EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (APPROVAL OF LICENSING CRITERIA) ORDER 2013

2013 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 This instrument contains the approval by the Secretary of State of the criteria which Monitor must set and publish and which applicants for a licence to provide NHS health care services must meet. The criteria are set out in Schedule 1 to the instrument.

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

3.1 None.

4. Legislative Context

4.1 The Health and Social Care Act 2012 ("the 2012 Act") provides for Monitor to regulate provisions of health care services for the purposes of the NHS, with a general duty to protect and promote the interests of people who use health care services by promoting health care provision which is economic, efficient and effective and maintain or improves the quality of services.

4.2 Part 3, Chapter 3 of the 2012 Act gives Monitor the duty to operate a licensing regime for providers of NHS services, and is a key tool which assists Monitor to fulfil its general duty and carry out its functions. Monitor also has duties under section 288 and 290 of the 2012 Act to co-operate with the Care Quality Commission (CQC) and other relevant bodies such as National Health Service Commissioning Board (known as and referred to below as NHS England). Under section 86 of the 2012 Act, Monitor is required to set and publish licensing criteria which must be approved by the Secretary of State.

4.3 This instrument is the first made under section 86(3) of the 2012 Act. The first order made under section 86(3) is subject to the affirmative resolution procedure (section 304(5)(c) of the 2012 Act). This is the third statutory instrument to be laid in relation to Monitor's licensing regime. The first is the National Health Service (Licensing and Pricing) Regulations 2013 (SI 2013/ 2214)[1]. The second instrument is the draft National Health Service (Licence

[1] http://www.legislation.gov.uk/uksi/2013/2214/contents/made

Exemptions, etc) Regulations 2013[2], which was being considered by Parliament at the time that this instrument was laid before Parliament.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Quality has made the following statement regarding Human Rights:

In my view, the provisions of the National Health Service (Approval of Licensing Criteria) Order 2013 are compatible with the Convention rights.

7. Policy background

7.1 The 2012 Act established a comprehensive legal framework for healthcare regulation. This included a new role for Monitor, building on its previous one as the regulator of NHS foundation trusts and designed to complement the role of the CQC, which will continue to set and monitor quality standards for NHS treatment and care.

7.2 As well as continuing to act as the regulator of Foundation Trusts (FTs), Monitor will have three key functions:

- working with NHS England to provide independent regulation of pricing for NHS services;
- protecting patient choice and using its specialist knowledge and healthcare expertise to address anti-competitive behaviour which acts against patients' interests; and
- working with commissioners to secure continuity of services, where necessary.

7.3 The provider licence is one of the main tools Monitor will use when exercising its functions in line with its main general statutory duty to protect and promote the interests of people who use healthcare services. Section 81 of the 2012 Act requires any person who provides NHS healthcare services to hold a licence from Monitor, unless exempt under regulations made under section 83 of the 2012 Act. Some NHS providers will be exempt from the requirement to hold a licence from Monitor as a result of the draft National Health Service (Licence Exemptions, etc.) Regulations 2013, because licensing these bodies would be disproportionate or duplicate regulatory oversight elsewhere in the system, for instance by the NHS Trust Development Authority. The licence is a regulatory tool, not a kitemark of quality, and nor is it a badge of financial stability or a guarantee of NHS contracts.

[2] http://www.legislation.gov.uk/ukdsi/2013/9780111100813/contents

7.4 Section 86(1) of the 2012 Act requires Monitor to set and publish licensing criteria, which must be met by a person in order for that person to be granted a licence under Chapter 3 of Part 3 of the Act. If the criteria are met, Monitor must issue a licence.

7.5 The purpose of the licence criteria and application process is fundamentally different from that of the process for application for foundation trust status that Monitor is responsible for under Chapter 5 of and Schedule 7 to, the National Health Service Act 2006 ("2006 Act"). Whereas the end result of the assessment process for acquiring FT status is to award independence from the Secretary of State, the objective of the licensing process is to give Monitor the ability to regulate the provider's behaviour.

