

*Draft Regulations laid before Parliament under section 304(5)(b) of the Health and Social Care Act 2012, for approval by resolution of each House of Parliament.*

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DRAFT STATUTORY INSTRUMENTS

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**2013 No.**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Licence Exemptions, etc.) Regulations 2013**

*Made* - - - - 2013  
*Coming into force* - - 1st April 2014

The Secretary of State for Health makes the following Regulations in exercise of the powers conferred by sections 81(2), 83, 150(1) and 304(9) and (10) of the Health and Social Care Act 2012<sup>(1)</sup>.

In accordance with section 83(4) to (7) of that Act, the Secretary of State has given notice to Monitor, the National Health Service Commissioning Board, and the Care Quality Commission and its Healthwatch England committee and published that notice.

A draft of these Regulations was laid before Parliament in accordance with section 304(5)(b) of the Health and Social Care Act 2012, and was approved by a resolution of each House of Parliament.

**Citation, commencement and interpretation**

1.—(1) These Regulations may be cited as the National Health Service (Licence Exemptions, etc.) Regulations 2013 and come into force on 1st April 2014.

(2) In these Regulations—

“the 2006 Act” means the National Health Service Act 2006<sup>(2)</sup>;

“the 2012 Act” means the Health and Social Care Act 2012;

“applicable turnover” means—

- (a) the amounts, calculated in conformity with accounting practices and principles which are generally accepted in England, which are derived by a person from the provision of health care services for the purposes of the NHS<sup>(3)</sup>, after deduction of trade discounts, value added tax and other taxes based on such amounts,

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(1) 2012 c. 7. See section 150(1) of the Health and Social Care Act 2012 (“the 2012 Act”) for the meaning of “prescribed”.

(2) 2006 c. 41.

(3) See section 64(3) and (4) of the 2012 Act for the meaning of “health care services” and “the NHS”.

- (b) less turnover from providing medical services under Part 4 of the 2006 Act or dental services under Part 5 of that Act, and
- (c) before 1st April 2015, less turnover from providing NHS Continuing Healthcare or NHS funded nursing care;

“business year” means a period of more than 6 months in respect of which a person who provides health care services for the purposes of the NHS or, if applicable, the business of which that person forms part, prepares or is required to prepare accounts;

“NHS Continuing Healthcare” means a package of care arranged and funded solely through the NHS for an individual aged 18 or over who has been assessed as having a primary health need, where such care is provided to meet physical or mental health needs which have arisen as a result of disability, accident or illness;

“NHS funded nursing care” means nursing care provided by a registered nurse which is funded by the NHS to support the provision in a home providing such care; and

“nursing care provided by a registered nurse” means any services provided by a registered nurse where such services involve—

- (a) the provision of care, or
  - (b) the planning, supervision or delegation of the provision of care,
- other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a registered nurse.

(3) Where a person’s business consists of two or more parts that each prepare accounts, the applicable turnover is to be calculated by adding together the applicable turnover of each of those parts, save that no account is to be taken of any turnover resulting from the supply of services by one part to another.

### **Persons to be regarded as the person who provides a health care service**

2.—(1) This regulation applies for the purposes of determining, in relation to a health care service provided by two or more persons acting in different capacities, which of those persons is providing the health care service for the purposes of Chapter 3 of Part 3 of the 2012 Act (Monitor: licensing).

(2) A person (A) is to be regarded as the person providing a health care service where that service is provided by A and one or more other persons who are—

- (a) individuals, and
- (b) employees of A for the purposes of providing that service.

(3) For the purposes of paragraph (2), a person is an employee of A where that person—

- (a) is employed by A under a contract of service, an apprenticeship, a contract for services or otherwise than under a contract, or
- (b) has been granted practising privileges by A.

(4) In paragraph (3)(a), the reference to “otherwise than under a contract” includes an agreement between A and a temporary work agency for the supply of an agency worker to A.

(5) Except where paragraph (2) applies, both a person (B) and another person (C) are to be regarded as the person who provides the health care service where—

- (a) B has contracted with the National Health Service Commissioning Board<sup>(4)</sup> or a clinical commissioning group<sup>(5)</sup> to provide that service, and

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(4) The National Health Service Commissioning Board is established by section 1H of the National Health Service Act 2006 (c. 41) (“the 2006 Act”). Section 1H is inserted by section 9(1) of the 2012 Act.

(b) C provides that service under arrangements made between B and C.

(6) In this regulation—

“agency worker” and “temporary work agency” have the same meaning as in the Agency Workers Regulations 2010<sup>(6)</sup>; and

“practising privileges” means the grant by A to a registered medical practitioner of permission to practise as a medical practitioner in a hospital (as defined in section 275 of the 2006 Act) managed by A.

### **Exemptions from the requirement under section 81(1) of the 2012 Act to hold a licence: application to NHS foundation trusts**

3. Insofar as they could apply, none of the exemptions granted under these Regulations is to apply to an NHS foundation trust.

### **Exemption from the requirement to hold a licence: NHS trusts**

4. An NHS trust established under section 25 of the 2006 Act is exempt from the requirement to hold a licence.

### **Exemption from the requirement to hold a licence: primary medical and dental services**

5. A person is exempt from the requirement to hold a licence to the extent that the health care services provided by that person for the purposes of the NHS are—

- (a) medical services provided under Part 4 of the 2006 Act (primary medical services), or
- (b) dental services provided under Part 5 of the 2006 Act (primary dental services).

### **Exemption from the requirement to hold a licence: NHS Continuing Healthcare and NHS funded nursing care**

6.—(1) A person is exempt from the requirement to hold a licence to the extent that the health care services provided by that person for the purposes of the NHS are NHS Continuing Healthcare or NHS funded nursing care.

