

Health Service Medical Supplies (Costs) Bill

EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by the Department of Health, are published separately as HL Bill 81 – EN.

EUROPEAN CONVENTION ON HUMAN RIGHTS

Lord Prior of Brampton 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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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.

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 of information to Secretary of State and disclosure**

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

“264A Provision of information about health service products

- | | | |
|-----|---|----|
| (1) | References in this section to a UK producer are to a person who manufactures, distributes or supplies any UK health service products. | 5 |
| (2) | Regulations may require any UK producer to – | |
| | (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (3), and | |
| | (b) provide that information to the Secretary of State,
(subject to subsection (7)). | 10 |
| (3) | The purpose is that of enabling or facilitating any of the following – | |
| | (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; | 15 |
| | (c) the consideration by the Secretary of State of whether – | |
| | (i) adequate supplies of English health service products are available, and | |
| | (ii) the terms on which those products are available represent value for money; | 20 |
| | (d) the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the National Health Service (Wales) Act 2006; | |
| | (e) the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of that Act; | 25 |
| | (f) the consideration by the Welsh Ministers of whether – | |
| | (i) adequate supplies of Welsh health service products are available, and | |
| | (ii) the terms on which those products are available represent value for money; | 30 |
| | (g) the determination of the payments to be made to any persons who provide primary medical services under section 2C(1) of the National Health Service (Scotland) Act 1978 (“the 1978 Act”); | 35 |
| | (h) the determination of the remuneration to be paid to any persons who provide pharmaceutical care services under section 2CA(1) of the 1978 Act; | |
| | (i) the consideration by the Scottish Ministers of whether – | |
| | (i) adequate supplies of Scottish health service products are available, and | 40 |
| | (ii) the terms on which those products are available represent value for money; | |
| | (j) the determination of the remuneration to be paid to any persons who provide primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social | 45 |

- Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14));
- (k) the consideration by a Northern Ireland department of whether—
- (i) adequate supplies of Northern Ireland health service products are available, and 5
 - (ii) the terms on which those products are available represent value for money;
- (l) the exercise by the Secretary of State of any powers under sections 260 to 264 and 265; 10
- (m) the operation of a voluntary scheme.
- (4) The information which the Secretary of State may require from a UK producer by virtue of this section includes the following—
- (a) the price charged or paid by the producer for UK health service products; 15
 - (b) the price charged or paid by the producer for delivery or other services in connection with the manufacturing, distribution or supply of UK health service products;
 - (c) the discounts or rebates or other payments given or received by the producer in connection with the manufacturing, distribution or supply of UK health service products; 20
 - (d) the revenue or profits accrued to the producer in connection with the manufacturing, distribution or supply of UK health service products;
 - (e) such information about medicinal products, other medical supplies or other related products as is necessary to verify whether they are UK health service products and, if so, which of the following they are— 25
 - (i) English health service products;
 - (ii) Welsh health service products; 30
 - (iii) Scottish health service products;
 - (iv) Northern Ireland health service products.
- (5) 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. 35
- (6) 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). 40
- (7) Regulations under this section may not do any of the following—
- (a) require any person who provides primary medical services under Part 4 of the National Health Service (Wales) Act 2006, or any person who provides pharmaceutical services under Part 7 of that Act, to record, keep or provide information relating to any Welsh health service products which are supplied by the person in providing the services in question; 45
 - (b) require any person who provides primary medical services under section 2C(1) of the 1978 Act, or any person who provides

- pharmaceutical care services under section 2CA(1) of that Act, to record, keep or provide information relating to any Scottish health service products which are supplied by the person in providing the services in question;
- (c) require any person who provides primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14)) to record, keep or provide information relating to Northern Ireland health service products which are supplied by the person in providing the services in question. 5
- (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. 10
- (9) “Medical supplies” is to be read in accordance with section 260(5). 15
- (10) “Northern Ireland health service products” means any medicinal products used to any extent for the purposes of health care provided by virtue of the Health and Social Care (Reform) Act (Northern Ireland) 2009 and any other medical supplies, or other related products, required for the purposes of health care provided by virtue of that Act. 20
- (11) “Scottish health service products” means any medicinal products used to any extent for the purposes of the health service within the meaning of the 1978 Act and any other medical supplies, or other related products, required for the purposes of that health service.
- (12) “UK health service products” means any English health service products, Welsh health service products, Scottish health service products or Northern Ireland health service products. 25
- (13) “Welsh health service products” means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006 and any other medical supplies, or other related products, required for the purposes of that health service. 30
- (14) Until the coming into force of the repeal of section 27 of the 1978 Act by schedule 3 to the Smoking, Health and Social Care (Scotland) Act 2005 the references in subsections (3)(h) and (7)(b) to pharmaceutical care services under section 2CA(1) of the 1978 Act are to be read as references to pharmaceutical services under section 27(1) of that Act. 35

