

HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

EXPLANATORY NOTES ON LORDS AMENDMENTS

What these notes do

- 1 These Explanatory Notes relate to the Lords Amendments to the Health Service Medical Supplies (Costs) Bill as brought from the House of Lords on 24th February 2017.
- 2 These Explanatory Notes have been prepared by the Department of Health in order to assist the reader of the Bill and the Lords amendments, and to help inform debate on the Lords Amendments. They do not form part of the Bill and have not been endorsed by Parliament.
- 3 These Explanatory Notes, like the Lords amendments themselves, refer to Bill 81, the Bill as first printed for the Lords.
- 4 These Explanatory Notes need to be read in conjunction with the Lords amendments and the text of the Bill. They are not, and are not meant to be, a comprehensive description of the Lords amendments.
- 5 Lords Amendments 1, 2 and 4 to 24 were tabled in the name of the Minister.
- 6 Lords Amendment *3 was tabled by Lord Warner and Lord Hunt, and was opposed by the Government.
- 7 In the following commentary, an asterisk (*) appears in the heading of any paragraph that deals with a non-Government amendment.

Commentary on Lords amendments

Special medicinal products - NHS Act 2006

- 8 The Lords Amendment 1 would add a new clause to the Bill, and relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.
- 9 Special medicinal products are medicines made to order for individual patients.
- 10 The new clause would amend section 164 of the NHS Act 2006, which relates to the remuneration for persons providing pharmaceutical services in England.
- 11 Subsection (8A) of the new clause would clarify that the Secretary of State could make regulations regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.
- 12 Subsection (8B) of the new clause would explain that the regulations made by the Secretary of State could relate to how the remuneration should be calculated and that also remuneration would not have to be provided in specified circumstances.

- 13 In terms of how the remuneration should be calculated, subsection (8C) would provide examples. Subsection (8C) would explain that this may include requiring a dispenser, health service body (as listed in section 9 (4) of the NHS Act) 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.
- 14 In terms of the circumstances in which remuneration would not have to be provided, subsection (8D) would provide examples. Subsection (8D) explain 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.
- 15 Subsection (8E) would provide definitions for "health service body" and "special medicinal product".
- 16 These changes would provide a legislative framework from which the Government can develop options for consultation.
- 17 The Secretary of State for Health has a legal duty to consult the representative body for those providing pharmaceutical services, and can consult anyone else he deems appropriate before making any changes in this area.
- 18 Lords amendment 1 would have the effect of providing the Secretary of State with the power to use new mechanisms to reduce public expenditure.

Special medicinal products - NHS (Wales) Act 2008

- 19 The Lords amendment 2 would add a new clause to the Bill, and relates to the remuneration for persons providing pharmaceutical services in respect of special medicinal products.
- 20 Special medicinal products are medicines made to order for individual patients.
- 21 The new clause would amend section 88 of the NHS (Wales) Act 2006, which relates to the remuneration for persons providing pharmaceutical services in Wales.
- 22 Subsection (8A) of the new clause would clarify regulations can be made in regarding remuneration for pharmaceutical services specifically with respect to special medicinal products.
- 23 Subsection (8B) of the new clause would explain that regulations could relate to how the remuneration should be calculated and also that remuneration would not have to be provided in specified circumstances.
- 24 In terms of how the remuneration should be calculated, subsection (8C) would explain that 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 authorized 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) would therefore allow for different payment arrangements to be established for special medicinal products compared to other products supplied through pharmaceutical services.

- 25 In terms of the circumstances in which remuneration would not have to be provided, subsection (8D) would explain 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 might for example, inform some form of central procurement for provision of special medicinal products, rather than the pharmaceutical provider purchasing the products.
- 26 Subsection (8E) would provide definitions for "health service body" and "special medicinal product".
- 27 Lords amendment 2 would have the effect of providing Welsh Ministers with the power to use new mechanisms to reduce public expenditure.

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

- 28 Lords amendment *3 would add a new clause to the Bill, regarding factors which the Government must have regard to when seeking to secure best value for money in the purchase of medicines and medical supplies.
- 29 The factors are: (a) promoting and supporting a growing life sciences sector in the UK; and (b) ensuring that patients have rapid access to medicines approved through a NICE technology appraisal.

Medical Supplies

- 30 Lords amendments 4 to 7 would amend clause 5 of the Bill, which relates to the power to control prices of medical supplies.
- 31 Amendments 4 to 6 provide that the Secretary of State must consult any body which appears to the Secretary of State appropriate to represent persons, who manufacture, distribute or supply medical supplies before making legislation to control prices of medical supplies. This is similar to the provisions which relate to health service medicines, which require the Secretary of State to consult with the industry body before making schemes to control the cost of health service medicines.
- 32 Lords Amendment 7 would provide that the first order to control prices of medical supplies would need to be subject to the affirmative resolution procedure.

