Trust Development Authority. Legally, there is no longer a requirement to have a separate unit called the NHS Leadership Academy - its activities are pursued under the general functions of NHS England, rather than any specific legislation.

(3) Devolved administrations

16. Nationally, multiple teams and individuals in NHS England work with the devolved nations. By way of illustration, NHS England's Chief Nursing Officer attends regular meetings with the chief nursing officers of the devolved administrations. A similar arrangement applies in relation to the National Medical Director and the chief medical officers of the devolved administrations, but noting that England is unique among the Four Nations in having both a Chief Medical Officer (who fulfils a government role) and a National Medical Director, who works solely for NHS England.

17. NHS England is under a duty to consider the cross-border implications of the way it commissions local services, as were CCGs and now ICBs. This means that for the most part, the principal level of engagement with, for example, the Welsh Health Boards, will generally be at the regional team level.

ANNEX 8: The Regional landscape of the legacy organisations

(1) The regional landscape of Monitor

1. As described in Section 1, Monitor operated with a combination of national and regional governance structures.

2. Each region was responsible for regulating healthcare providers within its jurisdiction. The relevant regions were responsible for assessing and enforcing compliance with the licence conditions, including consideration of risks to financial sustainability and good governance, based on information on performance, quality of care and financial health. As explained in Section 1, Monitor had a range of enforcement powers and regulatory action it could take where actual or potential breaches of the Provider Licence were identified. Its focus, both nationally and regionally, was on those Foundation Trusts that were struggling or who required additional support. Well-performing providers were less closely scrutinised, as is normal in all regulatory environments.

3. The routine reporting requirements that all NHS Foundation Trusts were required to comply with fell into four broad categories:

    a. annual submissions, such as strategic and operational plans;

    b. in-year submissions, such as financial and other service performance information;

    c. exception reports: the Risk Assessment Framework noted that this was "other information that may have material implications for a licence-holder's compliance …e.g., a report by a medical Royal College that identifies concerns relevant to the trust's governance of quality (and therefore to the trust's compliance with its licence)"; and

    d. other: this included the periodic reviews Monitor expected Foundation Trusts to commission and report on (specifically governance reviews).

4. As part of the relevant regional health system, Monitor operated as part of a collaborative regional structure that included close working with the equivalent structures in operation by the NHS Trust Development Authority, the CQC, commissioners (both NHS England and CCGs) and other partners.

5. In general, Monitor would be informed by the CQC that it was inspecting a Foundation Trust (however it was not given an annual schedule of inspections and information was generally shared in an informal way, either shortly prior to or at the same time as the inspection commenced). If the CQC found concerns during its inspection, and particularly if a Foundation Trust was found to require improvement or was rated inadequate, Monitor would be informed and would support the Foundation Trust to implement the action plan it had agreed with the CQC.

6. Monitor's Risk Assessment Framework emphasised the reliance placed on inspections and judgments made by the CQC, noting that "Monitor does not intend to duplicate [the Care Quality Commission's] regulation" but that "issues relating to quality of care can arise from or reflect poor governance", bringing them within Monitor's remit. As noted in Section 1, Foundation Trusts were also required to report to Monitor the outcomes of a CQC inspection or review.

(2) The regional landscape of NHS Improvement

7. As explained in Section 1, Monitor operated as part of NHS Improvement from 1 April 2016. Although this resulted in changes to the way the organisation operated, it did not fundamentally change the regional structures in place. One practical impact of the change was that NHS Improvement teams operated across the combined NHS Foundation Trust/Trust footprint, meaning that the overall number of organisations each Regional Director was responsible for increased.

8. A key part of each NHS Improvement Regional Director's role was to work with all Trusts (NHS trusts and Foundation Trusts) to enable them to exit quality and/or financial special measures, undertake use of resources assessments and to support and empower Chairs and Chief Executive Officers to deliver performance standards, financial control and patient care improvements.

9. NHS Improvement's primary focus shortly after it was established was on financial management at a provider level, due to the concerns that existed at the time around financial performance. Whilst NHS Improvement did have several workstreams that related to quality, it relied primarily on the oversight provided by the CQC and commissioners when it came to assessing the quality and safety of particular services. If there were concerns about a potential breach of license conditions then NHS Improvement would intervene.

10. As explained in Section 1, from 1 October 2016 NHS Improvement used information obtained from its Single Oversight Framework to offer targeted support to providers before serious concerns arise, as well as identifying and acting on more serious concerns, such as where there had been a license breach. Oversight was based on the principle of earned autonomy — with providers in segments 1 and 2 experiencing higher autonomy and those in segments 3 and 4 receiving mandated support.

11. Throughout the period May 2016 to April 2019, the Executive Regional Managing Director for the NHS Improvement relevant Region was supported by an executive team that included the following roles:

    a. Regional Chief Operating Officer;

    b. Operational Regional Director of Finance;

    c. Regional Medical Director; and

    d. Regional Nurse Director.

12. Within the Regional team, Delivery and Improvement Directors were responsible for smaller areas within the Region.

13. The NHS provider organisations that fell within the Executive Regional Management Director's remit included acute, community, mental health and ambulance Trusts.

