SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST

Registration with the Care Quality Commission

1. Introduction

- 1.1 A new system of regulation for all providers of health and social care services in England is being introduced.
- 1.2 From 1st April 2010, all NHS trusts (including primary care trusts as providers) that provide "regulated activities" will be required by law to be registered with the Care Quality Commission (CQC). Adult and social care and independent healthcare providers will follow from 1st October 2010, although these sectors are currently registered under the Care Standards Act 2000. Dental services will need to be registered by April 2011 and GP practices by April 2012.
- 1.3 The Standards for Better Health for NHS trusts are being replaced by new Essential Standards for Quality and Safety across the care sector. The CQC will expect providers to be compliant with the new Standards in order to be registered.
- 1.4 The new arrangements are designed to mark a change from regulation based primarily on systems, processes and policies to a framework based primarily on outcomes and what constitutes a quality experience for people who use services. They are also designed to make it easier for people to compare one provider with another.
- 1.5 This paper briefs the Board on the requirements for registration, how compliance with the relevant regulations has been assessed, and the Trust's proposed declaration to the CQC.

2. The regulations

- 2.1 The new regulated activities, and the requirements that service providers need to meet in respect of them, are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009, which will come into force on 1st April 2010.
- 2.2 The regulations set out the range of activities covered by registration. The types of services that trigger the need for registration are described as regulated activities. The categories of regulated activities include:
 - Personal care
 - Treatment of disease, disorder or injury
 - Surgical procedures
 - Diagnostic and screening procedures
 - Maternity and midwifery services

- 2.3 Trusts are required to declare that they comply with the regulations for each regulated activity for each location where this is provided. For registration purposes, a location is the place where the regulated activities are provided, i.e. where a type of service is carried out. Trusts are required to match regulated activities to registered locations.
- 2.4 There are 28 regulations, 16 of which relate most directly to the quality and safety of care and which apply to all types of provider. There are 12 regulations that relate to management of services that apply differently to different types of provider.
- 2.5 The new registration system focuses on outcomes rather than processes. The guidance issued to providers of health and social care by the CQC at the end of December 2009 describes 28 outcomes, each reflecting a specific regulation, and describes what a person using services can expect from a provider who is compliant with the regulations.
- 2.6 The regulations have been mapped to the following six outcome headings:
 - Involvement and information
 - Personalised care, treatment and support
 - Safeguarding and safety
 - Suitability of staffing
 - Quality and management
 - Suitability of management

3. Registration application and declaration of compliance process

- 3.1 Application for registration is based on provider self-assessment against the essential standards and regulations. This is a declaration only process. The CQC does not require evidence of compliance by this date only assurance.
- 3.2 In preparation for the registration process, trusts were required to submit a pre-application form to the CQC by 18th December that provided the following basic information:
 - Details of the individual leading the process for the trust
 - The regulated activities to be registered
 - The locations where regulated activities are provided
- 3.3 The full on-line application and declaration of compliance for registration has to be completed between 4th and 29th January 2010 and then submitted to the CQC. This document includes:
 - Statements on the Data Protection Act 1998 allowing the CQC to share information about providers with third parties as permitted by law.
 - Service provider details, i.e. the legal entity applying to register. In this case, Sandwell and West Birmingham Hospitals NHS Trust.

- Regulated activities provided
- Invoice details for annual fees for registration (details of fees to be confirmed following the outcome of consultation)
- Information about the nominated person (Chief Executive) making the application e.g. confirmation of identify, enhanced CRB status, qualifications and employment history
- Information about regulated activities provided and location
- Declaration of compliance with the relevant registration regulations listed in the Health and Social Care Act (Regulated Activities) Regulations 2009 guidance.
- Confirmation that the Trust Board or equivalent has discussed the content and agreed the declaration of compliance.
- Signature of approval of the application for registration e.g. Chief Executive or equivalent
- 3.4 To declare compliance CQC guidance states that compliance must be assessed against:
 - Regulation
 - what do the regulations say?
 - Outcome
 - what should people who use services experience?
 - Prompts
 - The CQC has provided several prompts for each outcome that highlight key factors to consider and assess against when collating evidence and declaring compliance.

4. Trust assessment of compliance

- 4.1 Executive leads have been identified for each outcome area to progress this work and undertake an assessment of the level of compliance.
- 4.2 The evidence available to support compliance with the regulations has been shared with Board members, together with details of relevant documentation and an assessment of the adequacy and robustness of the available information.
- 4.3 Based on a self-assessment process the Trust's application for registration will, subject to Board approval, declare full compliance with the relevant regulations for the regulated services provided by the Trust(see Appendix 1)
- 4.4 Evidence of assurance of compliance will be retained and made available to the CQC should it be requested.