7.6 The licence criteria aim to set the requirements which healthcare providers need to meet to be able to be granted a licence by Monitor and enter the licensing regulatory regime. The licence criteria are designed to be proportionate and minimise regulatory burdens on providers.

7.7 Once a provider is licensed, it is required to comply with the licence conditions set by Monitor under section 94 (standard conditions) of the 2012 Act. Licence conditions can take the form of standard conditions, which apply to all licence holders, or to particular types of licence holder; and special conditions (section 95 of the 2012 Act) which will apply to an individual provider. Sections 105 and 106 give Monitor the powers to take action against actual or suspected licence breaches. These provisions give Monitor powers to take action to stop a breach continuing, rectify the breach and to impose a fine, and under section 89 of the 2012 Act Monitor may revoke a licence. Monitor's enforcement guidance[3] sets out the principles it would follow in taking enforcement action.

7.8 This means that once a provider is licensed, Monitor has powers to monitor and regulate that provider and hold it to account to meet the obligations contained in the licence.

7.9 In setting the criteria, Monitor has been mindful to remain proportionate, use existing tests set in other contexts where appropriate, and focus on objectively measurable criteria. Monitor has therefore concluded that its licence criteria should consist of a criterion relating to quality and patient safety (criterion 1) and a criterion relating to the fitness of a provider as assessed by reference to those who perform influential roles in it (criterion 2).

7.10 The criteria impose requirements which providers must meet at the point of decision in order to be granted a licence. Requirements broadly consistent with these are included as two of Monitor's standard licence conditions which mean they are also ongoing obligations on providers.

7.11 Monitor proposes to set two licensing criteria:

[3] http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishEnforcementGuidance28March13_0.pdf

- Applicants must be registered with the CQC where they are carrying out a regulated activity, or will be registered in respect of that regulated activity by the date the licence is granted; and
- All applicants must be fit persons. Applicants are to be regarded as fit in the following way. Where an applicant is an individual, that individual must not fall within the definition of an unfit person. Where the applicant is not an individual (such as a company, partnership or other organisation), its directors, governors or persons performing similar or equivalent functions must not fall within the definition of an unfit person.

7.12 The Department supports this approach to the criteria which is consistent with assurances given in Parliament that Monitor's licensing criteria will be light-touch and broadly drawn, to encompass a wide range of providers[4]. Taken together, the licensing regime – the licence criteria, standard conditions and exemptions from the licence – ensures that providers will be subject to appropriate and proportionate levels of regulation. With this in mind, the Department's view is that Monitor's approach to the criteria will best enable Monitor to use the licence to fulfil its main duty to protect and promote the interests of people who use health care services by promoting health care provision which is economic, efficient and effective and maintain or improves the quality of services.

7.13 The intention is for the full licensing regime to come into operation on 1 April 2014, and Monitor will issue licences to non-Foundation Trust providers from 1 April 2014. This Order will come into force when section 86 of the 2012 Act is commenced, which is expected to take place on 1 January 2014. It is intended that applications may be made to Monitor from January 2014 to enable Monitor to start processing such applications.

Criterion 1: Requirement in relation to registration with the Care Quality Commission

This criterion requires an applicant for a licence to be registered with the CQC, if required to do so under the 2008 Act. This criterion provides consistency with existing regulatory requirements, by only licensing providers who have already satisfied CQC's requirements for healthcare providers. This criterion also acts as an objective measure to assess compliance with standards of quality and safety. Providers who are required to hold CQC registration and do not hold it at the point of decision on grant of a licence are unsuitable for delivering NHS services. It should be noted that the CQC consulted on revisions to CQC's registration requirements from June to September 2013[5]. This consultation followed recommendations from the Winterbourne View and Francis Inquiries which included strengthening requirements around the fitness of directors. The intention is that any new fitness test for directors as part of CQC registration would complement and

[4]Lords Hansard 13 Dec 2011: Column 1167
[5]https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/210734/Corporate_accountability.pdf

be consistent with the fitness test for directors in Monitor's licence conditions and licence criteria.

