

2022 No. 593

**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 2022**

<i>Made</i>	- - - -	<i>26th May 2022</i>
<i>Laid before Parliament</i>		<i>1st June 2022</i>
<i>Coming into force</i>		<i>1st July 2022</i>

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 263(1)(c), 264(3), 266(1) and (4A), and 272(7) and (8) of the National Health Service Act 2006(a).

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Branded Health Service Medicines (Costs) (Amendment) Regulations 2022 and come into force on 1st July 2022.

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

Amendment of the Branded Health Service Medicines (Costs) Regulations 2018

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

(2) In regulation 3 (payment scheme)—

(a) in paragraph (1), for the table substitute the following table—

(a) 2006 c. 41; section 263 was amended by the Health Service Medical Supplies (Costs) Act 2017 (c. 23) (“the 2017 Act”), section 5 and 10(5). Section 266 was amended by the 2017 Act, section 6(5) to (9) and 7(6). See section 275(1) of the National Health Service Act 2006 for the definition of “regulations” that are relevant to the powers being exercised.

(b) S.I. 2018/345; relevant amending instruments are S.I. 2018/1255 and S.I. 2020/258.

“Table

<i>Applicable Period</i>	<i>Payment Percentage</i>
1st July 2022 to the end of 2022	14.3%
2023 and any subsequent calendar year	24.4%”;

- (b) in paragraph (1B)—
- (i) for “1st April 2020 to the end of 2020” substitute “1st July 2022 to the end of 2022”;
 - (ii) for “5.0%” substitute “17.7%”, and
 - (iii) for “7.4%” substitute “14.3%”; and
- (c) in paragraph (1C)—
- (i) for “1st April 2020 to the end of 2020” substitute “1st July 2022 to the end of 2022”;
 - (ii) in sub-paragraph (a)—
 - (aa) for “1st January 2020” substitute “1st January 2022”, and
 - (bb) for “31st March 2020” substitute “30th June 2022”, and
 - (iii) in sub-paragraph (b), for “14.7%” substitute “10.9%”.

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

26th May 2022

Kamall
Parliamentary Under-Secretary of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to the whole of the United Kingdom, amend the Branded Health Service Medicines (Costs) Regulations 2018 (the “Statutory Scheme Regulations”). The Statutory Scheme Regulations, amongst other matters, make a scheme for the purposes of requiring specific manufacturers and suppliers of medicines for NHS use to pay amounts to the Secretary of State. These amounts are calculated by reference to their net sales income or estimated net sales income from supplies of such medicines.

Regulation 3(1) of the Statutory Scheme Regulations specifies the percentages of net sales income by which these payable amounts are to be calculated, and the periods in relation to which those percentages are to be applied. The new arrangements in place from 1st July 2022 increase these percentages: firstly, from 10.9% to 14.3% in the case of the percentage to be applied for the rest of 2022, in effect just to net sales income of new presentations of medicines; and secondly, to 24.4% in the case of the percentage to be applied to net sales income of all presentation from the start of 2023 (regulation 2(2)(a)).

Regulation 2(2)(b) and (c) make transitory provisions for manufacturers or suppliers who were required to make a payment in relation to a supply of a presentation of a medicine under regulation 3(1) of the Statutory Scheme Regulations at the former rate, 10.9%, during the period beginning with 1st January 2022 and ending at the end of 30th June 2022- in effect because the presentation was on the market at that time. The effect of these amendments is that manufacturers and suppliers who made payments under the Statutory Scheme Regulations in relation to such presentations will be subject to a higher payment percentage of 17.7% on their supplies of those presentations for the period beginning 1st July 2022 to the end of 2022, compared to the 14.3% payment percentage applied to presentations that are newly on the market on or after 1st July 2022. However, the net effect of both the higher percentage payment applied in respect of such supplies on and after 1st July 2022 and the lower payment percentage applied before that date is that, in a case where a presentation is available throughout the whole of 2022 and sales are constant, a payment percentage of 14.3% would apply in respect of the annual net sales income (or estimated net sales income) of that presentation in 2022.

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.

© Crown copyright 2022

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£4.90

<http://www.legislation.gov.uk/id/uksi/2022/593>

ISBN 978-0-34-823569-2



9 780348 235692