Introduction

The new infrastructure governing the NHS was established from 1 April 2013 with the creation of new organisations and new relationships. The All-Party Parliamentary Health Group document: A Guided Tour of the new NHS, looks to provide, through a series of essays, respective and collective rationale and objectives of the “main national bodies” in the new NHS landscape.

The Care Bill takes the issue of regulation further and will modernise the law to make sure that people’s wellbeing is at the heart of the care and support system. For NHS Trusts and Foundation Trusts, there are some important provisions within the Care Bill that will mean a much tougher regulatory regime, with the powers of the two main regulators of the NHS, the Care Quality Commission (CQC) and Monitor being increased.

Care Bill [HL] 2013-14 and how it affects regulation

The Care Bill is currently passing through Parliament and will, once it receives Royal Assent, become an Act of Parliament and therefore, law. The Bill is in three parts:

- Reform of care and support
- Response to the Francis Inquiry on failings at mid Staffordshire Hospital
- Establishing Health Education England and the Health Research Authority as statutory non departmental public bodies.

The Bill is currently at the committee stage in the House of Commons (who stopped receiving written evidence in early February 2014). To support introduction of the Bill, the Department of Health has produced a series of Factsheets, four of which have an impact on regulation.

DH Factsheet 12: The Care Bill – Single Failure Regime

The Care Bill creates a single failure regime that will be used where there are failures of quality, governance and/or finance at NHS Trusts and NHS Foundation Trusts. The factsheet sets out clearly the three stages that will be adopted by the CQC, Monitor and the NHS Trust Development Authority. The focus is on intervention if a poor performing provider has been unable to resolve the situation working with its commissioners. This regime is set around three stages of identification; intervention and administration.

DH Factsheet 14: The Care Bill – false or misleading information

The Care Bill will make it a criminal offence for healthcare providers to give false and misleading information. The Government will have the power to set the type of care provider and the type of information that the offence will cover. Such an offence will be a strict liability offence and means that it does not need to be proven that the provider ‘knew it had supplied false or misleading information’. A defence could be
made be if a provider can show they have taken all reasonable steps to ensure the information provided was correct. This criminal offence will apply to the organisation as a whole i.e. as a legal entity. Initially, the regulations will limit the criminal offence to providers of NHS secondary care. Any court punishment could include remedial orders; publication orders; an unlimited fine.

**DH Factsheet 17: The Care Bill – Chief Inspectors and the Independence of the CQC**

The Care Bill was amended to give the CQC greater operational freedom from Ministers. The CQC will have greater freedom to take action where poor care is provided to patients and service users. The appointment of new Chief Inspectors of Hospitals; Adult Social Care and General Practice has already been actioned by the CQC. The important issue here is that the CQC will be able to inspect any provider; and determine itself, how to conduct such inspections and report its findings.

**DH Factsheet 18: The Care Bill – Trust Special Administration**

The Care Bill introduces changes to the unsustainable provider regime to make sure that patient services are protected by dealing swiftly and effectively with failing trusts. This factsheet provides an important summary of what will happen if either the Secretary of State [in the case of an NHS Trust] or Monitor [in the case of a Foundation Trust] appoints a Trust Special Administrator. It sets out the role of commissioners of services as well as clarifying the statutory obligations of NHS England and Clinical Commissioning Groups where actions need to be taken as a result of a Trusts Special Administrator’s recommendations.

---

**The role of the CQC**

The CQC was established to regulate the quality and safety of care provided to patients. Its key role is to make sure that the care provided by CQC registered providers meets 16 governance standards of quality and safety. Where people are getting poor care, or inspections demonstrate failings, the CQC has powers to issue warning notices and can restrict services the care provider can offer; restrict admissions to a service; issue fixed penalty notices; and suspend or cancel a care provider’s registration with the CQC. In extreme cases, the CQC has the power to prosecute a care provider. The CQC website includes the following publications:

- About CQC
- Our strategy for 2013-2014
- Enforcement policy
- Useful leaflets: Standards for hospitals; Standards for GPs

The CQC, in line with the Care Bill expectations, has appointed Chief Inspectors of Hospitals; General Practice and Adult Social Care. The Chief Inspectors are responsible for overseeing inspections and for driving up improvements in quality and safety of care. The CQC’s website contains information for the public about their local hospitals and GP services. This includes information about where enforcement action is being taken by the CQC and details of any warning notices that may be issued. Their website identifies hospitals and organisations where enforcement action is being taken. The CQC have recently begun to publish detailed quality reports on the hospitals they are inspecting and these are readily available for members of the public and patients to read.

---

In the case of inspections of GP surgeries, the CQC have issued warning notices to some practices as a result of them failing to meet some of the government standards of care. Where there are serious failings, NHS England have to work with the GPs concerned to make sure that they either;

- improve their services in line with the CQC expectations, or,
- NHS England can consider withdrawal of a contract with the practice concerned.

Patients are now able to go to the CQC website and look at the CQC inspections of their local GP surgeries, including any information about failures against the standards expected in general practice.

---

**The role of Monitor**

Monitor was set up as the sector regulator and to ensure NHS Foundation Trusts provide high quality and sustainable services for patients. Monitor describe their role as being ‘to protect and promote the interests of patients by ensuring that the whole sector works for their benefit’. Monitor has produced some key documents that all NHS Boards should familiarise
themselves with. These include:

- **The new NHS Provider licence [14 February 2013]**
- **Enforcement Guidance [28 March 2013]**
- **Risk Assessment Framework [replaced the Compliance Framework on 1 October 2013]**
- **Code of Governance for NHS Foundation Trusts – issued December 2013**
- **Governance Reviews: Consultation Document [closing date 7 March 2014]**

The above set out the framework and rules against which Monitor will assess and judge the performance of NHS Foundation Trusts.

