

Health Service Medical Supplies (Costs) Bill

EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by the Department of Health, are published separately as Bill 72 – EN.

EUROPEAN CONVENTION ON HUMAN RIGHTS

Secretary Jeremy Hunt has made the following statement under section 19(1)(a) of the Human Rights Act 1998:

In my view the provisions of the Health Service Medical Supplies (Costs) Bill are compatible with the Convention rights.

Health Service Medical Supplies (Costs) Bill

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Make provision in connection with controlling the cost of health service medicines and other medical supplies; to make provision in connection with the provision of pricing and other information by those manufacturing, distributing or supplying those medicines and supplies, and other related products, and the disclosure of that information; and for connected purposes.

BE IT ENACTED by the Queen’s most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

Controlling cost of health service medicines

1 Voluntary schemes

- (1) Section 261 of the National Health Service Act 2006 (voluntary schemes for controlling the cost of health service medicines) is amended as follows.
- (2) In subsection (1) — 5
- (a) for “and 263” substitute “, 263 and 264A”,
- (b) for “the purpose of” substitute “one or more of the following purposes”,
- (c) omit the “or” before paragraph (b), and
- (d) after paragraph (b) insert — 10
- “(c) providing for any manufacturer or supplier to whom the scheme relates to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of any health service medicines (whether on the basis of net prices, average selling prices or otherwise).”
- (3) In subsection (4) for “either” substitute “any”. 15
- (4) After subsection (8) insert — 20
- “(9) The Secretary of State may provide for any amount payable in accordance with a voluntary scheme by any manufacturer or supplier to whom the scheme applies to be paid to the Secretary of State within a specified period.

- (10) Neither of the following affects any liability of a manufacturer or supplier to pay amounts to the Secretary of State arising during a period when a health service medicine was covered by a voluntary scheme treated as applying to the person or the taking of any action in relation to any such liability – 5
- (a) the withdrawal of consent by the person to the scheme being treated as applying to the person;
 - (b) the giving of notice to the person under subsection (4)."
- 2 Power to control prices**
- For section 262(2) of the National Health Service Act 2006 (circumstances in which powers not exercisable) substitute – 10
- “(2) If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine.” 15
- 3 Statutory schemes**
- (1) Section 263 of the National Health Service Act 2006 (statutory schemes for controlling the cost of health service medicines) is amended as follows.
- (2) In subsection (1) – 20
- (a) for “the purpose of” substitute “one or more of the following purposes”,
 - (b) omit the “or” before paragraph (b), and
 - (c) after paragraph (b) insert – 25
 - “(c) providing for any manufacturer or supplier of any health service medicines to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of those medicines (whether on the basis of net prices, average selling prices or otherwise).”
- (3) After subsection (5) insert –
- “(5A) The scheme may provide for any amount payable in accordance with the scheme by any manufacturer or supplier to whom the scheme applies to be paid to the Secretary of State within a specified period.” 30
- (4) For subsection (7) substitute –
- “(7) If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine.” 35
- (5) After subsection (7) insert –
- “(8) Subsection (7) does not affect any liability of a person to pay amounts to the Secretary of State arising during a period when a health service medicine was covered by a statutory scheme applying to the person or the taking of any action in relation to any such liability.” 40

4 Enforcement

- (1) The National Health Service Act 2006 is amended as follows.
- (2) Section 265 (enforcement) is amended as follows.
- (3) In subsection (4) –
 - (a) after “261(8)(b)” insert “or (9)”, and 5
 - (b) after “section 263(4), (5)” insert “, (5A)”.
- (4) After subsection (8) insert –

“(8A) Subsection (8) does not apply to any action by the Secretary of State to recover as a debt any amount required to be paid to the Secretary of State by virtue of any of sections 261 to 263 or this section.” 10
- (5) Section 266 (controls: supplementary) is amended as follows.
- (6) In subsection (1) (Secretary of State’s powers exercisable by making regulations or giving directions) for “(8)” substitute “(9)”.
- (7) In subsection (3) after “section 263(1)” insert “(a) or (b)”.
- (8) In subsection (4) after “section 263(1)” insert “(a) and (b)”. 15
- (9) After subsection (4) insert –

“(4A) The power under section 263(1)(c) is exercisable only with a view to requiring payments to be made which would be reasonable in all the circumstances, bearing in mind in particular –

 - (a) the need for medicinal products to be available for the health service on reasonable terms, and 20
 - (b) the costs of research and development.”

