Witness Name: Sir Julian Hartley Statement No: First Exhibits: JH1 to JH50 Dated: 27 March 2025

THE LAMPARD INQUIRY

FIRST WITNESS STATEMENT OF SIR JULIAN HARTLEY

I, Sir Julian Hartley, will say as follows:-

Introduction

- 1. I am the Chief Executive of the Care Quality Commission (CQC). I was appointed to this position in December 2024. Prior to this, I was Chief Executive at NHS Providers from February 2023 to November 2024 and was Chief Executive at various NHS Trusts prior to February 2023. My career in the NHS began as a general management trainee, before working in a number of NHS management posts at hospital, health authority, regional and national level. I have served as Chief Executive of several organisations, including ten years as Chief Executive of Leeds Teaching Hospitals NHS Trust.
- 2. This witness statement is made in response to a Rule 9 request made by the Lampard Inquiry (the Inquiry) to CQC dated 24 February 2025 (the Request). The Request required the preparation of a draft statement and the collation of substantial quantities of material to be submitted by 17 March 2025. CQC has now been asked to finalise the statement so that it can be disclosed to Core Participants in advance of the hearings scheduled to take place in April 2025. The Inquiry's Request for documents relating to the relevant Trusts is not one that CQC is reasonably able to comply with within the very short timeframe provided by the Inquiry given the magnitude of the task. The reason for this is twofold: firstly, the relevant time period relates to several predecessor organisations. The historic documentation that would have been held by those organisations and which is of

potential relevance to the Inquiry is held in paper form with an external document storage provider. CQC must manage the retrieval and review process of this documentation as well as conducting searches of various electronic repositories which are no longer used by CQC. Secondly, the complexity of the electronic repositories in use over the relevant time period requires careful navigation to ensure that all material of relevance to the Inquiry is captured. CQC continues to work at pace to search for, locate and collate the relevant material to assist the Inquiry but I wish to highlight that this is a considerable task which requires careful and thorough consideration. CQC is committed to assist the Inquiry by progressing with our document review as quickly as practically possible within the limits of our resource and infrastructure. On behalf of CQC, I wish to reiterate our desire to continue to work collaboratively with the Inquiry.

- 3. I am duly authorised to make this witness statement on behalf of CQC. The contents of this witness statement are true to the best of my knowledge and belief. As stated above, I joined CQC in December 2024, and in preparing this statement, I have therefore drawn on the institutional memory of the organisation, as conveyed to me through communications with other members of staff and I have also had reference to various documents. Where I have referred to information from other sources, I believe that information to be true. In preparing this statement (and the accompanying documents), I have been assisted by lawyers in the CQC Inquiries team and external Counsel, Jenni Richards KC.
- 4. On behalf of CQC, I would like to express my sincere condolences to the families of those who tragically lost their lives and confirm my commitment to assist the Inquiry so that lessons can be learnt.

Governance of CQC

Board

5. CQC has a unitary Board made up of Non-Executive and Executive members. The Chair and other Non-Executive Members, who must make up a majority of the Board, are appointed by the Secretary of State. Legislation sets out requirements governing these arrangements, including Schedule 1 of the 2008 Act (as amended), the Care Act 2014 and the Care Quality Commission (Membership) Regulations 2015. The Care Quality Commission (Membership) Regulations 2015, which came into force in September 2015, include a requirement for the

Board to have no fewer than six and no more than 14 members (not including the Chair). The Board is supported by a number of established committees, which provide assurance and advice to the Board on areas such as risk management and internal control, risks specific to the regulatory programme, and senior pay and succession planning.

- 6. During the relevant time period covered by the Inquiry's Terms of Reference (ToR), when CQC in its current guise was in existence (2009 to December 2023), the membership of the Board has changed. Exhibit JH1 shows the current membership of CQC's Board as at 17 March 2025. Professor Sir Mike Richards CBE has been named as the preferred candidate for next Chair of CQC. Subject to approval by the Health and Social Care Select Committee, Mike Richards will take over from the current Chair, Ian Dilks, when his appointment ends on 31 March 2025.
- 7. The Board ordinarily met monthly (save for August) in both public and private session from 2009 to 2023. As from February 2023, the frequency of Board meetings was varied. The Board now has six formal meetings a year as well as meeting for two Board Strategy Days a year.

Executive Team

 Our Executive Team (ET) meets formally twice a month. Current membership of the ET is listed on our website. [Exhibit JH2] Committees of ET meet to consider matters such as: strategic oversight, operational performance, and people, financial, and commercial resources.

Corporate Governance Framework

9. CQC has a corporate governance framework [Exhibit JH3]. This sets out the responsibilities and procedures that we use to make sure we govern our organisation to a high standard. This framework was refreshed in 2021, and again in 2022.

Framework Agreement

 In addition, a signed Framework Agreement is in place between CQC and DHSC [Exhibit JH4]. This sets out our governance, as well as accountability, management and financial responsibilities and reporting procedures. It includes the Accounting Officer's accountability responsibilities to Parliament. It was last reviewed in 2021 and is currently in the process of being updated. A draft has been shared with the DHSC and will in turn be reviewed by our Executive Team and Chair.

Overview of CQC and its functions

CQC's Duties and relevant Regulations

- 11. CQC was established on 1 April 2009 by the Health and Social Care Act 2008 (the 2008 Act) as the independent regulator of health and adult social care in England. CQC is an executive non-departmental public body, sponsored by the Department of Health and Social Care (DHSC), and accountable to Parliament through the Secretary of State for Health and Social Care.
- 12. Our functions, statutory duties and powers, which extend to England only, are set out principally in the 2008 Act¹. They can also be found in the Health and Social Care Act 2012 (the 2012 Act), the Care Act 2014 (the 2014 Act), the Health and Care Act 2022 (the 2022 Act), as well as in further primary and secondary legislation. In summary, we are responsible for the registration, monitoring, inspection and regulation of services which fall within our regulatory remit.
- 13. We have a duty to conduct reviews of the carrying on of prescribed regulated activities and service providers, assess performance following the review, and to publish a report of our assessment as set out in section 46 of the 2008 Act.
- 14. The 2022 Act received Royal Assent on 28 April 2022 and added to the list of regulatory duties owed by CQC. Section 31 and 163 of the 2022 Act inserted sections 46A and 46B into the 2008 Act, which extended CQC's duties to conduct reviews, assess performance and to publish reports relating to, among other things, the provision of relevant health care, and adult social care, within the area of each Integrated Care Board (ICB) and the exercise of regulated care functions by English Local Authorities.
- 15. We have a duty, under the Mental Health Act 1983 (MHA), to monitor how services exercise their powers and discharge their duties when patients are detained in

¹ As set out in Section 2 of the 2008 Act.

hospital, subject to community treatment orders or guardianship. In addition, we monitor how the Mental Capacity Act 2005 (MCA) is being used by health and adult social care providers and how they use the Deprivation of Liberty Safeguards (DoLS).

16. Our objectives when fulfilling these functions are set out in section 3 of the 2008 Act. Our purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and to encourage care services to improve. We report on how care is being delivered in England in our annual State of Care report which is available on our website.

Requirement for registration with CQC (CQC's regulatory remit)

- 17. Providers of 'regulated activities' must be registered with CQC unless a specified exemption or exception applies². These regulated activities are:
 - a) personal care;
 - b) accommodation for persons who require nursing or personal care;
 - c) accommodation for persons who require treatment for substance misuse;
 - d) treatment of disease, disorder or injury (TDDI);
 - e) assessment or medical treatment for persons detained under the 1983 Act;
 - f) surgical procedures;
 - g) diagnostic and screening procedures;
 - h) management of supply of blood and blood derived products;
 - i) transport services, triage and medical advice provided remotely;
 - j) maternity and midwifery services;
 - k) termination of pregnancies;
 - I) services in slimming clinics;
 - m) nursing care; and
 - n) family planning services.
- 18. It is an offence to carry on a regulated activity without being registered, and we can prosecute those who do this. Registered persons can be an individual, a partnership or an organisation. CQC will register the relevant legal entity that will be carrying on the regulated activity.

² Set out in Section 10 of the 2008 Act and defined in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Registration with CQC

- 19. When CQC decides whether to grant or refuse an application for registration of a service provider we must apply the test set out in section 12 of the 2008 Act. This provides that we must be satisfied that the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, and the Care Quality Registration Regulations 2009, and any other enactment which appears to us to be relevant, are being and will continue to be complied with in relation to the regulated activity for the application to be granted, otherwise we must refuse it. Prior to 2014, providers were required to comply with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. We have the power to grant an application subject to conditions and the power to impose, vary or remove conditions on the registration.
- 20. At the point of registration, we are required to issue a certificate of registration. This sets out the regulated activities that the provider is permitted to carry on, and the locations at which the provider may carry on the regulated activities by means of a locations condition which forms part of the conditions of registration. Other conditions may be placed on the registration of providers, depending on the type of provider and the type of service being operated.
- 21. Following registration, we monitor and inspect services in accordance with our published guidance and inspection framework.
- 22. Providers can apply to us to be registered to carry out one or more regulated activities. As an example, acute NHS trusts may be registered to carry on regulated activities such as treatment for disease, disorder or injury (TDDI), surgical procedures, diagnostic and screening procedures, maternity and midwifery services, depending upon the trust. It is for the provider to determine which regulated activities it carries on and therefore which activities it requires registration for. CQC's Scope of Registration offers guidance to providers to help them decide whether they need to register with CQC and explains what we mean by regulated activities, who and what needs to be registered and which regulated activities they are most likely to need to register for.

CQC Registered Providers within the scope of the Inquiry

- 23. CQC has reviewed its records and believes that the following NHS Trusts³ which provided mental health inpatient care in Essex were registered with it during the period with which the Inquiry is concerned⁴:
 - a) Mid Essex Hospital Services NHS Trust registered 1 April 2010, most recently inspected in November 2019;
 - b) North Essex Partnership University NHS Foundation Trust (NEFT) registered 1 April 2010, most recently inspected in September 2016;
 - c) South Essex Partnership University NHS Foundation Trust (SEFT) registered 1 April 2010, most recently inspected June/July 2015;
 - d) North East London NHS Foundation Trust (NELFT)– registered 1 April 2010, most recently inspected in June 2022;
 - e) Essex Partnership University NHS Foundation Trust (EPUT) formed by the merger of SEFT and NEFT; registered 1 April 2017, most recently inspected in December 2024 and January 2025. The report is currently being prepared and will be published when it is complete.
- 24. In response to Question 2 of the Request, we have liaised with operational colleagues and our registrations teams and understand that information regarding private providers linked to the Essex NHS Trusts is not readily available. We can provide a list of the registered NHS services under the Essex Trusts. Information relating to the contractual arrangements between the Trusts and private providers would only be held by the Trusts themselves.

