Department of Health

The regulation and oversight of NHS trusts and NHS foundation trusts

JOINT POLICY STATEMENT TO ACCOMPANY CARE BILL QUALITY OF SERVICES CLAUSES

Monitor

May 2013

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Summary

This joint policy statement provides further detail on the changes to the regulation and oversight of NHS trusts and NHS foundations trusts proposed in the Government's initial response to the Mid Staffordshire NHS Foundation Trust Public Inquiry and related clauses in Part 2 of the Care Bill.

- The Francis report makes a compelling case that the regulation of NHS trusts and foundation trusts should change in two key ways. Firstly, equal emphasis should be placed on addressing failures of quality as for failures of finance. And second, overlap and duplication in the roles of regulatory agencies must be removed. We agree.
- In future, this division of roles will be simpler and clearer: the Care Quality Commission (CQC) will focus on assessing and reporting on quality; and Monitor and the NHS Trust Development Authority (TDA) will be responsible for using their enforcement powers to address quality problems. To free up time to care, the overall regulatory burden on providers will be radically reduced but, where there are failings in quality of care, there will be a stronger response.
- The CQC, through the Chief Inspector of Hospitals, will become the authoritative voice on the overall quality of care provided. It will lead on defining the characteristics of high quality care, drawing on the input of other bodies in the system. This will include quality aspects of governance, aligning with Monitor's approach to assessing corporate and financial governance.
- The CQC's existing registration requirements will be simplified to include a new set of fundamental standards, which can be prosecuted directly where appropriate, backed up by a new model of inspection to expose the worst performers to greater scrutiny.
- This new approach to assessment and inspection will form the basis for a new system of provider ratings, informed by the Nuffield Trust's review, to provide a fair, balanced and easy to understand assessment of how each provider is performing relative to its peers.
- Where the CQC identifies failings, the onus will be on the provider, working with their commissioner to take the necessary action. Where these problems persist in NHS trusts and foundation trusts, it will be the role of Monitor and the TDA, not the CQC, to take enforcement action if they consider it appropriate.
- Ultimately, if it proves impossible for an NHS trust or foundation trust to turn their performance around, Monitor, or the CQC, will be able to place the organisation into special administration on quality grounds. Special administration will provide a framework for determining how best to secure a comprehensive range of high quality services that are both financially and clinically sustainable.

Introduction

1. This policy statement, issued jointly by the Department of Health, the CQC, NHS England, Monitor and the TDA, accompanies the Care Bill introduced to Parliament on 9 May 2013. It follows the Nuffield trust's review of aggregate ratings for providers of health and adult social care services, *Rating providers for quality: a policy worth pursuing?*[1], and the Government's initial response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, *Patients First and Foremost*[2], published on 26 March 2013. *Patients First and Foremost* sets out a number of significant changes to the regulation and oversight of NHS hospitals and this statement aims to set these changes and the clauses in Part 2 of the Bill into this broader context. It precedes the CQC's consultation on how these changes will be implemented which will be published in June 2013. Unless stated, the changes described in this document apply to all NHS trusts and foundation trusts.

The case for change

2. The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, led by Robert Francis QC and published on 6 February 2013, provides a damning account of a systemic failure of the most shocking kind. It sets out how regulators, commissioners, professional bodies and the Department of Health failed to act together where an NHS hospital let down the people it existed to care for and protect. In particular, Robert Francis concluded that:

    > *"In the case of Mid Staffordshire, the regulatory regime that allowed for overlap of functions led to a tendency for regulators to assume that the identification and resolution of non- compliance was the responsibility of someone else. Effective accountability to the public demands a simpler regime of regulation."*

3. Separate to the Inquiry, the Secretary of State for Health commissioned the Nuffield trust to review whether aggregate ratings of provider performance should be used in health and social care, and if so how best this might be done. The report of the review, published on 22 March 2013, identified an unmet need for clearly presented, comprehensive and trusted information on the quality of care delivered by different health and social care providers. The report concludes that aggregate ratings might be of value to the public in helping to choose the right services and to those organisations purchasing or providing services to seek better performance, if focused on quality and introduced incrementally.

