EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (LICENSING AND PRICING) (AMENDMENT) REGULATIONS 2015

2015 No. [XXXX]

1. Introduction

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

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

2. Purpose of the instrument

2.1 This instrument amends the National Health Service (Licensing and Pricing) Regulations 2013 (the 2013 Regulations) by increasing the prescribed objection percentages for clinical commissioning groups (the Commissioners) and relevant providers (the Providers) of NHS health care services, and removing the prescribed objection percentage for Providers weighted according to their share of the supply in England of such services as may be prescribed. Where any objection percentage is met, Monitor may not publish the National Tariff and must follow the procedure specified in section 120 of the Health and Social Care Act 2012 ("the 2012 Act").

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 There are two matters of special interest:

- The changes come into force on the day after the regulations are made. This is necessary to enable Monitor and the National Health Service Commissioning Board (known as and referred to below as "NHS England") to commence a statutory consultation on proposals for the 2016-17 National Tariff. This needs to commence as soon as possible in advance of the new financial year. The Department considers that delaying this consultation would prejudice the public interest in efficient use of public money. The Department considers this coming into force provision is reasonable because the Providers and Commissioners whose interests are affected by the regulations were informed of the possibility of the 2013 Regulations being amended by the Department's consultation, and the extent of the changes was confirmed in the Government's consultation response, published on 29 October 2015. All Providers and Commissioners were notified by email of the consultation and the Government response. The Department will notify them by email if the regulations are approved by Parliament and made.
- Section 120(2)(a) and (b) of the 2012 Act place a duty on the Secretary of State to prescribe the objection percentage for Commissioners and Providers, while section 120(2)(c) provides a power to prescribe the share of supply percentage. A Parliamentary briefing note "Protecting and Promoting Patients'

Interests: the role of sector regulation" published[1] by the Department in December 2011 explained the Government proposals for sector regulation in the NHS, including the tariff objection mechanism. The Department made copies available to Peers who referred to it in Parliamentary debate[2]. Paragraphs 104 and 105 of this briefing made clear that regulations would provide either two or three thresholds according to whether the Secretary of State prescribes a share of supply percentage. The Department regrets that the memorandum to the Delegated Powers and Regulatory Reform Committee and the Explanatory Note to the Bill, while accurately reflecting the language of the then Bill, did not emphasise this point. That should not have occurred and the Department will review how to prevent any similar reoccurrence in future. In 2012 the policy was that the share of supply should be prescribed and this was set out in Parliamentary debate.[3]

Other matters of interest to the House of Commons

3.2 This entire instrument applies only to England.

3.3 This instrument:

(i) Applies only to England because the functions exercised by Monitor and NHS England are limited to England. Generally the 2012 Act applies to England and Wales.

(ii) Has minor or consequential effects outside England. Commissioners in England may commission services from a Provider outside England. However, this instrument does not however impose obligations on a Provider, and the number of any Providers outside England is small.

3.4 In the view of the Department, for the purposes of House of Commons Standing Order 83P the subject-matter of this entire instrument would be within the devolved legislative competence of the Northern Ireland Assembly if equivalent provision in relation to Northern Ireland were included in an Act of the Northern Ireland Assembly as a transferred matter and the Scottish Parliament if equivalent provision in relation to Scotland were included in an Act of the Scottish Parliament and the National Assembly for Wales if equivalent provision in relation to Wales were included in an Act of the National Assembly for Wales.

3.5 The Department has reached this view because it considers that the primary purpose of the instrument relates to the promotion of health, which is within the devolved legislative competence of each of the three devolved legislatures: the primary purpose of the subject matter of the instrument is not within Schedules 2 or 3 to the Northern Ireland Act 1998 and is not otherwise outside the legislative competence of the Northern Ireland Assembly (see section 6 of that Act); the primary purpose of the subject matter of the instrument is not within Schedule 5 to the Scotland Act 1998 and is not otherwise outside the legislative competence of the Scottish Parliament (see section 29 of that Act); the primary purpose of the subject matter of the instrument is within paragraph 9 of Schedule 7 to the Government of Wales Act 2006 and is not within one of the exceptions listed therein, nor is it otherwise outside the legislative competence of the National Assembly for Wales (see section 108 of that Act).