**Monitor Provider Licence**

All NHS Foundation Trusts were issued with a Provider licence with effect from 1 April 2013. Any breaches against that licence could result in enforcement action. The Monitor website publicly sets out where it is currently undertaking investigations; other regulatory action it has taken; and enforcement action. It is important that NHS Boards understand the extent of information that is published about their organisation and are able to respond to any concerns that arise either in the local media; via their local MPs or from key patient groups, such as local voluntary organisations, Healthwatch etc. The website states that since 2008, some 40 Foundation Trusts [approx. 1 in 4] has been subject to formal investigation by Monitor. Investigations can cover;

- financial deficits and long-term financial viability;
- breaches of provider licences due to failure to meet targets, for example RTT [referral to treatment targets], and;
- concerns about poor governance of an organisation.

NHS Trusts who have not achieved Foundation Trust status are exempt from requiring a licence but once authorised as a foundation trust they will be granted a licence.

**Monitor: Consultation on Governance Reviews**

The Governance Reviews: Consultation Document is an important document for NHS Boards. It sets out Monitor’s expectation that all Foundation Trusts will conduct an external review of their governance [i.e. Board] every three years. It has some useful pointers for organisations on how they might structure a governance review. It particularly highlights the fact that the CQC, as part of its inspection regime, includes a view on how well led an organisation is; and whether or not it is fit for purpose.

**The role of NHS Trust Development Authority**

The NHS Trust Development Authority [NTDA] became effective from 1 April 2013. Its role is to ‘provide support, oversight and governance for NHS Trusts on their journey to Foundation Trust status’.

The NTDA works in partnership with the CQC to drive improvements in those NHS Trusts who have yet to achieve Foundation Trust status. The NTDA’s powers include the ability to place a Trust in special measures if the CQC issue a report that highlights serious failings.

In August 2013, the NTDA published its partnership agreement with Monitor. This sets out how the two organisations will work together and support each other when carrying out their respective statutory and non-statutory roles and responsibilities.

The NTDA also publish information about organisations that it places in special measures and its Board reports include publicly available information about the progress of NHS Trusts towards achieving foundation trust status.

**What does all this mean for NHS Boards?**

The emphasis on improving patient safety and quality of care is integral to the regulatory system now put in place by the Government. The Care Bill will take this further by enshrining many of the regulatory requirements in law. NHS Boards and their Directors must be fully cognisant of their responsibilities and understand the regulatory system that affects their organisation and what powers may be exercised against them if they are overseeing a failing organisation.
BRIEFING NOTE: REGULATION IN THE NEW NHS

Secondary care organisations

KEY QUESTIONS

✦ Have the Board/Directors/Lay Members been fully briefed on the Care Bill and its implications for NHS organisations? Do you fully understand the implications of the Bill on your responsibilities as a member of an NHS Board?

✦ As a Board, do you fully understand the CQC and Monitor assessment and inspection regimes; their powers if they identify failures; and what would happen if it is decided that you are failing to meet the expected standards of governance, financial probity and sustainability, and quality of care?

✦ Has the Board held a workshop or briefing session on the increased powers of the CQC and what this may mean for their hospitals; or Board?

✦ Is the Board aware that the Care Bill will make it a criminal offence to provide false or misleading information?

✦ How does the Board test and know that the information it is providing is accurate e.g. on mortality rates?

✦ What would constitute the reasonable steps needed to assure the Board that your information is accurate?

✦ Has the Board been provided with information about the Monitor consultation document on Governance Reviews and are you planning to submit a response?

✦ Has the Board ever had an external review on its governance? If not, has the Board considered whether an early review will be undertaken and the approach to be used?

✦ Does the Board regularly receive information about the outcome of CQC inspections and/or how it is meeting the requirements of the Monitor provider licence (where applicable)?

✦ Does the Board have an early warning system to identify any areas that may result in the organisation breaching the provisions in the Provider licence; or not attaining the CQC standards?

Clinical Commissioning Groups

KEY QUESTIONS

✦ Has your governing body been briefed on the Care Bill and any implications it may have for CCGs?

✦ Does your governing body understand the role of the regulators in the health system and how this may impact upon services that the CCG may be commissioning?

✦ How does the CCG receive reports identifying any enforcement action taken by any of the regulators on the service providers you commission services from?

✦ Does the CCG have clear processes in place for working with the NHS England area team if CQC issue warning notices to a practice within the CCG area, so that any consequent impact on other GP practices is fully understood e.g. impact on patient lists if a practice closes?

✦ Has your CCG been briefed upon the Monitor provider licence and the fact that NHS Foundation Trusts’ mandatory services are, since 1 April 2013, now known as CRS [commissioner requested services]?

✦ Do you have a process in place to review Monitor, CQC and NTDA websites for information about provider services and to make sure that as commissioners you are clear about your role in supporting improvement in services?

Providers and Commissioners

KEY QUESTIONS

✦ Do you have a clear process for liaising with communications teams when responding to queries from the media about regulatory notices/press releases?

✦ Do you have a clear process for responding to queries from the media about regulatory notices/press releases?

Contact Information

Steve Connor
Deputy Director
0151 285 4500
07768131785
Steve.Connor@miaa.nhs.uk