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[1] http://www.nuffieldtrust.org.uk/sites/files/nuffield/130322_ratings_providers_for_quality_full_report.pdf
[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

Proposed changes

4. *Patients First and Foremost* set out an initial overarching response to the Francis report on behalf of the health and care system as a whole, highlighting the urgent priority of ensuring safe, compassionate care in NHS hospitals. It includes a number of significant changes to the regulation and oversight of NHS trusts and NHS foundation trusts, which are based on the following principles:

   - Ensuring high quality care for all is the core purpose of every part of the NHS;
   - Clinicians and care givers have a responsibility to speak up and act if they see care that falls below acceptable standards;
   - The boards of providers, not external bodies, are accountable for fostering an open and supportive organisational culture and for providing high quality patient care;
   - Improvements in the quality of care are primarily driven by providers in partnership with their commissioners, including NHS England in its commissioning role; and
   - The regulatory and oversight bodies do not manage health services but act on behalf of the public at large to provide an impartial assessment of their performance, identify failures and, where necessary, secure improvement.

5. The majority of the measures announced in *Patients First and Foremost* will be achieved through new ways of working, joint protocols and agreements and changes to guidance and secondary legislation. A small number of changes require primary legislation and these are included in Part 2 of the Care Bill. Taken together these measures and changes will have a significant effect:

   - **Assessing performance:** The CQC, through the new Chief Inspector of Hospitals, will shine a powerful light on the culture of hospitals and make an assessment of every NHS hospital's performance, drawing on the views of commissioners, local patients and the public. This new approach to assessment will inform a new system of aggregate provider ratings developed and published by the CQC, independently of Government. It will ensure that regulators and commissioners are working to a common set of quality metrics that can be used to review and challenge providers;
   - **Identifying failure:** The CQC, working with the Department of Health, the National Institute for Health and Care Excellence (NICE), commissioners, professionals and the public, will review the existing registration requirements with the aim of producing a new set of simpler fundamental standards which make explicit the basic standards beneath which care should never fall. For NHS trusts and foundation trusts, the Chief Inspector will focus on identifying failures and requiring action;

- **Intervention:** To reduce duplication and provide clarity about who has responsibility for intervening, enforcement action will be overseen by Monitor for foundation trusts or the TDA for NHS trusts. The Health and Social Care Information Centre will be the single national hub for collecting data on behalf of all the arms-length bodies, with a duty to seek to reduce the data burden on the service year on year;
- **Administration:** Where normal commissioner engagement with NHS trusts and foundation trusts has been unable to address significant concerns about patient care, a new time-limited failure regime will ensure that firm action is taken until they are properly and promptly resolved.

6. The changes are described in more detail below.

Assessing performance

7. From autumn 2013, following the appointment of the Chief Inspector of Hospitals, the CQC will immediately begin phasing in a new approach to make it the primary voice on quality in the health and social care system. These will start with intensive inspections from October 2013 onwards of NHS providers, and a new approach to inspection in the new year.

8. To have authority and credibility, inspection will be led by individuals with deep insight and specialist experience in the areas for which they are responsible, with the close involvement of patients, staff and others. The CQC is developing a model of inspection that will secure thorough and insightful inspections which combine first-hand expert experience with data and feedback from patients and staff.

9. The basis for inspection will also change. In keeping with Robert Francis's recommendation, the CQC's inspections will be based on a simplified set of registration requirements that make it easier for robust action to be taken where care is poor or where there is deterioration in standards of care, while maintaining a sufficiently robust threshold for market entry for new providers. These will apply to all providers, and will incorporate fundamental standards, which will be directly prosecutable and will represent the basic requirements that should be the core of a quality service.

10. The Department of Health, the CQC - through the new Chief Inspector - and NICE will work together, in consultation with the public, clinicians and providers, to develop the new standards and lay regulations to underpin them. A consultation on incorporating fundamental standards into a revised set of registration requirements, including how these will inform provider ratings, will be launched in June.

