STATUTORY INSTRUMENTS

2025 No. 667

NATIONAL HEALTH SERVICE, ENGLAND AND WALES

NATIONAL HEALTH SERVICE, SCOTLAND

HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Branded Health Service Medicines (Costs) (Amendment) Regulations 2025

Made - - - -	*9th June 2025*
Laid before Parliament	*10th June 2025*
Coming into force - -	*1st July 2025*

The Secretary of State for Health and Social Care makes these Regulations in exercise of the powers conferred by sections 263(1)(b) and (c), (2) and (5), 264(1) and (3), 264A(2), (4) and (7), 266(1) and 272(7)(a) and (b) and (8) of the National Health Service Act 2006(**a**) having had regard to the matters specified in section 266(3), (4) and (4A) of that Act.

The Secretary of State has consulted in accordance with sections 263(1) and (1A), 264(1) and 264C(1) of that Act.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) Regulations 2025 and come into force on 1st July 2025.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

Amendments to the Branded Health Service Medicines (Costs) Regulation 2018

2. The Branded Health Service Medicines (Costs) Regulations 2018(**b**) are amended as follows.

Amendments to regulation 3

3.—(1) Regulation 3 (payment scheme) is amended as follows.

(**a**) 2006 c. 41. Section 263 was amended by the Health Service Medical Supplies (Costs) Act 2017 (c. 23) ("the 2017 Act"), sections 5 and 10(5). Section 264 was amended by the 2017 Act, section 10(6). Sections 264A and 264C were added by the 2017 Act, section 8. Section 266 was amended by the 2017 Act, sections 6(5) to (9) and 7(6). See section 275(1) of the National Health Service Act 2006 for definition of "regulations" that is relevant to the powers being exercised.

(**b**) S.I. 2018/345. Relevant amending instruments are S.I. 2018/1255, 2020/258, 2022/593, 2023/239, 2023/1307 and 2024/1277.

(2) In paragraph (1)—

(a) for "paragraphs (1AA), (4) and (5A)" substitute "paragraphs (1AA), (1AB), (4) and (5A)"; and

(b) for the table substitute the following table—

"Table

Applicable Period	**Newer presentation payment percentage**	**Older presentation payment percentage**
1st July 2025 to the end of 2025	23.4%	10.6%
1st January 2026 to the end of 2026	24.3%	11%
1st January 2027 to the end of 2027 and any subsequent calendar year	26.0%	10.9%".

(3) After paragraph (1AA) insert—

"(1AB) Where paragraph (1AC) applies, the newer presentation payment percentage referred to in paragraph (1) for the period beginning on 1st July 2025 and ending at the end of 2025 is 31.3% and not 23.4%.

(1AC) This paragraph applies in the case of the payments payable under paragraph (1) by a manufacturer or supplier in respect of supplies during the period beginning on 1st July 2025 and ending at the end of 2025, if, in respect of any of supply of an item of presentation that was a newer presentation of that manufacturer or supplier—

(a) a payment was payable under paragraph (1) in respect of a supply during the period beginning on 1st January 2025 and ending at the end of 30 June 2025; and

(b) the applicable payment percentage was 15.5%.".

Amendments to regulation 4

4. In regulation 4 (direction to make a payment)—

(a) in paragraph (2)(b) for "regulation 3(1) or (5A)" substitute "regulation 3(1), (1AA), (1AB) or (5A)"; and

(b) in paragraph (3)(c) for "regulation 3(1) or (5A)" substitute "regulation 3(1), (1AA), (1AB) or (5A)".

Amendment to regulation 23

5. In regulation 23 (audited information)—

(a) after paragraph (1B) insert—

"(1C) A manufacturer or supplier who provides a presentation report to the Secretary of State in accordance with Schedule 1 or Schedule 3 must, at the same time as providing an audited sales report, provide the Secretary of State with—

(a) a statement from the manufacturer or supplier that the most recently submitted presentation report has been subject to procedures agreed between the manufacturer or supplier and a qualified independent auditor in accordance with an applicable related services standard; and

(b) the relevant report of the qualified independent auditor produced in accordance with the applicable related services standard."; and

(b) in paragraph (2), omit "and" after the definition of "applicable auditing standards" and insert the following definition in the appropriate place—

""applicable related services standard" means any relevant International Standard on Related Services recognised by, or equivalent standard produced by, the Financial Reporting Council Limited(**a**); and".

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

Karin Smyth
Minister of State
9th June 2025 Department of Health and Social Care

(**a**) Registered Number 02486368. Information and standards can be obtained from the Financial Reporting Council Limited, 13th Floor 1 Harbour Exchange Square, London, E13 9GE or the website https://www.frc.org.uk .

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Branded Health Service Medicines (Costs) Regulations 2018 (S.I. 2018/345) (the "Statutory Scheme Regulations"). The Statutory Scheme Regulations, amongst other matters, make a scheme for the purpose of requiring specific manufacturers and suppliers of branded medicines for health service use to pay certain amounts to the Secretary of State. These amounts are calculated by reference to the net sales income or estimated net sales income from supplies of such medicines.

Regulation 3(2) makes provision to replace the payment percentages in the table in regulation 3(1) of the Statutory Scheme Regulations with new payment percentages of net sales income to be payable from the 1st July 2025 for each applicable period.

Regulation 3(3) inserts new paragraphs (1AB) and (1AC) into regulation 3 of the Statutory Scheme Regulations. These new provisions mean that a manufacturer or supplier who was required to make a payment on a supply of a medicine under regulation 3(1) at 15.5%, with respect to the period beginning with 1st January 2025 and ending at the end of 30th June 2025, will be subject to a newer presentation payment percentage of 31.3% on their supplies for the period beginning 1st July 2025 to the end of 2025. This is instead of the 23.4% as stated in the table in regulation 3(1), which would otherwise apply.

Regulation 4 makes consequential amendments to regulation 4 of the Statutory Scheme Regulations.

Regulation 5 inserts new paragraph (1C) and a new defined term into paragraph (2) of regulation 23 of the Statutory Scheme Regulations that alter the auditing arrangements for presentation reports. These changes allow manufacturers and suppliers to carry out an alternate assurance procedure, known as an agreed upon procedure, of their presentation reports in place of a full audit.

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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