Information powers - NHS Act 2006

- 33 Lords amendments 8 to 10 would amend clause 6 of the Bill, which relates to the provision and disclosure of information.
- 34 Amendment 8 would make clear that reference to information about profits in clause 6 of the Bill, includes references to costs incurred by a UK producer in connection with the

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manufacturing distribution or supply of the products.

- 35 Amendment 9 would make further provision about regulations relating to the provision of information and insert new sections (5), (5A) and (5B) into section 264A of the NHS Act 2006.
- 36 New subsection (5B) would set out what regulations may include in relation to the provision of information where an information notice is not required.
- 37 Amendment 10 would amend clause 6 with respect to the persons to whom information can be disclosed. In particular, it would amend the list of persons to whom the Secretary of State can disclose information by replacing the provision in the Bill, which refers to "any other prescribed person" with a provision which refers to any health service body already listed in section 9(4) of the NHS Act 2006 and NHS Foundation Trusts (which are not listed in section 9) as prescribed in regulations. This would have the effect of enabling Government, to prescribe in regulations, the sharing of data with NHS Foundation Trusts and health service bodies such as Clinical Commissioning Groups (CCGs) but not to other persons not included in the list.

Information powers - NHS (Wales) Act 2006

- 38 Lords amendments 11 to 14 would amend clause 7 of the Bill. Clause 7 of the Bill would insert new section 201A, 201B and 201C into the NHS (Wales) Act 2006. Sections 201A, 201B and 201C relate to the provision of information to Welsh Ministers and the disclosure of that information.
- 39 Under new section 201A, where a person has contravened regulations relating to the provisions of information to Welsh Ministers, clause 7 of the Bill would allow Welsh Ministers to be liable to a penalty as set out in regulations. Lords amendment 11 would set out in new section 201A of the NHS (Wales) Act 2006 maximum penalties that could be imposed by such regulations.
- 40 Lords amendment 12 would allow Welsh Ministers to make regulations to increase the maximum penalty and these regulations would be subject to the affirmative procedure.
- 41 Lords amendment 13 would amend new section 201B, relating to the disclosure of information to provide for the removal of the provision allowing Welsh Ministers to disclose information to persons prescribed in regulations. Instead section 201B would include the following persons to whom information may be disclosed. These include:
 - 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;
 - A National Health Service Trust established under section 18 of the National Health Service (Wales) Act 2006;
 - Any person who provides services to the Welsh Ministers or to any person falling within paragraph (a) or (b);
 - Any body which appears to the Welsh Ministers appropriate to represent Part 4 providers or Part 7 providers (as defined by section 201A(8)).

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- 42 As the Lords amendment 13 would remove any regulation making powers in section 201B, the Lords amendment 14 would consequentially remove the reference to the regulation making powers in section 201C.

Consequential Amendments

- 43 Lords amendments 15 to 17 would amend the consequential amendments set out at clause 8 of the Bill.
- 44 Amendment 15 and 16 would make consequential provisions to the amendment relating to information notices (Lords amendment 9), to ensure that the Secretary of State is required to provide UK producers with a right of appeal by regulations where an information notice has been given.
- 45 Amendment 17 would make a consequential amendment in relation to the Lords amendment for increasing the maximum penalty level in the NHS (Wales) Act 2008 by the affirmative procedure.

Extent

- 46 Lords amendments 18 to 20 would set out the extent of the Lords amendments.
- 47 Lords amendments 18 and 19 would set out in the Bill that Lords amendment 1 (Remuneration for persons providing special medicinal products: England) and Lords amendment 2 (Remuneration for persons providing special medicinal products: Wales) would extend to England and Wales only.
- 48 Lords amendment 20 would set out in the Bill that Lords amendment 17 (consequential provision relating to regulations which are subject to the affirmative procedure in the NHS (Wales) Act 2006) would also extend to England and Wales only.

Commencement

- 49 Lords amendment 21 to 24 would amend clause 10 of the Bill, which relates to the commencement of the provisions in the Bill.
- 50 Amendment 21 would allow for Lords amendment 2 (Remuneration for persons providing special medicinal products: Wales) and Lords amendment 17 (consequential provision relating to regulations which are subject to the affirmative procedure in the NHS (Wales) Act 2006) to come into force on such a day as the Welsh Ministers may by order appoint.
- 51 Amendment 22 to 24 would enable commencement orders or regulations to appoint different days, or make different provision, for different purposes or areas. This would mean that if necessary the part of the Bill applicable to Northern Ireland (NI) could be commenced separately through regulations once it has been possible to secure legislative consent from the Northern Ireland Assembly.

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Ordered by the House of Commons to be printed, 24 February 2017

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