EXPLANATORY MEMORANDUM TO

THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (MISCELLANEOUS AMENDMENTS) REGULATIONS

2018 No. 1322

1. Introduction

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

2. Purpose of the instrument

2.1 The purpose of this Statutory Instrument is to allow the National Institute for Health and Care Excellence (NICE) to:

- charge industry for the cost of making technology appraisal ("TA") recommendations and highly specialised technology ("HST") recommendations; and
- recruit to the Appeal Panel, established to hear appeals against TA and HST recommendations, members who are engaged in the provision of health care in the health services across the UK rather than being limited to the health service in England as currently provided for.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 ("the 2013 Regulations") provide currently that NICE may impose charges for or in connection with carrying out its functions but not in relation to TA or HST

recommendations made by NICE. This instrument will enable charges to be imposed in respect of the making of such recommendations.

6.2 The 2013 Regulations also require that the NICE Appeal Panel must include member(s) who are engaged in the provision of health care in the health services. "Health services" is defined in the Health and Social Care Act 2012 with reference to the NHS in England. This means that currently, NICE can only recruit Appeal Panel members fulfilling this role who work in the NHS in England. This instrument will enable NICE to recruit such members working in the health services anywhere in the UK.

7. Policy background

What is being done and why?

Charges

7.1 NICE's technology appraisal and highly specialised technology programmes, together with the associated requirement for NHS commissioners and local authorities as appropriate to fund NICE's recommended treatments, play a vital role in ensuring access for NHS patients to new and cost-effective treatments. As such, it is important that NICE's technology appraisal and highly specialised technology programmes operate in a sustainable and efficient way and in a way that allows it to be more responsive to developments in the life sciences sector.

7.2 The Triennial Review of NICE, published in 2015, recognised this and recommended that consideration should be given to the introduction of charges for technology appraisal and highly specialised technology recommendations as one of a set of possible measures to enable NICE to operate more efficiently.

7.3 In parallel, in recent years, there has been an increase in demand for NICE's technology appraisal and highly specialised technology guidance, at the same time as its taxpayers' funded budget, like that of other public bodies, is decreasing. In 2013/14, NICE received £66.4m from Government funding; in 2018/19 this has been reduced to £51.2 m.

7.4 Following NICE's engagement with industry in 2016, DHSC carried out a public consultation in 2018 in which three options were considered:

Option 1 – Do nothing: NICE's technology appraisal and highly specialised technology programmes would continue to be funded by Government. Given the requirement for NICE to reduce its reliance on grant-in-aid funding, NICE's technology appraisal or highly specialised technology programmes, or its other work, would have to be stopped or scaled back.

Option 2 – transfer the cost of making a technology appraisal or highly specialised technology recommendation to the private life sciences sector: amend the Regulations to allow NICE to impose an upfront charge on an individual life science company calculated to recover the full cost of making the recommendation for their product.

Option 3 – as per Option 2 but with more flexibility for small companies: amend the Regulations as for Option 2 but allow NICE to impose a charge on a small company (defined in accordance with the conditions specified in section 382 of the Companies Act 2006) calculated on an appropriate commercial basis (i.e. at a reduced rate) and to

agree that a small company may pay in instalments. A 25% discount was proposed in the consultation document to be funded by grant-in-aid from Government.

7.5 Taking into account consultation responses (summarised in section 10), DHSC and NICE have decided to proceed with Option 3 but to provide a larger discount for small companies. This will be by funding 75% of the cost of making TA and HST recommendations rather than 25% as proposed in the consultation document. The intention is to minimise barriers to the uptake of small companies' products. This instrument will also enable the Secretary of State to direct NICE in specific cases to calculate the charge on the basis NICE considers to be the appropriate commercial basis. This would enable NICE to flex its charging model in specific cases should this be required in the future.

7.6 Charging will provide a more sustainable model that enables NICE to continue to flex its capacity in response to the pipeline of technologies that require assessment by NICE, to adapt its methods and processes to different types of technology, and to be more responsive to developments in the life sciences sector.

7.7 Charging will also enable NICE to continue the full breadth of its important work, while at the same time reducing its reliance on central Government funding.

Appeal panel membership

7.8 The 2013 Regulations are also being amended to enable NICE to recruit to its Appeal Panel, established to hear appeals against TA and HST recommendations, members who are engaged in the provision of health care in the health services across the United Kingdom rather than being limited to the health service in England as the law currently prescribes.