Notifications and reporting patient safety incidents

- 25. Registered providers and/or registered managers are required to submit notifications to us about certain incidents, events or changes that affect a service, or the people using it. These are called 'statutory notifications'.
- 26. The statutory notification framework is set out in regulations 12, 14-18, and 20-22 of the Care Quality Commission (Registration) Regulations 2009 (the 2009 Regulations). The 2009 Regulations also state the timescales within which we

³ Where we refer to NHS trusts, in this statement and in the documentation we reference, we are including Trusts and Foundation Trusts.

⁴ Dates of last on-site visits taken from most recent inspection report, correct as at 17 March 2025.

must be notified, and these vary depending on the type of notification. CQC uses information from statutory notifications to:

- a. be aware of what is happening in a service;
- b. identify issues of concern;
- c. inform whether we need to take regulatory action; and
- d. monitor trends across health and care.
- 27. Regulation 25 of the 2009 Regulations states that it is an offence not to notify CQC when a relevant change, event or incident has happened, specifically in relation to regulations 12 and 14 to 20. Failure to notify under regulation 21 (death of a registered provider) is not in and of itself an offence, however, in this event, the service will no longer be registered and it is an offence to operate as an unregistered provider.
- 28. The information that must be provided to CQC varies depending on the type of notification being submitted. We hold a range of forms to enable providers to submit statutory notifications to us and there is a specific form for each different type of notification.
- 29. Providers are required by law to notify us of the death of a person accessing their service under Regulation 16 of the Care Quality Commission (Registration) Regulations 2009. We ask for a range of demographic information about the person who died, using a structured reporting form (SN16). Regulation 17 of the same Regulations requires providers to notify us about unauthorised absences and deaths of people detained or liable to be detained under the MHA.
- 30. We expect providers to have appropriate systems in place to report incidents. These apply to all of the regulated activities within CQC's remit, including mental health inpatient facilities.
- 31. Regulation 18 of the 2009 Regulations sets out a range of events or occurrences which providers must notify us of so that, where needed, we can take follow-up actions. Registered persons must send these notifications directly to us unless the provider is a health service body and it has followed the below process. A health service body, as defined by the 2009 Regulations, includes an English NHS body,

which is defined in section 97 of the 2008 Act to include an NHS trust or NHS Foundation Trust.⁵

- 32. Registered persons must notify us of incidents that affect the health, safety and welfare of people who use services. The list of notifiable incidents includes: certain types of injury; abuse or allegations of abuse; incidents involving the police (not applicable to an English NHS body); applications regarding deprivation of liberty; and events which could prevent the provider's ability to continue to carry on the regulated activity safely. Some examples of events which have necessitated a Regulation 18 notification include: staff shortages; utility access; damage to the premises; and malfunction or failure of safety devices such as fire alarms.
- 33. The 2009 Regulations state that in some circumstances, where the provider is a health service body, notifications about the death of a service user and other incidents impacting on the health or safe care and treatment of a service user do not need to be submitted to CQC. For this to be the case, the provider must have already submitted the information to the NHS Commissioning Board (now NHS England (NHSE)). In practice this would have been through the National Reporting and Learning System (NRLS) which was in use from 2005.
- 34. This would include those notifications relating to: deaths of people using the service (Regulation 16); allegations of abuse (Regulation 18(2)(e)); events that stop or may stop the service from running safely and properly (Regulation 18(2)(g)); or serious injuries of people using the activity (Regulation 18(2)(a) and (b)).
- 35. The notifications to NHSE via NRLS are shared with us under a data sharing agreement and are incorporated into our intelligence and monitoring. NRLS has now been replaced by the Learn from Patient Safety Events (LFPSE) service with effect from the end of June 2024 (although some trusts submitted data to LFPSE from 2022). Our Data Sharing Agreement continues to apply to the LFPSE service.

⁵ "a National Health Service trust all or most of whose hospitals, establishments and facilities are situated in England, NHS England, an integrated care board, an NHS foundation trust or a Special Health Authority performing functions only or mainly in respect of England".

- 36. CQC expects providers to have proper policies and processes in place to enable the reporting of statutory notifications. A failure to comply with the requirements of Regulations 12 and 14 to 20 of the 2009 Regulations is an offence.
- 37. Serious incidents were previously investigated by providers using the NHSE Serious Incident Framework. This framework describes the circumstances in which a heightened level of response to a serious incident may be required, and the processes and procedures for achieving that response. Any cases that met the criteria of serious incident were required to be reported on the Strategic Executive Information System (STEIS). This was to ensure that serious incidents were identified correctly, investigated thoroughly and learned from in order to prevent similar incidents happening again. This framework was replaced by NHSE's Patient Safety Incident Response Framework in Autumn 2023. CQC previously had access to STEIS data and continues to have access to data from the revised framework.
- 38. CQC sample checks, as part of our inspections, whether individual Management Reviews or Root Cause Analyses were completed by a trust, to contribute to a multi-agency Serious Case review. We look to see whether changes to practice were implemented as a result, and how regularly the service holds mortality and morbidity meetings when serious incidents occur (including who attends them and if they are minuted). CQC considered these issues during an unannounced comprehensive inspection of EPUT in November 2022.

Predecessor organisations

From 2000 – 2009

Commission for Health Improvement, Healthcare Commission, Mental Health Act Commission, National Care Standards Commission and the Commission for Social Care Inspection

39. Prior to the establishment of CQC, there were several organisations responsible for monitoring and regulating health and social care. CQC was created in 2009 following an amalgamation of the Healthcare Commission (HCC), the Mental Health Act Commission (MHAC) and the Commission for Social Care Inspection (CSCI). Each of these organisations had different duties, functions and areas of expertise. We have included an overview of the relevant organisations during the relevant time periods below.

Mental Health Act Commission

40. The MHAC was established in 1983 as a monitoring body to consider the legality of detention and the protection of human rights of individuals detained under the MHA. Its remit included reviewing the operation of the MHA in respect of detained patients and patients likely to be detained under it, investigating complaints and appointing medical practitioners to give second opinions in cases where this is required under the MHA. The MHAC was also required to provide a report to Parliament every two years.

Commission for Health Improvement

41. From 2000 until 1 April 2004, the Commission for Health Improvement (CHI) was the health sector regulator dealing with safety, quality and standards. CHI was established by the Health Act 1999 and its aim was to improve the quality of patient care. CHI conducted inspections of entities including NHS trusts, investigated where there had been serious failure, advised the NHS on best practice, checked that the NHS was following national guidelines, and was responsible for publishing an annual report on the state of the NHS. CHI was subsumed by the HCC in 2004. CHI did not have any enforcement powers.

Healthcare Commission

- 42. The HCC was created by the Health and Social Care (Community Health and Standards) Act 2003 and was subsumed by CQC in April 2009. The HCC was responsible for: "encouraging improvement in the provision of health care by and for NHS bodies" and its main functions were⁶:
 - a) To publish data relating to the provision of healthcare by NHS bodies;

⁶ Health and Social Care (Community Health and Standards) Act 2003, sections 49-52

- b) To conduct a review of the provision of healthcare by each NHS body and award a performance rating by reference to the standards devised by the Secretary of State, this was to be completed each financial year;
- c) To conduct inspections to inform the above functions;
- d) To conduct reviews of the overall provision of healthcare by NHS bodies;
- e) To conduct revies of the overall provision of particular kinds of healthcare; and
- f) To conduct particular reviews at the request of the Secretary of State.
- 43. If the HCC identified any significant failings during its inspections, it was obliged to report them to the Secretary of State and to make recommendations to remedy any failings identified. Until April 2008, the HCC could take enforcement action in relation to private and voluntary healthcare providers, under the Care Standards Act 2000 (CSA 2000). HCC was able to impose, vary or remove conditions, cancel registration, serve enforcement notices and had the power to prosecute for specified offences. HCC was also able to make recommendations to the relevant Department of Health Minister at the time and to Monitor (the independent regulator of Foundation Trusts).

National Care Standards Commission and Commission for Social Care Inspection

44. The Commission for Social Care Inspection (CSCI) was established as an inspectorate for adult social care in England in 2004⁷. It was concerned with the management of the services and the efficiency of their provision. CSCI produced inspection reports concerning the quality and quantity of social care services at a local and national level. CSCI also investigated complaints when services did not meet the relevant standards. CSCI was able to take enforcement action under CSA 2000 in relation to adult social care providers. CSCI ceased to exist upon the establishment of CQC. We do not consider that the work of CSCI or its predecessor the National Care Standards Commission (NCSC), which was in existence from 2001 to 2004, will be of direct relevance to the Inquiry's ToR.

Monitoring the Mental Health Act – 2009 to date

45. CQC has certain statutory duties in relation to the monitoring of mental health services which are of relevance to the Inquiry's ToR. These duties were previously

⁷ Health and Social Care Act 2003, section 42

conducted by the MHAC and were subsequently incorporated into CQC's functions in 2009. The visiting regime in place in 2009 has applied from 2009 to date and remains the same currently.

- 46. We have a duty, under the MHA, to monitor how services exercise their powers and discharge their duties when patients are either detained in hospital, subject to community treatment orders or subject to guardianship orders. We also have duties to review and powers to investigate MHA complaints raised by or on behalf of individuals, and to provide a Second Opinion Appointed Doctor Service (SOAD) to review or certify treatment.
- 47. MHA monitoring visits focus on monitoring the use of the formal powers of the MHA, the exercise of duties under the MHA and the experience of detained patients. Standard ward visits focus on speaking with detained patients, seeing the environment in which they are detained and reviewing records relating to detention and treatment.
- 48. Our MHA Reviewers visit all places where patients are detained under the MHA and meet with them in private. Where requested, arrangements can also be made to meet patients who are on a community treatment order. We also look at the day-to-day operation of powers and duties under the MHA. If we identify concerns this can trigger further monitoring or inspection activity. The frequency of visits varies, up to a maximum of two years.
- 49. Standard MHA monitoring visits were carried out to individual wards that treated detained patients on a regular cycle of 18 or 24 months, the frequency was determined by the service type. Focused or thematic MHA monitoring visits were carried out in response to risks or concerns. An MHA monitoring visit report was written following each monitoring visit and was sent directly to the service provider of the ward. The visit report included a summary of our findings and raised actions arising from the visit. Providers were required to provide an action statement in response to our reports advising of the action they would take/had taken in response to the issues raised.
- 50. From 2009, MHA reviewers conducted the MHA monitoring visits and were integrated into our wider mental health inspection teams, reporting directly to

mental health inspection managers. MHA reviewers shared intelligence and findings with the mental health inspectors in their teams.

