

LORDS AMENDMENTS TO THE
HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

[The page and line references are to HL Bill 81, the bill as first printed for the Lords]

Before Clause 1

1 Insert the following new Clause—

“Controlling costs of health service medicines

Remuneration for persons providing special medicinal products: England

In section 164 of the National Health Service Act 2006 (remuneration for persons providing pharmaceutical services), after subsection (8) insert—

- “(8A) Regulations may impose requirements in relation to remuneration in respect of special medicinal products.
- (8B) Such regulations may, for example, require determining authorities to ensure—
- (a) that remuneration is to be calculated by reference to the outcome of prescribed procedures, or
 - (b) that determinations do not provide for or permit remuneration to be paid in prescribed circumstances.
- (8C) Procedures prescribed by virtue of subsection (8B)(a) may include the person to whom remuneration is payable, a health service body or a determining authority—
- (a) carrying out inquiries to ensure that remuneration is reasonable, or
 - (b) estimating an amount of remuneration that is reasonable (whether or not the estimated amount corresponds exactly to expenses in respect of which remuneration is to be paid).
- (8D) Circumstances prescribed by virtue of subsection (8B)(b) may include circumstances in which special medicinal products are made available to persons who provide pharmaceutical services under this Part—
- (a) by a health service body, or

(b) under an arrangement for the supply of special medicinal products to which a health service body is a party.

(8E) In subsections (8A) to (8D) –
“health service body” has the meaning given by section 9(4);
“special medicinal product” means a product which is a special medicinal product for the purposes of regulation 167 of the Human Medicines Regulations 2012 (S.I. 2012/1916).”

2

Insert the following new Clause –

“Remuneration for persons providing special medicinal products: Wales

In section 88 of the National Health Service (Wales) Act 2006 (remuneration for persons providing pharmaceutical services), after subsection (8) insert –

“(8A) Regulations may impose requirements in relation to remuneration in respect of special medicinal products.

(8B) Such regulations may, for example, require determining authorities to ensure –

(a) that remuneration is to be calculated by reference to the outcome of prescribed procedures, or

(b) that determinations do not provide for or permit remuneration to be paid in prescribed circumstances.

(8C) Procedures prescribed by virtue of subsection (8B)(a) may include the person to whom remuneration is payable, a health service body or a determining authority –

(a) carrying out inquiries to ensure that remuneration is reasonable, or

(b) estimating an amount of remuneration that is reasonable (whether or not the estimated amount corresponds exactly to expenses in respect of which remuneration is to be paid).

(8D) Circumstances prescribed by virtue of subsection (8B)(b) may include circumstances in which special medicinal products are made available to persons who provide pharmaceutical services under this Part –

(a) by a health service body, or

(b) under an arrangement for the supply of special medicinal products to which a health service body is a party.

(8E) In subsections (8A) to (8D) –
“health service body” has the meaning given by section 7(4);
“special medicinal product” means a product which is a special medicinal product for the purposes of regulation 167 of the Human Medicines Regulations 2012 (S.I. 2012/1916).”

3 Insert the following new Clause –

“Duty to have regard to the life sciences sector and access to new medicines and treatments

In discharging, through the provisions established or amended by this Act, its responsibility to secure best value for the National Health Service in purchasing medicines and medical supplies, the Government must have full regard to the need to –

- (a) promote and support a growing life sciences sector within the United Kingdom economy; and
- (b) ensure that patients have rapid clinical access to new clinically effective and cost-effective medicines and treatments approved by the National Institute for Health and Care Excellence through their technology appraisal process.”

Clause 5

4 Page 3, line 25, at end insert –

“() Section 260 (control of maximum price of medical supplies, other than health service medicines) is amended in accordance with subsections (2) and (2A).”

5 Page 3, line 26, leave out from “In” to second “for” in line 27 and insert “subsection (1)”

6 Page 3, line 28, at end insert –

“(2A) After subsection (1) insert –

“(1A) Before making an order under subsection (1) the Secretary of State must consult any body which appears to the Secretary of State appropriate to represent persons who manufacture, distribute or supply medical supplies falling within subsection (1).”

