

EXPLANATORY MEMORANDUM TO
THE PRIVATE AND VOLUNTARY HEALTH CARE (ENGLAND) AMENDMENT
REGULATIONS 2008

2008 No. 2352

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

2. Description

2.1 This instrument removes certain private and voluntary healthcare services from regulation by the Healthcare Commission which the Secretary of State now considers to be a disproportionate requirement in terms of risk and cost and it clarifies the application of certain regulations to private and voluntary healthcare.

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

3.1 None

4. Legislative Background

4.1 These amending Regulations are made under the Care Standards Act 2000 which provides for the registration and inspection of establishments and agencies including private and voluntary health care establishments and agencies by the Healthcare Commission and also provides for regulations to govern their conduct. The main requirements are set out in the Private and Voluntary Healthcare (England) Regulations 2001 (S.I 2001/3968). The Government is developing a new system management and regulatory structure as part of our major programme of reform in health and adult social care. From April 2009, as provided for in the Health and Social Care Act 2008, the Care Quality Commission will operate an integrated, risk- based, proportionate system of regulation to ensure that providers of health and adult social care services – whether in the private or public sector, meet essential levels of quality and safety in the services which they provide to the public. These Regulations are intended, in the run up to these changes, to take steps now to regulate in a more proportionate manner while continuing to deliver assurances of quality and safety for patients.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

Not applicable.

7. Policy background

7.1 The Department of Health (the Department), plans to make major changes to the way that health and adult social care is regulated and performance managed from April 2009. These plans were first outlined in The future regulation of health and adult social care in England consultation, which ran from November 2006 to February 2007.

The Government has a responsibility to ensure that the regulatory systems it sets up are fit for purpose. The regulatory regime is intended to be focused on activities that have the potential to cause harm. Furthermore, it is needs to be proportionate to the nature and frequency of the risks involved.

Against this background, the Department keeps the services and establishments it regulates under review. After assessing the types of service currently in regulation, the Department considers that there is a need to reduce the current burden on providers through the removal of certain services from Healthcare Commission regulation, and to clarify some existing regulatory requirements. These changes are also intended to support the wider system reform changes planned for introduction from April 2009.

The Department of Health held a consultation on the proposed changes to the Private and Voluntary Healthcare Regulations 2008 between 18 March 2008 and 10 June 2008.

These changes included:

- The removal of the non-surgical use of class 3B and 4 lasers and intense pulsed light machinery (IPL) from Healthcare Commission Regulation.
- The removal of certain services from Healthcare Commission regulation where the risk to the public is small.
- The deregulation of Type 3 Hyperbaric Oxygen Therapy(HBOT3).
- The clarification of a small number of the regulations governing independent healthcare.

Responses to the consultation

Removal of the non-surgical use of class 3B and 4 lasers and intense pulsed light machinery (IPL) from Healthcare Commission Regulation

The deregulatory proposals in the consultation set out the rationale for believing that laser and IPL machinery no longer needed to be regulated by the Healthcare Commission - principally, that the current regulatory regime associated with these treatments was no longer appropriate to be within the remit of the Healthcare Commission. Most of the responses received were opposed to deregulation. This proposal is currently under review - a decision is awaited regarding whether the deregulatory proposals will proceed.

Removal of certain services from Healthcare Commission

At present both Human Fertilisation and Embryology Authority (HFEA) and the Healthcare Commission (HCC) regulate issues covered by the Human Fertilisation and Embryology Act 1990 (the HFEA Act). Our proposals are designed to end this dual regulation, and for the HFEA to have sole responsibility for issues falling within the HFEA Act. However, any IVF clinic which operated procedures or techniques which were the subject of other elements of Healthcare Commission regulation – principally the use of either anaesthesia or sedation – would continue to be regulated by the Healthcare Commission.

The deregulation of Type 3 Hyperbaric Oxygen Therapy Chambers

Hyperbaric Oxygen Therapy involves the administration of pure oxygen to patients in pressurised chambers. The Healthcare Commission divides HBOT chambers into three types in order to ensure adequate regulatory coverage depending on risk. HBOT1 and HBOT2 are used for patients with serious medical conditions who often need critical care.

HBOT3 is offered as a treatment to MS sufferers in the private sector; the lack of clinical evidence for its effectiveness means that it is not offered on the NHS.

All three Types of therapy are currently regulated. The main reason for regulating HBOT3 is to manage the risks of fire and oxygen toxicity posed by the use of pure oxygen – risks which, in recent years has not materialised in the UK. This was the primary reason for proposing to deregulate these types of facilities. We said that we proposed to retain HBOT1 and HBOT2 in regulation because the risks posed to patients who might undergo these types of treatment were significantly greater.

Minor Changes

The deregulation proposals included a number of changes to clarify certain minor elements of the regulations, and to end the requirement for providers to undertake unannounced inspections at regular intervals.

8. Impact

8.1 An impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from Adiba Enwonwu at the Department of Health. Tel: 020 7976 4010 or e-mail: adiba.enwonwu@dh.gsi.gov.uk.

8.2 The impact on the public sector is none.

9. Contact

Adiba Enwonwu at the Department of Health. Tel: 020 7976 4010 or e-mail: adiba.enwonwu@dh.gsi.gov.uk can answer any queries regarding the instrument.