*Controlling cost of other medical supplies***5 Control of maximum price of other medical supplies**

- (1) The National Health Service Act 2006 is amended as follows. 25
- (2) In section 260(1) (control of maximum price of medical supplies, other than health service medicines, required for the purposes of the Act) for “this Act” substitute “the health service”.
- (3) In section 265 (enforcement) –
 - (a) in subsection (1) for “regulations or directions under sections 261” substitute “orders, regulations or directions under sections 260”, 30
 - (b) in subsection (5) for “261” substitute “260”, and
 - (c) in subsection (8) for “261” substitute “260”.
- (4) In section 266(6) (interpretation) for “261” substitute “260”.
- (5) In section 278(3) (provisions which extend to Scotland and Northern Ireland) for “261” substitute “260”. 35
- (6) In Schedule 22 (which makes further provision in relation to section 260) omit paragraph 1 (which specifies provision which may be made by an order under section 260).

*Information about medical supplies etc***6 Provision and disclosure of information**

After section 264 of the National Health Service Act 2006 insert –

“264A Provision of information about health service products

- | | | |
|-----|--|----|
| (1) | Regulations may require any person who manufactures, distributes or supplies English health service products (an “English producer”) to – | 5 |
| | (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (2), and | |
| | (b) provide that information to the Secretary of State. | |
| (2) | The purpose is that of enabling or facilitating any of the following – | 10 |
| | (a) the determination of the payments to be made to any persons who provide primary medical services under Part 4; | |
| | (b) the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7; | |
| | (c) the consideration by the Secretary of State of whether – | 15 |
| | (i) adequate supplies of English health service products are available, and | |
| | (ii) the terms on which those products are available represent value for money. | |
| (3) | Regulations may require any English producer or person who manufactures, distributes or supplies other UK health service products (an “other UK producer”) to – | 20 |
| | (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (4), and | |
| | (b) provide that information to the Secretary of State. | 25 |
| (4) | The purpose is that of enabling or facilitating either of the following – | |
| | (a) the exercise by the Secretary of State of any powers under sections 260 to 265; | |
| | (b) the operation of a voluntary scheme. | |
| (5) | The information which the Secretary of State may require from an English producer or other UK producer by virtue of this section includes the following – | 30 |
| | (a) the price charged or paid by the producer for the English health service products or other UK health service products, as the case may require (“the products”); | 35 |
| | (b) the price charged or paid by the producer for delivery or other services in connection with the manufacturing, distribution or supply of the products; | |
| | (c) the discounts or rebates or other payments given or received by the producer in connection with the manufacturing, distribution or supply of the products; | 40 |
| | (d) the revenue or profits accrued to the producer in connection with the manufacturing, distribution or supply of the products; | |
| | (e) such information about medicinal products, other medical supplies or other related products as is necessary to verify | 45 |

- whether or not they are English health service products or other UK health service products.
- (6) Regulations under this section may require information to be provided in such form and manner, and at such time or within such period, as may be prescribed. 5
- (7) The provision of information by virtue of this section does not breach—
 (a) any obligation of confidence owed by the person providing it, or
 (b) any other restriction on the provision of information (however imposed). 10
- (8) “English health service products” means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) and any other medical supplies, or other related products, required for the purposes of that health service.
- (9) “Medical supplies” is to be read in accordance with section 260(5). 15
- (10) “Other UK health service products” means—
 (a) any medicinal products used to any extent for the purposes of—
 (i) the health service continued under section 1(1) of the National Health Service (Wales) Act 2006,
 (ii) the health service within the meaning of the National Health Service (Scotland) Act 1978, or
 (iii) health care provided by virtue of the Health and Social Care (Reform) Act (Northern Ireland) 2009, or
 (b) any other medical supplies, or other related products, required for the purposes of anything specified in sub-paragraphs (i) to (iii) of paragraph (a). 20
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264B Disclosure of information

- (1) Information provided by virtue of section 264A may be disclosed by the Secretary of State to any of the following persons—
 (a) the Board; 30
 (b) any Special Health Authority;
 (c) the Health and Social Care Information Centre;
 (d) any government department;
 (e) the Welsh Ministers;
 (f) the Scottish Ministers; 35
 (g) a Northern Ireland department;
 (h) any person who provides services to any person falling within any of paragraphs (a) to (g);
 (i) any prescribed body appearing to the Secretary of State to represent English producers or other UK producers; 40
 (j) any other prescribed person.
- (2) A person to whom any confidential or commercially sensitive information is disclosed under subsection (1) may not—
 (a) use the information for any purpose other than the purpose specified in relation to that person in subsection (3), or
 (b) disclose the information to another person. 45