Providers not required to hold CQC registration

7.14 Some providers of NHS healthcare services are not required to hold a CQC registration in order to provide such services (see **Annex A**). Such providers will be exempt from the requirement to hold a licence under the NHS (Licence Exemptions, etc.) Regulations 2013. In order to protect patients' interests, regulation 9 of those regulations provides for an exception to any exemption where a provider supplies 'commissioner requested services'[6].

7.15 Under Monitor's licensing regime, NHS England or clinical commissioning groups may determine that certain services require additional regulation in order to protect the interests of patients who use those services in the event that the provider gets into financial difficulty. Based on guidance[7] from Monitor, commissioners may designate such services as 'commissioner requested services'. If a service is designated a 'commissioner requested service' (CRS), then the provider is required to hold a licence granted by Monitor, even if they would otherwise be exempt from that requirement. Providers of such services who are not required to be registered with the CQC in respect of an activity therefore require a licence but do not have meet criterion 1. Such providers will have to meet criterion 2, described below.

Providers applying jointly for a Monitor licence and CQC registration

7.16 Section 288 of the 2012 Act provides that Monitor and CQC should ensure that one joint application can be submitted by a new provider to obtain both CQC registration and a Monitor licence. The intention is that this joint application process should operate from April 2014, when the requirement to hold a licence is intended to come into force for all providers. Monitor and CQC are working together to design a process which captures the information needed to be considered for both CQC registration and a Monitor licence. In practice, it is intended that CQC will consider whether a provider meets the requirements for registration before Monitor considers whether a provider meets the licence criteria. This means that, at the point of granting a licence, Monitor will have been informed by CQC whether CQC intends to register the provider, and therefore whether the provider meets licence criterion 1.

7.17 Criterion 1 avoids the situation whereby, on a joint application, a provider is granted a licence and refused CQC registration. In addition, it could result in a provider being registered with CQC and refused a Monitor licence, if that provider did not meet criterion 2.

Criterion 2: Requirement in relation to provider fitness

[6] Insert definition from exemptions regulations

[7] https://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browsecategory/guidance-health-care-providers-and-co-19

7.18 This criterion provides that an applicant is only fit to hold a licence if certain persons involved in overseeing the organisation and thus influencing the provision of healthcare services do not fall within the definition of unfit persons. The persons to be tested in this way are broadly all legal and natural persons who are directors or governors in the applicant provider, with directors and governors being defined to include those who perform similar or equivalent functions. The aim of this criterion is to exclude providers who have, in a position where they can have a relevant influence on the running of the provider, a person (whether an individual or a corporate body) that falls within the definition of unfit persons.

7.19 The unfit person descriptions are based on the requirements for directors and governors of FTs. Schedule 7 to the 2006 Act provides that persons may not become or continue as members of the council of governors or be appointed as a director of a FT if for example, they are an undischarged bankrupt; have undischarged arrangements with creditors; are subject to a moratorium period under a debt relief order; or have received a prison sentence of three months or longer during the previous five years. Under section 88 of the 2012 Act, FTs are treated as having applied for a licence and met the criteria for holding a licence. Monitor therefore concluded that the legislative requirements relating to fitness that apply to relevant FT personnel should form the basis for the fitness requirements set out in paragraph 2(4)(a) of the Criteria for all other providers that are to be licensed by Monitor. This ensures that providers of different types are treated consistently.

7.20 In addition to the requirements on directors, governors or equivalents of FTs, there are certain requirements on directors of companies which are relevant to an applicant's fitness. Paragraph 2(4)(a)(v) of the Criteria applies a similar requirement to all providers to ensure consistency. This means that a person subject to a disqualification order or disqualification undertaking under the Company Directors Disqualification Act 1986 would be unfit.