11. Alongside fundamental standards, the new inspection regime at the CQC will focus on five key questions:
    - Is the service safe?
    - Is the service effective?
    - Is it a caring service?
    - Does the service respond to what people say?
    - Is the service well led?

12. The CQC will also develop a methodology for assessing the overall performance of organisations in meeting the needs of patients and the public. In developing this it will consult with a range of bodies, including Monitor, the TDA and NHS England. This will ensure that all national organisations are working to a common definition of quality that is consistent with the Mandate to NHS England and the NHS Outcomes Framework, and takes account of local priorities. It will reduce the bureaucratic burdens on NHS trusts and foundation trusts and improve the coordination and alignment of regulatory judgements. NHS trusts and foundation trusts will be required to demonstrate how well they are meeting this single set of expectations, including through their annual Quality Accounts.

13. To better inform patients, service users and the public about the quality of services, this "single version of the truth" will form the basis of a new system of aggregate hospital ratings that draws not just on the available data but also on the CQC's inspection findings and the Chief Inspector's judgement and is informed by other commentaries on quality, for instance from Quality and Surveillance Groups or Healthwatch. The Government accepts the conclusions of the Nuffield trust review of aggregate ratings and, just as OFSTED offers clear reports on local schools, the new ratings system will give patients and the public a fair, balanced and easy to understand assessment of how well a provider is doing relative to its peers. Through the Care Bill, the CQC will be given a new legal duty to develop and publish aggregate ratings independently of Government, developed and produced in consultation with patients, service users and the hospital sector.

14. The CQC's approach to ratings will allow complex organisations, such as hospitals, to be rated in aggregate, but supported by more detailed service-specific ratings where possible. The new ratings system will provide a strong incentive for hospitals to improve the quality of their services. The targeting and frequency of inspections, based on the CQC's surveillance model, will be informed by ratings, creating a system of earned autonomy for high quality providers. Hospitals which perform the best will therefore enjoy greater freedom from regulatory bureaucracy. The CQC will consult on the new arrangements in June with the aim of publishing information on hospital ratings by the end of the year. This will be the start of a phased, evolutionary approach that allows ratings to develop over time, with clear plans for involving professionals, the public and providers in this process.

15. The Department of Health will also commission an independent evaluation of the operation of the new ratings system, and this will inform future adaptations. Subject to the findings of the evaluation, the Government expects to see incremental evolution of the ratings methodology, with providers given advance notice of any changes, so as to provide stability for providers and facilitate increasingly sophisticated comparison over time.

Identifying failure

16. The primary responsibility for delivering a high quality, sustainable service rests with the boards of NHS trusts and foundation trusts, working in partnership with commissioners. As set out in the National Quality Board's *Quality Governance in the NHS: A guide for provider boards*[3], boards should promote a quality-focused culture in their hospitals and take an active leadership role on quality. Boards should also ensure they have effective governance structures, reporting lines and performance and risk management systems.

17. From April 2013, a network of local and regional Quality Surveillance Groups (QSGs) have also been established to bring together commissioners, regulators, local Healthwatch representatives and other bodies on a regular basis to share information and intelligence about quality across the system, including the views of patients and the public, and proactively spot potential problems early on. QSGs are supported and facilitated by NHS England and will foster a culture of open and honest cooperation. This will support many of the recommendations made by Robert Francis in relation to the sharing of information. They also help support the coordination of any action that is needed to respond where risks to patients are identified. Once appointed, the Chief Inspector of Hospitals will assume, on behalf of the CQC, a leading role in these quality oversight and surveillance arrangements.

18. The local intelligence provided by QSGs will be supplemented by the CQC's inspection programme. The CQC's inspection reports will provide a vehicle for raising lower level problems and the link to ratings will provide a strong incentive to improve. The Care Bill therefore introduces a new warning notice for NHS trusts and foundation trusts, to replace the current notices, which will be issued where the CQC, through the Chief Inspector of Hospitals, concludes that there are systemic failures in the quality of services provided by an NHS trust or foundation trust and significant improvements are required. The CQC will revise their enforcement guidance to provide more detail on their approach to issuing the new warning notices but we envisage this would cover circumstances such as a persistent failure to meet fundamental standards. The notice will identify where improvement is needed and require action within a clearly specified timeframe. They will be published and a copy sent to either the TDA or Monitor. The existing warning notices will continue to apply to other providers of health and social care.