[1] www.gov.uk/government/news/protecting-and-promoting-patients-interests-the-role-of-sector-regulation

[2] See the debate on 13 December 2011, column 1220 and 1231 at www.publications.parliament.uk/pa/ld201011/ldhansrd/text/111213-0003.htm

[3] www.publications.parliament.uk/pa/ld201011/ldhansrd/text/111213-0003.htm

4. Legislative Context

4.1 The 2012 Act provided for Monitor to regulate NHS services, with a main duty to protect and promote the interests of patients by promoting NHS provision which is economic, efficient and effective, and maintains or improves the quality of the services.

4.2 Part 3, Chapter 3 of the 2012 Act gives Monitor the function of working with NHS England to provide independent regulation of pricing for NHS services, and to publish the pricing and reimbursement framework in a document called the National Tariff.

4.3 Monitor is required to consult on proposals for a National Tariff under section 118 of the 2012 Act. As part of this process Commissioners and Providers have the opportunity to object to the proposed method for determining national prices for specified healthcare services. Under section 120(2) of the Act, where a prescribed objection percentage is met, Monitor may not publish the National Tariff (section 120 also specifies what else Monitor must do in this situation). The 2013 Regulations prescribe the objection thresholds, and who is a relevant provider, for the purposes of section 120(2)(a), (b) and (c) of the Act.

4.4 This instrument amends regulation 5 and 6 of the 2013 Regulations, by increasing the objection percentages in regulation 5(1) and (2), removing the share of supply objection percentage in regulation 5(3), and making consequential amendments.

5. Extent and Territorial Application

5.1 The territorial application of this instrument is set out in Section 3 under "Other matters of interest to the House of Commons".

6. European Convention on Human Rights

6.1 The Parliamentary under-Secretary of State for NHS Productivity has made the following statement regarding Human Rights:

6.2 In my view the provisions of the National Health Service (Licensing and Pricing) (Amendment) Regulations 2015 are compatible with the Convention rights.

7. Policy background

7.1 The 2012 Act introduced a new independent, transparent and fair pricing system for NHS services that requires Monitor and NHS England to collaborate to set prices and further develop new payment models across different services. Monitor and NHS England must comply with a range of duties when exercising these functions. The intention was to create a more stable, predictable environment, allowing Providers and Commissioners to invest in technology and innovative service models to improve patient care. Transferring pricing from the Department of Health, and making it an independent function was intended to provide that stability.

7.2 Pricing proposals must be agreed between Monitor and NHS England. In particular, NHS England considers which health services should be priced at a national level and Monitor considers how the prices should be calculated.

7.3 Under section 116 of the 2012 Act, Monitor must publish a document which is known as the National Tariff. This specifies:

- A set of healthcare services, provided for the purposes of the NHS, which are to have national prices;

- The method used for determining the national prices for those specific services;
- The national price for each of those specified services;
- The methods to be used for approving an agreement between a provider and a commissioner to modify a nationally determined price and for determining a provider's application to Monitor to modify a nationally determined price; and
- The rules under which providers and commissioners may agree to vary the currency or the national price of a service.

7.4 The National Tariff may also contain rules for determining prices for services not specified in the tariff.

7.5 Monitor is required to publish its proposals for the National Tariff and allow 28 days (section 118 of the 2012 Act) for Commissioners and Providers to raise formal objections (section 120 of the 2012 Act). Objections may only be raised to the method proposed for calculating the national prices. The method is the data, methodology and calculations used to arrive at the proposed set of national prices, but not the prices themselves. If sufficient objections are made, so that the "objection percentage" for Commissioners or Providers, or if prescribed the "share of supply percentage" for Providers, is met, Monitor has to:

- Reconsider the proposed method and then publish a revised final draft of the national tariff for further consultation; or
- Refer the proposed method and the objections received to the Competition and Markets Authority.

7.6 Until a new National Tariff is published, an existing unexpired tariff remains in force.

7.7 Following consultation in 2012, each of the three percentages described in paragraph 3.1 was prescribed at 51 per cent. The Department also announced that it intended to keep these percentages under review as the system bedded down.