(2) Paragraph (1) ceases to have effect after 31st March 2015.

### **Exemption from the requirement to hold a licence: activities not required to be registered with Care Quality Commission**

7.—(1) A person who provides health care services for the purposes of the NHS is exempt from the requirement to hold a licence if the provision of such services is not a regulated activity for the purposes of registration with the Care Quality Commission under Chapter 2 of Part 1 of the Health and Social Care Act 2008<sup>(7)</sup> (registration in respect of provision of health care).

(2) The exemption granted to a person under paragraph (1) is withdrawn at the same time as that person is required, in respect of the provision of any one or more of the health care services provided by them for the purposes of the NHS, to be registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008.

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(5) A clinical commissioning group is a body established under section 14D of the 2006 Act. Section 14D is inserted by section 25(1) of the 2012 Act. *See also* section 11 of the 2006 Act, inserted by section 10 of the 2012 Act.

(6) S.I. 2010/93. Relevant amendments were made by S.I. 2011/1941.

(7) 2008 c. 14.

### **Exemption from the requirement to hold a licence: applicable turnover**

8.—(1) A person who provides health care services for the purposes of the NHS (P) is exempt from the requirement to hold a licence if their applicable turnover for the relevant business year is less than, or is reasonably expected to be less than, £10 million.

(2) Where P's relevant business year is more or less than 12 months, P's applicable turnover is to be the applicable turnover in that business year divided by the number of complete months in that business year and multiplied by 12.

(3) P must notify Monitor as soon as reasonably practicable after P becomes aware that the criterion laid down in paragraph (1) ceases to apply in relation to P.

(4) Where P ceases to meet the criterion laid down in paragraph (1), P is to be deemed to be aware that P ceases to meet that criterion on the day that P's accounts for the relevant business year are signed by P.

(5) The exemption granted to P under paragraph (1) is withdrawn from the earlier of—

- (a) the end of the period of 60 days starting on the date on which P becomes aware that P ceases to meet the criterion laid down in that paragraph, or
- (b) the issuing by Monitor of a licence to P under section 87(3) of the 2012 Act (grant or refusal of a licence).

(6) In this regulation, "relevant business year" means the last business year in respect of which figures for P's applicable turnover are available.

### **Exemptions: general conditions and withdrawal**

9.—(1) An exemption granted by regulation 5, 6, 7 or 8 is subject to the condition that the health care services provided by the person benefiting from that exemption are not services to which this paragraph applies.

(2) Paragraph (1) applies to services in respect of which Monitor, on the request of the National Health Service Commissioning Board or a clinical commissioning group, considers a licence condition under section 97(1)(i), (j) or (k) of the 2012 Act (conditions: supplementary) should be imposed.

(3) Where the condition in paragraph (1) is no longer met, an exemption granted under regulation 5, 6, 7 or 8 (as the case may be) is withdrawn from the earlier of—

- (a) the end of the period of 60 days starting on the date on which the person benefiting from the exemption is notified by the Board or a clinical commissioning group that it has requested Monitor to impose a condition under section 97(1)(i), (j) or (k) of the 2012 Act in relation to the services benefiting from the exemption, or
- (b) the issuing by Monitor of a licence to that person under section 87(3) of the 2012 Act.

(4) An exemption granted by regulation 5, 6, 7 or 8 is subject to the condition that a person providing a service pursuant to the exemption complies with any requirement imposed on that person by Monitor under section 104(1) of the 2012 Act (power to require documents and information).

(5) The Secretary of State may by direction withdraw an exemption granted by regulation 5, 6, 7 or 8 from any person who benefits from such an exemption if the Secretary of State considers that that person has consistently failed to comply with the condition imposed by paragraph (4).

Signed by the authority of the Secretary of State for Health.

Date

*Name*  
Parliamentary Under-Secretary of State  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations make provision in relation to the licensing of providers of health care services for the purposes of the NHS under Chapter 3 of Part 3 of the Health and Social Care Act 2012 (“the Act”) (Monitor: licensing).

Regulation 2 contains provision in relation to the persons to be regarded as the person who provides a health care service for the purposes of the licensing regime established by Chapter 3 of Part 3 of the Act.

Regulations 3 to 9 make provision in relation to the grant of exemptions from the requirement under section 81(1) of the Act for providers of health care services for the purposes of the NHS to hold a licence to provide such services. None of the exemptions granted are to apply to an NHS foundation trust (regulation 3).

Regulation 4 exempts NHS trusts from the requirement to hold a licence. Regulation 5 exempts from such requirement providers of medical services under Part 4 of the National Health Service Act 2006 and providers of dental services under Part 5 of that Act.

Regulation 6 provides an exemption for providers of NHS Continuing Healthcare or NHS funded nursing care. This exemption is time limited and will cease to apply after 31st March 2015.

Exemptions are also provided for: (a) persons who do not carry out an activity which requires them to be registered with the Care Quality Commission under Part 1 of the Health and Social Care Act 2008 (regulation 7); and (b) persons whose applicable turnover for the last business year is less than £10 million (regulation 8). “Applicable turnover” is defined in regulation 1(2) and (3) of the Regulations. Provision is also made for withdrawal of these exemptions where the criteria for the exemptions are no longer met.

Regulation 9 makes provision for the exemptions granted by regulations 5 to 8 to be subject to conditions and for the withdrawal of those exemptions where one or more of these conditions are no longer met.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS ([www.gov.uk/government/organisations/department-of-health](http://www.gov.uk/government/organisations/department-of-health)) and is published alongside this instrument and its Explanatory Memorandum at [www.legislation.gov.uk](http://www.legislation.gov.uk).