

**EXPLANATORY MEMORANDUM TO**  
**THE HEALTH AND SOCIAL CARE ACT 2008 (NHS BLOOD AND TRANSPLANT**  
**PERIODIC REVIEW) REGULATIONS 2009**

**2009 No. 3049**

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

**2. Purpose of the instrument**

2.1 These Regulations extend the Care Quality Commission's ("the Commission") function of periodic reviews under section 46 of the Health and Social Care Act 2008 ("the Act") to the regulated activity of the management by NHS Blood and Transplant of:

- The supply of blood, blood components and blood derived products intended for transfusion;
- The supply of tissues and tissue derived products intended to transplant, grafting or use in a surgical procedure; and
- The matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

**3. Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 None

**4. Legislative Context**

4.1 The Commission took over responsibility for the regulation of health and adult social care in England on 1<sup>st</sup> April 2009. The Act established the Commission and set out its functions.

4.2 Under the section 46 of the Act, the Commission is required to conduct a periodic review of each Primary Care Trust, each English NHS provider and each English local authority.

4.3 The Act also establishes a new registration system and providers of regulated activities are required to register with the Commission and comply with regulatory requirements. The regulated activities are set out in Regulations see SI 2009/660.

4.4 Section 49 of the Act enables the Secretary of State to make Regulations that require the Commission to conduct a periodic review of the carrying on of regulated activities by registered service providers (other than those already covered by section 46 of the Act). These Regulations therefore extend the periodic review function to one of those regulated activities, namely the activities of NHSBT.

## **5. Territorial Extent and Application**

5.1 This instrument applies to England only as the Commission is an England only body.

## **6. European Convention on Human Rights**

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy background**

### **• *What is being done and why***

7.1 These regulations require the Commission to carry out a periodic review of the regulated activity of the management by NHS Blood and Transplant of:

- The supply of blood, blood components and blood derived products intended for transfusion;
- The supply of tissues and tissue derived products intended to transplant, grafting or use in a surgical procedure; and
- The matching and allocation of donor organs intended for transplant, and of stem cells and bone marrow intended for transfusion.

7.2 Under the Health and Social Care (Community Health and Standards) Act 2003, the Healthcare Commission (one of the predecessor bodies to the Commission) was required to carry out annual reviews of cross-border special health authorities. These Regulations therefore continue the requirement for a review of NHS Blood and Transplant.

## **8. Consultation outcome**

8.1 None

## **9. Guidance**

9.1 The Care Quality Commission will publish the indicators of quality against which NHS Blood and Transplant will be assessed and a statement describing the method it will use to assess evaluate performance.

## **10. Impact**

10.1 No Impact Assessment has been prepared for this instrument.

## **11. Regulating small business**

11.1 The legislation does not apply to small business.

**12. Monitoring & review**

12.1 The Department of Health retains a sponsorship role in respect of the Commission and will monitor and review the carrying out of its functions.

**13. Contact**

Aidan Smith at the Department of Health Tel: 0113 2546320 or email: Aidan.Smith@dh.gsi.gov.uk can answer any queries regarding the instrument.