51. We report annually on deaths of detained patients in our MHA Monitoring the Mental Health Act annual reports. This data is also routinely shared with the Ministerial Board of Deaths in Custody.

Care Quality Commission Inspection Framework - 2009 to 2013

52. To explain our role in monitoring and inspecting NHS trusts and mental health inpatient care, we have provided detail of the various inspection frameworks that were in force from the creation of CQC in 2009 to present day.

Approach to registration

- 53. In 2009, following its creation, CQC worked to integrate its new regulatory functions and to begin the task of registering providers. Initially, CQC focussed on the complex task of registering providers. The requirement to be registered was a vast change in healthcare registration and it was the first time in the history of the NHS that its services had to be licensed to operate by the regulator⁸.
- 54. The registration system came into force at different points in time for different types of care. All NHS trusts had to be registered by 1 April 2010. Providers of social care and independent health care had to be registered by October 2010. Dentists and ambulance services needed to be registered by April 2011, and GPs by April 2012.
- 55. CQC recognised that applying for registration was an unfamiliar process for NHS trusts and therefore worked hard to ensure that all trusts knew what they needed to do and by when. The registration process and its requirements were communicated in various ways, including regional workshops, e-bulletins, direct mail, and an online 'Q&A' resource internally which allowed CQC staff to answer questions quickly and accurately.

⁸ CQC Annual Report and Accounts 2009/2010.

- 56. To ensure that the guidance on compliance was user-friendly, CQC developed a dedicated microsite that automatically customised the information for each trust as soon as they entered their service types.
- 57. CQC's Annual Report and Accounts dated 2009/2010 ([Exhibit JH5]) note the enormity of the registration process: "*The most pressing challenge of CQC's first year was delivering the programmes of work needed to register England's 378 provider trusts by 1 April 2010. It was an enormous task, but the hard work and commitment of CQC staff, along with the enthusiasm and dedication of the NHS, ensured that every trust was registered in time".⁹*

Inspection framework and methodology

- 58. CQC continued to undertake Annual Health Checks of some providers during 2010. Conducting Annual Health Checks was a legacy way of working adopted from the HCC. As mentioned above, from April 2010, all health and social care providers who carried out regulated activities were legally required to register with CQC. Following registration of providers, CQC generic inspectors undertook short compliance inspections using the Guidance about Compliance which was in place at the time but did not rate services. Generic inspectors were responsible for inspecting the full range of services covered by CQC rather than specialising in particular health or social care services.
- 59. In 2010, CQC introduced a "field force model" where inspection teams were based regionally and focussed on the compliance of a specified number of organisations. This model meant that inspectors were generic and were able to inspect all organisations regulated by CQC. We began carrying out compliance reviews of NHS trusts and hospitals in April 2010. Not every essential standard outcome was covered in every review. Responsive reviews looked at fewer outcomes, as they focussed on very specific issues, depending on the nature of the concern. Therefore, each compliance review looked at a different range of outcomes. CQC's annual 'State of health care and adult social care in England' dated 2010/11 ([Exhibit JH6]) states that "It is also important to note that our initial compliance reviews included a relatively large proportion that were responsive conducted in response to concerns being raised about particular services and therefore the outcomes are likely to show disproportionately high levels of non-compliance." As

⁹ CQC Annual Report and accounts 2009/2010

with later time periods, inspections between 2010 and 2013 were informed by information and intelligence obtained by CQC, including Quality and Risk Profiling (QRP), mortality analysis, information from the National Patient Safety Agency (NPSA) and the CQC's helpline.

- 60. Inspections from 2010 concentrated on the essential standards of quality and safety. These consisted of 28 regulations (and associated outcomes) that are set out in two pieces of legislation: the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010¹⁰ and the Care Quality Commission (Registration) Regulations 2009. For each regulation, there was an associated outcome that people using the service could expect to experience and which inspectors used to assess providers from 2010. Inspectors focused on 16 out of the 28 regulations that were within Part 4 of the 2010 Regulations as these most directly related to the quality and safety of care. Providers were required to evidence how they had met the outcomes. It is worth noting that the outcome numbers are different to the regulation numbers because the outcomes were grouped into six overall themes: Information and involvement; Personalised care, treatment and support; Safeguarding and safety; Suitability of staffing; Quality and management; and Suitability of management.
- 61. The essential standards were¹¹:
 - a) Outcome 1 respecting and involving people who use services (Regulation 17)
 - b) Outcome 2 consent to care and treatment (Regulation 18)
 - c) Outcome 4 care and welfare of people who use services (Regulation 9)
 - d) Outcome 5 meeting nutritional needs (Regulation 14)
 - e) Outcome 6 cooperating with other providers (Regulation 24)
 - f) Outcome 7 safeguarding (Regulation 11)
 - g) Outcome 8 cleanliness and infection control (Regulation 12)
 - h) Outcome 9 management of medicines (Regulation 13)
 - i) Outcome 10 safety and suitability of premises (Regulation 15)
 - j) Outcome 11 safety, availability and suitability of equipment (Regulation 16)
 - k) Outcome 12 requirements relating to workers (Regulation 21)
 - I) Outcome 13 staffing (Regulation 22)

¹⁰ Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 came into force 1 April 2010, revoked by the 2014 regulations in November 2014.

¹¹ Note that the outcome numbers are different to the regulation numbers because the outcomes were grouped into six overall themes.

- m) Outcome 14 supporting workers (Regulation 23)
- n) Outcome 16 assessing and monitoring the quality of service provision (Regulation 10)
- o) Outcome 17 handling of comments and complaints ((Regulation 19)
- p) Outcome 21 records ((Regulation 20)
- 62. Central to our inspection methodology from 2013, were the five key questions that we asked of all services we inspected:
 - Are they safe?
 - Are they effective?
 - Are they caring?
 - Are they responsive to people's needs?
 - Are they well-led?
- 63. From 2013, CQC's operational teams were organised into three overarching directorates: Primary Medical Services, Hospitals and Adult Social Care. The three directorates covered the specific service types that we regulate.
- 64. From October 2013, CQC's inspection and regulatory approach was overhauled, and changes were made which included the introduction of the Fundamental Standards which are discussed in more detail in the 2014 to 2023 section of this statement (paragraphs 70 to 72). CQC introduced a new approach to inspection and rating, using larger and more specialised inspection teams and introducing longer and more in-depth inspections.
- 65. From October 2013, CQC had five directorates. The majority of people worked in specialist teams in one of the three inspection directorates:
 - (1) hospitals (including ambulances and mental health);

(2) primary medical services and integrated care (including dentists, health and justice); and

(3) adult social care (ASC).

66. The two further directorates comprised: (4) Strategy and Intelligence and (5) Corporate Services (renamed Customer and Corporate Services and then Regulatory, Customer and Corporate Operations). From April 2019, an additional Directorate, Digital, was created.

Notifications and reporting patient safety incidents

67. Notifications to CQC during this period were in accordance with the statutory requirements as set out in paragraphs 25 to 35 of this statement.

Monitoring the Mental Health Act

68. The frequency and format of the statutory MHA visits from 2009 to 2013 remained the same as those described for the 2000 to 2009 period.

CQC Inspection Framework - 2014 to 2023

Approach to registration

69. CQC's current Scope of Registration guidance (updated in May 2022 and applicable since 2014) outlines the regulated activities set out in Schedule 1 of the 2014 Regulations. [Exhibit JH7]

Fundamental Standards

- 70. Central to the manner in which CQC regulates is the application of 'fundamental standards'. These are the standards which everybody receiving care has the right to expect and below which care must never fall. Introduced following the Mid Staffordshire NHS Foundation Trust Public Inquiry, led by Sir Robert Francis KC, they impose obligations that registered providers must meet in order to be registered with CQC.
- 71. There are 13 fundamental standards. These are set out in the 2014 Regulations and set out below at paragraph 73. Regulations 5 and 20 came into force in December 2014 whilst the other provisions of these regulations came into force on 1 April 2015. They replaced the Health & Social Care Act 2008 (Regulated Activities) Regulations 2010, which set out the previous 16 essential standards. Since 2010, the relevant Trusts have been required to meet the various fundamental standards which are applicable now and the essential standards which were in place from 2010.
- 72. The fundamental standards, as summarised on CQC's website, are:
 - a) Regulation 9 Person centred care;
 - b) Regulation 10 Dignity and respect;

- c) Regulation 11 Need for consent;
- d) Regulation 12 Safe care and treatment;
- e) Regulation 13 Safeguarding services users from abuse and improper treatment;
- f) Regulation 14 Meeting nutritional and hydration needs;
- g) Regulation 15 Premises and equipment;
- h) Regulation 16 Receiving and acting on complaints;
- i) Regulation 17 Good governance;
- j) Regulation 18 Staffing;
- k) Regulation 19 Fit and proper persons employed;
- I) Regulation 20 Duty of candour;
- m) Regulation 20A Requirement as to display of performance assessments display of ratings.

Notifications and reporting patient safety incidents

73. Reporting requirements and notifications to CQC during this period remained the same as 2009 to 2013.

Inspection framework and methodology

- 74. In April 2014, comprehensive inspections were commenced which used Key Lines of Enquiry (KLOEs) to help inspectors direct the focus of inspections and help them form a judgement about the quality of a service and award a rating. These inspections were first piloted in the autumn of 2013.
- 75. In accordance with section 23 of the 2008 Act, CQC produced guidance to help providers to comply with the regulations made under the Act. In April 2015, CQC issued 'Guidance for providers on meeting the Regulations' [Exhibit JH8]. This document replaced the previous guidance available to providers: 'Guidance about Compliance: Essential standards of quality and safety'. [Exhibit JH9] The guidance was developed with the help of people who use services, organisations that represent them, health and adult social care providers, other regulators and professional bodies.
- 76. The mental health directorate was established in April 2014 to have specialist inspectors and inspection teams undertaking inspections of Mental Health services (both in the NHS and independent providers).

