HEALTH SERVICE MEDICAL SUPPLIES (COSTS) ACT 2017

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Health Service Medical Supplies (Costs) Act 2017 ("the Act") (c. 23) which received Royal Assent on 27 April 2017.

- These Explanatory Notes have been prepared by the Department of Health in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Act will mean in practice; provide background information on the development of policy; and provide additional information on how the Act will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Act. They are not, and are not intended to be, a comprehensive description of the Act.

Table of Contents

Overview of the Act

1 The Health Service Medical Supplies (Costs) Act amends and extends existing provisions of the National Health Service Act 2006 ("the NHS Act 2006") which relate to:

- the remuneration for person providing special medicinal products;
- the control of the cost of health service medicines and other medical supplies;
- the provision of pricing and other information to the Secretary of State by those manufacturing, distributing or supplying health service medicines, medical supplies or other related products required for the purposes of the health service; and
- the disclosure of the information referred to in the preceding paragraph in specified circumstances.

2 The Act also amends existing provisions of the National Health Service (Wales) Act 2006 ("NHS (Wales) Act") which relate to:

- the remuneration for persons providing special medicinal products;
- the provision of pricing and other information to the Welsh Ministers by persons who provide primary medical services under Part 4 of the NHS (Wales) Act or persons who provide pharmaceutical services under Part 7 of the NHS (Wales) Act; and
- the disclosure of the information referred to in the preceding paragraph in specified circumstances.

Sections relating to remuneration for persons providing special medicinal products

3 Sections 1 and 2 of the Act relate to remuneration for persons providing special medicinal products as part of the health services in England and Wales. The new sections amend the NHS Act 2006 and clarify that the Secretary of State can make regulations regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.

Sections relating to the control of the cost of health service medicines

4 Sections 3 to 6 of the Act relate to the control of the cost of health service medicines. The provisions in the Act amend the NHS Act 2006 clarifying that the Secretary of State may make regulations or directions to limit the costs of health service medicines by requiring manufacturers and suppliers of health service medicines to make payments calculated by reference to sales or estimated sales of those medicines. The provisions in the Act also amend the NHS Act 2006 to enable the Secretary of State to recover and enforce those payments.

Sections relating to the control of the cost of other medical supplies

5 Section 260 of the NHS Act 2006 provides the Secretary of State with the power to control the maximum price of medical supplies other than health service medicines. Section 7 makes the

enforcement provisions and the territorial extent provisions relating to section 260 consistent with the enforcement and territorial extent provisions relating to the powers to control the cost of health service medicines.

6 Section 7 of the Act also amends section 260 of the NHS Act 2006 so that the Secretary of State must consult representatives of manufacturers, distributors and suppliers before making an order to control prices, and for the first order to be subject to the affirmative resolution procedure.

Sections relating to the provision and disclosure of information

7 Section 8 introduces a new power in the NHS Act 2006 to enable the Secretary of State to make regulations to obtain information from any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purposes of the health service, for purposes specified in the Act. The provisions in the Act would also allow the information to be disclosed in specified circumstances.

8 Section 9 amends the NHS (Wales) Act to provide Welsh Ministers with the power to make regulations to obtain information from persons who provide primary medical services under Part 4 of the NHS (Wales) Act and from persons who provide pharmaceutical services under Part 7 of the NHS (Wales) Act.

Policy background

Sections relating to remuneration for persons providing special medicinal products

9 In England and Wales, reimbursement prices for community pharmacies for most commonly prescribed special medicinal products are listed in the Drug Tariff. In England, reimbursement prices are based on sales and volume data, which the Department currently obtains from specials manufacturers under a voluntary arrangement. A special medicinal product is manufactured to meet the specific needs of a specific patient. The unique nature of these medicines and their manufacturing arrangements mean that different approaches for special medicinal products need be considered than those used for other types of medicines to ensure that the prices paid by the NHS represent value for money.

10 The Act amends the NHS Act 2006 and the NHS (Wales) Act to enable the Secretary of State and Welsh Ministers to make regulations to establish different payment arrangements for special medicinal products compared to other products. These regulations could include how remuneration should be calculated, for example by means of quotes, and the circumstances in which remuneration would not be provided, for example where special medicinal products are centrally procured.

Sections relating to the control of the cost of health service medicines

11 The Secretary of State currently primarily controls the cost of most branded health service medicines by way of a voluntary scheme agreed with industry. The current voluntary scheme is the 2014 Pharmaceutical Price Regulation Scheme (PPRS). Companies that are members of the scheme make payments to ensure that spending on branded health service medicines stays

at the agreed level.

12 The powers under the NHS Act 2006 allow the Secretary of State, after consultation with the appropriate industry body[1], to make a statutory scheme for the purpose of limiting the prices of, or profits accruing from, the sales of health service medicines by companies that choose not to be members of the voluntary scheme.

13 Currently, manufacturers or suppliers of health service medicines can choose (primarily based on the nature of their business) to be controlled either by the voluntary scheme or the statutory scheme.

Voluntary scheme

14 There has been a succession of voluntary schemes agreed between the Secretary of State and the Association of the British Pharmaceutical Industry (ABPI) since the 1950s. The schemes are normally agreed on a five-year term.

15 The current PPRS was agreed in January 2014, and includes for the first time a payment mechanism requiring members of the scheme to pay a defined percentage of the value of their sales revenue from specified branded health service medicines to the Secretary of State, provided that the growth in health service expenditure on branded health service medicines exceeds a pre-agreed level set out in the scheme.

16 Section 261 of the NHS Act 2006 refers to the existence of voluntary schemes made between the Department of Health and industry for the purpose of limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines or limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines. Although the scheme itself is voluntary, section 261 provides the Secretary of State with specific statutory powers in relation to members of such voluntary schemes.

Statutory scheme

17 Sections 262 to 266 of the NHS Act 2006 provide the Secretary of State with the power, including by way of a statutory scheme, to limit the prices which may be charged by any manufacturer or supplier for the supply of any health service medicine, or to limit the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines by way of regulations or directions.

