

# LEGISLATIVE CONSENT MEMORANDUM

## HEALTH AND CARE BILL

1. This legislative consent memorandum is laid under Standing Order (“SO”) 29.2. SO29 prescribes that a legislative consent memorandum must be laid, and a legislative consent motion may be tabled, before Senedd Cymru if a UK Parliamentary Bill makes provision in relation to Wales for any purpose within, or which modifies the legislative competence of Senedd Cymru.
2. The Health and Care Bill (“the Bill”) was introduced in the House of Commons on 6 July 2021. The Bill as introduced can be found at: <https://bills.parliament.uk/bills/3022>.

### Policy Objective(s)

3. The UK Government’s stated objective is to enact policies set out in the NHS’s recommendations for legislative reform, following the NHS Long Term Plan, and the White Paper, Integration and Innovation: working together to improve health and social care for all. The UK Government says that the Bill builds on the NHS’s own proposals for reform, aiming to make it less bureaucratic, more accountable, and more integrated, and to incorporate lessons learnt from the pandemic.

### Summary of the Bill

4. The Bill is sponsored by the Department of Health and Social Care.
5. The key provisions of the Bill cover a number of areas, set out briefly below.
  - a) Addressing of concerns raised by NHS England, such as establishing existing Integrated Care Systems (ICSs) on a statutory footing, formally merging NHS England and NHS Improvement, and making changes to procurement and competition rules relating to health services. The Bill also includes proposals to give the Secretary of State for Health and Social Care powers to direct NHS England and to decide how some other health services are organised. It gives the Secretary of State powers to transfer functions between some of the ‘Arm’s Length Bodies’ that lead, support and regulate healthcare services in England and to delegate other functions of the Secretary of State to those bodies both in relation to the health service in England, and to intervene in proposed changes to the way health services are delivered.
  - b) The Bill does not cover wider reforms of the social care and public health systems, although it does provide for some changes in these areas; ICSs are intended to improve coordination between the NHS and local authority services. For social care, the Bill provides for the Care Quality Commission (CQC) to assess how local authorities in

England deliver their adult social care functions and it aims to improve data sharing. There are also measures to streamline how people with ongoing care needs are discharged from hospitals.

- c) Public health measures in the Bill relate to food advertising, food information for consumers and water fluoridation.
- d) The Bill also addresses safety investigations and establishes the Health Services Safety Investigations Body as a statutory body, and makes changes to the system of medical examiners.
- e) Other matters covered by the Bill include the regulation of health and care professionals, the collection and sharing of data (including measures to support the development of new medicine registries), international healthcare, and hospital food standards.

### **Provisions in the Bill for which consent is required**

- 6. The following provisions of the Bill are within (or modify) the legislative competence of Senedd Cymru. These are:

#### **Clause 75 - Tidying up etc provisions about accounts of certain NHS bodies**

- 7. Clause 75 of the Bill will insert a new section into the National Health Service Act 2006 that will place obligations on Special Health Authorities (“SHAs”) in relation to their accounts and auditing. The new section will also provide powers to the Secretary of State to issue directions to SHAs in respect of the form any accounts are to take. SHAs are defined for this purpose as SHAs that perform functions only or mainly in respect of England, or those that exercise functions on a cross border basis.
- 8. There are two SHAs that exercise cross border functions: the NHS Business Services Authority and NHS Blood and Transplant. Cross border SHAs are considered as established under both the NHS Act 2006 and the NHS (Wales) Act 2006 (“the NHS Wales Act”). Under the NHS Wales Act, the Welsh Ministers may give directions to a cross-border SHA about the exercise of its functions. However, the new provision will apply to those cross-border SHAs meaning that the Secretary of State will have the power to issue directions to cross-border SHAs about the form their accounts should take.
- 9. The UK Government has not identified this as a clause that requires the legislative consent of Senedd Cymru.
- 10. The Welsh Government considers that consent is required as Senedd Cymru has competence to legislate in respect of the NHS Business Services Authority and the NHS Blood and Transplant, both of which are cross border SHAs established under the NHS Wales Act.