- 77. Following the introduction of the 2014 Regulations, core services were introduced by service type (for example wards for older people, wards for adults of working age etc.). The comprehensive inspections undertaken during this period were large in scale and all core services at all Mental Health trusts were inspected and rated. Inspection teams began to include Experts by Experience and Specialist Advisors (who were specialist to the core services they helped inspect). Providers were given 'Must do' and 'Should do' actions following inspections to ensure they were in compliance with the regulations or took action if they were not.
- 78. In early 2015, updated guidance was developed for providers¹² on meeting the new regulations and applied from 1 April 2015. This guidance replaced entirely the CQC's 'Guidance about Compliance: Essential standards of quality and safety'. Internally, CQC developed brief guides and core service frameworks to help both inspectors and providers. These were shared on the CQC website.
- 79. In May 2016, CQC's strategy for 2016 to 2021 was launched with the aim of being more targeted, responsive and collaborative in our approach to regulation. CQC sought views from providers in relation to the evolution of the assessment framework and regulatory model. The consultation document dated December 2016 set out specific proposals in relation to the regulation of new models of care and complex providers; changes to the assessment framework across all sectors; and how NHS trusts would be regulated from April 2017. [Exhibit JH10]
- 80. 'How CQC monitors, inspects and regulates NHS trusts' (Updated November 2022) set out how CQC monitored and inspected NHS trusts, shared information and the steps taken post-inspection. [Exhibit JH11] Alongside this we had various inspection frameworks, depending on the service. Exhibit JH11 confirms the approach that inspectors took when inspecting mental health care in acute trusts and the 11 mental health core services¹³ that we inspected.
- 81. Structured using the five key questions, these frameworks covered the following:
 - areas to inspect
 - interviews / focus group observations

¹² See Exhibit JH8.

¹³ Page 17 refers to mental health care in acute trusts and pages 21 – 23 refer to mental health core services.

- service-specific considerations
- KLOEs and related prompts for inspectors.
- 82. Each of the five key questions was broken down into a subset of questions, called KLOEs. When CQC carried out inspections, up to November 2023, we used KLOEs to help us decide what we needed to focus on. For example, the inspection team might have looked at how risks were identified and managed to help them understand whether a service was safe. We used different KLOEs in different sectors. Using the KLOEs helped us to make sure we were consistent in what we looked at under each of the five key questions and that we focused on the areas that mattered most. An updated copy of the 'Key lines of enquiry, prompts and ratings characteristics for healthcare services' which was first published in 2015 and confirming that the revised assessment framework for NHS trusts was introduced in June 2017, is attached as Exhibit JH12.
- 83. The inspection approach in force from April 2014 to 2023 can broadly be described across three main phases:
 - a) Monitoring and Information Sharing This involved the review of information we had collected on a service via various sources. The exact information reviewed varied depending on service type but generally included a review of CQC Insight (a tool used by CQC from October 2016 to monitor potential changes to the quality of care), information gathered from providers, local and national organisations and the public as well as any experiences shared directly with CQC through our website, helpline or social media channels.
 - b) Inspection The frequency of inspections varied depending on the previous CQC rating of the service. For example, services rated as good or outstanding were normally inspected within 30 months of the publication of the last comprehensive inspection report whereas services rated as inadequate were normally inspected within six months of the publication of the last comprehensive inspection report.
 - c) After Inspection The report which was drafted by the lead inspector, contained a description of the good and outstanding practice found, as well as any concerns we may have had. The report included the findings in relation to the key questions that were inspected and what this meant for the people who use the service.

- 84. Prior to undertaking an inspection, we would review the information we held on a service. The exact information reviewed varied depending on service type. 'CQC Insight' (discussed further at paragraphs 116 to 119 below) was used to monitor quality of care. There were specific Insight tools for the different health and care sectors which aimed to: bring together information from people who used services, knowledge from our inspectors and data from our partners; indicate where the risk to the quality of care provided was greatest; monitor change over time for each of the measures; and point to services where the quality may have been improving.
- 85. We also continued to gather information directly from a service via statutory notifications as well as information from national, regional and local stakeholders and until 2023, relationship management meetings.
- 86. In the past, frequency principles, based on a service's existing rating, were the primary trigger for inspection. Information of concern received through the monitoring and information sharing phase could also trigger a smaller focused inspection to examine specific KLOEs. More significant concerns could also have prompted a comprehensive inspection. More recently, notably since the start of the Covid-19 pandemic, we have adopted a risk-based approach to triggering an inspection. Regulatory history continues to play an important part in making the decision to inspect a provider.
- 87. The different types of inspections were as follows:
 - a) Comprehensive inspections:
 - An in-depth and holistic view was taken across the whole service.
 - Inspectors looked at all five key questions to consider if the service was safe, effective, caring, responsive and well-led. A rating of either outstanding, good, requires improvement or inadequate was given for each key question, as well as an overall rating for the service.
 - These were carried out:
 - (1) within the timescales set out above; or
 - (2) where there was a risk to the safety or wellbeing of people who use the service, or there had been a significant deterioration in the quality of the service; or
 - (3) where there was a substantial improvement in quality that could increase the overall rating.

- These were usually unannounced, although there were circumstances where the provider was notified of the inspection in advance (for example, we may have contacted a small residential service within 48 hours of the start of the inspection to check that people were home, or given up to a week's notice to very complicated community services where careful planning was needed).
- b) Focused inspections:
 - These were more targeted than comprehensive inspections and were conducted in response to specific information received or to follow up on findings from a previous inspection.
 - We did not necessarily look at all five key questions, however we would always look at the well-led key question, plus any other key question that was relevant to the information that triggered the inspection.
 - Focused inspections could be converted into comprehensive inspections if the scope needed to be broadened.
 - These were structured according to the reason why they needed to be conducted which may have included:
 - (1) Risks or concerns raised;
 - (2) Timing, evidence or engagement required;
 - (3) Resources entailed, including use of Experts by Experience and/or Special Advisors.
 - They were smaller in scale than a comprehensive inspection.
 - They broadly followed the same process as a comprehensive inspection.
 - They could have resulted in a change to the overall rating of a service at any time by using key question ratings from the focused inspection as well as the remaining key question ratings from the last comprehensive inspection.
 - Focused inspections were normally unannounced.
- 88. Combined inspections:
 - These were aimed at those providers who delivered services across the health and social care sectors (for example, mental health, community health and care homes).
 - Where possible, we aligned the inspection process.
 - Each service was inspected by a specialist inspector.

- 89. Most inspections continued to be either unannounced or have a short notice period (normally two weeks). In some cases, inspections were announced, for example an inspection of the Well-Led key question across an NHS Trust, which necessitated interviews and discussions with all senior board members and therefore required a degree of coordination.
- 90. The size of an inspection team varied according to the provider and service type, but broadly continued to be made up of our inspectors and be supported by Specialist Advisors and Experts by Experience. The former are akin to peer reviewers, who provide specialist advice to support our regulatory activity in an ad hoc role undertaken alongside their existing employment. The latter are patients, people who use services and carers who have experience of a service.
- 91. The report and the ratings of each type of service were provided in a comparable way by using a combination of the different inspection approaches. Overall ratings were aggregated from the ratings for all of the services of that provider that were inspected.
- 92. Following an inspection, we can ask for additional information from the provider to confirm evidence gathered during the inspection. After a period of quality assurance and factual accuracy review with the provider, a written report was published on our website. This continues to be the case. In most cases, our inspection reports continue to include ratings.
- 93. The written reports typically included:
 - a) Contextual information about the service and the inspection;
 - b) A description of the inspection team's findings;
 - c) Ratings for each key question inspected and the overall rating given;
 - d) Evidence about any breaches of the regulations, the action we told the provider to take, and any enforcement activity that CQC may have taken;
 - e) Recommendations made to the provider about improvements to their service; and
 - f) A summary section for the provider to share with each person using their service, their family and carers, and staff.

- 94. If the inspection identified regulatory breaches, further regulatory action may have been taken following the inspection, as appropriate. The regulatory action available for CQC to take in these circumstances is explained in detail in the Enforcement section of this statement from paragraph 128.
- 95. It is important to note that we have now undergone wide organisational change and in November 2023, commenced the transition to a Single Assessment Framework. As discussed at paragraph 107 below the Single Assessment Framework approach was rolled out over a transition period, from November 2023 to March 2024. Where relevant, we will refer to this new Framework.

Changes to Mental Health Act Visits in 2020 as a result of the Covid-19 pandemic

- 96. Following our decision to pause routine inspection activity and take a revised approach to regulation as a result of the Covid-19 pandemic, our view was that, given our unique role in supporting those people detained under the MHA, visits should be continued wherever possible. However, we moved routine visits to a digitally enabled format, including remotely monitoring mental health wards through contact with staff, patients, carers and advocates, virtual tours of wards, remote SOAD assessments and electronic certification by SOADs. Throughout the pandemic, where we had specific and urgent concerns, we engaged with services and continued to carry out on-site visits.
- 97. Where we believed there were risks of harm, ill-treatment or human rights breaches for people detained in services then, with oversight from the Chief Inspector, we carried out additional activity which may have included a site visit to a service.
- 98. From 11 May 2020, we began prioritising inpatient complaints, to ensure that during the pandemic we were focusing on protecting the human rights of the most vulnerable people, redirecting them to our MHA Reviewers to seek immediate resolution. These interventions provided an opportunity for MHA Reviewers to identify services for remote monitoring activity where a serious concern or high number of concerns had been raised.

- 99. Our teams collected data remotely from a range of sources, and where we identified risks of harm, ill-treatment, or human rights breaches we carried out additional activity, which could include on-site MHA visits.
- 100. This remote-led approach continued through 2020 and 2021, with routine on-site MHA visits restarting in July 2021, and direct SOAD visits restarting in February 2022. Some elements of the remote review methodology were retained in a blended approach, in particular, continuing to contact carers and advocates outside of the physical visit. We have found that these contacts increased in remote reviews and provided a more well-rounded picture of services.