18 The current statutory scheme is set out in regulations[2] and applies to any manufacturer or supplier of branded health service medicines who is not a member of the voluntary scheme. The current statutory scheme operates through a cut in list price (i.e. the manufacturer's published price).

Amendments to the NHS Act 2006

19 The Act amends the NHS Act 2006 to clarify that the Secretary of State can also make a

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[1] For example the Association of the British Pharmaceutical Industry (ABPI)

[2] The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007

statutory scheme for the purpose of requiring any manufacturer or supplier to whom the scheme applies to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of any health service medicines.

20 Additionally, the Act amends the NHS Act 2006 to clarify that the powers relating to voluntary schemes are exercisable in relation to voluntary schemes whereby scheme members make payments based on their sales of health service medicines. The Act adds a new power to the NHS Act 2006 to enable the Secretary of State to require a voluntary scheme member to pay a sum due under that scheme. If the scheme member fails to pay, the existing provisions (in section 265 of the NHS Act 2006) would allow recovery through the courts. The amendment also makes clear that payments owed whilst the manufacturer or supplier was a member of the voluntary scheme may be recovered notwithstanding that a member of a voluntary scheme moves to the statutory scheme or vice versa.

21 Currently, provisions in the NHS Act 2006 state that regulations or directions made under sections 262 or 263 for the purposes of limiting prices of, or profits accrued from health service medicines cannot apply to members of a voluntary scheme. This is the case, even if the regulations or directions are directed at health service medicines manufactured or supplied by that scheme member which are not covered by the voluntary scheme. For example, the current PPRS covers branded health service medicines. However, a member of the PPRS may also manufacture unbranded health service medicines. The current provisions in the NHS Act 2006 prevent the Secretary of State from making regulations or directions to limit prices or profits that apply to a member of the PPRS, even if the regulations or directions are directed at the member's unbranded medicines. The Act therefore amends the provisions of the NHS Act 2006, so that the Secretary of State can make directions or regulations under section 262 or 263 to limit the prices of, or profits relating to, health service medicines of a manufacturer or supplier in the voluntary scheme, as long as their health service medicine to which the directions or regulations relate is not covered by the voluntary scheme. The Secretary of State will continue to be able to exercise their power in relation to a supplier not in the voluntary scheme even where the health service medicine has already been subject to controls under the voluntary scheme by virtue of the manufacturer of the health service medicine being a member of the voluntary scheme.

Section relating to the control of cost of other medical supplies

22 Section 260 of the NHS Act 2006 provides the Secretary of State with the power to control the maximum price of medical supplies other than health service medicines. Section 7 of the Act amends sections 260, 265 and 278 so that the enforcement provisions at section 265 (which currently only apply to health service medicines) and the relevant territorial extent provisions at section 278 (which currently only extend the health service medicines provisions to the United Kingdom) also apply to the control of cost of other medical supplies required for the purposes of the health services in the United Kingdom.

23 The Act amends the NHS Act 2006 to provide that before making an order to control the maximum price of medical supplies the Secretary of State is required to consult industry representative bodies. A similar requirement is already in the NHS Act 2006 for the control of costs of health service medicines. The Act also amends the NHS Act 2006 to provide that the first order to control the maximum price of medical supplies would be subject to the affirmative procedure, so that both Houses of Parliament debate the order.

Sections relating to the provision and disclosure of information

24 The Act amends the NHS Act 2006 to provide for a single information gathering power in relation to health service products which will replace the existing statutory information gathering powers relating to the statutory and voluntary schemes, providing a clearer basis for collecting and using that information. The Act amends the NHS Act 2006 so that information can be shared with specified persons for specified defined purposes.

25 The Act amends the NHS Act 2006 to remove existing powers to request information under sections 260 to 264, and introduces a new section to the NHS Act 2006 to allow the Secretary of State to make, subject to certain limitations, regulations to require a person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purposes of the health services in the United Kingdom, to keep and supply information with regards to those products.

26 It is also possible for the Secretary of State to disclose that information to specified persons for specified purposes (see commentary on section 8 below).

27 The amendments to the NHS Act 2006 do not provide the Secretary of State with the power to request information from persons providing primary care services and pharmaceutical services in Wales, Scotland and Northern Ireland, where those persons are supplying products used or required for the purposes of the health services in their nation, and where those products are supplied under primary medical services or pharmaceutical services as part of their health services. This reflects the agreement between the Department and the Devolved Administrations that the Secretary of State collects information from wholesalers and manufacturers from across the UK and that each nation collects information from pharmacies and GP practices across their own territories.

28 The Act also amends the NHS (Wales) Act to allow Welsh Ministers to request information from pharmacists or GPs for Welsh purposes as specified in the Act (see commentary on section 9 below).

Legal background

29 The relevant legal background is explained in the policy background section of these Notes.

Territorial extent and application

30 Most of the sections in the Act extend to England, Wales, Scotland and Northern Ireland. However, section 9, which relates to the provision of information from those providing primary medical services or pharmaceutical services, and the disclosure of the information, amends the NHS (Wales) Act and extends to England and Wales only and applies to Wales only. Also, subsection (1) of section 10 extends and applies to Scotland only (see commentary on territorial extent below).

31 Regulation of the price of medicines and medical supplies used for the purpose of the health services in England, Scotland and Wales is reserved with regards to Scotland and Wales. The regulation of the price of medicines and medical supplies is not reserved with regards to Northern Ireland.

32 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.

Sections relating to the remuneration for persons providing special medicinal products

33 Section 1 of the Act amends section 164 of the NHS Act 2006. Section 164 extends to England and Wales and applies to England only. Section 1 of the Act therefore also extends to England and Wales only and applies to England only.

34 Section 2 of the Act amends section 88 of the NHS (Wales) Act. Section 88 extends to England and Wales and applies to Wales only. Section 2 of the Act therefore also extends to England and Wales only and applies to Wales only.

