EXPLANATORY MEMORANDUM TO

THE NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (AMENDMENT) REGULATIONS 2026

2026 No. 202

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Secondary Legislation Scrutiny Committee.

2. Declaration

2.1 Dr Zubir Ahmed MP, Parliamentary Under-Secretary of State for Health Innovation and Safety, confirms that this Explanatory Memorandum meets the required standard.

2.2 Victoria Dare, Deputy Director for Medicines Regulation and Prescribing, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 David Wright at the Department of Health and Social Care can be contacted at mbnicesponsorteam@dhsc.gov.uk with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 These Regulations amend the National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Information Functions) Regulations 2013 to introduce a limited power for the Secretary of State to direct National Institute for Health and Care Excellence (NICE) on the applicable cost-effectiveness threshold for technology appraisals and highly specialised technologies. The Regulations also remove the obligation on NICE to consult when procedural changes are required solely to give effect to such a direction. This places responsibility for setting the cost-effectiveness threshold used to determine value for money in NICE recommendations with ministers.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect is England.

5. Policy Context

What is being done and why?

5.1 NICE technology appraisals and highly specialised technology appraisals are able to make recommendations on whether health technologies should be routinely funded by the NHS in England based on an assessment of clinical and cost effectiveness. Any health technology, including pharmaceuticals and medical devices, may be evaluated through a technology appraisal or highly specialised technology appraisal. Topics for evaluation through either process are formally referred to NICE by Department of Health and Social Care Ministers. The current policy is that all new licensed medicines and significant licence extensions for existing medicines are referred to NICE for evaluation. Most new medicines are evaluated through the technology appraisals programme. The highly specialised technology appraisal programme is reserved for a small number of medicines for very rare, very severe diseases that are not considered suitable for a standard technology appraisal. Other non-medicinal health technologies are selected for the technology appraisals programme through a prioritisation process that is overseen by NICE.

5.2 NICE uses a cost-effectiveness threshold when evaluating health technologies. The threshold represents the amount that the Government is willing to pay for a treatment taking into account its costs and benefits and plays a central role in determining whether technologies are recommended for use in the NHS. The cost-effectiveness threshold for NICE's highly specialised technology appraisal programme is much higher than for NICE's technology appraisals programme allowing treatments for very rare, very severe diseases to be recommended at higher prices. The Government's policy objective is to ensure transparency, accountability and ministerial oversight in how NICE's cost-effectiveness thresholds are set, given their direct impact on NHS affordability and patient access. Introducing a power of direction ensures thresholds remain aligned with wider health system priorities and public spending decisions. The introduction of the power at this time will enable the implementation of commitments that the Government has made in the UK-US trade deal concerning pharmaceuticals.

What was the previous policy, how is this different?

5.3 Previously, thresholds were determined independently by NICE. The Government and NICE consider that the cost-effectiveness threshold that NICE uses in its evaluations should take into account a range of factors, such as industrial policy objectives, economic growth and investment, which are properly matters for the elected government. Under the new policy, the Secretary of State may issue directions specifying the threshold (whether as a single figure or a range). This introduces a formal mechanism for oversight and alignment with fiscal and strategic priorities across the health system.

6. Legislative and Legal Context

How has the law changed?

6.1 The Regulations amend Regulations 7 and 8 of the 2013 Regulations (SI 2013/259). The amendments insert new powers allowing the Secretary of State to direct NICE regarding thresholds. It also removes the requirement for NICE to consult on changes to its procedures where they are necessary to implement or give effect to a direction given under this new power. The amendments are made under sections 237 and 304 of the Health and Social Care Act 2012.

Why was this approach taken to change the law?

6.2 This legislative approach was chosen because it provides the most proportionate and efficient way to introduce a limited power of direction that clearly defines the scope of Ministers' powers whilst retaining NICE's independence and responsibilities. Non-regulatory options such as the NICE cost-effectiveness threshold being set by the NICE board were deemed insufficient to ensure the Secretary of State is accountable for decisions which impact on delivery of wider government objectives. It is, in the Government's view, for the elected Government to determine how best to achieve the appropriate balance between affordability, patient access to medicines, and a flourishing economy, while preserving the independence of NICE in making decisions on the other methods it uses in health technology appraisals and on individual products within the framework set out by Ministers.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Government carried out a public consultation on the proposed changes to the NICE regulations from 9 December 2025 to 13 January 2026. The Government considered that a 5 week consultation was appropriate taking account of the limited scope of the proposed changes and the engagement that had taken place with NICE and the pharmaceutical industry prior to the public consultation. NICE agreed that the cost-effectiveness threshold that is used in its evaluations is properly a matter for the elected Government.

7.2 There were 203 responses to the consultation from a broad range of interested parties, including the pharmaceutical industry, patient groups, NHS bodies, academics and members of the public. Overall, the consultation responses were polarised with academics, patient groups and members of the public generally objecting to Ministers having a power to direct NICE with respect to the cost-effectiveness threshold citing concerns about political interference in NICE and its processes, and potential threats to NICE's independence.

7.3 Responses from the life sciences industry tended to be in favour of an increase to the threshold but generally considered that the scope of the power should be broader and not limited to the cost-effectiveness threshold. Across the board, there was considerable opposition to the proposed removal of the NICE consultation requirement on changes where these result from a Ministerial direction. Although there was opposition to some of the proposals, the Government does not consider that any of the concerns raised should materially change the proposals that were consulted and is proceeding with implementation of the changes as set out in the consultation document[1]. The Government response to the consultation can be found here[2].

8. Applicable Guidance

8.1 No additional statutory guidance is required as a result of these Regulations.

[1] https://www.gov.uk/government/consultations/changes-to-nice-regulations-cost-effectiveness-threshold/changes-to-nice-regulations-cost-effectiveness-threshold-consultation-document

[2] https://www.gov.uk/government/consultations/changes-to-nice-regulations-cost-effectiveness-threshold

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website. The impact of the regulations would depend on the specific exercise of the power.

Impact on businesses, charities and voluntary bodies

9.2 There is no significant impact on businesses, charities or voluntary organisations because the Regulations concern internal governance and do not impose regulatory requirements on external bodies. Any impacts will be associated with Ministers' exercise of the power of direction not by the change to the regulations itself.

9.3 The Regulations impact small or micro-businesses. Any impacts will be associated with Ministers' exercise of the power of direction not by the change to the regulations itself.

9.4 There is no significant impact on the public sector beyond NICE and the Department of Health and Social Care, as the changes concern ministerial direction-setting only.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is that the Department will monitor the operation of the power of direction through regular engagement with NICE and keep its use under review as part of standard sponsorship arrangements.

10.2 The instrument does not include a statutory review clause and is in line with the requirements of the Small Business, Enterprise and Employment Act 2015.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 Introducing this new power to direct NICE as to the cost effectiveness threshold to be applied reflects the long-standing view of Ministers and NICE that the cost-effectiveness threshold should be set by Ministers. The change to the legislation has been brought forward to enable the Government to implement the uplift to the NICE cost-effectiveness threshold that has been agreed as part of the US-UK Economic Prosperity Deal for pharmaceuticals. Parliament was informed of the agreement of the deal in a Written Ministerial Statement by the Secretary of State for Department for Business and Trade on 2 December 2025[3]. The use of the new power to increase the threshold as indicated in the statement will be subject to further Ministerial decision after the power has come into force.

12. European Convention on Human Rights

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

[3] Full statement available at https://commonsbusiness.parliament.uk/Document/99831/Pdf?subType=Standard

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020, or the Retained EU Law (Revocation and Reform) Act 2023.