CQC inspection framework – Post 2023

New inspection framework – the Single Assessment Framework

- 101. The Single Assessment Framework is a redesign of our approach to regulating services. In July 2022, we published an update on our website on the developing work on our new approach to regulation and the Single Assessment Framework, with a further update in December 2023. We started the rollout of this new assessment framework in the South region and with 'early adopter' providers that volunteered to take part (a small number of providers across various types of services and sectors). Planned assessments and subsequent feedback from these providers has helped to shape our approach as we have rolled out this new Framework.
- 102. Whilst quality ratings and the five key questions will remain central to our approach to regulation, we have replaced our KLOEs and prompts with new 'quality statements'. These will reduce the duplication in our current separate assessment frameworks and allow us to focus on specific topic areas under each key question. Our assessments across all types of services at all levels will be based on this Single Assessment Framework. Assessments of local authorities and integrated care systems will use a subset of the quality statements.
- 103. The principle of our on-site and off-site work, analysing data, and the approach to incorporating the opinions of those who work in and use services continues, but with a more structured approach to scoring and rating individual quality statements, rather than scoring only the five key questions. We expect that the

new approach will help providers take a structured approach to improvement, will take less time to carry out, and will provide the public with clearer comparisons with other services and offer a more granular view than the single word judgement offers.

- 104. The evidence we will collect will fall into six categories:
 - people's experiences;
 - feedback from staff and leaders;
 - observations of care;
 - feedback from partners;
 - processes; and
 - outcomes of care.
- 105. For each quality statement we will state which evidence we will always need to collect and look at, although this may vary by the type of service under assessment. It may also depend on the level at which we are assessing, for example a newly registered service.

Current position in relation to the Single Assessment Framework

- 106. In May 2021, CQC published a new strategy setting out our ambition to regulate in a smarter way. Prior to this a transformation programme had started in 2019. Following this a transformation programme was initiated with three key components. These were, the development of a Single Assessment Framework, changes to the organisational structure and changes to IT systems, with a new regulatory platform and provider portal replacing existing systems.
- 107. The Single Assessment Framework was a redesign of our approach to regulating services which was introduced in November 2023. It was intended to have more planning and testing prior to roll out. However, the transformation programme was delayed, and the roll out continued. At first it was rolled out to a small number of 'early adopter' providers across sectors. Planned assessments and subsequent feedback from these providers helped shape the phased introduction of the new approach.
- 108. Despite the well-intended strategic intent of the transformation programme, its implementation resulted in significant problems for CQC and caused concern

amongst staff, providers, and stakeholders about our ability to fulfil our role as a regulator. The reviews of Dr Penny Dash (the Dash Review) and Professor Sir Mike Richards outlined later in this statement cover these matters in detail. CQC is now working to recover from this period, provide stability and re-build trust in our regulation.

CQC inspections in Essex

- 109. Question 3.a of the Request asks CQC to provide details of dates and outcomes of all inspections in respect of the registered providers set out at paragraph 18 of CQC's Opening Statement (and set out in this statement at paragraph 23) from within the relevant period. We attach the spreadsheet requested by the Inquiry as Exhibit JH12A.
- 110. As mentioned above at paragraph 23, the most recent inspection at EPUT took place in December 2024 and January 2025. We inspected acute wards in Colchester, Derwent Centre, Linden Centre, Basildon Mental Health Unit and Rochford. The report is currently being prepared¹⁴.

Data

Guidance issued by CQC

- 111. Since its inception, CQC has issued guidance to help providers to comply with the requirements of the various applicable Regulations. Our guidance covers many aspects of CQC's inspection and monitoring powers and responsibilities including registration, notifications, enforcement and inspection. We consider that the guidance (and compliance with it) may be considered relevant for the broad 'safe' delivery of mental health inpatient care.
- 112. Our Guidance for providers has been updated several times since 2010 and reiterates the fact that providers are responsible for meeting the regulations and deciding how to do this. It is not CQC's role to tell providers what they must do to deliver their services. However, where providers choose not to follow the guidance,

¹⁴ Correct as at 17 March 2025.

we ask them to provide evidence that their approach enables them to meet the requirements of the regulations.

- 113. The guidance clearly sets out: a copy of the actual text of the regulation; a summary of the intention of the regulation; and guidance on the requirements of specific components of the regulation. It is intended to assist providers, including NHS Trusts providing mental health inpatient services, to understand the specific regulations in delivering safe services and regulated activities.
- 114. Copies of the Guidance for providers dated March 2010 ([Exhibit JH9]), March 2015 ([Exhibit JH8]) and July 2024 ([Exhibit JH13]) are exhibited to this statement.
- 115. In response to Question 1c of the Request, CQC has been unable to identify any guidance issued to trusts which is specific to the safe provision of mental health services.

Data collated by CQC - CQC Insight and 'Give Feedback on Care'

- 116. We used CQC Insight until November 2023 to monitor potential changes to the quality of care. CQC Insight brought together in one place the information we hold about services, and analysed it to monitor services at provider, location, or core service level. This helped us to decide what, where and when to inspect and provided analysis to support the evidence in our inspection reports. CQC Insight produced monitoring reports, which we shared with trusts. We also shared the reports with other key partners including NHSE, clinical commissioning groups and Healthwatch.
- 117. Until November 2023, our inspectors and assessors regularly checked CQC Insight. If it suggested an improvement or decline in the quality of care for a service, we may have followed this up between inspections. Depending on the report generated using CQC Insight, we may have been prompted to ask the trusts for further information or to discuss issues at our regular relationship management meetings which were held until late 2023. We may also have decided to re-inspect that service.

118. For all NHS trusts, CQC Insight gave inspectors:

• Facts and figures: contextual and descriptive information such as levels of activity, staffing and financial information.

- A ratings overview: the trust's latest CQC ratings with information about the direction of potential change suggested by the performance monitoring indicators.
- Intelligence overview: a summary of the analysis of the indicators selected to monitor performance. It is presented at provider, key question and, where available, core service level.
- Performance monitoring indicators: these show a trust's performance compared with national standards or with other providers. They also indicate changes in a trust's performance over time, including benchmarking from 12 months before. All indicators are mapped to our five key questions and quality statements (previously KLOEs).
- Featured data sources: this might include, for example, the findings from national surveys, incident reports, mortality ratios and outliers. We coordinate our monitoring activities for 'complex providers' that operate across sectors and, where possible, combine information about each of their services within our Insight model.

119. Copies of CQC Insight relating to EPUT are attached as Exhibits [JH14] to [JH38].

- 120. 'Give Feedback on Care' is part of our approach to gathering peoples' experiences as part of assessments. We ask providers to print and display assessment posters that promote our 'give feedback on care' service. The posters signpost members of the public to an online form where they can share information about poor care, abuse and neglect. People can also share information about good care, which adds to our picture of the overall standard of care and by sharing good examples which we can use to help all providers to improve.
- 121. CQC uses information shared via 'Give Feedback on Care' alongside information from the service itself or what we found when we last inspected them. CQC can take a number of actions in response to the reports, including: asking the care provider to give us their response to the information, meeting with management at the care provider, sharing information with other relevant agencies that need to know about it, carrying out an urgent inspection or bringing forward a planned inspection, and warning, fining, or placing conditions on how a care service operates.

Mental Health Crisis Care Review in Essex – 2015

- 122. We have identified that Essex was included in the sample of 15 local area inspections of health and care services reviewed for the Mental Health Crisis Review between 2013 and 2015. A copy of the Report is attached as Exhibit JH39. The site visits in Essex took place in December 2014 and focused on the north of Essex (including NEFT). The Essex Summary Report (the Report) was published in June 2015.
- 123. The inspection was carried out under section 48 of the Health and Social Care Act 2012 which gives CQC the power to assess how well services work together, and the effectiveness of care pathways, rather than the quality and safety of care of one single provider. Under Section 48, CQC has no power to rate a service or services.
- 124. This Report describes the key findings from CQC's local area inspection of health and social care providers delivering care and support to people experiencing a mental health crisis within the local area of Essex County Council. Where appropriate, it references the role of the police force, voluntary organisations and commissioners. The Report assesses the services available through different providers within the council's local authority area. This was based on a combination of what we found when we inspected, information from our national data review on mental health crisis care, and information provided to us from patients, the public and other organisations. Using the key lines of enquiry (KLOE), the reviewers made narrative judgements on the health or social care services, but the Report should not be seen as a sole judgement on any one provider. The findings of this inspection were used to inform our national report on mental health crisis care in England. They were also available to CQC inspectors who undertook future inspection activity in this area.
- 125. The following areas of good practice were identified:
 - a) Committed, caring and professional staff who employed the least restrictive means of caring for people.
 - b) Implementation of the street triage teams. The improved information shared with staff ahead of attendance allowed them to consider risks and identify how best to meet the person's needs.

- c) Strong working relationships between section 136 staff and the police, supported by monthly liaison meetings to review issues and concerns.
- d) Services to meet the needs of specific groups. For example, services for the military community.
- e) Strategic recognition and commitment by partner services to address barriers to people experiencing mental health crisis receiving timely and appropriate assessment and care.
- 126. The following areas for development were identified:
 - a) Improved access to crisis services for people known to the service or recently referred. People need to be aware of the response capacity of the service and alternative means of accessing crisis services if staff are unavailable.
 - b) Evaluation of and improvements in the responsiveness of the out of hours telephone helplines.
 - c) Engagement with people using services to support improvements to care and development of services that meet the needs of the population.
 - d) Development of multi- agency training to support partnership working and increased knowledge and skills of staff.
 - e) Increased knowledge within primary medical services on the routes into crisis mental health services. All practice staff should be able to support and refer people in crisis to appropriate crisis mental health services.
 - f) Ensure assessments are individualised to reflect people's needs and inform the consistent management and delivery of their care across services. For example, assessments should be sufficiently individualised to aid the Crisis and Trust Line staff to best support patients, at a time when they are vulnerable.

Data collected by providers

127. CQC expects providers to submit the following national data returns:

- a. safety of mental health services statutory reporting requirements, such as the notifications that registered providers are required to submit to CQC;
- b. national datasets created to support quality initiatives, for example, Mental Health Services Data Set (MHSDS);
- c. routine national data collections, including submissions to defined commissioning datasets run by NHSE, for example Hospital Episode Statistics (HES); and

d. information relating to people's experience, for example, any data collection of experiences of service users of mental health services or their families.