Sections relating to the control of the cost of the health service medicines

35 Sections 261 to 266, relating to the control of the cost of health service medicines, extend and apply to the United Kingdom.

Section relating to the control of other medical supplies

36 Section 260, relating to the control of the cost of medical supplies, has been amended so that it extends to England and Wales, Scotland and Northern Ireland.

37 Subsection (1) of section 10 of the Act makes consequential amendments so as to remove the provisions relating to medical supplies in the National Health Service (Scotland) Act 1978 ("the NHS (Scotland) Act"). Subsection (1) of section 10 therefore extends and applies to Scotland only.

Sections relating to the provision and disclosure of information

38 Subject to certain limitations section 8 amends the NHS Act 2006 to allow the Secretary of State to request information from manufacturers, suppliers and distributers of health service medicines, medical supplies and other related products required for the purposes of the health service in the United Kingdom. The Secretary of State can request the information for England only, devolved and United Kingdom purposes. The Secretary of State can disclose that information to specified persons and only for specified purposes, including to the Devolved Administrations for devolved purposes. Section 8 extends and applies to the United Kingdom.

Commentary on provisions of Act

Part 1: Controlling cost of health service medicines

39 The Act is made up of thirteen sections. The substantive sections make amendments to, or insert new provisions into, the NHS Act 2006, the NHS (Wales) Act and the NHS (Scotland) Act. The first two sections relate to the remuneration for persons providing pharmaceutical services in respect of special medicinal products. Sections 3 to 6 amend provisions of the NHS Act 2006 which deal with the control of the costs of health service medicines. Section 7 relates to the control of cost of other medical supplies and sections 8 and 9 concern the provision and disclosure of information relating to health service products. Section 10 makes consequential amendments. Section 11 relates to the territorial extent of the provisions. Section 12 makes provision for the commencement of the Act and section 13 provides for the short title of the Act.

Section 1: Special medicinal products – NHS Act 2006

40 Section 1 of the Act relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.

41 Special medicinal products are medicines made to order for individual patients.

42 Section 1 of the Act inserts additional subsections in section 164 of the NHS Act 2006, which relate to the remuneration for persons providing pharmaceutical services in England.

43 New subsection (8A) of section 164 clarifies that the Secretary of State can make regulations regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.

44 New subsection (8B) explains that the regulations made by the Secretary of State can relate to how the remuneration should be calculated and that also remuneration does not have to be provided in specified circumstances.

45 New subsection (8C) provides examples of how remuneration should be calculated. New subsection (8C) explains that, this may include requiring a dispenser, health service body (as listed in section 9(4) of the NHS Act 2006) or a determining authority (which includes the Secretary of State or where authorised by the Secretary of State, NHS England or any other person) to make inquiries to ensure that remuneration is reasonable or estimating an amount of remuneration that is reasonable. Subsection (8C) would therefore allow for different payment arrangements to be established for special medicinal products compared to other products supplied through pharmaceutical services.

46 New subsection (8D) provides examples of the circumstances in which remuneration would not have to be provided. Subsection (8D) explains that this may include circumstances where special medicinal products are provided to persons providing pharmaceutical services by a health service body or under an arrangement between a health service body and other person. This could inform some form of central procurement for provision of special medicinal products, rather than the pharmaceutical provider purchasing the products.

47 New subsection (8E) defines "health service body" and "special medicinal product".

Section 2: Special medicinal products – NHS (Wales) Act 2006

48 Section 2 of the Act relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.

49 Special medicinal products are medicines made to order for individual patients.

50 Section 2 adds new subsections to section 88 of the NHS (Wales) Act, which relates to the remuneration for persons providing pharmaceutical services in Wales.

51 New subsection (8A) clarifies that regulations can be made regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.

52 New subsection (8B) explains that regulations can relate to how the remuneration should be calculated and also that remuneration does not have to be provided in specified circumstances.

53 New subsection (8C) provides example of how remuneration could be calculated. This may include requiring a dispenser, health service body (as listed in section 7(4) of the NHS (Wales) Act) or a determining authority (which includes the Welsh Ministers or where authorised by the Welsh Minister, any local health board or other person appointed by the Welsh Ministers in an instrument) to make inquiries to ensure that remuneration is reasonable or estimating an amount of remuneration that is reasonable. Subsection (8C) therefore allows for different payment arrangements to be established for special medicinal products compared to other

products supplied through pharmaceutical services.

54 New subsection (8D) provides examples of the circumstances in which remuneration would not have to be provided. This may include circumstances where special medicinal products are provided to persons providing pharmaceutical services by a health service body or under an arrangement between a health service body and other person. This might for example, inform some form of central procurement for provision of special medicinal products, rather than the pharmaceutical provider purchasing the products.

55 Subsection (8E) defines "health service body" and "special medicinal product".

Section 3: Voluntary schemes

56 Section 3 of the Act amends section 261 (Powers relating to voluntary schemes) of the NHS Act 2006.

57 Section 261(1) of the NHS Act 2006 refers to the existence of a voluntary scheme made by the Secretary of State and Industry for the purpose of:

a. limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines; or

b. limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines.

58 Subsections (2) to (8) of section 261 of the Act provide the Secretary of State with specific statutory powers in relation to members of such voluntary schemes.

59 Subsection (2) of section 3 of the Act amends section 261(1) of the NHS Act 2006 to add a new paragraph (c) to expand the description of the kinds of schemes which are within the scope of the powers of the Secretary of State relating to voluntary schemes. New paragraph (c) refers to a scheme which provides 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 health service medicines.

60 Subsection (3) of section 3 clarifies that a voluntary scheme, as referred to in section 261 of the NHS Act 2006, and to which the powers in the Act relate, can include any or all of the purposes set out at paragraphs (a) to (c) of section 261(1) namely price control, profit control or a requirement to make payments.