11. Paragraphs 8 and 10 of Schedule 7B of the Government of Wales Act 2006 (“GoWA”) contains restrictions on Senedd Cymru in respect of conferring, imposing, removing or modifying functions on a public authority. However there are exceptions in paragraph 9(2) and 10. Importantly, the NHS Business Services Authority and the NHS Blood and Transplant are exempted. Senedd Cymru therefore has competence to legislate in respect of both of these cross border SHAs.

### **Clause 78 - Hospital patients with care and support needs**

12. Clause 78 repeals the Community Care (Delayed Discharges etc) Act 2003 (“the 2003 Act”), which applies to England and to Wales. The 2003 Act requires a person’s need to for care and support to be assessed before the person is discharged from hospital. It also provides powers for notices and financial penalties between local authorities and NHS bodies in relation to delayed discharges. The relevant provisions of the 2003 Act have not been commenced in relation to Wales and there is no policy intention to do this as the provisions are not in line with current Welsh Government policy under discharge guidance or general principles of partnership working and integration. The repeal of the provisions will therefore remove redundant legislation from the statute book.
13. In addition, clause 78 makes amendments to the Social Services and Well-being (Wales) Act 2014, in consequence of the repeal in relation to Wales (i.e. to omit reference to the 2003 Act).
14. The UK Government has identified this as a clause that requires the legislative consent of Senedd Cymru.
15. Health and social care are devolved areas and the Welsh Government considers the provisions above to be within the legislative competence of Senedd Cymru.

### **Clause 85: Medicines information systems**

16. Clause 85 of the Bill creates a power for the Secretary of State to make regulations providing for a system of information regarding medicines to be established and operated by the Health and Social Care Information Centre (known as NHS Digital) to allow for the creation of centrally held UK-wide medicine registries.
17. NHS Digital is a statutory body responsible for health data in England. The power is restricted to creating information systems for purposes relating to the safety, quality and efficacy of human medicines and the improvement of clinical decision-making in relation to human medicines.
18. Regulations made under Clause 85 may also impose requirements on any person in the UK who provides services, or exercises any powers or duties relating to human medicines, health or education to provide information to NHS Digital and make provision about the use or disclosure of that information. The provisions therefore provide that NHS Digital is

able to mandate the provision of specific information to be included in the information system and that NHS Digital would be able to use and disclose such information.

19. The power enables the regulations to provide that disclosure of information for the purposes of medicines information systems does not contravene an obligation of confidence owed by the person making the disclosure.
20. Medicinal products are a matter reserved to UK Government however the proposals relating to medicines information systems are cross cutting and will impact on Wales.
21. The UK Government has identified this as a clause which requires Senedd consent.
22. Under paragraph 147 of Schedule 7A to GoWA, medicinal products including manufacture, authorisations for use and regulation of prices is a reserved matter. However, the power provided to the Secretary of State in clause 85 to make regulations making provision about the establishment and operation of medicine information systems is very broad.
23. The regulation making power also provides that information systems can be established and operate in relation to the improvement of clinical decision-making in relation to human medicines. The information systems could therefore be used for purposes of recognising trends in patient healthcare outcomes in Wales for example and improving patient healthcare. Such a use of that power would not be reserved to the UK (provided it does not relate to reserved matters).
24. The Welsh Government considers that Senedd Cymru could legislate to give the Welsh Ministers some of the powers that are conferred on the Secretary of State in clause 85 (though Senedd Cymru could not legislate to achieve all of it).
25. Furthermore, paragraph 34 of the Devolution Guidance Note (“DGN”), which is produced by the UK Government for its civil servants, indicates that the consent of Senedd Cymru is required where a UK Parliament Bill confers or imposes a function on a Devolved Welsh Authority. It is highly probable that regulations made by the Secretary of State under this amendment will confer functions and/or obligations on Devolved Welsh Authorities, in particular Welsh health bodies (i.e. an obligation to provide data to NHS Digital for purposes connected with medicines).