Enforcement

- 128. Enforcement is one of the core components of the operating model that CQC uses to achieve our purpose and perform our role. We use our enforcement powers to promote our statutory objective of protecting and promoting the health, safety and welfare of people who use health and social care services.
- 129. The 2008 Act gives CQC both civil and criminal enforcement powers to address issues of non-compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (the 2014 Regulations) and the Care Quality Commission (Registration) Regulations 2009 (the 2009 Regulations). We also have powers to undertake civil and criminal enforcement action against registered persons who fail to comply with a condition of their registration or the relevant Regulations.

Enforcement action and other steps that can be taken by CQC

- 130. CQC has powers to undertake civil and criminal enforcement action against registered persons who fail to comply with a condition of their registration or the relevant regulations, and those carrying on regulated activities without registration. These powers continue to apply under the new Single Assessment Framework.
- 131.CQC's civil enforcement powers, as set out in the 2008 Act (as amended by the 2014 Act), include powers to cancel or suspend a registered person's registration (sections 17, 18 and 30 to 31), to impose, vary or remove conditions of registration in respect of a registered person (sections 12 (5), 15 (5), and 31) or to serve a "warning notice" where the test set out in sections 29 and 29A is met.
- 132. Criminal enforcement action can be taken, in response to breaches of certain regulations and sections of the 2008 Act, against any registered person, and against any unregistered person where they are carrying out regulated activities without registration. It can also be used against any person who obstructs us during an inspection and against registered or unregistered persons where they have made a false or misleading statement in any application to us. CQC's criminal

enforcement powers include cautions, fixed penalty notices and prosecution. CQC also has powers under section 91 of the 2008 Act that enable us to consider the actions of an individual director, manager or secretary of the body corporate, where there is evidence that they have committed an offence or with their consent, connivance or neglect allowed an offence to be committed.

- 133. We can issue Requirement Notices where we identify breaches of regulation that have not placed people using the service at immediate risk of harm. The Requirement Notice requires the provider to send us a report detailing what action is being taken by them to comply with regulation and the timeframe they will do this in. Under the new Single Assessment Framework, Requirement Notices will be named 'Action Plan Requests.'
- 134. CQC is now the primary enforcement body at a national level in England for ensuring that people using health and social care services receive safe care of the right quality¹⁵. We have a wide range of enforcement powers and we can take enforcement action against anyone who provides regulated activities without registration. We can also take enforcement action against registered persons who breach either:
 - conditions of their registration; and/or
 - relevant sections of:
 - $\circ \quad \text{the 2008 Act} \quad$
 - o The Care Quality Commission (Registration) Regulations 2009
 - The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
 - Other legislation that is relevant to achieving registration requirements.
- 135. Where breaches of regulations do not constitute a criminal offence, we can enforce the standards using our civil enforcement powers which are explained in greater detail below. Failure to comply with the steps required when we use our civil enforcement powers is a criminal offence and therefore may result in a prosecution. The breaches that constitute criminal offences are explained in greater detail below.

¹⁵ In April 2015 new powers came into force widening CQC's ability to bring criminal prosecutions against providers who are in breach of, or who fail to comply with, the fundamental standards. CQC also gained powers from the Health and Safety Executive (HSE).

136. CQC also has a wide set of powers that allow us to protect the public and hold registered providers to account. CQC's statutory powers are detailed in the 2008 Act and include powers of entry and inspection (sections 60 to 63 of the 2008 Act) and powers to require information and documentation (sections 64 and 65 of the 2008 Act). Failing to comply without reasonable excuse is an offence.

Enforcement Policy

- 137. Our Enforcement Policy sets out the principles and approach we will follow when using our enforcement powers under the 2008 Act, as amended by the Care Act 2014, and is intended to be a general guide to good practice when carrying out or considering carrying out enforcement action.
- 138. Several versions of our Enforcement Policy have been in existence during the relevant time period. We have set out below the versions that we have been able to locate following a search of our document repositories:
 - a) April 2009 This policy set out how we intended to use our new enforcement powers. The document had been finalised following consideration of comments made during a 12-week consultation. The Foreword notes "We see this as the start of an ongoing conversation about how we can all work together to help ensure safer, higher quality care for the people who need it." This policy confirmed that powers under the 2008 Act would be used for any enforcement action taken against an NHS provider over healthcare-associated infection. However, for all other purposes, during 2009 and until April 2010, when the full range of enforcement powers under the 2008 Act came into force, CQC used the same powers and same enforcement frameworks that the HCC had used. A copy of the April 2009 Enforcement Policy is attached as Exhibit JH40.
 - b) October 2010 This version replaced the April 2009 policy. A copy of the October 2010 Enforcement Policy is attached as Exhibit JH41.
 - c) April 2012 This version replaced the October 2010 policy. A copy of the April 2012 Enforcement Policy is attached as Exhibit JH42. This version introduced our Judgement Framework (Exhibit JH43) which was to be used alongside the policy and which helped inspectors to assess compliance with the essential standards;
 - d) June 2013 A copy of the June 2013 Enforcement Policy is attached as Exhibit JH44. This version includes a 'regulatory response escalator' model to assist

in determining the appropriate regulatory response to any non-compliance identified.

- e) February 2015 A copy of the February 2015 Enforcement Policy is attached as Exhibit JH45. This policy is discussed in more detail below.
- f) November 2023 A copy of the November 2023 Enforcement Policy is attached as Exhibit JH46.
- 139. Following the changes to our enforcement powers in 2015, which meant that we were able to bring criminal prosecutions against health and social care providers for failing to provide care and treatment in a safe way, in addition to prosecuting specified breaches of the Regulations, a new Enforcement Policy was introduced in 2015. From 1 April 2015 to 21 November 2023, we used the 2015 version of our Enforcement Policy (dated February 2015, effective from 1 April 2015) ([Exhibit JH45]), which was replaced with an updated Enforcement Policy on 21 November 2023.
- 140. For the purposes of this statement, we will focus on the Enforcement Policy (as amended) which was in place from April 2015 onwards as it contains details of our updated prosecution powers.
- 141. All versions of the Enforcement Policy operated alongside the following other key guidance documents:
 - Our Judgement Framework (from April 2012 to 2015);
 - Our enforcement decision tree for selecting appropriate enforcement powers, (applicable from 2015 and explained in greater detail below);
 - Our provider handbooks that described our approach to inspecting, regulating and, where applicable, rating each of our sectors; and
 - Our guidance for providers on meeting the regulations.
- 142. As set out in our 2015 Enforcement Policy, we have two primary purposes when using our enforcement powers:
 - To protect people who use regulated services from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard; and
 - To hold providers and individuals to account for failures in how the service is provided.

143. When a service falls below the required standards, we will consider both purposes.

- 144. In addition, the 2015 Enforcement Policy set out the five principles which guide our enforcement decision making as follows:
 - Being on the side of people who use regulated services;
 - Integrating enforcement into our regulatory model;
 - Proportionality;
 - Consistency; and
 - Transparency
- 145. We updated our Enforcement Policy in 2023 to bring it in line with our new regulatory approach and the new version took effect from 21 November 2023 ([Exhibit JH46). The changes included, but were not limited to, removing principle *(ii); 'integrating enforcement into our regulatory model'*, as we considered that this requirement was no longer relevant. Therefore, the 2023 Enforcement Policy refers to the remaining four principles referred to above to guide the use of our enforcement powers.
- 146. Our current Enforcement Policy was updated in 2024 (taking effect from 23 December 2024). The policy was first published in 2015 and as set out above, has since been updated to refer to our current assessment methods and terminology. The changes in 2024 noted updates to terminology as a result of the introduction of the Single Assessment Framework. We have included reference to the 2024 Policy for the sake of completeness as we recognise that it falls outside of the time period of relevance to the ToR.
- 147. Since 2015, the 'Enforcement Decision Tree' has been at the core of how we apply our Enforcement Policy. This describes the process that guides how CQC makes decisions on the use and selection of appropriate enforcement powers to ensure consistency and proportionality. From 2017, we were using the 2017 version of the Enforcement Decision Tree ([Exhibit JH47]). We updated our Enforcement Decision Tree in 2023 to bring it in line with the amended 2023 Enforcement Policy ([Exhibit JH48]).

- 148. The Enforcement Decision Tree sets out a four-stage decision-making process which we use to select the appropriate enforcement power. Below is a high-level summary of the process:
 - a) Initial assessment:
 - before commencing enforcement action, the first stage is to consider the case at a Management Review Meeting (MRM) (these are now known as Decision Review Meetings (DRM)). In the overwhelming majority of cases, the MRM will be followed up through standard direct checks such as a focused inspection. Urgent cases may proceed directly to evidence collection for potential urgent action or prosecution.
 - b) Legal and evidential review:
 - At this stage we check that the evidence we hold demonstrates a breach of the regulations or relevant requirements. We also ensure that we take account of our statutory guidance and any other relevant legislation. The purpose of this stage is to check that the evidence is sufficient to enable us to proceed to take enforcement action, and that the initial logging and registering of evidence has been done correctly.
 - c) Selection of the appropriate enforcement action:
 - Stage 3A looks at the seriousness of the concern and the facts that gave rise to it. It does not take account of other incidents that may have taken place nor the provider's response to them. It is an assessment of the likelihood of the concern happening again, and if it were to happen again, the impact it would have on the people using the service.
 - Stage 3B takes account of other incidents that may have taken place relating to the provider and their response. It requires inspectors to consider whether there is sufficient evidence of systemic failings in the quality of care and/or management which may result in recurrent issues. The outcome of assessment at stage 3B can result in an increase or decrease to the severity of the enforcement action we decide to take, as well as determining whether we need to hold a provider and/or individual to account through criminal sanctions.
 - d) Final review:
 - The final decision about which enforcement action to take is made at an MRM meeting where CQC's sector enforcement priorities are considered. These are the priorities set by CQC's Board and agreed in our business plan. They set expectations for our overall approach to enforcement,

providing a transparent message to the sectors as well as to our inspectors. Consideration of these priorities could result in a change to the type or severity of the planned enforcement action. At the final review stage we also check that the recommendation is in line with the enforcement policy and that the decision-making process has been followed properly.

