

EXPLANATORY MEMORANDUM TO
THE CARE QUALITY COMMISSION (REGISTRATION) REGULATIONS 2009

2009 No. 3112

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 The Regulations contain provisions in relation to the registration of health and adult social care providers of regulated activities under the Health and Social Care Act 2008 (“the Act”).

2.2 The Regulations set out requirements in relation to the register of regulated activities that the Care Quality Commission (“the Commission”) must maintain, provisions relating to the publication of information by the Commission and its power to require an explanation from persons and requirements on registered persons. The Regulations also set out provisions in relation to compliance with the Regulations and offences. They contain provisions for providers to notify the Commission of certain incidents.

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

3.1 None

4. Legislative Context

4.1 The Act establishes the Care Quality Commission and gives it the function of setting up and maintaining a registration system for providers of health and adult social care who carry out regulated activities (Section 8 of the Act). Those providers are then required to meet the registration requirements (Section 20 of the Act). Failure to meet the requirements will be an offence.

4.2 Earlier Regulations, which came into force on 1st April 2009, (*the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009*¹, (SI 2009/660), (“the 2009 Regulations”) prescribed certain regulated activities for NHS bodies, relating to the prevention, detection, control and treatment of health care associated infections.

4.3 Further Regulations were laid in draft before Parliament for approval on 29th October 2009 (*The Health and Social Care Act 2008 (Regulated Activities) Regulations 2009*²), which put in place an expanded registration system to cover a wider range of regulated activities and impose an increased number of registration requirements. These set out the health and social care activities which are to be

¹ http://www.opsi.gov.uk/si/si2009/pdf/uksi_20090660_en.pdf

² http://www.opsi.gov.uk/si/si2009/draft/ukdsi_9780111487006_en_1

“regulated activities” for the purposes of the Act; the registration requirements that providers of regulated activities must meet and provisions in relation to fixed penalty notices. Subject to parliamentary approval, it is intended that these will come into force on 1st April 2010.

4.4 This Instrument sets out further requirements in relation to the new registration system.

4.5 The Health and Social Care Act 2008 (Commencement No. 13, Transitory and Transitional Provisions and Electronic Communications) Order 2009 (SI 2009/3023)³ puts in place transitional provisions in order to move NHS providers of regulated activities to the full registration system under the Act on 1st April 2010.

4.6 A further statutory instrument will be made which will make transitional provisions to bring providers of regulated activities who are currently registered under the Care Standards Act 2000, and any new providers of regulated activities, into the new registration system on 1st October 2010. There will also be statutory instruments to make consequential amendments and then further transitional provisions to bring primary dental care and private ambulance services into the registration system in 2011 and primary medical care services in 2012.

5. Territorial Extent and Application

5.1 This instrument applies to England 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 The Act creates a new system of registration for providers of health and adult social care and establishes the Commission as the new single regulator responsible for regulating health care and adult social care and for monitoring the operation of the Mental Health Act 1983. On 1st April 2009, the new Commission began to carry out its statutory functions and replaced the existing regulatory bodies: the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission), the Commission for Social Care Inspection and the Mental Health Act Commission.

7.2 The policy objective behind the reorganisation was to achieve the integration and alignment of health and adult social care regulation across all types of providers, whether public, private or third sector. This will ensure, for example, that the NHS and private and voluntary healthcare are subject to common regulatory procedures and standards. In addition, for many individuals, care outcomes depend on health and

³ http://www.opsi.gov.uk./si/si2009/uksi_20093023_en_1

social care services working well together. Having a single regulatory framework across these sectors is intended to help achieve this.

7.3 In accordance with the ministerial commitment in *Response to the consultation on the future regulation of health and adult social care in England*⁴, published in October 2007, the new registration system was introduced for NHS providers of prescribed health care services on 1st April 2009. These providers must meet requirements relating to the prevention, detection, control and treatment of health care associated infections as set out in the 2009 Regulations.

7.4 These Regulations and draft Regulations that were laid before Parliament for approval on 29th October 2009 (*The Health and Social Care Act 2008 (Regulated Activities) Regulations 2009*⁵) set out the detail of the new registration system. This instrument contains various miscellaneous provisions in relation to the new registration system.