7.21 In advance of the date from which licence applications can be made, Monitor intends to issue guidance for providers relating to the application process. This will include guidance on how applicants can identify whether persons are carrying out functions equivalent or similar to those of FTs' directors and governors.

7.22 Given the exemptions which are set out in the draft National Health Service (Licence Exemptions, etc) Regulations 2013, Monitor expects the majority of applicants for a licence to be organisations e.g. corporate bodies.

Applicants who are individuals

7.23 In the circumstances where a provider who applies for a licence is an individual (e.g. a sole trader) and is required to hold a licence, Monitor believe that such an applicant should have to meet the fitness requirement. In such a case, the applicant must not fall within certain descriptions set out in paragraph 2(4)(a) of the Schedule.

Applicants who are corporate bodies

7.24 Where the provider applicant is not an individual (B) and is, for example a corporate body, its directors or governors who are individuals must not fall within the description of unfit persons which is set out in in paragraph 2(4)(a) of the Schedule. Some of those directors may be corporate bodies – e.g. another company may hold a position on the applicant's (B's) Board – these corporate directors must not be unfit, as described in paragraph 2(4)(b) of the Schedule.

7.25 The objective is to ensure that those who have a relevant influence over the running of the applicant's business and the provision of NHS health care services are not in a position that might indicate that a person is not effective in governing the applicant and managing the applicant's financial affairs. With this in mind, the criteria also ensure that all partners in a partnership would need to fall outside the description of unfit persons in paragraph 2(4)(a).

7.26 However, the applicant organisation itself does not need to fall outside the description in paragraph 2(4)(b). For some services, upon failure, there will be alternative providers that patients can access. For other services, however, one provider may be the only option available to patients, in which case the commissioner would designate the service as a CRS. This would mean that once that CRS provider was licensed, Monitor would have powers to work with that provider to regulate its financial governance and financial management. Monitor is therefore better placed to ensure the continuity of those services by licensing and working with those providers in financial difficulty than if it had simply refused that provider a licence. This is in contrast to the relationship between Monitor and any corporate directors of the applicant, who would not be licensed by Monitor, and therefore Monitor would not be able to affect their financial governance and financial management. This is why the corporate director must satisfy the requirements in paragraph 2(4)(b) but the provider itself does not need to satisfy the requirements in paragraph 2(4)(b).

8. Consultation Outcome

8.1 Monitor has carried out extensive consultation on its proposed licensing criteria. Between 6 February 2012 and 5 March 2012, Monitor conducted a stakeholder engagement exercise to seek views on its initial proposals for the licensing criteria[8]. 95 responses were received and changes were made to the proposed criteria as a result of stakeholders' suggestions.

[8] http://www.monitor-nhsft.gov.uk/our-publications/browse-category/consultations/consultations-and-engagement-monitors-role-sector-reg-2

8.2 Between 31 July 2012 and 23 October 2012, Monitor conducted the statutory consultation on its proposed licence conditions[9], which included the licensing criteria.

8.3 Monitor asked stakeholders whether or not it should be able to waive the fit and proper persons requirements, contained in both the proposed licence conditions and the licensing criteria, in very exceptional circumstances and at its discretion. The question was asked in response to concerns that a rigid test would prevent the appointment of current or past service users who may fail the test but whose experience may be valuable. Stakeholder views were mixed and the decision was taken to retain this discretion, noting that it would in any event apply only in exceptional circumstances and therefore be capable of being exercised in very limited situations. Monitor has since reconsidered the policy to retain such a discretion on the basis of greater understanding of its potential risks versus benefits and wider implications. As a consequence, this waiver is not included in the intended criteria to be published.