61 Subsection (4) of section 3 adds a new subsection (9) to section 261 which enables the Secretary of State, by regulations or directions (see section 266(1)), to require a manufacturer or supplier who has not made payments in accordance with the terms of a voluntary scheme, to make a payment to the Secretary of State within a time period specified in the regulations or directions.

62 Subsection (4) of section 3 of the Act also adds new subsection (10) to section 261 of the NHS Act 2006. This provision provides that where a manufacturer or supplier leaves the voluntary scheme that does not affect any liability to make payments which arose during the period that the health service medicine was covered by the voluntary scheme when the manufacturer or supplier was a member of the voluntary scheme.

Section 4: Power to control prices

63 Section 262 of the NHS Act 2006 provides the Secretary of State with the power to limit prices of health service medicines and to provide for any amount representing sums charged for that medicine, in excess of the limit, to be paid to the Secretary of State. Section 266(1) of the NHS Act 2006 allows the Secretary of State to do this by way of regulations or directions.

64 Section 4 amends section 262(2) so that if at any time a health service medicine is covered by a voluntary scheme that applies to its manufacturer or supplier, the powers in section 262 cannot be exercised in relation to that manufacturer or supplier as regards that medicine. This clause would allow the Secretary of State to make directions or regulations under section 262 to limit the prices of health service medicines of a manufacturer or supplier in the voluntary scheme, as long as their health service medicine is not covered by the voluntary scheme.

Section 5: Statutory schemes

65 Section 5 of the Act amends section 263 (Statutory Schemes) of the NHS Act 2006.

66 Section 263(1) provides the Secretary of State with the power to make a statutory scheme for the purpose of:

a. limiting the prices which may be charged by any manufacturer or supplier for the supply of any health service medicines, or

b. limiting the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines.

67 Subsection (2) of section 5 amends section 263(1) of the NHS Act 2006 to add a new paragraph (c) which clarifies that the Secretary of State can make a statutory scheme for the purpose of 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 health service medicines.

68 Subsections (2)(a) and (3) of the Act amend the consultation requirements under section 263 of the NHS Act 2006. In particular, the requirement to consult with the industry body is amended so that the Secretary of State also must consult with any other person the Secretary of State thinks appropriate. In addition, when carrying out the consultation the Secretary of State must consult about the economic consequences for the life sciences industry in the United Kingdom, the consequences for the economy of the United Kingdom and the consequences for patients to whom any health service medicines are to be supplied and for other health service patients.

69 Subsection (4) of section 5 adds a new subsection (5A) to section 263 to enable the Secretary of State by regulations or directions to require a manufacturer or supplier who has not made payments in accordance with the statutory scheme, to make a payment to the Secretary of State within a time period specified in the regulations or directions.

70 Subsection (5) of section 5 substitutes section 263(7) which used to have the effect that the power to create a statutory scheme could not be applied to a manufacturer or supplier to whom the voluntary scheme applied even if the price of the medicine they supplied was not controlled by the voluntary scheme. The effect of the amendment is that if, at any time, a health service medicine is covered by a voluntary scheme that applies to its manufacturer or supplier, the power in section 263 cannot be exercised in relation to that manufacturer or supplier as regards that medicine. The Secretary of State would continue to be able to exercise the power in section 263 in relation to a supplier who is not in the voluntary scheme even where the health service medicine has already been subject to controls under the voluntary scheme by virtue of the manufacturer of the health service medicine being a member of the voluntary scheme.

71 Subsection (6) of section 5 adds new subsection (8) to section 263 of the NHS Act 2006. This provision provides that any liability of a manufacturer or supplier to pay amounts that arose at a time when the health service medicine was covered by a statutory scheme which applied to the manufacturer or supplier is not affected by the manufacturer or supplier joining a voluntary scheme.

Section 6: Enforcement

72 Section 6 of the Act amends sections 265 (Enforcement) and section 266 (Controls: supplementary) of the NHS Act 2006.

73 Subsection (3) of section 6 makes consequential amendments to section 265 of the NHS Act 2006, which sets out the enforcement mechanism for the control of the cost of health service medicines provisions of the NHS Act 2006. In particular, subsection (3) of section 6 ensures that the enforcement provisions of the NHS Act 2006 apply to the new provisions inserted into sections 261, 262 and 263. This includes the power to apply a penalty where there has been a breach of any of the provisions and the power to provide for any amount payable to the Secretary of State by virtue of new sections 261(8) (voluntary schemes) and new section 263(5A) (statutory schemes) to carry interest at a rate specified or referred to in the regulations.

74 Subsection (4) of section 6 of the Act clarifies subsection (8) of section 265 of the NHS Act 2006 by inserting subsection (8A) into section 265. Subsection (8) of section 265 of the NHS Act 2006 provides that a prohibition or requirement under sections 261 to 264 may not be relied upon in any proceedings other than proceedings under sections 265. Subsection (8) was capable of being misconstrued in such a way that it might be said that the Secretary of State could not enforce payments that are due in a Court. New subsection (8A) in the Act makes clear that that is not the case. It explains that 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 by virtue of the enforcement provisions in section 265.

75 Subsections (5) to (9) make consequential amendments to section 266 of the NHS Act 2006. Section 266 makes supplementary provisions for sections 261-265 which relate to the control of costs of health service medicines. Subsections (5) to (9) would ensure that the supplementary provisions of the NHS Act 2006 apply to new provisions inserted into sections 261 (voluntary schemes), section 262 (power to control prices) and 263 (statutory schemes) of the NHS Act 2006. This includes enabling the Secretary of State to exercise the new powers by making regulations or giving directions to a specific manufacturer or supplier, clarifying that the powers which relate to a direct limit of prices or profits, continue only to apply to provisions which directly limit prices or profits, and inserting new subsection (4A) so that the new power in subsection 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 the need for medicinal products to be available for the health service on reasonable terms as well as the costs of research and development.