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 – 40
- (a) the Board;
- (b) any Special Health Authority;
- (c) the Health and Social Care Information Centre;
- (d) any government department;
- (e) the Welsh Ministers; 45
- (f) the Scottish Ministers;
- (g) the Common Services Agency for the Scottish Health Service constituted under section 10 of the 1978 Act;

- (h) a Northern Ireland department;
 - (i) the Regional Business Services Organisation established under section 14 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;
 - (j) any person who provides services to any person falling within any of paragraphs (a) to (i); 5
 - (k) any prescribed body appearing to the Secretary of State to represent UK producers;
 - (l) any other prescribed person.
- (2) A person to whom any confidential or commercially sensitive information is disclosed under subsection (1) may not— 10
- (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 (subject to subsection (4)). 15
- (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(3)(a) to (c), (l) or (m);
 - (b) in relation to a person falling within subsection (1)(d), the purpose is that of— 20
 - (i) exercising functions connected with any of the matters specified in section 264A(3)(a) to (c), (l) or (m), or
 - (ii) preventing, detecting or investigating any unlawful activities; 25
 - (c) in relation to a person falling within subsection (1)(e), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(d) to (f), (l) or (m);
 - (d) in relation to a person falling within subsection (1)(f) or (g), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(g) to (i), (l) or (m); 30
 - (e) in relation to a person falling within subsection (1)(h) or (i), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(j) to (m);
 - (f) in relation to a person falling within subsection (1)(j), 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 (e) above; 35
 - (g) in relation to a person falling within subsection (1)(k) or (l), the purpose is any prescribed purpose connected with any of the matters specified in section 264A(3). 40
- (4) The Welsh Ministers may disclose any confidential or commercially sensitive information disclosed to them under subsection (1) to any of the following persons—
- (a) a Local Health Board or other person appointed under section 88(3)(b) of the National Health Service (Wales) Act 2006 to exercise the functions of a determining authority under Part 7 of that Act; 45
 - (b) a National Health Service trust established under section 18 of the National Health Service (Wales) Act 2006; 50

- (c) any person who provides services to the Welsh Ministers or to any person falling within paragraph (a) or (b).
- (5) A person to whom any confidential or commercially sensitive information is disclosed under subsection (4) may not—
- (a) use the information for any purpose other than the purpose of exercising functions connected with any of the matters specified in section 264A(3)(d) to (f), (l) or (m), or
 - (b) disclose the information to another person.
- 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 UK producers. 10
 - (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. 15
 - (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.”
- 7 Provision of information to Welsh Ministers and disclosure**
- After section 201 of the National Health Service (Wales) Act 2006 insert— 20
- “Provision of information about medical supplies etc*
- 201A Provision of information by persons providing primary medical services or pharmaceutical services**
- (1) Regulations may make provision requiring any Part 4 provider or Part 7 provider to— 25
 - (a) record and keep information, or information of a description, specified in the regulations, and
 - (b) provide that information to the Welsh Ministers.
 - (2) Information, or a description of information, may not be specified in the regulations by virtue of subsection (1) unless the Welsh Ministers consider that the information may be required for the purpose of enabling or facilitating any of the following— 30
 - (a) the determination of the payments to be made to any Part 4 providers;
 - (b) the determination of the remuneration to be paid to any Part 7 providers; 35
 - (c) the consideration by the Welsh Ministers of whether—
 - (i) adequate supplies of health service products are available, and
 - (ii) the terms on which those products are available represent value for money. 40
 - (3) The information which the Welsh Ministers may require from a Part 4 provider or Part 7 provider by virtue of this section includes the following—