ANNEX 9: Sustainability and Transformation Partnerships

1. As a direct result of the Five Year Forward View, the establishment of Sustainability and Transformation Partnerships was announced in December 2015 (through the Delivering the Forward View: NHS planning guidance 2016/17-2020/21 in December 2015 **[Exhibit DB/101]**). This marked a key shift, as it:

    a. reduced the focus solely on individual organisations, with a requirement for organisations to work collaboratively, across a 'place' footprint and for the totality of the population within that footprint;

    b. committed to multi-year planning and allocations, spanning the period October 2016 to March 2021;

    c. encouraged integrated pathways, spanning primary, secondary and community care, with an expectation that social care was also aligned; and

    d. directed focus on a number of nationally set areas of focus, including seven-day services; investment in prevention; improved cancer outcomes.

2. Regional teams led on the development of Sustainability and Transformation Partnership footprints and the appointment in March 2016 of leaders for each Sustainability and Transformation Partnership area. Working with Sustainability and Transformation Partnership leaders to progress the vision of the Five Year Forward View and the associated NHS planning guidance was a major area of focus for the regional teams in the period from December 2015.

3. Alongside the development of Sustainability and Transformation Partnerships, another parallel policy development was being implemented in the form of the devolution agenda, which was part of the Government's overall northern powerhouse approach. Devolution was an area of national and regional focus during the period from 2015-2018.

4. Further steps were taken towards integration at the national regulator level in 2016, when NHS Improvement was established. This close collaboration was expanded in 2019, when NHS Improvement and NHS England began working as a single organisation.

ANNEX 10: Professional regulation

(1) General Medical Council

1. In addition to the quality governance structures summarised above, which enable sharing between NHS England and professional and system regulators, NHS England also has responsibilities for engaging with the General Medical Council (GMC) about fitness to practise matters through the Responsible Officer requirements.

2. In summary, designated bodies under the Medical Profession (Responsible Officers) Regulations 2010 (as amended) are required to appoint a Responsible Officer. Responsible Officers are accountable for the local clinical governance processes in particular healthcare organisations, focusing on the conduct and performance of doctors. Their duties include evaluating a doctor's fitness to practise and liaising with the GMC to make recommendations based on which the GMC can decide whether a doctor should be revalidated.

3. Responsible Officers also liaise with the GMC in individual fitness to practise cases. Responsible Officers can make referrals to the GMC, which lead to investigations in relation to a doctor's behaviour, health or performance. The GMC publishes 'thresholds guidance' which explains to Responsible Officers the thresholds for referrals and the process for making referrals. Additionally, the GMC has Employer Liaison Advisors who can assist Responsible Officers to understand the thresholds and processes. If there are serious concerns about a doctor's fitness to practise, to the extent that there is a threat to patient safety, the Responsible Officer should immediately refer the doctor to the GMC.

4.

5. Where a doctor works for an NHS Trust or Foundation Trust, their Responsible Officer will usually be the single Responsible Officer for that body. For both NHS Trusts and Foundation Trusts, the Responsible Officer is appointed by the boards of those organisations and will typically be a senior clinician. It can be the Chief Medical Officer, but it does not have to be. A Responsible Officer must be a registered medical practitioner and have been a registered doctor for the preceding five years.

6.

7. As Responsible Officers within NHS Trusts and Foundation Trusts must be registered medical practitioners and fit to practise, they will themselves have Responsible Officers. NHS England ordinarily hosts these higher-level Responsible Officers. The higher-level Responsible Officer will submit revalidation recommendations to the GMC for all Responsible Officers connected to them. The recommendation will be based, as it is for all doctors, on information from appraisals and from routine monitoring of performance and fitness to practise. Assessment of fitness to practise of the Responsible Officers includes how a doctor carries out his/her functions as a Responsible Officer.

(2) Nursing and Midwifery Council

8. The Nursing and Midwifery Council (NMC) is the independent regulator for nurses and midwives in the UK, and for nursing associates in England (this role only exists in England). NHS England and the NMC work together nationally to agree key strategic matters including supporting the NMC in the development of regulatory standards and codes of practice. As an example, NHS England worked closely with the NMC during the recent pandemic, including on the opening of the temporary NMC register for COVID-19.

9. Like the GMC, the NMC operates guidance and has an Employer Link Service to support referrals. It is expected that referrals are made by appropriately authorised individuals within employing organisations (e.g., within NHS Trusts and NHS Foundation Trusts). Individual fitness to practise concerns in relation to those regulated by the NMC are not routinely discussed or raised with NHS England. Intelligence, information and opportunities for learning and improvement which arise from investigations and other activities by the CQC is often shared with NHS England, primarily through the regional and local quality governance structures described above.

(3) The Health & Care Professions Council

10. The Health and Care Professions Council (HCPC) is the regulator to the following 15 health and care professions in the UK

    a. Arts therapists

    b. Biomedical scientists

    c. Chiropodists/podiatrists

d. Clinical scientists

e. Dietitians

f. Hearing aid dispensers

g. Occupational therapists

h. Operating department practitioners

i. Orthoptists

j. Paramedics

k. Physiotherapists

l. Practitioner psychologists

m. Prosthetists/orthotists

n. Radiographers

o. Speech and language therapists

11. Like the other regulators, HCPC provide standard and guidance to relevant health care professionals and works with NHS England on strategic matters including supporting the development of frameworks and policies. The HCPC also investigates referrals into concerns regarding the health and care professionals within its remit through fitness to practice proceedings.