EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (LICENSING AND PRICING) REGULATIONS 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 provides for the levels of objections that would require further consideration of any proposals by Monitor for:

- modifications to the standard conditions included in licences, which all providers of NHS services will have to hold, unless exempt under separate regulations made under section 83 of the Health and Social Care Act 2012 ("the 2012 Act"); and
- its proposed methodology for calculating national prices to be paid for NHS services as set out in the National Tariff.

2.2 The instrument also makes provision in respect of which providers of health care services for the purposes of the NHS can object to Monitor's proposed methodology for calculating national prices.

2.3 The instrument also defines turnover for the purposes of determining maximum fines Monitor could impose.

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

3.1 None.

4. Legislative Context

4.1 The 2012 Act provided for Monitor to regulate NHS services, with an overarching duty to protect and promote the interests of patients by promoting NHS provision which is economic, efficient and effective.

4.2 Part 3, Chapter 3 of the 2012 Act gives Monitor the power to operate a licensing regime for providers of NHS services and work with the National Health Service Commissioning Board (known as and referred to below as "NHS England") to provide independent regulation of pricing for NHS services.

4.3 This instrument is the first made under sections 100(7) to (9), 105(4), 118(14)(b) and 120(2) and (6) of the 2012 Act.

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 (Licensing and Pricing) Regulations 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 foundation trusts and designed to complement the role of the Care Quality Commission, which will continue to set and monitor quality standards for NHS treatment and care.

7.2 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 Licensing providers of NHS services will be one of the main tools Monitor will use when exercising its functions in order to meets its main statutory duty to protect and promote the interests of people who use the health service.

Modifying standard licence conditions

7.4 The licence will set out the conditions that licence holders will have to meet in order to provide NHS funded services. There will be standard conditions, which will apply to all licence holders, or to particular types of licence holder; and special conditions which will apply to an individual provider. As required under section 94(1) of the 2012 Act Monitor published the standard licence conditions on 14 February 2013[1].

7.5 Under section 95 of the 2012 Act, Monitor may, with the consent of the provider, include a special condition in a provider's licence. Objections to special conditions follow a separate process set out in the 2012 Act.

7.6 Monitor will be able to modify standard licence conditions but will first have to consult with those licence holders who would be affected by the proposed modification of any of the standard conditions – the "relevant providers". If the number of objections to the proposal exceeds either the prescribed "objection

[1] http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-8

percentage" or the prescribed "share of supply percentage" for relevant providers, then Monitor cannot implement the modification(s) without further consideration.

7.7 The "objection percentage" is the percentage of relevant providers who object to the proposed modification. The "share of supply" threshold for objections to licence conditions is to be calculated by defining share of supply as the number of licence holders affected by the proposed modification, weighted by NHS turnover.

7.8 The purpose of the "share of supply" threshold is to weight objections from "relevant providers" according to the degree to which they are affected by the modification(s) being proposed. For calculating "share of supply", the denominator for the share of supply calculation will be the entirety of NHS turnover from relevant providers.

7.9 For example, if Monitor proposed a modification to standard licence conditions which only apply to FTs, and 30 out of 145 FTs objected, the objection threshold would be exceeded as this represents objections from 21% of relevant providers and Monitor would be unable to proceed with that modification. If 20 out of 145 FTs objected, the objection threshold would not be met as this represents objections from 14% of relevant providers. In this case, if the NHS turnover of the 20 FTs who objected represented 20% or more of the NHS turnover of all relevant providers, the share of supply threshold would be exceeded and Monitor would be unable to proceed with the modification.

7.10 Regulation 2 of this instrument provides what the levels of the "objection percentage" and "share of supply percentage" will be, and also how the "share of supply percentage" will be calculated.

7.11 The threshold for "objection percentage" and "share of supply percentage" are both 20%. OFGEM previously used thresholds of 20% for a similar objection process in relation to modifications to providers' licences in the energy industry.

7.12 If Monitor consults on modifying standard licence conditions and either the objection or share of supply thresholds is met, Monitor may:

- drop the proposed modification in light of the objections received;
- put forward alternative proposals in the light of the objections received and publish these for consultation under section 100(2) and (3) of the 2012 Act; or
- refer the proposed modification to the Competition Commission (section 101(2) of the 2012 Act).

7.13 Once a referral is made, the Competition Commission will be required to investigate and report on whether the proposal is consistent with Monitor's duty to protect and promote patients' interests. This will ensure that standard licence conditions protect the interests of patients. The provision also protects licence holders from modifications that would be overly burdensome or unfair.

