

EXPLANATORY MEMORANDUM TO
THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES)
(AMENDMENT) REGULATIONS 2012

2012 No. 1513

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 instrument makes a series of amendments to the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the Regulated Activities Regulations”) (S.I. 2010/781). The amendments change the scope of regulated activities, make some technical amendments and provide clarification.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Context**
 - 4.1 The Department of Health, working together with the Care Quality Commission (“the Commission”), has, in the light of the first year of full operation of the registration system, reviewed the regulations that underpin the registration system operated by the Commission. These consist of a number of regulations including the Regulated Activity Regulations. This review identified a number of areas where the regulations were not operating in the way intended, and where technical amendments or further clarification were required.
 - 4.2 The Department carried out a consultation in the summer and autumn of 2011 on proposed changes to regulations arising from this initial review. The majority of responses to the consultation were supportive of the proposed amendments.
 - 4.3 The amendments that are contained in this instrument implement the proposals which relate to the Regulated Activity Regulations only. They are part of the Department’s on-going commitment to keep the registration system under review in order to ensure that the Commission is able to fulfil its role as an effective independent regulator of health and adult social care providers in England, and to ensure that the efforts of the Commission are focused on those areas where it is likely to have the greatest impact and where the burden of regulation on providers can be justified.

5. Territorial Extent and Application

- 5.1 This instrument applies to England.
- 5.2 The Regulated Activities Regulations provide that an activity is only a regulated activity if it is carried on in England (see regulation 3(5) of the Regulated Activities Regulations). The Regulations do not, therefore, apply to providers of health or social care services in Wales, Scotland or Northern Ireland.

6. European Convention on Human Rights

The Minister of State for Health Services has made the following statement regarding Human Rights:

In my view, the provisions of the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 are compatible with Convention rights.

7. Policy background

- 7.1 All providers of regulated activities are required to register with the Commission. Regulated activities are defined by section 8 of the Health and Social Care Act 2008 as being “any activity of a prescribed kind”. Those activities are prescribed in the Regulated Activities Regulations.
- 7.2 Registration requirements which establish the essential levels of safety and quality in the provision of health and adult social care in England are set out in the Regulated Activities Regulations, while further registration requirements are set out in the Care Quality Commission (Registration) Regulations 2009 (S.I. 2009/3112). Providers of regulated activities are required to meet these registration requirements in order to become and remain registered with the Commission. Where a provider does not meet the registration requirements the Commission has a range of enforcement powers that it can use in order to protect patients and service users from the risk of harm.
- 7.3 Regulation 3 amends the requirements which apply where a service provider is a partnership. The effect of the amendment is that each partner will be required to be of good character and physically and mentally able to carry on the regulated activity, but that the partnership collectively should have the necessary qualifications, skills and experience to carry on the regulated activity. This change is being made in recognition of the fact that a legal partnership may include partners who have little or no day to day involvement in carrying on a regulated activity. It is disproportionate to require such partners to have skills and qualifications beyond those required for their role in the partnership.
- 7.4 Regulation 4 inserts a definition of medical device into the registration requirement relating to cleanliness and infection control. This change clarifies the

meaning of this registration requirement.

- 7.5 Regulation 5 amends the registration requirement relating to arrangements for consent to care and treatment so that service providers put in place suitable arrangements when a service user is not able to give their consent. This amendment is necessary because the registration requirement does not currently make express provision for arrangements when a service user is unable to give consent themselves.
- 7.6 Regulation 6 makes an amendment to the defence provision for the offence of failing to comply with the registration requirements. It will now be a defence for a provider to show that they took all reasonable steps and exercised all due diligence to meet the registration requirements. This change will correct an inaccuracy in the regulations.
- 7.7 Regulation 7 inserts a new Part 8 into the Regulated Activities Regulations which places a duty on the Government to review the Regulated Activity Regulations and to publish a report before 1st October 2017. This commitment is in line with both the Department's aim to keep the registration system under ongoing review and also with the Government's aim to keep the burden of regulation under review and to a minimum.
- 7.8 Regulation 8 makes a series of changes to the definitions of the regulated activities contained in Schedule 1 to the Regulated Activities Regulations.
- 7.9 The personal care regulated activity is amended so that a carer does not require registration where they provide care to an individual and that care is organised by a parent, a person with authority to organise that care or by a trust set up to provide services to meet the care needs of an individual. This amendment makes the approach consistent with the arrangements that apply where an individual organises such care themselves.
- 7.10 The regulated activity of assessment or medical treatment for persons detained under the Mental Health Act 1983 is amended to exempt the activities of second opinion appointed doctors (SOADs) from registration. The role of a SOAD is to review whether treatment recommended is appropriate and whether due consideration has been given to the views and rights of the patient. The amendment clarifies that this does not constitute part of the regulated activity.
- 7.11 The regulated activity of surgical procedures is amended so that it includes surgery for sterilisation or reversal of sterilisation. These procedures are unintentionally exempted in the regulations and the amendment corrects this.
- 7.12 The regulated activity of diagnostic and screening procedures is amended to take a number of lower risk activities outside the scope of registration. The lowest risk procedures, such as the taking of urine samples where these do not require sending