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[3] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_125239.pdf

Intervention

19. Where the CQC issues a new warning notice to an NHS trust or foundation trust it will be primarily the responsibility of their board to ensure a comprehensive response is put in place and assure itself that the necessary improvements are made. The TDA (for NHS trusts) and Monitor (for foundation trusts) will exercise their judgement over whether the trust is taking reasonable steps to rectify the problem and whether there is a need for them to intervene to secure the necessary improvements.

20. The TDA has published *Delivering High Quality Care for Patients*[4], the accountability framework for NHS trust boards. The accountability framework describes the oversight model the TDA will use to assess the progress NHS trusts are making, the development support it will provide and how it will hold them to account. It sets out that, if the TDA considers it needs to intervene, the options it will consider include:
    - requesting recovery plans and additional reporting;
    - increasing the frequency and seniority of engagement with the organisation;
    - commissioning an independent 'deep dive' investigation or audit;
    - reviewing the skills and competences of executive and non-executive board members; and
    - commissioning interim support to provide additional management capacity.

21. All foundation trusts are now licensed by Monitor and this is the main tool it uses to regulate them. The licence incorporates a set of conditions covering financial viability and governance as well as other areas reflecting Monitor's expanded role within the health sector. The conditions on governance include the requirement on all foundation trusts to establish and effectively implement systems and/or processes to ensure compliance with health care standards binding on the foundation trust, including standards set by Secretary of State or the Care Quality Commission. Monitor assesses a breach or a potential breach of the licence conditions through a risk-based system of regulation which determines the intensity of the monitoring at each foundation trust.

22. Where Monitor determines that poor governance means a foundation trust has breached, or is at risk of breaching, the conditions of its licence it may impose additional conditions, such as requiring the licensee to have in place board and management capacity and capability sufficient to implement a required urgent care plan. These powers are in addition to Monitor's powers to apply discretionary requirements or seek enforcement undertakings from any licensed provider that breaches the conditions of their licence.

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[4] http://www.ntda.nhs.uk/wp-content/uploads/2012/04/framework_050413_web.pdf

23. To ensure that Monitor can take prompt action where the CQC, through the Chief Inspector, has identified a need for significant improvements in quality of health services provided by a foundation trust, the Care Bill will clarify that Monitor can apply additional licence conditions to be imposed where the CQC has issued a warning notice to a foundation trust. Failure to comply with these extra conditions provides grounds for Monitor to remove, suspend or replace the foundation trust's governors or directors. These powers will apply to all foundation trusts until at least 1 April 2016. After that date, the Secretary of State may exercise his discretion under the Health and Social Care Act 2012 to order that they should no longer apply to foundation trusts that have been authorised for at least two years, if they meet certain criteria. Those criteria would be developed by Monitor and would be subject to consultation and approval by the Secretary of State before they could take effect.

24. In less serious cases it will be sufficient for the TDA or Monitor to monitor the situation, whereas more serious cases will require a more hands on approach at an early stage. In the event of a catastrophic failure, these changes will ensure both the TDA and Monitor will be able to move swiftly to intervene to ensure the provision of safe services for patients and service users.

25. At the end of the timeframe specified in the warning notice the CQC will be required to consider whether the required improvements have been made and, if not, review whether further action is required. This could include recommending the TDA or Monitor intervene or, if enforcement action has already been taken, that they escalate their involvement with the trust. As part of its review, the CQC must consider whether special administration would be an appropriate next step. This will prevent hospitals from being allowed to continue failing indefinitely.