7 Page 3, line 34, at end insert –

“() In section 272(6) (orders, regulations, rules and directions subject to affirmative procedure), after paragraph (a) insert –
“(aa) the first order under section 260.”

Clause 6

8 Page 5, line 24, at end insert “(including, in relation to profits, the costs incurred by the producer in connection with the manufacturing, distribution or supply of the products)”

9 Page 5, leave out lines 33 to 35 and insert –

“(5) Regulations under this section must require the Secretary of State to give a UK producer an information notice if information is required in respect of the costs incurred by the producer in connection with the manufacturing, distribution or supply of a particular UK health service product (other than costs which relate to any transaction between the producer and a UK producer for that product).

- (5A) An information notice is a notice stating –
- (a) the period in relation to or for which, or intervals at which, information is required to be provided,
 - (b) the form and manner in which information is required to be provided,
 - (c) the time at which or period within which information is required to be provided, and
 - (d) that a right of appeal is conferred by virtue of section 265(5A).

- (5B) Regulations under this section may require information which does not fall within subsection (5) to be provided –
- (a) in relation to or for a prescribed period or at prescribed intervals,
 - (b) in a prescribed form and manner, and
 - (c) at a prescribed time or within a prescribed period.”

10 Page 7, leave out line 9 and insert –

- “(l) such of the following as may be prescribed –
- (i) an NHS foundation trust;
 - (ii) any health service body within the meaning of section 9(4) (not falling within any of paragraphs (a) to (k) above).”

Clause 7

11 Page 9, line 18, at end insert –

- “(5A) The penalty may be –
- (a) a single penalty not exceeding £10,000, or
 - (b) a daily penalty not exceeding £100 for every day on which the contravention occurs or continues.”

12 Page 9, line 27, at end insert –

- “(7A) The Welsh Ministers may by regulations increase (or further increase) either of the sums mentioned in subsection (5A).”

13 Page 9, line 46, leave out from “any” to end of line 47 and insert “of the following persons –

- (a) a Local Health Board or other person appointed under section 88(3)(b) to exercise the functions of a determining authority under Part 7;
- (b) an NHS trust established under section 18;
- (c) any person who provides services to the Welsh Ministers or to any person falling within paragraph (a) or (b);
- (d) any body which appears to the Welsh Ministers appropriate to represent Part 4 providers or Part 7 providers (as defined by section 201A(8)).”

14 Page 10, line 7, leave out “or 201B”

Clause 8

15 Page 11, line 4, after second “section” insert “(other than enforcement decisions falling within subsection (5A))”

- 16 Page 11, line 4, at end insert –
“() After subsection (5) insert –
“(5A) Provision must be made by regulations for conferring on UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and this section if the enforcement decisions relate to information notices given by virtue of section 264A(5).”

- 17 Page 11, line 20, at end insert –
“(18) In section 203(6) of the National Health Service (Wales) Act 2006 (statutory instruments which are subject to affirmative procedure) after “section 25B(3)(c) or” insert “201A(7A) or”.

Clause 9

- 18 Page 11, line 24, after “Section” insert “(*Remuneration for persons providing special medicinal products: England*) and”
19 Page 11, line 24, after “Section” insert “(*Remuneration for persons providing special medicinal products: Wales*) and”
20 Page 11, line 24, after “7” insert “and 8(18)”

Clause 10

- 21 Page 11, line 29, leave out “Section 7 comes” and insert “Sections (*Remuneration for persons providing special medicinal products: Wales*) and 7 and 8(18) come”
22 Page 11, line 33, leave out “make”
23 Page 11, line 34, leave out paragraph (a) and insert –
“() appoint different days, or make different provision, for different purposes or areas, and”
24 Page 11, line 35, at beginning insert “make”

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