Part 2: Controlling costs of other medical supplies

Section 7: Control of maximum price of other medical supplies

76 Section 260 of the NHS Act 2006 enables the Secretary of State to make an order to provide for the control of maximum prices to be charged for any medical supplies other than health service medicines which are required for the purposes of the NHS Act 2006. Schedule 22 used to make further provision in relation to section 260 of the NHS Act 2006.

77 The territorial extent of section 260 is extended by virtue of subsection (8) of section 7 so that, as a result of an amendment to section 278(3), it extends to Scotland and Northern Ireland as well as England and Wales. Subsection (3) of section 7 therefore also amends section 260 so that it refers to "medical supplies…required for the purposes of the health service" rather than "for the purposes of this Act". The definition of "health service" here includes the health services in England, Wales, Scotland and Northern Ireland.

78 Consequential to these amendments, subsection (1) of section 10 makes amendments to the

NHS (Scotland) Act 1978. See commentary on section 10 on consequential amendments.

79 Subsection (5) of section 7 amends section 265 of the NHS Act 2006 so that some of the enforcement powers in section 265 which currently apply to health service medicines also apply to other medical supplies. In particular, section 265(1) of the NHS Act 2006 is amended so that penalties can be applied to any person who breaches any provisions made by way of an order under section 260.

80 As mentioned in relation to the enforcement provisions, subsection (8) of section 265 of the NHS Act 2006 provides that a prohibition or requirement under sections 261 to 264 may not be relied upon in any proceedings other than proceedings under sections 265 and new subsection (8A) explains that 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 by virtue of the enforcement provisions in section 265. Subsection (5) of section 7 amends subsection (8) of section 265 so that it also applies to section 260.

81 Subsection (6) of section 7 amends section 266(6) (interpretation) of the NHS Act 2006 so that the definitions in this section also apply to section 260. Section 266(6) defines health service, health service medicine, the industry body, manufacture, medicinal product and supplier.

82 Subsection (9) of section 7 omits reference to paragraph 1 of Schedule 22. Paragraph 1 provides further detail as to the contents of an order. This paragraph is no longer necessary for the purposes of applying section 260.

Part 3: Information about medical supplies

Section 8: Provision and disclosure of information

83 Section 8 inserts new sections 264A, 264B and 264C into the NHS Act 2006.

New section 264A

84 Section 264A allows the Secretary of State to make regulations to require any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purpose of the health service to record, keep and provide information to the Secretary of State for specified purposes.

85 The information may include but will not be limited to:

- The price charged or paid for the products;
- The price charged or paid for the delivery or other services in connection with the manufacturing, distribution or supply of those products;
- The discounts or rebates or other payments given or received in connection with the manufacturing, distribution or supply of those products;
- The revenue or profits accrued in connection with manufacturing, distribution or supply of those products (including in relation to profits, the costs incurred by the producer in connection with the manufacturing, distribution or supply of the products);
- Such information about medicinal products, other medical supplies, or other related products as is necessary to verify whether or not they are products which have been supplied to the health service in England or the United Kingdom and if so, whether they are used or required for the purposes of the health service in

England, Wales, Scotland or Northern Ireland.

86 The Secretary of State can require that manufacturers, distributors and suppliers of UK health service products (medicinal) products used for the purposes of health service in the United Kingdom, or medical supplies or other related products required for the purposes of the health service in the United Kingdom) record, keep and provide information for England only, Wales only, Scotland only, Northern Ireland only and United Kingdom purposes set out below.

England only purposes

- the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the NHS Act 2006 (such as dispensing GPs);
- the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of the NHS Act 2006 (such as community pharmacists);
- the consideration by the Secretary of State of whether adequate supplies of English health service products (medicinal products used for the purposes of the health service in England or medical supplies or other related products required for the purposes of the health service in England) are available and whether the terms on which those products are available represent value for money.

Wales only purposes

- the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the NHS (Wales) Act (such as dispensing GPs in Wales);
- the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of the NHS (Wales) Act (such as community pharmacists);
- the consideration by Welsh Ministers of whether adequate supplies of Welsh health service products (medicinal products used for the purposes of the health service in Wales or medical supplies or other related products required for the purposes of the health service in Wales) are available and whether the terms on which those products are available, represent value for money.

Scotland only purposes

- the determination of the payments to be made to any persons who provide primary medical services under section 2C(1) of the NHS (Scotland) Act;
- the determination of the remuneration to be paid to any persons who provide pharmaceutical care services under section 2CA(1) of the NHS (Scotland Act);
- the consideration by Scottish Ministers of whether adequate supplies of Scottish health service products (medicinal products used for the purposes of the health service in Scotland or medical supplies or other related products required for the purposes of the health service in Scotland) are available and whether the terms on which those products are available represent value for money.

Northern Ireland purposes

- 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 Services (Northern Ireland) Order 1972;
- the consideration by a Northern Ireland department of whether adequate supplies of Northern Ireland health service products (medicinal products used for the purposes of the health service in Northern Ireland, or medical supplies or other related products required for the purposes of the health service in Northern Ireland) are available and the terms on which those products are available represent value for money.

United Kingdom purposes

- the exercise by the Secretary of State of any powers under sections 260 to 265 (these sections relate to the control of the cost of health service medicines and supplies); or
- the operation of a voluntary scheme.

87 Section 264A also provides that:

a. regulations made under new section 264A must require the Secretary of State to give a UK producer an information notice if information is required in respect of costs incurred by the producer in connection with the manufacturing, distribution or supply of a particular product (other than costs which relate to any transaction between the producer and a UK producer for that product). Section 264A sets out the information that must be included in an information notice.

b. where an information notice is not required, regulations may set out that information is provided in relation to or for a prescribed period or at prescribed intervals, the form and manner the information is to be provided, and the time or period within which information is to be provided.

88 The provision of information under section 264A does not breach any obligation of confidentiality owed by a person providing the information nor can it breach any other restriction that may have been imposed on the disclosure of that information to the Secretary of State.