5. How will compliance with the regulations be assessed?

5.1 Following submission of the application, the CQC will assess the organisation's compliance with the regulations and reach a judgement about each provider's registration status.

- 5.2 To do this the CQC will review the Quality and Risk Profile (QRP) it holds for each NHS trust. This profile uses the information from existing sources such as previous core standards declaration, patient and staff surveys, existing targets, and NHSLA reports. It is used to determine where the risks lie for each organisation and the likelihood of non-compliance with any of the regulations. A similar process was previously used to determine the risk of noncompliance with the core standards.
- 5.3 Individual, pre-populated QRPs were due to be sent to each trust in January to assist their registration applications. Although the Trust only received this information on 22nd January 2010, it has been taken into account in forming a final view about compliance.
- 5.4 From February to March 2010 the CQC will assess applications, make followup enquiries where needed, arrange site visits if necessary and make decisions about registration.
- 5.5 The CQC will use its Judgement Framework when making decisions about compliance and reach judgement about registration status.
- 5.6 Mid-February to mid-March 2010 the CQC will communicate decisions about registration status to individual trusts as soon as a decision has been made.
- 5.7 The decision options available to the CQC are:
 - register **or**
 - register with conditions **or**
 - refuse all or part of registration
- 5.8 From 1st April 2010 the register of providers will be publicly available and ongoing monitoring of compliance begins.

6. Enforcement Action

Once registered, the CQC will monitor whether providers continue to comply with the regulations. If a trust is found to not be meeting the essential standards the CQC will use its new wider range of enforcement powers to make sure that swift action is taken. This could include warning notices, imposition or variation of conditions, suspension of registration to provide certain services, fines, prosecution or in extreme instances cancellation of registration.

7. Health Care Associated Infections

NHS trusts have been required to be registered with the CQC since April 2009 for Health Care Associated Infections and will still be required to declare compliance with these requirements when applying under the new registration system.

8. Registration Fees

NHS providers will enter the registration system, and the interim scheme of fees for NHS providers will begin and last for 12 months, until March 2011. The CQC has yet to publish full regulations regarding fees for providers to register following its public consultation on this in late 2009. If what was proposed in the consultation is implemented however, the intention is for the CQC to introduce a 'size-based' system for the NHS from April 2010. Under the proposals in the consultation the Trust would be subject to a registration fee in the first year of \pounds 60,000.

9. Recommendations

The Board is asked to:

- a) NOTE the new statutory registration requirements and CQC Essential Standards of Quality and Safety.
- b) APPROVE the Trust's assessment of compliance against the new standards for declaration to the CQC.

Kam Dhami Director of Governance

January 2010

Appendix 1

Sandwell and West Birmingham Hospitals NHS Trust

Care Quality Commission Registration Declaration of Compliance – January 2010

				Compliant		
			Yes	No		
Involvement a	nd information					
Regulation 17	Outcome 1:	Respecting and involving people who use services	✓			
Regulation 18	Outcome 2:	Consent to care and treatment	•			
Personalised care, treatment and support						
Regulation 9	Outcome 4:	Care and welfare of people who use services	√			
Regulation 14	Outcome 5:	Meeting nutritional needs	✓			
Regulation 24	Outcome 6:	Co-operating with other providers	✓			
Safeguarding and safety						
Regulation 11	Outcome 7:	Safeguarding people who use services from abuse	✓			
Regulation 12	Outcome 8:	Cleanliness and infection control	✓			
Regulation 13	Outcome 9:	Management of medicines	✓			
Regulation 15	Outcome 10:	Safety and suitability of premises	✓			
Regulation 16	Outcome 11:	Safety, availability and suitability of equipment	•			
Suitability of sto	affing					
Regulation 21	Outcome 12:	Requirements relating to workers	✓			
Regulation 22	Outcome 13:	Staffing	✓			
Regulation 23	Outcome 14:	Supporting workers	✓			
Quality and management						
Regulation 10	Outcome 16:	Assessing and monitoring the quality of services	~			
Regulation 19	Outcome 17:	Complaints	✓			
Regulation 20	Outcome 21:	Records	~			

Where non-compliance is declared details should be provided below (a maximum 2000 characters per question) setting out the measures to be taken to achieve compliance with the Registration Regulations for each regulated activity.

Regulation: [insert number]							
Describe in what ways you are non-compliant?	What will you do to become compliant?	When will you do this by?	How will you make sure that you continue to be compliant?				