7.8 No objection threshold was met when the first proposed National Tariff was consulted on, and this tariff was published. Monitor consulted on the second National Tariff for the financial year 2015 -16. The share of supply objection threshold was met and the proposed tariff was not published. Analysis of consultation responses demonstrated the following objection rates:

- 8.1% of Commissioners by number;
- 36 % of Providers by number (134 of 361 Providers); and
- 73.7% of Providers by share of supply.

7.9 The Department has been informed by Monitor and NHS England that the threshold was exceeded due to objections on the efficiency factor of 3.8%. The Department understands that Monitor and NHS England also believe that another significant trigger for formal objections related to a variation to the payment of national prices for specialised services, rather than the underlying method for the price (to which statutory objections are made).

7.10 A new National Tariff was not published and so the existing unexpired 2014-15 National Tariff remained in force. NHS England calculated the cost pressures of Commissioners and Providers continuing to operate on pay at 2014-15 tariff levels rather than those that would have been introduced through the 2015-16 National Tariff proposals at an estimated £1 billion. Following the offer to Providers described in

paragraph 7.11, the Department understands that the final cost to commissioners is estimated to be in the region of £0.5 billion.

7.11 In February 2015, Monitor and NHS England offered Providers the option of agreeing local variations to the 2014-15 tariff (the Enhanced Tariff Option or ETO) or remaining on the 2014-15 tariff prices (Default Tariff Rollover or DTR). The ETO offered Providers a reduction in efficiency savings from the originally proposed 3.8% to 3.5%, an increase in the proposed marginal rate for specialised services from 50% to 70% and an increase in the marginal rate for emergency admissions from 30% to 70%. Providers opting for ETO have the opportunity to earn "CQUIN" (Commissioning for Quality and Innovation Programme) payments, which are worth 2.5% of contract income. As Providers on the DTR would not be contributing proportionately to the shared NHS wide 2015-16 efficiency goals through the efficiency factor, Providers would not be eligible for discretionary payments, including CQUIN. 88 % of Providers accepted the ETO by 4 March 2015.

7.12 NHS England have indicated that if a similar system were to continue in 2016-17, there would be a negative impact on planned investment which would have serious implications for the health service as a whole.

7.13 Commissioners and Providers need timely and accurate price information to allow them to plan, consult and make decisions on services that meet their identified need in advance of the new financial year. This is particularly relevant as prices in a new National Tariff apply to services delivered in the future under existing contracts.

7.14 The Department has considered what options for change would be proportionate. A consultation invited views on proposals for amending the objection mechanism. This instrument makes changes in the light of that consultation.

7.15 This instrument is not intended to have any retrospective effect.

Share of supply objection threshold

7.16 The Department has considered whether it would be appropriate to raise the share of supply threshold, or revise the method for determining the share of supply. The Department decided not to revise the method because there were no benefits in making this more complex. Increasing the threshold from the current 51% was also discounted because sourcing accurate and reliable data to use in the calculation of a provider's share of supply has proved to be difficult. The current calculation of share of supply also gives weight to a proportion of providers supplying a large share of the healthcare market to the disadvantage of smaller, more rural and local care providers. Therefore, the Department has decided that revising the share of supply threshold or the method would not sufficiently rebalance the system.

7.17 The Department considers that a fairer balance will be maintained in the system as a whole if larger Providers have the opportunity to object to proposals as part of the overall Provider response, rather than as a separate voice. They will continue to form an important part of the stakeholder engagement by Monitor and NHS England as part of the tariff development process. In addition, the Impact Assessment which Monitor is required to prepare for a National Tariff will have to consider and report on the differential impacts of tariff proposals, including any impact on larger Providers.

7.18 This instrument therefore removes the prescribed share of supply threshold.

Objection thresholds for Providers and Commissioners

7.19 In 2013, the Department prescribed the thresholds at 51% for Providers and Commissioners. The Department's intention was that the thresholds should be high enough to prevent any unnecessary delay to the tariff caused by objections that were not sufficiently representative, but low enough to highlight systematic issues with the method.