89 Subsection (9) of section 264A limits the Secretary of State's power to obtain information, by making clear that the Secretary of State is not be able to request information from persons providing primary care services and pharmaceutical services in Wales, Scotland and Northern Ireland, where those persons are supplying products used or required for the purposes of the respective health services, and where those products are supplied under primary medical services or pharmaceutical services as part of their health services.

90 Subsections (8), (10), (11), (12) and (13) of new section 264A, inserted by section 8 of the Act, define various terms used in the new section. In particular they define what is meant by “English health service products”, "Welsh health service products", "Scottish health service products", and “UK health service products” by setting out the distinction between the meaning of “health service” in England and the rest of the UK by reference to the relevant legislation in England, Wales, Scotland and Northern Ireland. In explaining what is meant by

"products" the subsections clarify that the term includes medicinal products used for the purpose of those health services and any other medical supplies or other related products required for the purposes of those health services.

91 The meaning of "medical supplies" is confirmed by reference to section 260(5) (Control of maximum price of medical supplies other than health service medicines) so that the meaning includes surgical, dental and optical materials and equipment.

New section 264B

92 Section 264B allows the Secretary of State to disclose the information obtained from manufacturers, distributors and suppliers by virtue of new section 264A in specified circumstances.

93 It allows the information obtained to be disclosed to certain health service bodies including NHS England, any special health authority (such as the NHS Business Services Authority) and the Health and Social Care Information Centre. If the information disclosed to the health service bodies is confidential or commercially sensitive, they can only use the information for the purpose of exercising their functions, and only if those functions are connected with referenced matters specified in section 264A(3) of the NHS Act 2006. These include matters relating to the control of the cost of health service medicines in the United Kingdom, and the England only purposes set out at paragraph 89.

94 Section 264B allows the information obtained under section 264A to be disclosed to any government department. If the information is confidential or commercially sensitive the government department will only be able to use the information for either the purpose of exercising their functions, and again only if those functions are connected with England only purposes or United Kingdom purposes (described at paragraph 89), or for the purpose of preventing, detecting or investigating any unlawful activities.

95 Section 264B allows the information under section 264A to be disclosed also to Welsh Ministers, Scottish Ministers, the Commons Services Agency for Scottish Health Service, and a Northern Ireland Department and the Regional Business Services Organisation (in Northern Ireland). If the information is confidential or commercially sensitive, they can use that information for the purpose of exercising their functions if their functions are connected to specified United Kingdom purposes. Welsh Ministers can also use the information for specified Welsh purposes. Scottish Ministers and the Commons Services Agency can use the information for specified Scottish purposes and the Northern Ireland Department and the Regional Business Services Organisation can use the information for specified Northern Ireland purposes. The specified purposes are set out at paragraph 89 above.

96 Section 264B allows information obtained under section 264A to be disclosed to any persons who provide services to NHS England, any Special Health Authority, the Health and Social Care Information Centre, any government department, Welsh Ministers, Scottish Ministers, the Common Services Agency a Northern Ireland Department or the Regional Business Services Organisation. Where, in this circumstance, the information is confidential or commercially sensitive, the purposes for which the information can be used are subject to the same limitations as those applied to the person to whom the services are being provided, as specified in the Act.

97 Section 264B also provides the Secretary of State with the power to make regulations to disclose information obtained under section 264A to a body that represents manufacturers, suppliers and distributors of health service medicines, medical supplies and other related products required for the purposes of the health services an NHS foundation trust, or any health service body as listed in section 9(4) of the NHS Act 2006. If the information is

confidential or commercially sensitive, the representative body can only use the information for purposes prescribed in regulations and for matters connected to the purposes set out at sections 264A, as set out at paragraph.

98 Section 264B also makes provision for Welsh Ministers to disclose information that they have received from the Secretary of State to:

- a Local Health Board or another person appointed to exercise the functions of a determining authority under Part 7 of the NHS (Wales) Act;
- a National Health Service Trust established under section 18 of the NHS (Wales) Act 2006;
- to any person who provides services to the Welsh Ministers; or
- to any person who provides services to a Local Health Board/or other person as appointed to exercise functions of a determining authority or a National Health Service Trust established under the NHS (Wales) Act.

New section 264C

99 Section 264C supplements new sections 264A and 264B. In particular, it requires the Secretary of State to consult any body (such as the Association of the British Pharmaceutical Industry) which appears to the Secretary of State to represent manufacturers, distributors and suppliers of health service medicines, medical supplies or other related products required for the purposes of the health service in the United Kingdom before making any regulations under section 264A or 264B.

100 Section 264C also clarifies that regulations made under section 264A cannot require information to be provided or for disclosure of information under section 264B to be in contravention of the Data Protection Act 1998.

101 Finally, section 264C clarifies that regulations for the provision of information made under new section 264A or the disclosure of information by virtue of new section 264B does not affect any other existing powers, obligations or duties that already exist to require or authorise information to be provided, disclosed or used.

Section 9: Provision of information to Welsh Ministers and disclosure

102 Section 9 of the Act inserts new sections 201A, 201B and 201C into the NHS (Wales) Act.

Section 201A

103 New section 201A provides Welsh Ministers with the power to make regulations to require a person who provides primary medical services or pharmaceutical services as set out in the NHS (Wales) Act to record and keep information, and to provide that information to the Welsh Ministers.

104 Welsh Ministers would not be able to make such regulations unless the information is required for the purpose of enabling or facilitating the determination of the payments or remuneration to be made to those providers of primary medical services or pharmaceutical services for the consideration by the Welsh Ministers of whether adequate supplies of health service products are available, and the terms on which those products are available represent value for money.

105 Subsection (3) of new section 201A sets out a non-exhaustive list of the type of information that Welsh Ministers would be able to request. These include-

- the price charged or paid by the provider for health service products;
- the price paid by the provider for delivery or other services in connection with health service products;
- the discounts or rebates or other payments given or received by the provider in connection with the supply of health service products;
- the revenue or profits accrued to the provider in connection with the supply of health service products;
- 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.