- 149. There are three enforcement actions that we use in order to require a provider to protect people who use regulated services from harm and the risk of harm, and to ensure that the services they receive are of an appropriate standard. These are:
 - a) Requirement Notices (now known as Action Plan Requests)
 - Where a registered person is in breach of a regulation or has poor ability to maintain compliance with the regulations, but the people using the service are not at immediate risk of harm, we may use our power to require a report from the provider by serving a Requirement Notice. The response from the provider must show how they will comply with their legal obligations and must explain the action they are taking or propose to take to do so. Failure to send us a report in the timescales set out in the Requirement Notice is an offence and could lead to us using other enforcement powers.
 - b) Warning Notices
 - Warning Notices notify a registered person that we consider they are not meeting a condition of their registration, a requirement in the 2008 Act, a regulation, or any other legal requirement that we think is relevant. We cannot issue Warning Notices against unregistered persons. We can serve Warning Notices about past failures or about a continuing breach of a legal requirement. If a registered person does not comply with the Warning Notice we will consider further enforcement action under civil or criminal law. The regulations allow us to publish Warning Notices as long as registered persons are given the opportunity in advance to make representations about the proposed publication.
 - c) Section 29A Warning Notices
 - Section 29A of the 2008 Act make provision for Warning Notices that are addressed to NHS Trusts or foundation trusts. We may issue such a notice where we find that an NHS trust requires significant improvement.

Use of enforcement actions in Essex

- 150. We have interrogated our records to identify any material which is responsive to Question 3c of the Request. We have identified instances when we have used enforcement actions, including Section 29A Warning Notices and Requirement Notices, in order to require the relevant provider to protect people from harm or the risk of harm.
- 151. We are aware that CQC has issued Requirement Notices and Section 29A Warning Notices to the relevant Trusts during the relevant time period and will provide a list of s29A Warning Notices as part of our ongoing discovery exercise. We have been unable to provide a similar list of Requirement Notices as inspectors issuing Requirement Notices are not required to formally record their existence on our enforcement records in the same way as a s29A Warning Notice.

CQC's Civil Enforcement Powers

- 152. We may use the following discretionary civil enforcement powers to force a provider to protect people who use services from harm and the risk of harm, and to ensure that they receive services of an appropriate standard:
 - Impose, vary or remove conditions of registration;
 - Suspend a registration;
 - Cancel a registration;
 - Urgent procedures; and
 - Special measures a time limited approach ensures inadequate care does not continue and co-ordination with other oversight bodies.

153. A high-level explanation of each of these powers is provided below.

Impose, vary or remove conditions of registration

- 154. As explained above, registered persons may have conditions attached to their registration. Imposing, varying or removing conditions of registration is a flexible enforcement process that we can use in a variety of different ways to ensure that providers comply with their legal obligations. For example, we may use a condition to stop a regulated activity at one location but allow the provider to continue providing services at its other locations. This allows us to remove the condition if, and when, the concern has been addressed. We can apply conditions at whole-provider level and/or at certain targeted geographic locations.
- 155. We can also use conditions to require a registered person to take some action where further improvement is necessary. We design and communicate these conditions so that they explain what we require to be achieved but leave the provider to decide exactly how that will be delivered. We will not define precisely how a provider should operate or manage its service. It should be the provider's choice to decide precisely how to operate its business, provided it complied with all relevant legal requirements.
- 156. We will consider imposing conditions on the provider's registration if we assess that by imposing a condition it is likely to result in the provider addressing the matters of concern within an acceptable timescale.

Suspend registration

- 157. We can suspend the registration of a registered person for a specified period of time. This period can also be extended if necessary. This power allows us to compel the provider to address a specific concern within a fixed period, for example, to hire new staff.
- 158. This power is rarely used as suspension affects all of the locations where the registered person carries on or manages the relevant regulated activity. We will therefore pay particular attention to the likely outcomes of suspending registration before taking this action. If a provider carries on providing a regulated activity following suspension, we may prosecute this as a criminal offence.

159. We will consider suspending a provider's registration if we assess that suspension is reasonably necessary to prevent the breaches of the provider's legal requirements but that the provider will be able to provide a lawful service at an identifiable time in the future.

Cancellation of registration

- 160. One of our most powerful civil enforcement powers is to cancel a registration. As with suspension, this will affect all of the locations where the provider carries on or manages the relevant regulated activity. Cancellation normally follows considerable efforts to get the registered person to meet the legal requirements. However, where appropriate we will use the cancellation process without following other processes first.
- 161. If a provider carries on providing a regulated activity following cancellation, we may prosecute this as a criminal offence.
- 162. We will consider the cancellation of a registration if we assess that the registered person does not have the capability or the capacity to substantially comply with regulations, or is likely to fail to do so.

Urgent procedures

- 163. In certain circumstances we can use our powers to impose, vary or remove conditions or suspend a registration on an urgent basis with immediate effect. Section 31 of the Health and Social Care Act 2008 states that we can use urgent procedures where the evidence demonstrates that unless there is an urgent use or amendment of conditions, or urgent suspension of registration, a person will or may be exposed to harm.
- 164. Under section 30 of the Health and Social Care Act 2008, we can apply to a magistrate for an order to immediately cancel a registration. We can apply for these orders if not cancelling the registration would pose a serious, immediate risk to a person's life, health or wellbeing.

- 165. Providers are entitled to appeal against the use of these urgent powers, but this does not prevent the conditions, suspension or cancellation from taking effect immediately.
- 166. Urgent procedures are an important part of our enforcement powers so that we can act quickly to protect people using a registered service. We expect urgent procedures to be a significant element of our enforcement activity and we will also consider criminal sanctions in serious cases.

Special measures

- 167. Special measures are an administrative framework which helps CQC to manage providers who are failing to comply with their legal requirements and require a higher than usual level of regulatory supervision. For these providers, special measures assist us to deliver our statutory functions.
- 168. For NHS trusts, we have powers to require NHSE to appoint an administrator and thereby place the trust in 'special administration'. This is a form of time-limited, rules-based administration that will result in an administrator making recommendations that are designed to ensure that the NHS body improves its standards so that it provides secure, sustainable and high quality services. To use these powers, we must first have issued a section 29A Warning Notice and be satisfied that the provider has not complied with it. Before requiring the appointment of an administrator, we will consult the Secretary of State for Health and Social Care and NHSEI.
- 169. Part of any special measures regime is the effective use of enforcement powers to ensure that improvements are made to the standard of care provided by the registered provider. A provider that is operating under special measures may also be working under the close supervision of another oversight body. Where appropriate, we will work closely with relevant oversight bodies to ensure that the registered provider makes improvements to the standards of service provision.

Use of Civil Enforcement Powers in Essex

170. We have interrogated our records to identify any material which is responsive to Question 3c of the Request. In summary, we have not identified any civil enforcement action taken by CQC against any of the relevant Trusts. Should we identify any relevant material during our review of historic document repositories, we will prioritise disclosure of this information to the Inquiry.

CQC's Criminal Enforcement Powers

- 171. Failure to comply with the steps required when we use certain civil enforcement powers is a criminal offence and may result in a prosecution. Some of the regulations have offences attached, and as part of our enforcement action, CQC is able to bring prosecutions if these regulations are breached. CQC is able to bring prosecutions for breaches of the following regulations:
 - The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
 - The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015
 - The Care Quality Commission (Registration) Regulations 2009
- 172. Since 1 April 2015, we have been able to bring criminal prosecutions against health and social care providers for failing to provide care and treatment in a safe way.¹⁶
- 173. Our Enforcement Policy provides lists of the specific regulations in respect of which a prosecution may be brought directly if the offences listed in the regulations are breached; and the regulations in respect of which further qualification is required before CQC can prosecute (which are that the breach results in people who use services being exposed to avoidable harm or significant risk of such harm occurring or suffering a loss of money or property as a result of theft, misuse or misappropriation).

¹⁶ In accordance with Regulations 12 to14 of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 These powers sit alongside those that exist for the Health and Safety Executive (HSE) under the Health and Safety at Work etc. Act 1974.

- 174. CQC can use a variety of methods to hold providers and individuals to account for failures in how the service is provided. Our criminal powers include using:
 - Simple cautions;
 - Fixed Penalty Notice; or
 - Prosecutions

175. Each of these methods is briefly described below.

Simple Caution

- 176. A simple caution ensures that there is a formal record of an offence when a person has admitted to it but is not prosecuted. There is no obligation on a provider to accept a caution and, where the offer of a caution is refused, we will consider prosecution. We will consider using a simple caution when:
 - we have evidence of an offence and that evidence is sufficient that we would be able to bring criminal prosecution;
 - although we could prosecute, we consider that achieving improvements without initiating lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution;
 - the provider has demonstrated to us that they will be able to put these improvements in place within a reasonable timescale;
 - the Code for Crown Prosecutors indicates that this option would be appropriate; and
 - the offence has an insubstantial impact on people using the service.

Fixed Penalty Notices

- 177. Our power to issue Fixed Penalty Notices (FPNs) is set out in sections 86 and 87 of the 2008 Act, and in Regulation 28 and Schedule 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A FPN requires a provider or individual to pay a specified amount of money to CQC, which is then passed on to the Secretary of State for Health and Social Care. Paying a FPN enables a registered person to avoid a potential prosecution for an offence. It is only appropriate to issue a FPN where CQC would have been entitled to prosecute.
- 178. We have the discretion over whether to serve a FPN as an alternative to a prosecution. There is no obligation on a registered person to pay the sum under a FPN and, if a registered person decides not to pay the penalty, we will consider

using other enforcement powers. The failure to pay sums under a FPN will normally lead to a prosecution.

179. We will consider using the power to issue a FPN when:

- we have evidence of an offence and that evidence is sufficient to bring a criminal prosecution;
- although we could prosecute, we consider that achieving improvements without initiating potentially lengthy and costly proceedings is a realistic alternative and is more proportionate than proceeding with prosecution; and
- the offence has an insubstantial impact on the people using the service.

Prosecutions

180. Prosecution can be used to:

- hold a registered person to account for breaches of prosecutable fundamental standards (those regulations with prosecutable clauses that specifically relate to harm or the risk of harm), or for failing to comply with conditions of registration;
- enforce the offence of carrying on a service without registration (in which case we may prosecute the person who appears to be carrying it on);
- ensure accountability for any person who obstructs us during an inspection, or any person who makes a false or misleading statement in an application to be registered with us.
- 181. Where appropriate, we may prosecute at the same time as taking other enforcement action, for example, alongside urgent procedures. We may also prosecute more than one offence at the same time. There may be occasions where, even if the above criteria are satisfied, we will decide to serve a Warning Notice as an alternative to immediate prosecution. However, we will generally prosecute providers where there are serious, multiple or persistent breaches of the fundamental standards (those regulations with prosecutable clauses that specifically relate to harm or the risk of harm) without issuing a Warning Notice first. Failure to make the improvements set out in a Warning Notice is likely to lead to a prosecution.
- 182. Although we are not required by law to publish details of all criminal law procedures that we undertake, we have a general power to publish this type of

information and will normally do so. We must publish information about any offence for which a registered person has been convicted.

