

**EXPLANATORY MEMORANDUM TO  
THE CARE QUALITY COMMISSION (REGISTRATION) AND (ADDITIONAL  
FUNCTIONS) AND HEALTH AND SOCIAL CARE ACT 2008 (REGULATED  
ACTIVITIES) (AMENDMENT) REGULATIONS 2012**

**2012 No. 921**

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Purpose of the instrument**

- 2.1 The instrument makes a series of amendments to the Care Quality Commission (Registration) Regulations 2009 (“the Registration Regulations”) (S.I. 2009/3112), and a single amendment to both the Care Quality Commission (Additional Functions) Regulations 2011 (“the Additional Functions Regulations”) (S.I. 2011/1551) and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the Regulated Activities Regulations”) (S.I. 2010/781). The amendments make changes to notifications that registered providers are required to make to the Care Quality Commission (“the Commission”), and to the cases where the Commission can issue a penalty notice in lieu of prosecution for prescribed offences.

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

- 3.1 The Regulations amend the Additional Functions Regulations<sup>1</sup> to remedy the defective drafting reported by the JCSI so that on receipt of an application to review decisions to record and monitor telephone calls in high security hospitals, the Commission may still direct that recording and monitoring of the patient’s telephone calls continue in ten per cent of a patient’s incoming and outgoing telephone calls over a seven day period.

4. **Legislative Context**

- 4.1 The Department of Health, working together with the Commission, has reviewed the regulations that underpin the registration system operated by the Commission in the light of the first year of full operation of the registration system. 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.

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<sup>1</sup> S.I. 211/1551, regulation 4(2) and JCSI report of its meeting on 19<sup>th</sup> October 2011, paragraph 3.5

- 4.2 The Department carried out a consultation in the summer and autumn of 2011 on proposed changes to the 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 these proposals in relation to the Registration Regulations and Additional Function Regulations as well as inserting a penalty notice provision into the Regulated Activity Regulations. 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 Registration Regulations provide for the registration of persons carrying on a regulated activity. 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 Care Quality Commission (Registration) and (Additional Functions) and 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 Registration Regulations. 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 makes amendments to the requirement for providers to notify the Commission of the death of a service user. It extends to providers of NHS primary medical services the arrangements for such notifications that apply to a health service body. Such a service provider must notify the Commission of the unexpected death of a patient which may have resulted from the carrying on of the regulated activity. Restricting the notifications to these circumstances will mean that the information received by the Commission will be limited to that which is most likely to indicate possible failure by providers to comply with the registration requirements. Most providers of NHS primary medical services will be registered with the Commission from 1<sup>st</sup> April 2013.
- 7.4 Regulation 4 amends the notifications that providers are required to make to the Commission of the unauthorised absence of a service user detained under the Mental Health Act 1983. The amendment will restrict such notifications to absences from secure psychiatric services only. The amendment also requires the service provider to notify the Commission when such an absence comes to an end. Restricting the notifications in this way will greatly reduce the number received by the Commission so as to focus on information from those services where an absence has greater potential to cause harm.
- 7.5 Regulation 5 makes a number of amendments to other notifications that service providers are required to make to the Commission. It introduces a new requirement to notify the Commission when a service user under the age of eighteen is placed in a psychiatric unit designed for adults for more than 48 hours. This will provide the Commission with information about the appropriateness of the services being provided. The requirement to notify the Commission of an application to deprive a person of their liberty is amended so that such a notification will be made once the outcome of the application is known. This will reduce the number of notifications which are currently required both when an application is made and when the outcome of the application is known.
- 7.6 Regulation 6 requires providers to notify the Commission of any event required by the Registration Regulations using forms provided by the Commission. This will ensure that the notifications are provided in a standard format which will assist providers in providing appropriate information and will also simplify analysis of the information by the Commission.
- 7.7 Regulation 8 inserts a new Part 7 into the Registration Regulations which places a duty on the Government to review the Registration Regulations and to publish a report before 1<sup>st</sup> 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 9 amends the statement of purpose that providers are required to submit to the Commission to include an address for the service of documents. This will improve the process for communicating with service providers and registered managers.
- 7.9 Regulation 10 amends the Additional Functions Regulations to correct defective drafting in the regulations.
- 7.10 Regulation 11 amends the table of fixed penalty offences in schedule 4 of the Regulated Activities Regulations to include the offences in the Registration Regulations. These are already fixed penalty offences, but the amendment locates all of the fixed penalty offences in the same place in the Regulations. Regulations 7 and 13 make revocations associated with this amendment.

## **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](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 Regulations<sup>2</sup>. 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](http://www.legislation.gov.uk).

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<sup>2</sup><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 Registration Regulations before 1<sup>st</sup> October 2017.

## **13. Contact**

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