### **Clauses 86-92; Arm’s Length Bodies Transfer of Functions**

26. These clauses confer powers on the Secretary of State to transfer functions between specified Arm’s Length Bodies (“ALBs”) defined as “relevant bodies” and to delegate certain health functions of the Secretary

of State to them. The bodies specified are all health Non-Departmental Public Bodies<sup>1</sup>.

27. These powers are exercisable by the Secretary of State by way of regulations and even if the Secretary of State exercises the power to delegate his functions, the responsibility for those functions will remain with the Secretary of State.
28. Section 87 makes provision for the power to transfer functions between relevant bodies and section 88 makes provision for the power to provide for the exercise of functions of the Secretary of State by a relevant body.
29. The power under section 87 provides that the Secretary of State can modify the functions, constitution or funding of a relevant body, and abolish the relevant body if it has become redundant as a consequence of the transfer of functions.
30. In respect of any regulations made under section 87 or 88 that relate to a function that is exercisable in relation to Scotland, Wales or Northern Ireland, where there is a pre-existing requirement in the constitution of the body from which the function is transferred for the representation of the interests of one of the devolved nations, the Secretary of State must make provision for maintaining such representation by way of modifying, if necessary, the constitutional arrangements of the body receiving the function.
31. There is also a requirement on the Secretary of State to consult (clause 92) where draft regulations are made in the exercise of the powers under section 87 and 88. They must consult any body to which draft regulations relate, any other persons the Secretary of State considers appropriate, and the relevant Devolved Government if the regulations would apply in a devolved nation.
32. Clause 89 makes provision as to the scope of the powers conferred on the Secretary of State and provides that a provision which may be made in regulations under clause 87 or 88 may include provision repealing, revoking or amending provision made by or under an Act whenever passed or made. This includes provision in a Measure or Act of Senedd Cymru.
33. Clause 90 makes provision for transfer schemes in connection with the regulations. It provides that the regulations provide for the transfer of functions between relevant bodies, the transfer scheme may make provision for the transfer of property, rights or liabilities to any appropriate person from the relevant body from which functions are being transferred.

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<sup>1</sup> They are limited to Health Education England; The Health and Social Care Information Centre; The Health Research Authority; The Human Fertilisation and Embryology Authority; The Human Tissue Authority, and NHS England.

34. Clause 91 provides that the Treasury may make provision to vary the way in which a relevant tax has effect in relation to assets and liabilities that are transferred under a scheme made under clause 90 and anything done for the purpose of, or in relation to, a transfer.
35. The UK Government has identified these as clauses which require the legislative consent of Senedd Cymru.
36. The Welsh Government consider that in relation to clauses 86 to 89 and 92, Senedd Cymru consent is required. Whilst the majority of these clauses relate to functions of the Secretary of State and reserved bodies, potential impacts on legislative competence and the Welsh Ministers executive competence have been identified.
37. One of the bodies from or to whom the Secretary of State may transfer functions under clause 87 is the Human Tissue Authority, which exercises functions in relation to Wales. Whilst ordinarily an Act of Senedd Cymru cannot remove or modify functions of a public authority, without Minister of the Crown consent, there is an exception for the Human Tissue Authority under GoWA. Therefore Senedd Cymru would have legislative competence in respect of this body. It is therefore conceivable that, depending on the particular functions involved, a transfer of functions from the Human Tissue Authority might relate to devolved matters. In those circumstances, it would impinge on devolved powers because those functions would instead be exercised by a body established by the Secretary of State only.
38. The Secretary of State may also provide under clause 88 for the Human Tissue Authority to exercise specified functions of the Secretary of State on their behalf if they are functions of the Secretary of State which relate to the health service in England or any other functions that the Secretary of State may provide for a SHA to exercise. This would also arguably have regard to devolved matters under section 107(6) of GoWA as Senedd Cymru has legislative competence in respect of the Human Tissue Authority.
39. Thus the Welsh Government is of the view that Senedd consent is required in respect of clauses 90 and 91 as they extend to the Welsh Ministers.
40. In addition, subsection (6) of Clause 89 requires Senedd consent because it confers a Henry VIII power on the Secretary of State to make repealing, revoking or amending provision to Senedd legislation in regulations made by the Secretary of State under clauses 87 or 88. There is no requirement for the Secretary of State to obtain the consent of the Welsh Ministers before exercising this Henry VIII power.