Administration

26. In some cases, it may be clear that more fundamental issues prevent an NHS trust or foundation trust from making the necessary improvements in quality of care and/or financial performance. For example:

   - An NHS trust or foundation trust may become clinically unsustainable if it proves impossible for it to provide acceptable levels of care in its current form, whether as a result of a failure of clinical governance or because volumes of clinical activity for some services have reduced to levels at which they may become unsafe.
   - Equally, an NHS trust or foundation trust which cannot generate sufficient income to cover its expenditure will need to consider how to provide its services in a more efficient way. If it cannot be realistically expected to achieve the necessary level of efficiency then it may not be able to pay its bills and could be considered insolvent, or financially unsustainable.

27. Managing the process of reconfiguring local services to provide sustainable, high quality healthcare that meets patient expectations and needs is primarily a role for local commissioners, supported by NHS England. In the event that an NHS trust or foundation trust has failed to make improvements and commissioner-led efforts to resolve the issue have not succeeded, special administration may, as a last resort, provide a mechanism for dealing with NHS trusts and foundation trusts which have become either clinically and/or financially unsustainable. Where the TDA considers it is in the interests of the health service, it can already advise the Secretary of State to place an NHS trust which it considers to be either clinically and/or financially unsustainable into special administration. The Board of the trust is suspended and the Secretary of State appoints a trust special administrator to run the trust and consider options for securing high quality services which can be sustained in the long-term. Monitor can also place a foundation trust into special administration directly, following consultation with the Secretary of State and the CQC, on the grounds that it has, or is likely to become, financially unsustainable. The changes proposed in the Care Bill will enable it to also do this where it is apparent that a provider is clinically unsustainable.

28. The CQC and the TDA or Monitor will work closely together to determine whether special administration is an appropriate option for an NHS trust or foundation trust. If, however, there is uncertainty over how to proceed and the CQC, through the Chief Inspector, believes special administration is appropriate, it will be able to direct Monitor to place a foundation trust into special administration. In doing so, the CQC would first need to be satisfied that there has been a serious failure in the quality of care and that special administration is appropriate. The CQC would also need to have consulted with the Secretary of State and Monitor before it could trigger such an action. Equivalent provision for the CQC to trigger similar action in respect of NHS trusts will be made through directions to the TDA.

29. Further clauses in the Care Bill will make securing the provision of essential services which are of sufficient quality and safety an explicit objective of special administration. The CQC will have a more clearly defined role in determining whether the solution proposed by the trust special administrator will secure this objective, in the same way that commissioners are responsible for determining whether the administrator's proposals will protect essential services. However, oversight of the special administration process will remain the responsibility either of the TDA (on behalf of the Secretary of State for NHS trusts) and Monitor (for foundation trusts).

Next Steps

30. The Care Bill began its passage through Parliament on 9 May. It has its second reading in the Lords on 21 May and will begin its first committee stage in June. The CQC will be

publishing further information on their approach to their new role and the development of ratings in June.

Annex: Summary of roles and responsibilities

31. This annex summarises the respective roles of CQC, Monitor, TDA and commissioners (including NHS England) in regulating and overseeing NHS trusts and foundation trusts.

32. **NHS England** and **clinical commissioning groups** are responsible for assessing the needs of their populations and purchasing the services that will best meet those needs within a fixed budget. Commissioners play a key role in improving standards of care and shaping local service provision. To be effective, they should keep the performance of providers with whom they contract under review and monitor the outcomes achieved, so they can address areas of under-performance, make informed decisions about the planning of service provision in the future and support patients to make informed choices. As part of their role, commissioners work closely with providers to determine the services needed for local areas, which may involve discussing changes to how services are organised to ensure that they are sustainable for the future.

33. The **CQC** monitors, inspects and regulates health and social care services to make sure they meet fundamental standards of quality and safety. Once appointed, the Chief Inspector of Hospitals will be responsible for assessing and judging how well hospitals put the quality of care at the heart of everything they do, serving and protecting the interests of people that use their services. These assessments will make the CQC the primary commentator on quality in the health and social care system and identify areas where improvements are needed. They will provide the basis of the new system of aggregate provider ratings, which will be developed by the CQC on the basis of the Nuffield trust review. And they will provide a basis for further enforcement and intervention where necessary.