106 Subsection (4) of new section 201A provides that the regulations can prescribe the form and manner, and the time within such information must be provided.

107 Subsections (5) of new section 201A provides that the regulations may provide for a person who contravenes any of the provisions in the regulations to be liable to a penalty, and subsection (6) sets out the maximum level of penalty which could only be increased by an order (see subsection 9) subject to the affirmative procedure (see subsection 19 of consequential amendments of section 10 of the Act). Subsection (7) provides that the person must have a right of appeal against a decision made by Welsh Ministers to impose a penalty.

108 Subsection (8) of new section 201A makes clear that the provision of information does not breach any obligation of confidence owed by the person providing the information and does not breach any other type of restriction that may have been in place on the provision of that information.

109 Subsection (10) of new section 201A defines various terms referred to in the section. "Health service products" as referred to in new section 201A of the NHS (Wales) Act are defined as medicinal products used for the purposes of the health service in Wales, and any other medical supplies, or other related products, required for the purposes of that health service. Subsection () also clarifies that "medical supplies" includes surgical, dental and optical materials and equipment and that "equipment" includes any machinery, apparatus or appliance, whether fixed or not, and any vehicle. "Medicinal product" is given the same meaning as that given in legislation regulating medicines. Subsection (10) also clarifies that the term "Part 4 provider" is used to refer to a person who provides primary medical services under Part 4 of the NHS (Wales) Act and "Part 7 provider" is used to refer to a person who provides pharmaceutical services under Part 7 of the NHS (Wales) Act.

Section 201B

110 New section 201B of the NHS (Wales) Act would provide Welsh Ministers with the power to disclose information to:

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)).

111 Section 201B makes clear that where confidential or commercially sensitive information is disclosed to such persons, those prescribed persons may not use the information for a purpose other than the purposes set out in section 201A(2) (set out above) and may not disclose that information to another person.

Section 201C

112 New section 201C makes supplementary provisions to section 201A and 201B. These include that Welsh Ministers, when making regulations under section 201A, must consult with bodies which appear to them to be appropriate to represent providers of primary care services and pharmaceutical services as referred to in the NHS (Wales) Act. It also clarifies that nothing in section 201A or 201B requires information to be provided in contravention of the Data Protection Act 1998, and finally that 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.

Part 4: Supplementary and final provisions

Section 10: Consequential amendments

113 Section 10 would make a number of consequential amendments to section 49 and Schedule 10 of the NHS (Scotland) Act and sections 260 to 266 and Schedule 22 of the NHS Act 2006.

Existing information provisions

114 Section 10 of the Act removes any existing information gathering powers under sections 260, 261, 263 and 264 which have been rendered unnecessary as a consequence of new section 264A.

Section 260 and Schedule 22

115 Section 260 of the NHS Act 2006 enables the Secretary of State to make an order to provide for the control of maximum prices to be charged for any medical supplies other than health service medicines which are required for the purposes of the NHS Act 2006. Schedule 22 used to make further provision in relation to section 260 of the NHS Act 2006.

116 Subsection (3) of section 10 of the Act omits reference to 'undertakings' from section 260. This definition is no longer accurate for the purposes of defining the persons that may be affected by section 260.

117 Subsection (3)(b)(i) of section 10 of the Act in relation to section 260 of the NHS Act 2006, and subsection (15) of section 10 of the Act in relation to section 271 (Territorial limit of exercise of functions) of the NHS Act 2006 omits reference to Schedule 22. This is because paragraph 1 of Schedule 22 is omitted by subsection (9) of section 7 of the Act (as referred to in the description of section 7 above) and the remaining paragraphs of Schedule 22 by subsection (18) of section 10. Paragraphs 2 to 11 of Schedule 22 provided further detail as to the delivery or service of documents where required for the purposes of section 260, the territorial extent of section 260, the restrictions on disclosing information, the criminal offences committed by corporations under section 260 or Schedule 22, the circumstances in which documents must be produced and the penalties for offences. The enforcement provisions in Schedule 22 are inconsistent with the enforcement provisions in section 265 of the NHS Act 2006 which relate to the control of the cost of health service medicines. The other provisions in Schedule 22, which are not related directly to enforcement, are unnecessary for the purpose of exercising the powers in section 260.

118 Subsection (9) of section 10 of the Act, amends section 265(5) of the NHS Act 2006 so that

provisions can be made by way of regulations for conferring on manufacturers and suppliers a right of appeal where an enforcement decision has been made in respect of section 260. Subsection (9) requires that regulations are made for conferring on UK producers a right of appeal if an information notice has been given.

119 Section 260 and Schedule 22 of the NHS Act 2006 do not currently extend to Scotland. Instead, section 49 and Schedule 10 of the NHS (Scotland) Act are drafted in the same terms as section 260 and schedule 22 of the NHS Act 2006 and extend to Scotland. As section 7 of the Act would extend the territorial extent of section 260 and Schedule 22 of the NHS Act 2006 to Scotland, there would be a duplication in the same provisions in the NHS Act 2006 and the NHS (Scotland) Act. Therefore, subsection (1) of section 10 makes a consequential amendment so as to omit section 49 and schedule 10 from the NHS (Scotland) Act.

Other consequential information provisions

120 Subsection (8) of section 10 amends section 265(1) of the Act so that the Secretary of State can apply penalties to breaches of the information provisions made by regulations under new section 264A.

121 Subsection (9) of section 10 amends section 265(5) so that manufacturers, distributors and suppliers referred to in new section 264A who have had an enforcement decision made against them have the right to appeal.

122 Subsection (11) amends section 265(7)(a) and (d) so that the definition of "enforcement decision" includes decisions made against manufacturers, distributors and suppliers referred to in new section 264A.

123 Subsection (13) replaces the existing consultation requirement so that the Secretary of State must consult not only the industry body, as is already the case, but also any other body which appears to the Secretary of State appropriate to represent persons who distribute health service medicines or persons who manufacture, distribute or supply any other medical supplies, or other related products, required for the purposes of the health service.