## **Clause 120: International healthcare arrangements**

41. This clause makes provision to widen the scope of existing powers conferred on Secretary of State under Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (“HEEASAA”) relating to reciprocal healthcare to enable agreements to be made with countries outside the EEA.
42. HEEASAA provides the Secretary of State with a legal framework for implementing comprehensive healthcare arrangements with European Economic Area states, Switzerland or international organisations. The clause amends the HEEASAA to enable the UK Government to implement comprehensive reciprocal healthcare agreements with countries outside the EEA and Switzerland by removing the territorial restrictions of HEEASAA. In particular, it amends the Secretary of State’s power to make payments (or arrangements for payment) in relation to healthcare provided in a country or territory outside of the UK and to make related regulations.
43. HEEASAA requires the Secretary of State to consult with the Devolved Administrations. The statutory obligation to consult is supplemented by a Memorandum of Understanding (MoU) agreed between UK Government, Wales and the Northern Ireland Permanent Secretary (in the absence of NI Ministers).
44. Clause 120 will only extend the territorial extent of countries and the Secretary of State will still be required to consult with the Welsh Ministers, as is currently the case under the HEEASAA, before making any regulations to give effect to reciprocal agreements.
45. The UK Government has identified this as a clause which requires the legislative consent of Senedd Cymru.
46. Legislation in relation to health is devolved. Foreign affairs is generally reserved under paragraph 10(1) of Schedule 7A to GoWA, subject to exceptions which exist for the purpose of observing and implementing international obligations.
47. The purpose of clause 120 is to enable the Secretary of State to make payments in respect of healthcare overseas to give effect to healthcare agreements, with clause 120 of the Bill. Such a purpose would fall within the exception to the reservation and be within the legislative competence of Senedd Cymru.
48. The exceptions to the reservation in GoWA enables Senedd Cymru to legislate for the purpose of observing and implementing international obligations and for the purpose of assisting a Minister of the Crown in relation to international relations (insofar as they relate to devolved matters and no other restriction is breached). If a healthcare agreement is

an 'international obligation' then it is within Senedd Cymru's competence to legislate in relation to observing and implementing it or assisting a Minister of the Crown

49. Clause 120 also amends HEEASAA to enable the Secretary of State to confer functions on and/or delegate functions to public authorities, when making regulations to make provision for the purpose of giving effect to healthcare agreements. "Public authority" is defined as a person who exercises functions of a public nature (but does not include a person who does so only because of exercising functions on behalf of another). This definition would include the Welsh Ministers but excludes Welsh health bodies established under the NHS (Wales) Act 2006. As Devolved Welsh Authorities fall within the scope of this clause, the Senedd could legislate to confer a similar function on the Welsh Ministers in relation to Wales.

### **Clause 123: Regulation of health care and associated professions**

50. Clause 123 of the Bill makes a number of amendments to section 60 and Schedule 3 of the Health Act 1999 Act ("the 1999 Act") relating to the regulation of health professions.
51. This includes an amendment that would amend the existing provision allowing an Order in Council to be made regulating "any other profession" concerned with the physical or mental health of individuals, so that the reference to a profession is treated as including "any group of workers who are concerned with the physical or mental health of individuals", whether or not they are generally regarded as a profession.
52. The UK Government has identified this as a clause which requires the legislative consent of Senedd Cymru.
53. Though the regulation of healthcare professions is a reserved matter under GOWA, the regulation of persons who are not professionals but who are concerned with the physical or mental health of individuals falls within devolved competence.