34. For independent sector providers such enforcement action would continue to be the responsibility of CQC. For NHS Trusts and NHS foundation trusts, however, the CQC will not normally intervene directly and will look to the TDA (for NHS trusts) and Monitor (for foundation trusts) to take appropriate enforcement action. The CQC has a range of other enforcement powers – including imposing conditions on, and suspending or cancelling a provider's registration. These can and are used to good effect in other parts of the health and care sector. In respect of NHS hospitals, however, the case for closing or suspending failing hospital services has generally been outweighed by the need to maintain patients' access to the service, so the CQC has only been able to use warning notices to identify where improvements are needed.

35. Other than in exceptional circumstances, the CQC will therefore no longer seek to exercise its existing enforcement powers in respect of NHS trusts and foundation trusts under the Health and Social Care Act 2008, beyond the issuing of the new warning notices. In the event that the exercise of CQC's powers in relation to registration is deemed appropriate, Monitor or the TDA would ask the CQC to take the necessary steps. The CQC will, however, retain the ability to prosecute against the fundamental standards and may refer serious incidences of poor care to the Health and Safety Executive. It would not, therefore, be constrained in the event that its inspectors find evidence that patients are being put at direct risk of harm.

36. **Monitor** continues to regulate foundation trusts to ensure they are well-led and financially sustainable such that they can deliver quality care. It assesses the suitability of NHS trusts that apply for foundation trust status. It monitors foundation trusts as part of its licensing regime (which will be extended to other eligible providers of NHS services from April 2014) and acts in relation to breaches or potential breaches of the licence conditions. It uses a risk-based system which determines the intensity of the monitoring undertaken for each licensee. Where it identifies potential or actual problems it will take steps to deal with them effectively, which could include additional support, direction or intervention or, for foundation trusts, appointing new directors and/or governors.

37. All foundation trusts remain subject to Monitor's transitional powers under section 111 of the Health and Social Care Act 2012 until the Secretary of State makes an order to release either some or all trusts from the powers. It has a duty to protect and promote the interests of people who use healthcare services through the promotion of the provision of health care services which is economic, efficient and effective, and which maintains or improves the quality of services. In its wider role as sector regulator for healthcare, it sets prices for NHS-funded care in partnership with NHS England, enables integrated care, safeguards choice and prevents anti-competitive behaviour which is against the interests of patients, and supports commissioners to protect essential health services for patients if a provider gets into financial difficulties.

38. The **TDA** provides leadership, support and development for the remaining NHS trusts. It performance manages NHS trusts and assures itself that trusts have robust arrangements for clinical governance and risk management, with the aim of supporting NHS trusts to develop sustainable, high quality services and thereby achieve foundation trust status or a suitable alternative, in line with the Government's objective of ensuring all trusts can become foundation trusts. It holds NHS trusts to account on key areas such as quality and finance as well as other key deliverables, including progress against trusts' plans for becoming foundation trusts. When an NHS trust is not able to achieve its goals, the TDA uses a clear, rules-based escalation process to consider its needs for additional support, further direction or even, in extreme cases, intervention.

39. The TDA is a Special Health Authority established under the NHS Act 2006 and, as such, it is not featured in primary legislation, including the Care Bill. It operates in accordance with the directions issued to it by the Secretary of State and will continue to fulfil its role until all NHS trusts are authorised as foundation trusts.

40. The **Department of Health**, on behalf of the Secretary of State, acts as 'system steward'. It is the only body with oversight over the whole health and care system and is responsible for creating and updating the policy and legislative frameworks within which the health and care system operates. As such, it will keep the system under review to ensure that the changes proposed in this are effective. The Department is also responsible for sponsoring individual national health and care system bodies, by supporting them and holding them to account for the delivery of their role. This includes ensuring they are delivering their functions, meeting their statutory duties, and using public money efficiently and effectively. It is also an important stakeholder and shareholder in NHS provider organisations, and is a key source of funding for capital investment.