124 Subsection (14) confirms the definition of "UK producer" so that it would be consistent with the definition in new section 264A.

125 Subsection (16) of section 10 of the Act omits subsection (9) from section 272 (orders, regulations, rules and directions) of the NHS Act 2006, so that subsections (7) and (8) of section 272, which relate to the exercise of the power to make orders apply to section 260 of the NHS Act 2006, in the same way they do to the health service medicines provisions.

126 Subsection (17) of section 10 of the Act amends section 278 of the NHS Act 2006 so that the supplementary provisions in the NHS Act 2006 also extend to Scotland and Northern Ireland, to the extent that the supplementary provisions apply to sections 260 to 266 of the NHS Act 2006.

Section 11: Extent

127 Section 11 of the Act confirms that:

- Section 1 (remuneration for persons providing special medicinal products: England) extends to England and Wales and applies to England only.
- Section 2 (remuneration for persons providing special medicinal products: Wales), section 9 (which amends the NHS (Wales) Act) and subsection (19) of section 10 (consequential amendments regarding affirmative procedure) extend to England and Wales and apply to Wales only.

- Subsection (1) of section 10 (which amends the NHS (Scotland) Act) extends and applies to Scotland only.
- The remaining sections extend and apply to England and Wales, Scotland and Northern Ireland.

Commencement

128 Section 11 (extent), section 12 (commencement) and section 13 (the short title) come into force on the day that the Act is passed.

129 Sections 2 (remuneration for persons providing special medicinal products:Wales) , 9 (provision of information to Welsh Ministers and disclosure) and 10(19) come into force on such day as Welsh Ministers by order appoint.

130 The remaining sections in the Act come into force on a date determined by the Secretary of State by way of Regulations.

131 An order or regulations made under section 12, may appoint different days or make different provision, for different purposes or areas, and make transitional, transitory or saving provision.

Related documents

132 The following documents are relevant to the Act and can be read at the stated locations:

- Impact assessment: https://www.gov.uk/government/publications/health-service-medical-supplies-costs

Annex A - Territorial extent and application in the United Kingdom

133 Section 2, section 9 and subsection (17) of section 10 extend to England and Wales and apply to Wales only. Subsection (1) of section 10 extends and applies to Scotland only. The remaining clauses extend and apply to England, Wales, Scotland and Northern Ireland.

134 Section 1 (remuneration for persons providing special medicinal products: England) has been certified, for the purposes of Standing Order No. 830, as relating exclusively to England and within devolved legislative competence, as defined in Standing Order No. 83J.

135 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.[3]

Provision	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?
Section 1	Yes	No	No	No
Section 2	No	Yes	No	No
Section 3	Yes	Yes	Yes	Yes
Section 4	Yes	Yes	Yes	Yes
Section 5	Yes	Yes	Yes	Yes
Section 6	Yes	Yes	Yes	Yes
Section 7	Yes	Yes	Yes	Yes
Section 8	Yes	Yes	Yes	Yes
Section 9	No	Yes	No	No
Section 10	Yes	Yes	Yes	Yes
Section 11	Yes	Yes	Yes	Yes
Section 12	Yes	Yes	Yes	Yes

[3] References in this Annex to a provision being within the legislative competence of the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly are to the provision being within the legislative competence of the relevant devolved legislature for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.

Annex B - Hansard References

136 The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
Introduction	15 09 2016	Vol. 614 Col. 1080
Second Reading	24 10 2016	Vol. 616 Col. 72
Public Bill Committee	08 11 2016 (1st) 15 11 2016 (2nd) 15 11 2016 (3nd)	Vol. n/a/ Col. 1 Vol. n/a Col. 27 Vol. n/a Col. 55
Report and Third Reading	06 12 2016	Vol. 618 Col. 150
House of Lords		
Introduction	07 12 2016	Vol. 777 Col. n/a
Second Reading	21 12 2016	Vol. 777 Col. 1667
Grand Committee	23 01 2017 25 01 2017	Vol. 778 Col. 34 Vol. 778 Col. 148
Report	07 02 2017	Vol. 778 Col. 1623
Third Reading	23 02 2017	Vol. 779 Col. 415
Commons Consideration of Lords Amendments	15 03 2017	Vol. 623 Col. 463
Lords Consideration of Commons Amendments	05 04 2017	Vol. 782 Col. 1059
Commons Consideration of Lords Amendments	25 04 2017	Vol. 624 Col. 1060
Lords Consideration of Commons Amendments	26 04 2017	Vol. 782 Col. 1394
Royal Assent	27 04 2017	House of Commons Vol. 624 Col. 1230 House of Lords Vol. 782 Col. 1528

Annex C - Progress of Bill Table

137 This Annex shows how each section and Schedule of the Act was numbered during the passage of the Bill through Parliament.

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 1	n/a	n/a	n/a	n/a	Clause 1
Section 2	n/a	n/a	n/a	n/a	Clause 2
Section 3	Clause 1	Clause 1	Clause 1	Clause 1	Clause 4
Section 4	Clause 2	Clause 2	Clause 2	Clause 2	Clause 5
Section 5	Clause 3	Clause 3	Clause 3	Clause 3	Clause 6
Section 6	Clause 4	Clause 4	Clause 4	Clause 4	Clause 7
Section 7	Clause 5	Clause 5	Clause 5	Clause 5	Clause 8
Section 8	Clause 6	Clause 6	Clause 6	Clause 6	Clause 9
Section 9	n/a	Clause 7	Clause 7	Clause 7	Clause 10
Section 10	Clause 7	Clause 8	Clause 8	Clause 8	Clause 11
Section 11	Clause 8	Clause 9	Clause 9	Clause 9	Clause 12
Section 12	Clause 9	Clause 10	Clause 10	Clause 10	Clause 13
Section 13	Clause 10	Clause 11	Clause 11	Clause 11	Clause 14

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