Definition of turnover for the purpose of setting maximum fines

7.14 Under section 105 of the 2012 Act, Monitor will have the power to place discretionary requirements on a provider which breaches a licence condition or fails to hold a licence when it is required to. Monitor may also place a discretionary requirement on a provider or commissioner who fails to provide Monitor with required information (section 104 of the 2012 Act).

7.15 The discretionary requirements available to Monitor under section 105(2) of the 2012 Act are:

- a 'variable monetary penalty' – a monetary penalty of such amount as Monitor may determine, up to 10% of the organisation's turnover in England;
- a 'compliance requirement' – action to stop the breach in question, or to make sure it does not happen again, eg a requirement that a provider cease plans to dispose of an asset needed for the provision of a specified service; and
- a 'restoration requirement' – action to restore the position to what it was before the breach occurred. For example, Monitor could require that a provider re-open a service that it had closed in breach of a licence condition.

7.16 It would be for Monitor, in the individual circumstances of a particular case, to decide whether to impose one of the discretionary requirements and if so, which one and the detail of it, including the amount of any variable monetary penalty. Under section 108 of the 2012 Act, Monitor is required to consult on and publish guidance about the way in which it will exercise its powers to impose discretionary requirements. The guidance must include details of when Monitor is likely to impose discretionary requirements, how it will decide the amount of variable monetary penalties, and how decisions may be appealed. Monitor published its enforcement guidance[2] on 28 March 2013.

7.17 Section 105(4) of the 2012 Act provides that a variable monetary penalty must not exceed 10% of an organisation's turnover in England. Regulations 3 and 4 of this instrument prescribe how that amount is to be calculated. It is Monitor who will decide in an individual case as to whether a discretionary requirement should be imposed and the level of any penalty.

7.18 Regulation 3 provides for the manner in respect of which "turnover" for providers of NHS services is to be calculated. This will ensure the maximum fine that can be imposed on a provider is proportionate to the scale of NHS services they supply. Regulation 4 provides that the manner of calculating "turnover" in respect of the maximum variable monetary penalty Monitor could impose on NHS England or a clinical commissioning group ("commissioners") would be their administrative expenditure. There is no requirement on commissioners to hold a Monitor licence: hence, the only circumstances in which Monitor would be able to levy a variable monetary penalty on a commissioner would be if that commissioner did not supply Monitor with information that Monitor required.

[2] http://www.monitor-nhsft.gov.uk/node/2622

Objections to Monitor's pricing methodology

7.19 Under section 116 of the 2012 Act, Monitor must publish a document which is known as the National Tariff. This document must specify services and 'currencies' (ie a service specification which may include one or more service); the methodology used for determining the prices payable for specified services and currencies, and the prices so determined; and the methodology used when considering agreements under section 124, or applications under section 125 for locally agreed modifications to national prices. The National Tariff may also contain rules, including those governing local agreements to vary the prices or specifications of tariff services (eg to support innovation in service delivery, integration of services, or unbundling of services to enable components of care to be delivered and paid for separately, where this would be in patients' best interests) and for determining prices for services not specified in the tariff.

7.20 It is intended that Monitor will be responsible for publishing the National Tariff Document from April 2014. Monitor will develop its proposals for the tariff with NHS England and engage widely on them, giving providers, commissioners and others an opportunity to raise any concerns and offer suggestions for improvement.

7.21 Monitor will then be required to publish a final draft of the National Tariff Document and allow 28 days for commissioners (section 118 of the 2012 Act) and providers (section 120 of the 2012 Act) to raise formal objections. Objections may only be raised to the methodology proposed for calculating the prices for nationally priced services. If sufficient objections are made, so that either the "objection percentage" or "share of supply percentage" are met, Monitor will have to either:

- reconsider the proposed methodology and re-consult on revised proposals; or
- refer the proposed methodology to the Competition Commission for a decision on whether it is appropriate.

The "objection" and "share of supply" percentages

7.22 The new arrangements set out in the 2012 Act will enhance stakeholder engagement throughout the tariff development process and the objections mechanism is merely a 'backstop' to this engagement. The Department has therefore set the thresholds so that a majority share (ie 51%) of 'relevant' providers or commissioners must object to trigger a referral or reconsideration of the methodology.