away for analysis, are removed from the regulated activity in all cases. Bringing a provider into registration with the Commission solely on the basis of carrying on such low risk activities is disproportionate to the risks posed to service users and is counter to the aim of allowing the Commission to focus its regulatory activities on those areas where it will deliver most benefit. The amendment will also exempt from the regulated activity any diagnostic and screening procedures carried on in connection with an activity which is licensed under the Human Fertilisation and Embryology Act 1990. This will prevent such activities falling under two different regulatory systems. A number of further activities, which pose slightly higher risks to service users, are exempted from the diagnostic and screening procedures regulated activity where the provider is registered to provide any other regulated activity. In these cases compliance with registration requirements for the other regulated activities, such as personal care, provides sufficient assurance of low risk diagnostic procedures without requiring registration for a separate regulated activity.

- 7.13 The regulated activity of management of supply of blood, tissue and blood and tissue-related products is amended so that registration is only required where there is direct contact with a patient or donor. This had always been the intention of the regulation, and the amendment clarifies this position.
- 7.14 The regulated activity of transport services, triage and medical advice provided remotely is amended in two ways. First, the provision of transport services within a site used for a sporting or cultural event is exempted from registration. This will remove the requirement for ambulance services provided purely in such circumstances to register, and make the position consistent with that that applies to the registration of first aid at such events. The registration of such temporary services would be overly burdensome for the limited benefit it would confer. The second amendment exempts transport services where these are also regulated by the Civil Aviation Authority (CAA). Regulation of transport only services by the Commission adds little to regulation of air vehicles carried out by the CAA. Any treatment provided on air ambulance services will still require registration with the Commission.
- 7.15 Regulation 9 makes several amendments to the general exemptions to the regulated activities contained in Schedule 2 to the Regulated Activities Regulations.
- 7.16 The exemption for the private practice of medical practitioners in a surgery or consulting room is amended so that it applies consistently to practitioners employed by any registered provider, rather than only to those employed by the NHS. The amendment will exempt from registration with the Commission treatment by a medical practitioner who is either a service provider registered for treatment of disease, disorder or injury, or is employed by such a provider, and the practitioner is on the performers list of a designated body or is employed by a designated body for professional appraisal. Such medical practitioners will be

exempt on the basis that they are employed by a provider that is registered with the Commission and their private practice is assessed as part of the professional appraisal system. In these circumstances registration of their private practice is likely to provide little additional assurance. However, this general exemption does not apply to a number of listed, higher risk procedures, provision of which will still require registration with the Commission.

- 7.17 Regulation 9 also inserts a new general exemption from registration for services provided under temporary arrangements provided in connection with the Olympic or Paralympic Games. Given the time-limited nature of these services and the security arrangements that will be in place, registration of these services would be unlikely to confer benefits.

8. Consultation outcome

- 8.1 The Department of Health consulted on proposed changes to the regulations underpinning the registration system in the summer and autumn of 2011. The consultation targeted registered providers, NHS bodies, professional bodies and other regulators.
- 8.2 In total, 117 organisations and individuals responded to the consultation. There was support for all of the proposed changes that were set out in the consultation document.
- 8.3 We have considered the proposals in light of the comments that we received and have made a number of changes to the proposals. Three of the proposals that were consulted on are not being taken forward for the time being. The Government's response to the consultation is available on the Department of Health's website at: http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_133119

9. Guidance

- 9.1 The Commission has issued guidance for providers of health and adult social care on how they may comply with the Regulated Activities Regulations and the Registration Regulations¹. It will revise this guidance to reflect the changes to the Regulations made by this Instrument.

10. Impact

- 10.1 The impact of each of the amendments made by the Instrument has been analysed and is set out in an Impact Assessment that has been published alongside the Explanatory Memorandum on www.legislation.gov.uk.

¹<http://www.cqc.org.uk/guidanceforprofessionals/introductiontoregistration/howthenewregistrationsystemworks/complyingwithnewregulations.cfm>

11. Regulating small business

11.1 All providers of regulated activities are required to register with the Commission regardless of their size. As such the Instrument does apply to small businesses. The aim of the registration system is to provide assurance to patients and service users that wherever they receive care it meets essential levels of safety and quality. There is no case to exempt small businesses from this regulation, since there is no evidence to suggest that the risk of harm to patients and service users is lower when care is provided by small businesses.

12. Monitoring and review

12.1 The Department will keep the registration system under review with a view to keeping it up to date and effective. The Regulations place a duty on the Department to carry out a review of the registration system and the Regulated Activity Regulations before 1st October 2017.

13. Contact

Mark Bennett at the Department of Health (Tel: 0113 254 6501 or email: mark.bennett@dh.gsi.gov.uk) can answer any queries regarding the instrument.