

EXPLANATORY MEMORANDUM TO
THE HEALTH AND SOCIAL CARE ACT 2008 (REGULATED ACTIVITIES)
(AMENDMENT) REGULATIONS 2011

2011 No. [XXXX]

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 amends the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the Regulated Activities Regulations”), so that providers of NHS primary medical services that provide out of hours services to patients who are not registered with the provider will be required to register with the Care Quality Commission (“the Commission”) from 1st April 2012. All other providers of NHS primary medical services will be required to register with the Commission from 1st April 2013 rather than 1st April 2012. The instrument also revokes a number of spent provisions.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Context**
 - 4.1 Under the Health and Social Care Act 2008 (“the Act”), all providers of regulated activities must register with the Commission. Regulated activities are defined by section 8 of the Act as being “any activity of a prescribed kind”. The Regulated Activities Regulations have been made under section 8 of the Act.
 - 4.2 The draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2011 (“the Amending Regulations”), which are proposed to come into force on 30th November 2011, amend the Regulated Activities Regulations.
 - 4.3 The Regulated Activities Regulations exempt providers of certain regulated activities from the requirement to register with the Commission until 1st April 2012 - see regulation 3(8)(a) of the Regulated Activities Regulations. The provision of all medical services by a provider whose sole or main purpose is the provision of NHS primary medical services is one of the current exempted regulated activities – see Schedule 2, paragraphs 3, 6 and 7 to the Regulated Activities Regulations.
 - 4.4 The Amending Regulations amend the Regulated Activities Regulations so that providers of NHS primary medical services that provide out of hours services to patients who are not registered with the provider will be required to register with the Commission from 1st April 2012. All other providers of the NHS primary medical services will be required to register with the Commission from 1st April 2013 rather than 1st April 2012. They also revoke a number of exemptions from registration that no longer apply.

- 4.5 The Government also intends to amend the Health and Social Care Act 2008 (Primary Dental Services, Private Ambulance Services and Primary Medical Services) (Regulated Activities) (Transitory and Transitional Provisions) Order 2010 (S.I. 2010/2484) to make transitory and transitional provision for providers registering from 1st April 2013 and to make consequential amendments to reflect the changes made by the Amending Regulations.

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 2011 are compatible with the 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. Providers of NHS primary medical services are exempt from the requirement to register with the Commission until 1st April 2012 by means of a sunset clause. This covers all providers of primary medical care services under arrangements made pursuant to sections 3, 83(2)(b), 84 or 92 of the National Health Service Act 2006, such as GP practices, out of hours primary medical care services providers and NHS walk-in centres.
- 7.2 The Government is committed to bringing all these providers into the registration system operated by the Commission. Registration of these providers will provide assurance to patients that services are meeting essential levels of safety and quality and will provide a mechanism to address poorly performing service providers.
- 7.3 However, in the light of the Commission’s experiences in bringing other providers into the new registration system, the Government has reconsidered the timing of the registration of providers of NHS primary medical services providers. There are strong reasons to implement the registration of providers of NHS primary medical services in two waves – from April 2012 and from April 2013.
- 7.4 Postponing the registration of most providers of NHS primary medical services will enable the Commission to ensure that, when registration does go ahead, the Commission will have assessed and refined its systems to reflect the experience of the earlier registration rounds and piloting with primary medical care providers themselves. In addition, it will give the Commission time to deal with its backlog

of work and enable it to have the capacity to run an effective registration round for the majority of providers of NHS primary medical services. It will also give the Commission time to focus on its core business of providing assurance of safety and quality for patients.

- 7.5 However, the amendments made by the Amending Regulations will still require out of hours providers of primary medical services to be registered from 1st April 2012. This reflects the Government's commitment to bringing out of hours providers into registration at the earliest opportunity.
- 7.6 In the case of out of hours providers of NHS primary medical services who provide out of hours services to patients who are not registered with the provider, there are risk factors which could be mitigated by registration from 1st April 2012 and justify the earlier registration of these providers.
- 7.7 The circumstances in which out of hours primary medical services are delivered are different to most other primary medical services. Out of hours services can involve unfamiliar patients, initial assessment often being completed on the phone, colleagues who may not be well-known to the clinician prior to the shift, unfamiliar surroundings and equipment and a higher proportion of vulnerable patients with urgent care needs which are often more complex than those generally found in daytime general practice. In addition, the GP Patient Survey shows that patient satisfaction with out of hours primary care services trails that of in-hours GP practices and health centres.
- 7.8 An estimated 150 providers will require registration in April 2012. The Commission will be able to register this small group of providers alongside refining its registration methodology.
- 7.9 For these reasons providers of out of hours NHS primary medical services to patients who are not registered with the provider will be required to register with the Commission from 1st April 2012.
- 7.10 The Department is keeping the regulations under review, and is likely to make further amendments in due course. We will consider consolidation as part of that review.

8. Consultation outcome

- 8.1 The Department of Health has consulted on a proposal to delay the registration of most providers of NHS primary medical services for one year until 1st April 2013. The Commission and the Department also engaged with relevant professional bodies during the consultation period.
- 8.2 In total, 250 organisations and individuals responded to the consultation. Ninety-six per cent of respondents supported the proposal to defer the registration of most providers of NHS primary medical services until April 2013.
- 8.3 A small majority of respondents who commented on the registration of out of hours providers of NHS primary medical services were in favour of the proposal to go ahead with the registration of these providers from 1st April 2012.

- 8.4 Taking account of the consultation responses and the engagement with relevant professional bodies, we have decided to amend the Regulated Activities Regulations so that providers of NHS primary medical services who are not out of hours providers will have their requirement to register delayed by one further year. The Government's response to the consultation will be available on the Department of Health's website in due course.

9. Guidance

- 9.1 The Care Quality Commission has issued guidance for providers of health and adult social care on how to comply with the Regulated Activities Regulations and the Care Quality Commission (Registration) Regulations 2009¹. It has also issued guidance for providers of out of hours primary medical services on the process for registration for April 2012². The Commission will issue further guidance in due course for those providers that will register for April 2013.

10. Impact

- 10.1 As set out in the impact assessment, the original timetable of bringing all primary medical care providers into regulation by April 2012 may undermine effective compliance monitoring by the Commission. The demands placed on the Commission by a succession of new registration rounds has led to a backlog of registration work which has constrained its capacity to monitor compliance effectively. The Commission has also learnt from its earlier experience of registering new groups and wants to improve its approach to registration.
- 10.2 The impact assessment demonstrate that the preferred option is to register providers of out of hours NHS primary medical services to patients that are not registered with the provider from April 2012 and to defer the registration of all other providers of NHS primary medical care services until April 2013. This will give the Commission time to deal with the backlog of work and adapt its processes in response to previous registration rounds, and will enable the Commission to reduce the burden of registration to the Commission and providers. This justifies foregoing some benefits of regulating all providers of primary medical services from April 2012.
- 10.3 The impact assessment considers the marginal impacts of changing the date of registration for the majority of providers of NHS primary medical care services until April 2013. As this is a change in the timetable of an existing policy the overall marginal impacts, in particular the costs, are relatively small. The impact assessment estimates that the net economic benefit of this change is £44.28m.
- 10.4 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

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

²<http://www.cqc.org.uk/guidanceforprofessionals/primarymedicalservices/out-of-hoursservices.cfm>

11. Regulating small business

- 11.1 The legislation does not apply to small businesses as NHS contracted services are out of scope of this requirement.

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.

13. Contact

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mark.bennett@dh.gsi.gov.uk can answer any queries regarding the instrument.