7.23 Regulation 5 of this instrument sets the objection percentage threshold at 51% of the total number of commissioners or 51% of the total number of "relevant providers". This means that, if there were 100 "relevant providers", 51 of them would need to object, or, if there were 100 commissioners, 51 commissioners would need to object to trigger a referral of reconsideration of the methodology. It also sets the share of supply threshold at 51% for "relevant providers". For example, if the total spend on nationally priced tariff services was £30m, and an individual provider's income for nationally priced services was £3m, then their share of supply would be 10%. If a number of providers, whose collective income from nationally priced tariff services was greater than £15.3m, (51% of the total

7.24 The threshold of 51% for the pricing objection process is distinct from the licensing threshold. The 20% licensing threshold is based on precedents for objections to licence changes set in the energy sector. There are no precedents for price-setting, so we have taken a decision in consultation with Monitor, NHS England and stakeholders , based on what the Department deems to be a fair and proportionate starting point for the new system. The definition of "relevant provider" is less inclusive in licensing, as **only** those providers who have the condition to which the modification applies in their licence can object to the modification. For pricing, **any** provider providing **any** service for which a national price is specified in the National Tariff Document may object to **any** part of the methodology used for calculating national prices, even if they do not supply the services to which the specific part of the methodology applies. This is because it would have been too burdensome to administer service-specific objections. Arguably therefore, a higher threshold is necessary given the scope of "relevant" is more inclusive. In addition, the 2012 Act provides for the tariff to include various flexibilities to national prices, for example, to account for unavoidable costs, innovation and locally agreed prices where national pricing is not appropriate.

"Relevant providers"

7.25 All commissioners will be commissioning services with national prices and so all commissioners will be able to object. However, not all providers will be providing nationally priced services. Therefore, only objections from "relevant providers" – ie those directly affected by the methodology – will be counted towards the thresholds. Regulation 6 provides two categories of "relevant providers":

- those which are both currently providing services under national prices and who will continue to do so under the National Tariff being consulted upon, and;
- those which will provide services under national prices in the National Tariff being consulted upon.

7.26 Regulation 6(2) provides that, in the case of the objection percentage, both types of "relevant provider" will be entitled to raise objections. In the case of the share of supply percentage, it provides that only objections from the first category of relevant provider are applicable. The reason for applying different definitions is explained in paragraph 8.9 below. In addition, it specifies which providers would be considered 'relevant' for the purposes of the processing of a referral to the Competition Commission under section 120 of, and Schedule 12 to, the 2012 Act.

The share of supply calculation

7.27 The purpose of the "share of supply" threshold is to weight objections from "relevant providers" according to the degree to which they are affected by the

7.28 It is planned that Monitor will introduce its first National Tariff in April 2014. The consultation on the 2016 tariff, which would be likely to take place in 2015, would be the first time that the financial information used to calculate the share of supply percentage would reflect income under a Monitor tariff. This is because the share of supply, under regulation 5, will be calculated on the accounts for the financial year preceding the year of the consultation. Provision has been made at regulation 5(8) to provide clarity that, until this time, share of supply is to be calculated according to providers' income for nationally priced services under the tariff as published by the Secretary of State. Similar adjustments for local flexibilities to reflect unavoidable costs will be made during these transitional years. This regulation also specifies that the price to be used in the share of supply calculation is that which applied to the service at the time the payment became due. This is to provide legal clarity in the case of service provided over a period, which straddle more than one tariff, eg a Year of Care service or Maternity Care Pathway service. It specifies that the price to be used for calculating the share of supply is the one which applied at the time the payment became due.

7.29 The Department intends to keep the objection mechanisms under review as the system beds down.

8. Consultation Outcome

Protecting and promoting patients' interests – licensing providers of NHS services – Consultation on proposals (Regulations 2, 3 and 4)

8.1 From 15 August to 22 October 2012, the Department of Health consulted on proposals for the objection and share of supply percentages in relation to licence modifications and the definition of turnover in relation to Monitor imposing a variable monetary penalty on providers. The Department received 70 responses from various organisations. The responses to the consultation and the Government's response can be found on the Department's website.[3] Those responses were largely supportive of the proposals in the consultation, which were the same as those now included in this statutory instrument. Some respondents wanted a more refined objection process. However, the actual process is provided for in the 2012 Act. Some wanted definition of turnover to be wider than NHS services, while others argued that fines should be pre-determined. The process of fining is set out in both the 2012 Act and in guidance produced by Monitor. Turnover has been defined as NHS turnover as it is fair,

[3] https://www.gov.uk/government/publications/new-licensing-regime-for-providers-of-nhs-services-response-to-consultation--2

proportionate and simple to calculate. During 2016/17, the Government intends to carry out a full review of how all aspects of the licensing regime are operating.

8.2 The Department sought views from NHS England in determining how a commissioner's turnover should be calculated. Turnover for the purpose of calculating the maximum variable monetary penalty for commissioners will be defined as the commissioner's administrative spend.