8.4 Monitor asked stakeholders if they thought that Monitor should include a requirement to adhere to relevant standards of personal behaviour, technical competence and business practices within the fit and proper persons requirements. Stakeholder views were mixed, but the decision was taken to not to introduce such standards initially so that these issues could be considered as part of work on the response to the Francis Inquiry, in advance of the full Government response to the Inquiry in Autumn 2013.

8.5 Monitor also asked stakeholders if they were supportive of the proposal to limit the fit and proper persons requirements to directors and governors, or those performing similar or equivalent functions. The overwhelming majority of respondents supported this proposal.

9. Guidance

9.1 Monitor will publish its final licensing criteria following approval by Parliament. Monitor also intends to issue guidance to providers about how they can apply for a licence, including how the licensing criteria will be assessed. The intention is to issue this guidance in advance of the date from which licence applications can be made.

10. Impact

10.1. An Impact Assessment has not been prepared for this instrument by the Department. The two licence criteria are based on conditions contained within Monitor's provider licence. Monitor conducted an impact assessment[10] of the provider licence and the Department of Health analysed the impact of the

[9] http://www.monitor-nhsft.gov.uk/home/news-events-publications/consultations/closed-consultations/2012/the-new-nhs-provider-licence-c

[10] http://www.monitor-nhsft.gov.uk/sites/default/files/Final%20report%20IA.pdf

different licence conditions on providers as part of its impact assessment[11] of The National Health Service (Licence Exemptions, etc.) Regulations 2013.

11. Regulating small business

11.1 The National Health Service (Licence Exemptions, etc.) Regulations 2013 provide for exemptions to the requirement to hold a licence and include an exemption for providers with annual NHS revenue of less than £10m, unless that provider is delivering a CRS. It is not expected that many providers with NHS revenues of less than £10m will provide CRS and, for those that do, the regulatory burden of meeting the licensing criteria is low. Therefore, the additional regulatory impact of this instrument is minimal.

12. Monitoring and review

12.1 Monitor will keep the licensing criteria and the licence conditions under review. It is required to keep the exercise of its functions under review and secure that it does not impose or maintain unnecessary burdens. In keeping the exercise of its functions under review, Monitor must have regard to the principles of regulatory best practice.

12.2 Monitor has committed to keeping its position on criterion 2 under review and to work with others to make any necessary changes to the licence as the the Winterbourne View and Francis Inquiries are considered, in advance of the full Government response to the Francis Inquiry in Autumn 2013. Monitor intends to conduct a general review of licence conditions following their introduction and use, and this will include looking at the criteria. If it is appropriate or necessary, Monitor will review licence conditions earlier.

12.3 The Department of Health will keep Monitor's performance as sector regulator under review through quarterly accountability meetings. These reviews will cover performance of its pricing, licensing and competition functions. In addition, during 2016/17, the Government intends to carry out a full review of how the licensing regime is operating.

13. Contact

Catherine Fiegehen at the Department of Health (Tel: 020 7210 6074 or email: catherine.fiegehen@dh.gsi.gov.uk) can answer any queries regarding the instrument.

[11] http://www.legislation.gov.uk/ukdsi/2013/9780111100813/impacts

ANNEX A: Services and professions not subject to CQC registration

Services

- primary ophthalmic services (eg high street optometrists);
- primary pharmaceutical services (eg high street pharmacies);
- activity carried on unpaid by a personal friend or family member living in the same household;
- activity carried on by an establishment or agency required to be registered and regulated by Ofsted (eg children's homes);
- provision of first aid, even if by a health care professional who would otherwise be subject to CQC registration;
- medical and dental services provided by the Armed Services;
- School nurses, where they are directly employed and directed by the school.

Professions

- Arts therapists
- some chiropodists and podiatrists
- Chiropractors
- Dietitians
- Occupational therapists
- Orthoptists;
- Osteopaths;
- Physiotherapists;
- Prosthetists and Orthotists;
- Psychotherapists and Counsellors
- Speech and language therapists