7.20 The Department now considers that the objection percentage for Providers and Commissioners should be higher, but remain equal in the interest of fairness. This retains the ability of Commissioners and Providers to object to the proposed method during the statutory consultation, while requiring levels of objection to be more significant to prevent Monitor publishing the National Tariff.

7.21 This instrument therefore increases the objection percentage for Providers and Commissioners to 66 per cent.

8. Consultation outcome

8.1 From 13 August 2015 to 11 September 2015 the Department consulted on options for revising the objections mechanism to the pricing method. The Department received 221 responses. The largest numbers of responses came from Providers (123 out of 221) and Commissioners (67 out of 221). There were responses from Monitor, NHS England, 16 representative and other organisations, and 13 individuals or unidentified. The Government's response[4] can be found on the Department's website.

8.2 The consultation ran for 4 weeks only in order to allow resolution of the policy issue before statutory consultation starts on proposals for the 2016-17 National Tariff. The number of responses received was significantly higher than the 48 responses received to the previous consultation in 2012.

8.3 Overall there was general disagreement to the Department's proposals, where respondents stated that the current system had not been long enough to enable proper evaluation and assessment. Also, that the objection process worked as it was intended: 2015-16 represented exceptional financial circumstances and the decision to object was not taken lightly. There were calls for a wider review of the tariff development process with suggestions for a multi-year tariff and definition of relevant provider.

8.4 52% of responses overall disagreed that the objection mechanism for the NHS national tariff should be revised to provide greater certainty on prices in advance of a new financial year. However, 46% of respondents agreed with this proposal which included Monitor, NHS England, and 65 Commissioners.

8.5 65% of responses overall disagreed that the objection threshold based on providers' share of supply should be removed. However, 34% of respondents agreed with this proposal, which included Monitor, NHS England, and 57 Commissioners.

8.6 82% of responses disagreed that the objection threshold for Providers and Commissioners should be raised. However, 15% of respondents agreed with this proposal, which included NHS England, and 22 Commissioners.

8.7 The Department considered all responses to the consultation, including any suggestions on alternative ways to address the issue, such as requesting two thresholds to be met rather than one. Following consultation with NHS England and Monitor, the

[4] www.gov.uk/government/consultations/objections-to-how-prices-for-nhs-services-are-calculated

Department decided that the need to improve financial stability requires the implementation of measures that many respondents opposed. While additional steps may be taken to address concerns raised by respondents, the share of supply threshold should now be removed and the objection percentage for Providers and Commissioners raised to 66 per cent equally in the interest of fairness. Providers and Commissioners have been notified by email of the Government's consultation response, published on 29 October 2015.

9. Guidance

9.1 The Government does not intend to issue guidance on these regulations. The Providers and Commissioners whose interests are affected by the regulations have received substantial advance information. Monitor will issue guidance on various aspects of the objections process at the time of statutory consultation on its proposals for the National Tariff.

10. Impact

10.1 The impact on business, charities or voluntary bodies is negligible or zero. The Department anticipates no direct costs or benefits to business with regard to changes in the objection thresholds. No direct costs or benefits were identified by the small number of independent sector providers responding to the consultation. Increased certainty in pricing will inform future decisions on investment by independent sector providers. The indirect impact of the amended objection thresholds is difficult to measure, as it will depend on the detail of each future proposed tariff and the response to it from Commissioners and Providers (including where relevant, businesses, charities or voluntary bodies).

10.2 There is no change to the impact on the public sector to that stated in the 2012 Act Impact Assessment, number 6031[5].

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses if they are a Provider.

11.2 To minimise the impact of the requirements on small businesses (employing up to 50 people) no specific measures are necessary.

11.3 The basis for the final decision on what action to take to assist small business is that the exercise of an objection by any Provider is a simple matter. The legislation has no direct costs for small business.

12. Monitoring & review

12.1 The Department will keep Monitor's performance under review through quarterly financial and accountability meetings. These meetings will continue to cover performance of its pricing functions. The Department also intends to keep the objection thresholds under review.

[5] www.gov.uk/government/publications/health-and-social-care-bill-2011-combined-impact-assessments

13. Contact

13.1 Tony Meredith at the Department of Health Tel: 020 7210 4873 or email: Tony.Meredith@dh.gsi.gov.uk can answer any queries regarding the instrument.