## 2017 No. 809 (C. 67)

# NATIONAL HEALTH SERVICE, ENGLAND AND WALES

### NATIONAL HEALTH SERVICE, SCOTLAND

## HEALTH AND PERSONAL SOCIAL SERVICES, NORTHERN IRELAND

The Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017

Made - - - - 31st July 2017

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 12(3) and (4)(b) of the Health Service Medical Supplies (Costs) Act 2017(a).

#### Citation

**1.** These Regulations may be cited as the Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.

#### **Appointed Day**

- 2. 7th August 2017 is the day appointed for the coming into force of the following provisions—
  - (a) section 1 (remuneration for persons providing special medicinal products: England);
  - (b) section 3 (voluntary schemes);
  - (c) section 4 (power to control prices);
  - (d) section 5 (statutory schemes);
  - (e) section 6 (enforcement);
  - (f) section 7 (control of maximum price of other medical supplies);
  - (g) section 8 (provision of information to Secretary of State and disclosure); and
  - (h) subsections (1) to (18) of section 10 (consequential amendments).

#### **Saving**

**3.** For the purposes of the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007(**b**) and the Health Service Branded Medicines (Control of Prices

<sup>(</sup>a) 2017 c.23.

<sup>(</sup>b) S.I. 2007/1320; as amended by S.I. 2008/1938 and 3258, 2013/325 and 2881 and 2015/233.

and Supply of Information) (No. 2) Regulations 2008(a), the repeal of subsection (2) of section 264 of the National Health Service Act 2006(b) by subsection (6) of section 10 of the Health Service Medical Supplies (Costs) Act 2017 does not have effect.

Signed by authority of the Secretary of State for Health.

O'Shaughnessy
Parliamentary Under-Secretary of State,
Department of Health

31st July 2017

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations commence provisions of the Health Service Medical Supplies (Costs) Act 2017 ("the 2017 Act"). Regulation 2 commences sections 1, 3, 4, 5, 6, 7, and 8 of the 2017 Act, and subsections (1) to (18) of section 10 of that Act.

Section 1 amends section 164 of the National Health Service Act 2006(c) ("the NHS Act 2006") and provides the Secretary of State with powers in relation to the remuneration for persons providing pharmaceutical services in England in respect of special medicinal products.

Section 3 amends section 261 of the NHS Act 2006, providing the Secretary of State with additional powers in relation to voluntary schemes to control the cost of health service medicines. Previously, the powers could only be exercised in relation to a voluntary scheme made for the purposes of limiting prices of health service medicines, or limiting the profits accrued in connection with the manufacture or supply of health service medicines. Going forward, the powers in section 261 could be exercised in relation to voluntary schemes which provide for payments to the Secretary of State to be calculated by reference to sales or estimated sales of any health service medicines. There are also new provisions relating to sanctions and departure from voluntary schemes.

Section 4 amends section 262(2) of the NHS Act 2006, providing the Secretary of State with the power to control the prices of health service medicines that are not covered by the voluntary scheme, where the manufacturer or supplier is a member of the scheme.

Section 5 amends section 263 of the NHS Act 2006, providing the Secretary of State with additional powers when making a statutory scheme to control the cost of health service medicines. The additional powers provide for payments to the Secretary of State to be calculated by reference to sales or estimated sales of health service medicines.

Section 6 amends section 265 and 266 of the NHS Act 2006, providing the Secretary of State with additional enforcement powers to control the cost of health service medicines.

Section 7 amends section 260 of the NHS Act 2006, relating to the control of prices of medical supplies other than health service medicines. It extends the territorial extent of section 260 to Scotland and Northern Ireland, and applies the enforcement provisions in section 265 to section 260. Section 7 also amends section 260 to require the Secretary of State to consult before controlling prices of medical supplies and for the first order made under section 260 to be subject to the affirmative procedure. Section 7 also omits paragraph 1 of Schedule 22 which made supplementary provisions in relation to section 260 from the NHS Act 2006.

Section 8 inserts new section 264A into the NHS Act 2006 and relates to the provision of information about health service products for specified purposes, and the disclosure of that information in specified circumstances.

<sup>(</sup>a) S.I. 2008/3258; as amended by S.I. 2012/1916, 2013/2881 and 2015/233.

<sup>(</sup>b) 2006 c.41.

<sup>(</sup>c) 2006 c.41.

Subsections (1) to (17) of section 10 makes consequential amendments to sections 260, 261, 263, 264, 265, 271, 272 and 278 of the NHS Act 2006. Subsection (18) of section 10 omits paragraphs 2 to 11 of Schedule 22 which contains supplementary provisions in relation to section 260.

Regulation 3 saves the effect of section 264(2) of the NHS Act 2006 for the purposes of the provision of information requirements under the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007 and the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008. Subsection (2) is otherwise repealed by the commencement of section 10(6) of the 2017 Act.

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