STATUTORY INSTRUMENTS

2026 No. 202

HEALTH AND SOCIAL CARE, ENGLAND AND WALES

The National Institute for Health and Care Excellence (Amendment) Regulations 2026

Made - - - -	*2nd March 2026*
Laid before Parliament	*3rd March 2026*
Coming into force - -	*24th March 2026*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 237(1) and (2) and 304(9) and (10) of the Health and Social Care Act 2012(**a**).

Citation, commencement and extent

1.—(1) These Regulations may be cited as the National Institute for Health and Care Excellence (Amendment) Regulations 2026 and comes into force on 24th March 2026.

(2) These Regulations extend to England and Wales.

Amendment of the National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Information Functions) Regulations 2013

2. The National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Information Functions) Regulations 2013(**b**) are amended as follows.

Amendment to regulation 7

3.—(1) Regulation 7 (NICE technology appraisal recommendations) is amended as follows.

(2) After paragraph (1) insert—

> "(1A) The Secretary of State may direct NICE as to the applicable cost-effectiveness threshold to apply to a health technology undergoing appraisal.".

(3) In paragraph (9) before "NICE must" insert "Subject to paragraph (9A),".

(4) After paragraph (9) insert—

> "(9A) The obligation to consult does not apply to a change to procedures that are necessary to give effect to a direction given by the Secretary of State made under paragraph (1A).".

(**a**) 2012 c. 7. Sections 237(1) and (2) were amended by the Health and Care Act 2022 (c. 31) section 1 and Schedule 1 paragraph 1. There are no relevant amendments to section 304.
(**b**) S.I. 2013/259. The relevant amending instruments are S.I. 2022/634 and 2023/98.

(5) After paragraph (14) insert—

"(15) In this regulation and regulation 8—

"cost-effectiveness threshold" means the value, whether expressed as a single figure or a range, against which NICE evaluates the cost-effectiveness or value for money of a health technology or highly specialised health technology.".

Amendment to regulation 8

4.—(1) Regulation 8 (NICE highly specialised technology recommendations) is amended as follows.

(2) After paragraph (1) insert—

"(1A) The Secretary of State may direct NICE as to the applicable cost-effectiveness threshold to apply to a highly specialised health technology undergoing appraisal.".

(3) In paragraph (8) before "NICE must" insert "Subject to paragraph (8A),".

(4) After paragraph (8) insert—

"(8A) The obligation to consult does not apply to a change to procedures necessary to give effect to a direction given by the Secretary of State made under paragraph (1A).".

Signed by the authority of the Secretary of State for Health and Social Care.

Zubir Ahmed
Parliamentary Under Secretary of State
Department of Health and Social Care

2nd March 2026

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Functions) Regulations 2013 (S.I. 2013/259) ("2013 Regulations"). The purpose of these amendments is to introduce a power for the Secretary of State to direct the National Institute of Health and Care Excellence ("NICE") with regard to the cost-effectiveness threshold NICE is to apply to health technologies when carrying out technology appraisals under regulation 7 of the 2013 Regulations or appraising highly specialised health technologies under regulation 8 of the 2013 Regulations.

Regulation 3 amends regulation 7 of the 2013 Regulations to introduce a power of direction to specify the cost-effectiveness threshold NICE must apply to technology appraisals it carries out. Regulations 3(3) and (4) introduce amendments that relieve NICE of its obligation to consult under regulation 7(9) of the 2013 Regulations where relevant changes to procedures are necessary to give effect to a direction concerning the cost-effectiveness threshold.

Regulation 4 amends regulation 8 of the 2013 Regulations to introduce a power of direction to specify the cost-effectiveness threshold NICE must apply to highly specialised health technology appraisals it carries out. Regulations 4(3) and (4) introduce amendments that relieve NICE of its obligation to consult under regulation 8(8) of the 2013 Regulations where the relevant changes to procedures are necessary to give effect to a direction concerning the cost-effectiveness threshold.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU and is available on the www.legislation.gov.uk website.

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ISBN 978-0-34-828020-3

£6.40

http://www.legislation.gov.uk/id/uksi/2026/202