7.9 The role of an Appeal Panel member is very specialised and it is important that NICE is able to recruit from a wide enough pool of people to ensure that it is able to appoint members of a high calibre to ensure sufficient challenge to its decision making processes. This change would also be more consistent with membership of other NICE committees, such as the committees responsible for developing TA and HST recommendations, to which NICE is able to appoint members from across the United Kingdom.

Regulations

7.10 These Regulations amend the 2013 Regulations to make the following provisions:

- Enable NICE to charge companies up front for the full cost of making TA and HST recommendations about their products, with separate provisions allowing NICE to charge small companies at a discounted rate and allowing those companies to pay the charges in instalments;
- Enable the Secretary of State to direct NICE in other cases to charge companies on the basis that NICE considers to be the appropriate commercial basis;
- Require NICE to publish its policies and procedures for imposing charges in relation to its TA and HST recommendations, keep those policies and procedures under review, and to consult the Secretary of State and other interested parties on any changes;
- Require NICE to refund any charge where it is unable to proceed with a recommendation, less any costs incurred by that point;

- Require NICE to pay monies received from charging to Secretary of State, except where the Secretary of State directs otherwise. In practice, Ministers intend to direct NICE to retain the monies it receives from charging; and
- Enable NICE to recruit Appeal Panel members who are engaged in the provision of health care from anywhere in the UK health services.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal of the United Kingdom from the European Union so as to trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 As this is the first time the 2013 Regulations have been amended, consolidation is not appropriate.

10. Consultation outcome

10.1 DHSC carried out a public consultation on proposed amendments to the 2013 Regulations that ran from 10 August to 14 September 2018. There were 78 responses to the consultation, of which 41 respondents represented views from the life sciences industry, including pharmaceutical companies, industry representatives, consultancies and Medtech companies. The next largest group of responses came from patient groups (12, 15%) with other responses from NHS organisations and individuals.

10.2 The majority of respondents (62%, 48/78) disagreed with the main proposal that NICE may charge companies for making TA and HST recommendations. However, an analysis of key themes from the responses shows that just over half (51%) of respondents agreed that life sciences companies should contribute to the cost of developing NICE recommendations. Respondents supported (59%, 24/41) a mechanism for reducing the impact on small companies, but felt that the proposed 25% discount did not go far enough and that a more complex system than a discounted cost would be more appropriate.

10.3 The majority (85%, 66/78) agreed that it was appropriate to extend the pool of potential NICE appeal panel members engaged in the provision of health care in the health services across the UK rather than limit it to England.

10.4 The Government has considered the consultation responses with NICE and has decided to increase the level of discount that will be offered to small companies to 75%. In addition, the Government has included a new provision in the amending Regulations to enable the Secretary of State to direct NICE in other circumstances to charge companies on the basis that it considers to be the appropriate commercial basis to provide more flexibility for reduced charges should this be required in future.

10.5 The Government is also proceeding with the proposals related to appeal panel membership.

10.6 A more detailed analysis of the consultation will be available on Gov.uk on Wednesday 12 December.

11. Guidance

11.1 The 2013 Regulations as amended by these Regulations will require NICE to publish its policies and procedures relating to the imposition and payment of charges.

12. Impact

12.1 The impact on business is a cost of approximately £10m per year to the global life sciences industry, taking into account the discount for small companies. There is not expected to be any impact on charities or voluntary bodies.

12.2 The costs and benefits associated with the changes to the membership of Appeals Panels are not monetisable and are likely to be small.

12.3 Improved patient health is expected to lead to wider economic benefits, for example through increased productivity and reduced need for informal and formal care, valued at £220m over the period.

12.4 The impact on the public sector is a commensurate saving of approximately £9.3m per year.

12.5 An Impact Assessment is submitted with this memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses (as defined by the Companies Act 2006), the approach taken will be to provide a subsidy of 75% to small companies (in effect by funding 75% of the cost of appraisals for small companies from NICE's government funds) and to allow small companies to pay by instalments.

14. Monitoring & review

14.1 The 2013 Regulations as amended by these Regulations will require NICE to keep the policies and procedures relating to the imposition and payment of charges under review and to consult the Secretary of State and other interested parties on any changes.

15. Contact

15.1 Jane Newton at the Department of Health and Social Care Telephone: [Direct line 0113 2545605] or email: jane.newton@dhsc.gov.uk can be contacted with any queries regarding the instrument

15.2 Carly McGurry, Deputy Director for Medicines Regulation and Pricing at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Parliamentary Under Secretary of State for Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.