- (a) the price charged or paid by the provider for health service products;
 - (b) the price paid by the provider for delivery or other services in connection with health service products;
 - (c) the discounts or rebates or other payments given or received by the provider in connection with the supply of health service products; 5
 - (d) the revenue or profits accrued to the provider in connection with the supply of health service products;
 - (e) such information about medicinal products, other medical supplies or other related products as is necessary to verify whether or not they are health service products. 10
- (4) 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. 15
- (5) Regulations under this section may provide for a person who contravenes any provision of the regulations to be liable to pay a penalty to the Welsh Ministers.
- (6) If regulations under this section make provision by virtue of subsection (5) they must include provision conferring on Part 4 providers and Part 7 providers a right of appeal against a decision of the Welsh Ministers to impose a penalty. 20
- (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). 25
- (8) In this section—
- “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; 30
 - “medical supplies” includes surgical, dental and optical materials and equipment (and for this purpose “equipment” includes any machinery, apparatus or appliance, whether fixed or not, and any vehicle); 35
 - “medicinal product” has the meaning given by section 130 of the Medicines Act 1968;
 - “Part 4 provider” means a person who provides primary medical services under Part 4; 40
 - “Part 7 provider” means a person who provides pharmaceutical services under Part 7.

201B Disclosure of information

- (1) Information provided by virtue of section 201A may be disclosed by the Welsh Ministers to any prescribed person or person of a prescribed description. 45

- (2) A person to whom any confidential or commercially sensitive information is disclosed under subsection (1) may not –
- (a) use the information for a purpose other than a purpose specified in section 201A(2), or
 - (b) disclose the information to another person. 5

201C Sections 201A and 201B: supplementary

- (1) Before making regulations under section 201A or 201B the Welsh Ministers must consult any body which appears to the Welsh Ministers appropriate to represent Part 4 providers or Part 7 providers.
- (2) Nothing in section 201A or 201B requires information to be provided, or authorises information to be disclosed or used, in contravention of the Data Protection Act 1998. 10
- (3) Nothing in section 201A or 201B affects any duties, obligations or powers to require or authorise information to be provided, disclosed or used which exist apart from that section.” 15

Supplementary and final provisions

8 Consequential amendments

- (1) Omit the following provisions of the National Health Service (Scotland) Act 1978 –
- (a) section 49 (control of maximum prices for medical supplies other than health service medicines), and 20
 - (b) Schedule 10 (additional provisions as to control of maximum prices for medical supplies other than health service medicines).
- (2) The National Health Service Act 2006 is amended as follows.
- (3) In section 260 (control of maximum price of medical supplies other than health service medicines) – 25
- (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). 30
- (4) In section 261 (powers relating to voluntary schemes) omit subsection (7).
- (5) In section 263 (statutory schemes) –
- (a) in subsection (2) for “(3)” substitute “(4)”, and
 - (b) omit subsection (3).
- (6) In section 264 (statutory schemes: supplementary) omit subsection (2). 35
- (7) Section 265 (enforcement) is amended in accordance with subsections (8) to (13).
- (8) In subsection (1) for “264” substitute “264A”.
- (9) In subsection (5) – 40
- (a) the words from “conferring” to the end become paragraph (a), and

- (b) after paragraph (a) insert “, and
 (b) conferring on UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and this section.”
- (10) In subsection (7)(a) and (d) after “supplier” insert “, or other person who is a UK producer,”. 5
- (11) In subsection (8) for “264” substitute “264A”.
- (12) 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 UK producers.” 10
- (13) After subsection (10) insert –
 “(11) In this section “UK producer” is to be read in accordance with section 264A.”
- (14) In section 271 (territorial limit of exercise of functions), in subsection (3)(i) omit “and Schedule 22”. 15
- (15) In section 272 (orders, regulations, rules and directions) omit subsection (9).
- (16) In section 278 (extent), in subsection (3), after “supplies” insert “, and this Part to the extent that it applies to those sections,”.
- (17) In Schedule 22 (provisions in relation to section 260) omit paragraphs 2 to 11. 20

9 Extent

- (1) Subject as follows, this Act extends to England and Wales, Scotland and Northern Ireland.
- (2) Section 7 extends to England and Wales only.
- (3) Section 8(1) extends to Scotland only. 25

10 Commencement

- (1) Section 9, this section and section 11 come into force on the day on which this Act is passed.
- (2) Section 7 comes into force on such day as the Welsh Ministers may by order appoint. 30
- (3) The remaining provisions of this Act come into force on such day as the Secretary of State may by regulations appoint.
- (4) An order or regulations under this section may make –
 (a) different provision for different purposes, and
 (b) transitional, transitory or saving provision. 35
- (5) An order or regulations under this section is or are to be made by statutory instrument.

11 Short title

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

Health Service Medical Supplies (Costs) Bill

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B I L L

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.

Brought from the Commons on 7th December 2016

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