Consultation on ensuring fair and transparent pricing for NHS services (Regulations 5 and 6)

8.3 From 5 October 2012 to 21 December 2012, the Department of Health consulted on the proposal for pricing objections provided for in this instrument. The Department received 48 responses from various organisations. The responses to the consultation and the Government's response can be found on the Government's website.[4]

8.4 Respondents were supportive of the extra transparency and engagement being introduced into the tariff development process and the statutory duty to consult.

8.5 There was general agreement that the calculation should include providers of services in the tariff in operation at the time at which Monitor consults on the next tariff. However, a number of respondents wanted previous or potential providers of tariff services to be included in the objection calculations. Regulation 6 therefore provides that existing providers not currently providing services under the National Tariff to which the forthcoming National Tariff will apply, will be eligible to object.

8.6 Two other key issues raised during consultation were the proposed objection thresholds and the method for calculating the share of supply levels. We received mixed responses to our proposals on the objections threshold. A number of respondents supported the proposed threshold. However, a number suggested that the objection thresholds were too high, others felt there should be consistency with the threshold for licensing objections and some respondents thought a higher threshold would be more appropriate. The majority view was that the share of supply percentage should be calculated across all tariff income, and that it should be weighted according to income for nationally priced tariff services. However, some felt they would prefer the percentage to be based on a service-specific specification, which they felt would give smaller providers a fairer say in the process.

8.7 Following consultation with NHS England and Monitor, the thresholds for both objections and share of supply have remained at 51%, and the calculation for the share of supply has remained as the proportion of total tariff income. The rationale is that this new process created by the 2012 Act is intended to act as an additional backstop. The new joint arrangements for price-setting will improve transparency and confidence in the system, and the statutory requirements to consult on the National Tariff will themselves act as checks and balances. In addition, it was felt that requiring a service-specific share of supply calculation

[4] https://www.gov.uk/government/publications/ensuring-fair-and-transparent-pricing-for-nhs-services-response-to-consultation--2

would impose a disproportionate regulatory burden on the sector at this time, though we will keep this under review.

8.8 These decisions should also be seen within the context of Monitor developing its new role, and the changes being embedded within the NHS as a whole. The Department would expect that, as the objections mechanism beds down, it will be in a position to review whether any changes to the threshold are necessary to ensure the system operates optimally.

9. Guidance

9.1 The Government does not intend to issue guidance on these regulations. Monitor will issue guidance at the time of the consultation on the National Tariff, on various aspects of the objections process.

9.2 In relation to licence modifications, Monitor is required to publish a notice of the proposed modification and send this notice to all relevant providers, the Secretary of State, NHS England, all clinical commissioning groups and the Care Quality Commission and its Healthwatch England committee.

9.3 Monitor intends to update its enforcement guidance to reflect the regulations on definition of turnover coming into force.

10. Impact

10.1 An impact assessment has not been produced for these provisions. The regulations do not deviate or create any additional impacts from the policy as stated in the 2012 Act. The impact of the original proposals is therefore covered by a previous supporting impact assessment (IA number 6031[5]. This instrument makes provisions in respect of "turnover" for the purposes of setting maximum fines and sets the thresholds for objections to a licence modification or the pricing methodology. The impact of the definition of turnover will depend on the behaviour of providers and Monitor's regulatory approach. The cost impact of fines is not assessed here. This will be individually determined when and if the need for fining occurs.

10.2 With regard to the objection thresholds, there are no direct costs or benefits resulting from these regulations. The impact of the objection thresholds is difficult to measure, as it will depend on the behaviour of providers and commissioners and whether or not they choose to object. The Department has therefore looked at precedents set in other sectors and taken into account stakeholder views through public consultation. The Government will keep the objection thresholds under review.

11. Regulating small business

11.1 These provisions will only apply to providers who enter into an NHS contract to deliver healthcare services for the purposes of the NHS. For these reasons, any impact on the private sector is through contractual arrangements, should a

[5] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147536/dh_129917.pdf.pdf

provider wish to enter into a contract. Therefore, there is no additional regulatory impact from these regulations.

12. Monitoring and review

12.1 The Department of Health will keep Monitor's performance as sector regulator under review through quarterly financial and 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.

12.2 The Department also intends to review the objections thresholds in due course once the new system beds down.

13. Contact

Catherine Fiegehen at the Department of Health (Tel: 020 7210 5569 or email: catherine.fiegehen@dh.gsi.gov.uk) can answer any queries regarding the instrument.