- (3) For the purposes of subsection (2) –
- (a) in relation to a person falling within subsection (1)(a) to (c), the purpose is that of exercising functions connected with any of the matters specified in section 264A(2) or (4);
 - (b) in relation to a person falling within subsection (1)(d), the purpose is that of –
 - (i) exercising functions connected with any of the matters specified in section 264A(2) or (4), or
 - (ii) preventing, detecting or investigating any unlawful activities;
 - (c) in relation to a person falling within subsection (1)(e) to (g), the purpose is that of exercising functions connected with either of the matters specified in section 264A(4);
 - (d) in relation to a person falling within subsection (1)(h), the purpose is that of providing services in connection with any purpose specified in relation to the person for whom the services are provided in any of paragraphs (a) to (c) above;
 - (e) in relation to a person falling within subsection (1)(i) or (j), the purpose is any prescribed purpose connected with any of the matters specified in section 264A(2) or (4).

264C Sections 264A and 264B: supplementary

- (1) Before making regulations under section 264A or 264B the Secretary of State must consult any body which appears to the Secretary of State appropriate to represent English producers or other UK producers.
- (2) Nothing in section 264A or 264B requires information to be provided, or authorises information to be disclosed or used, in contravention of the Data Protection Act 1998.
- (3) Nothing in section 264A or 264B affects any duties, obligations or powers to require or authorise information to be provided, disclosed or used which exist apart from that section.”

Supplementary and final provisions

7 Consequential amendments

- (1) The National Health Service Act 2006 is amended as follows.
- (2) In section 260 (control of maximum price of medical supplies other than health service medicines) –
 - (a) omit subsections (2) to (4), and
 - (b) in subsection (5) omit –
 - (i) “and Schedule 22”, and
 - (ii) the definition of “undertaking” (and the “and” before it).
- (3) In section 261 (powers relating to voluntary schemes) omit subsection (7).
- (4) In section 263 (statutory schemes) –
 - (a) in subsection (2) for “(3)” substitute “(4)”, and
 - (b) omit subsection (3).
- (5) In section 264 (statutory schemes: supplementary) omit subsection (2).

- (6) Section 265 (enforcement) is amended in accordance with subsections (7) to (12).
- (7) In subsection (1) for “264” substitute “264A”.
- (8) In subsection (5) –
- (a) the words from “conferring” to the end become paragraph (a), and 5
 - (b) after paragraph (a) insert “, and
(b) conferring on English producers and other UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and this section.” 10
- (9) In subsection (7)(a) and (d) after “supplier” insert “, or other person who is an English producer or other UK producer,”.
- (10) In subsection (8) for “264” substitute “264A”.
- (11) For subsection (9) substitute –
- “(9) Before making any regulations under this section the Secretary of State must consult the industry body and any other body which appears to the Secretary of State appropriate to represent English producers or other UK producers.” 15
- (12) After subsection (10) insert –
- “(11) In this section “English producer” and “other UK producer” are to be read in accordance with section 264A.” 20
- (13) In section 271 (territorial limit of exercise of functions), in subsection (3)(i) omit “and Schedule 22”.
- (14) In section 272 (orders, regulations, rules and directions) omit subsection (9).
- (15) In section 278 (extent), in subsection (3), after “supplies” insert “, and this Part to the extent that it applies to those sections,”. 25
- (16) In Schedule 22 (provisions in relation to section 260) omit paragraphs 2 to 11.

8 Extent

This Act extends to England and Wales, Scotland and Northern Ireland.

9 Commencement

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- (1) Section 8, this section and section 10 come into force on the day on which this Act is passed.
- (2) The remaining provisions of this Act come into force on such day as the Secretary of State may by regulations appoint.
- (3) Regulations under this section may make – 35
- (a) different provision for different purposes, and
 - (b) transitional, transitory or saving provision.
- (4) Regulations under this section are to be made by statutory instrument.

10 Short title

This Act may be cited as the Health Service Medical Supplies (Costs) Act 2016.

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To make provision in connection with controlling the cost of health service medicines and other medical supplies; to make provision in connection with the provision of pricing and other information by those manufacturing, distributing or supplying those medicines and supplies, and other related products, and the disclosure of that information; and for connected purposes.

*Presented by Secretary Jeremy Hunt
supported by
The Prime Minister,
Mr Chancellor of the Exchequer,
Secretary Greg Clark,
Mr Philip Dunne and
Nicola Blackwood.*

*Ordered, by The House of Commons,
to be Printed, 15 September 2016.*

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