- 183. We are required to carry out all investigations of criminal offences in accordance with the Police and Criminal Evidence Act 1984 (PACE) principles and Codes of Practice. Where another regulator has the power to prosecute, we will coordinate our activity with them at an early stage to ensure the right action is taken, to avoid inconsistency, and to ensure that any proceedings taken are for the most appropriate offence. Where we successfully prosecute, the court will decide on the penalty to be imposed and we must publish information about any offence for which a registered person has been convicted. The court may impose a prison sentence as well as, or instead of, a fine following conviction for carrying on a regulated activity without being registered.
- 184. We will consider using our powers to prosecute where:
 - the breach of legislation is assessed by us to be serious and there are multiple or persistent breaches; or
 - we have sufficient evidence so there is a realistic prospect of conviction; and
 - we assess that it is in the public interest for us to use our powers of prosecution.
- 185. In making decisions about whether to prosecute, we will be guided by the Code for Crown Prosecutors.

Use of Criminal Enforcement Powers in Essex

186. We have interrogated our records to identify any material which is responsive to Question 3d of the Request. In summary, we have not identified any prosecutions brought by CQC against any of the relevant Trusts. We acknowledge that there is the possibility that during our discovery process, we may identify cases which were considered for prosecution but where the relevant threshold was not met. We will of course prioritise disclosure of any such material should it exist.

Notifications to CQC in respect of those detained under the Mental Health Act

187. We have collated information which is responsive to Question 3e of the Request. Details of reports of deaths made to CQC in respect of those detained or liable to be detained under the MHA are included in the spreadsheet attached as Exhibit JH49. Please note that Exhibit JH49 does not currently include details of injury or abuse of patients in respect of those detained or liable to be detained under the MHA, or injury or abuse more broadly if otherwise under mental health inpatient care. Due to the way that these reports are ordinarily recorded on our CRM platform, it is not possible to identify them without completing a review of the records. As the Inquiry is aware, our review of these records is ongoing and we will prioritise disclosure of this information to the Inquiry.

CQC's ongoing review of its regulatory approach

Review of Single Assessment Framework

- 188. The CQC board commissioned Professor Sir Mike Richards (former Chief Inspector of Hospitals at CQC between 2013 to 2017) to undertake a review of the SAF to address concerns identified in the interim report of the Dash Review. The review was initially proposed by CQC leadership before release of the interim Dash report, and was announced by DHSC to coincide with publication of the interim report of the Dash Review.
- 189. Findings from the first part of the review were published on 15 October 2024. The report makes 35 recommendations based on Sir Mike's informed opinion following engagement with relevant parties including current and former staff, and representatives of NHS and adult social care providers. These recommendations are organised in relation to five key areas being organisational structure, the inspection assessment framework, data and insight, staffing, and prioritisation of future inspections. When making his conclusions, Sir Mike noted the report is intended to complement the work of the Dash Review and that his overall findings are in line with those of Dr Penny Dash.
- 190. For the next phase of this review, CQC worked with Professor Vic Rayner (Chair of the Care Provider Alliance and Chief Executive Officer of the National Care Forum). Professor Rayner gathered further feedback from adult social care providers on their use of the assessment framework, to build on Sir Mike's findings

to date. Additionally, Sir Mike and Professor Rayner have supported CQC in determining what good regulatory assessment looks like in different sectors and services, an understanding of what providers want from an inspection and the inspection reporting process and reports. The ToR for the second phase of their review were published in January 2025. The report was published on 11 February 2025 [Exhibit JH50].

CQC's Response to the Dash Review

- 191. CQC published a response to the interim findings of the Dash Review on 26 July 2024, accepting the findings and recommendations in full. Many of the areas identified in the report as requiring urgent improvement aligned with CQC plans and priorities.
- 192. On 3 October 2024, CQC published a detailed announcement on our website titled "Re-building a trusted approach to our regulation" which outlined the immediate changes being made in response to the interim report of the Dash Review.
- 193.CQC also published a response to the final report of the Dash Review and the review of the SAF by Professor Sir Mike Richards on 15 October 2024 accepting all high-level recommendations.

CQC's Programme of Priorities

- 194. This section outlines key parts of CQC's programme of priorities and our future strategy in response to recommendations of the Dash Review and the review of the assessment framework.
- 195. For each recommendation of the Dash Review, we have developed a set of actions in our programme of priorities, and where possible, have taken steps to make changes with immediate effect. With respect to Professor Sir Mike Richard's review, as noted above, we have accepted all high-level recommendations and at present are working through our management response to each individual recommendation.
- 196. It should be noted this work is ongoing and will continue to evolve as further phases of these reviews are completed.

Organisational Structure and Leadership

197.CQC is working towards realigning our organisational structure around sector expertise. We have announced we will appoint four Chief Inspectors to lead on regulation and improvements of hospitals, primary care and adult social care services. In 2023, we appointed an Interim Chief Inspector of Adult Social Care and Integrated Care. In February 2025, we appointed an Interim Chief Inspector of Healthcare. In March 2025, we appointed a Chief Inspector to lead on mental health services.

Assessment Framework

- 198. In addition to the ongoing work with Professor Sir Mike Richards and Professor Vic Rayner, we are taking internal actions to improve the assessment framework, drawing directly on the recommendations from Sir Mike's review.
- 199.A part of this is taking steps to enable our inspections to be carried out and reported more quickly, and to ensure the current assessment framework is simpler and made relevant to each sector. For example, we have committed to retain the five key questions in inspections across all sectors but will amend the 34 quality statements to ensure clarity and relevance to each sector and remove duplication. We have also stated we will stop scoring individual evidence categories. This will also help our reports to be clearer about our judgements and ratings.

Provider engagement

- 200. Provider engagement is another key aspect of CQC's programme of priorities. We are keen to implement changes that will rapidly improve how we work with providers and support a clearer view of the quality of care.
- 201. Our initial focus is working with providers to co-design our approach to what a rating of good looks like and to develop a clear and accessible regulatory handbook.

- 202. Provider roadshows are another aspect of this engagement. We have undertaken a series of roadshows and breakfast meetings which enabled providers to connect with their local CQC team, learn more about the assessment approach and take part in activities to co-design the improvements we are making. As part of the ongoing CQC Way initiative, external provider events have taken place in Newcastle and London. These events brought together 400 external stakeholders and provided opportunities to reflect honestly and work collaboratively with providers to shape our goals and ways of working. Further provider roadshows will be hosted from April 2025.
- 203. CQC's engagement also extends to our work assessing local authorities. We continue to engage with health and care providers, as well as the local government sector for feedback on this aspect of our work.

Technology and Systems

- 204. The Dash review concluded that poorly performing IT systems are hampering our ability to roll out the new Single Assessment Framework and in turn is causing considerable frustration and time loss for providers and CQC staff. I have commissioned an independent review by Peter Gill, a senior IT consultant who has held senior roles within the NHS. The review will consider the cause of the disruption and what can be done to make our systems fit for purpose. The review will be undertaken as a mixture of documentation review and interviews with individuals and teams from CQC and its partners involved in our programme of priorities.
- 205. CQC is also taking steps to change how we use technology. This will improve how we carry out assessments and the processes for factual accuracy checks, producing reports and registration.
- 206. We are taking steps to improve the provider portal and regulatory platform in the immediate term. This includes an urgent review of specific changes needed to the provider portal to improve the experience for providers registering with CQC. At the same time, we are exploring options for delivering assessment activity away from current systems so we can rapidly assess, rate and publish reports.

Pilot Projects

- 207. Several pilot projects have also been instigated by CQC in response to the Dash Review. One pilot project is looking at how operations managers can manage teams in specific sectors.
- 208. Another pilot project is focused on how we manage relationships with our providers. This pilot has started with NHS trusts, with the intention to expand to provider groups from each sector. We intend for these pilots to run throughout early 2025, at which point we will draw on findings from the projects and decide how to apply the most effective approach to relationship management.

ICS Assessments

209. CQC has paused our assessments of integrated care systems (ICS) for six months in agreement with DHSC. This allows us to free up capacity to carry out more provider assessments while modifications are made to the current assessment framework.

Reflections

- 210. CQC is fully committed to rebuilding a trusted approach to our regulation so that we can be the strong, credible and effective regulator of health and care services that the public and providers need and deserve. Aspects of CQC's programme of priorities go beyond the organisation and will require wider system consideration. This is acknowledged in the Dash Review.
- 211. People within our organisation have been self-aware of the issues we face. Many people had expressed concerns and been working hard to try and fix problems within their area of the organisation in the years before the Dash Review. The reality is a lot of these problems required major decisions to be made and a system level fix.
- 212. It is worth noting that both the Dash Review and Professor Sir Mike Richard's review were, and continue to be, informed to a large extent by staff and leaders within CQC. As was noted by Ian Dilks, Chair of CQC in our response to the final

report of the Dash Review and Professor Sir Mike Richard's review, the dedication and experience of CQC staff and leaders was recognised in each review.

213. Since I joined CQC in December 2024, I have established four immediate priorities: to significantly increase the number of assessments CQC conducts; to address the backlog of assessment currently stuck in the regulatory platform; to tackle the backlog of notifications and information of concern; and to improve processes for registering new providers. I am also concentrating on five medium-term priorities: Embedding cultural development (The CQC Way); Integration of Operations and Regulatory Leadership, reflecting on recommendations from Professor Sir Mike Richards and moving to having four chief inspectors; Reflecting on the Dash review: single assessment framework, growing the operational workforce and having four chief inspectors; Work to stabilise and fix the regulatory platform/provider portal; and Review longstanding issues around data quality and consistency. Work on all of these important issues continues at pace and CQC will provide a progress update to the Inquiry in any future Rule 9 statements.

Statement of Truth

I believe the content of this statement to be true.

[I/S] Signed

Dated 27/03/2025