7.5 Under Part 2 of the Regulations, the Commission is required to keep a register of regulated activities containing accessible public information. This Part also puts in place provisions to clarify who is to be regarded as carrying on the regulated activity, where two or more persons are carrying on the regulated activity in different capacities. The Act provides for certain regulated activities to be subject to a condition requiring the service provider to appoint a manager, referred to as a “registered manager”, who must be registered with the Commission. The Regulations set out the circumstances in which a registered manager is required. They also set out grounds on which the Commission may cancel the registration of a registered person, in addition to those set out under section 17 of the Act.

7.6 Part 3 of the Regulations sets out a number of provisions in relation to the publication of information relating to enforcement action by the Commission. The Act gives the Commission the power to require an explanation of matters from prescribed persons and this Part sets out details of the persons from whom the Commission is authorised to require an explanation.

7.7 Under Part 4 of the Regulations, various requirements are placed on the registered person. They require the registered person to provide the Commission with a statement of purpose setting out details relating to the service provider and the carrying on of the regulated activity and place requirements on the registered provider in relation to the financial viability of the carrying on of the regulated activity. Regulations 14 to 18 require the registered person to notify the Commission of certain changes affecting the carrying on of the regulated activity and of various incidents involving service users such as the death of a service user and other serious occurrences. Under Regulation 19, the service provider is required to give service users information in connection with fees for their care or treatment where the service user is responsible for the cost of the care. Regulation 20 sets out requirements in relation to providers carrying out the termination of pregnancies (which is prescribed as a regulated activity in the draft Regulations referred to above). This Regulation is intended to carry forward the requirements on private and voluntary healthcare

⁴ http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_078227

⁵ http://www.opsi.gov.uk/si/si2009/draft/ukdsi_9780111487006_en_1

providers, in relation to these services, that are currently in force under the Care Standards Act 2000.

7.8 Part 5 of the Regulations covers other miscellaneous requirements. Regulation 21 set out the requirements in the event of the death of an individual service provider— or a partner if the service provider is a partnership and regulation 22 requires a liquidator to notify the Commission when they are appointed to a registered provider.

7.9 Part 6 of the Regulations details who is responsible for complying with the Regulations where there is more than one registered person in respect of a regulated activity and the guidance that registered persons must have regard to for the purposes of compliance with the regulations. Regulation 25 creates the offence of failing to comply with the certain registration requirements in Part 4 of the Regulations.

8. Consultation outcome

8.1 The Department has previously held a full 12-week consultation and a number of stakeholder events on both the broad principles of the new system and the detailed policy considerations behind these Regulations. There was strong support for the proposals across a wide range of stakeholders.

8.2 It has since consulted publicly over a nine-week period during spring 2009 on draft Regulations specifying the regulated activities and the registration requirements (which we laid in draft before Parliament on 29 October 2009) and on the policy content of this set of regulations.

8.3 There were 72 responses to that consultation, from respondents covering both health and social care, public, private and third sectors.

8.4 69% of consultation respondents thought that the proposals for other regulations to support the registration framework generally created a practical framework with responses focusing on the financial position requirement and the proposals for notifications. These responses have informed the drafting of these Regulations and the Department's *Response to the consultation on draft Regulations for the framework for the registration of health and adult social care providers* can be found on its website⁶.

9. Guidance

9.1 The Care Quality Commission has carried out a full 12-week consultation on the guidance it will use to assess compliance with the new registration requirements, in accordance with section 23 of the Act. This closed on 24th August 2009 and the Commission is currently analysing the responses and duly refining the guidance in the light of those responses. The Commission intends to publish its guidance in early December 2009.

⁶ <http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

9.2 The Commission has also carried out a series of consultation stakeholder events and is committed to keeping stakeholders informed about development of the new registration system.

10. Impact

10.1 The impact on business, charities or voluntary bodies is detailed in the Impact Assessment that accompanied the draft Health and Social Care Act 2008 (Regulated Activities) Regulations 2009.

10.2 The impact on the public sector is detailed in the Impact Assessment that accompanied the draft Health and Social Care Act 2008 (Regulated Activities) Regulations 2009.

10.3 The Impact Assessment can be found at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_107628

11. Regulating small business

11.1 The legislation applies to small business.

12. Monitoring and review

12.1 The Regulations aim to ensure that health and adult social care providers carrying on a regulated activity are all registered with the Commission in relation to such an activity and that they meet the requirements necessary to ensure that care provided meets the essential safety and quality requirements. The Department will keep the registration system under review with a view to keeping it up-to-date and relevant.

13. Contact

Lisa Smedley at the Department of Health, tel: 0113 2545464 or email: lisa.smedley@dh.gsi.gov.uk can answer any queries regarding the instrument.