### **Clause 125 and Schedule 16: Advertising of less healthy food and drink**

54. Clause 125 refers to Schedule 16 which amends the Communications Act 2003 to restrict the advertising of certain food and drink products in relation to the UK. These products are to be identified by a two stage process: first they need to be included in one of the product categories that will be set out in regulations made by the Secretary of State, then the 'relevant guidance' - the "Nutrient Profiling Technical Guidance" will need to be applied. The Secretary of State may amend the definition of 'relevant guidance'.
55. The television programme services element of Schedule 16 imposes an obligation on OFCOM – a statutory corporation and the UK regulatory and competition authority for the broadcasting, telecommunications and postal



industries – to set standards prohibiting television programme services provided between 5.30am and 9pm from including advertisements for identifiable unhealthy products, subject to exceptions. Schedule 16 also makes provision which prohibits the advertising of these products on demand television services shown between 5.30am and 9.00pm, and prohibiting a person from placing an advert for these products online. Both these prohibitions are subject to certain exemptions and there are powers for the Secretary of State to make regulations providing for further exemptions.

56. The purpose of these provisions is to reduce children’s exposure to the advertising of less healthy food and drink products on TV and online, pursuant to the UK Government’s obesity strategy which committed to: “banning the advertising of less healthy food and drink products being shown on TV and online before 9.00pm”.
57. Clause 125 also contains a consequential power. It amends the Communications Act 2003 to allow the Secretary of State to make consequential provision by way of Regulations which amend, repeal or revoke provisions of an Act or Measure of Senedd Cymru, or secondary legislation made under such provisions or under an Act of Parliament. This power is limited to extending the prohibition on placing or arranging online advertising to persons not already covered under Part C of the Communications Act 2003.
58. The UK Government has not identified this as a clause which requires the legislative consent of Senedd Cymru.
59. Senedd Cymru does not have competence to confer functions on OFCOM unless the relevant Minister of the Crown consents to such provision, and it cannot legislate for purposes which relate to broadcasting and internet services (as these are reserved). However, the Welsh Government considers that the provisions fall within the competence of Senedd Cymru because the purpose of the provisions primarily relate to public health (i.e. reducing obesity among the population and improving health outcomes) rather than broadcasting and internet services. Any engagement with those reservations is only incidental to the main, public health purpose of the clause which has the effect of reducing children’s exposure to advertising of unhealthy food.
60. The power to make consequential provision is also considered to be within the legislative competence of Senedd Cymru. There is no requirement for the Secretary of State to obtain the consent of the Welsh Ministers before exercising this Henry VIII power which could be used to amend Senedd legislation.

## **Clause 127: Food information for consumers - power to amend retained EU law**

61. Clause 127 introduces new sections into the Food Safety Act 1990 to enable regulations made under section 16(1)(e) of that Act to in turn make amendments to the retained Regulation (EU) No. 1169/2011 on the provision of food information to consumers. Section 16 of the Food Safety Act 1990 is exercisable by the Secretary of State (in relation to England), the Scottish Ministers (in relation to Scotland) and the Welsh Ministers (in relation to Wales). This will allow the Welsh Ministers to deliver a number of Welsh Government policies proposals on tackling obesity, which may require the amendment of this retained legislation.
62. The UK Government has identified this as a clause which requires the legislative consent of Senedd Cymru.
63. The Welsh Government agree as an Act of Senedd Cymru could legislate to confer the power insofar as it is exercisable within devolved competence. Whilst GoWA contains reservations in relation to consumer protection and in relation to product labelling, both those sections contain exceptions for food and food products. Food labelling and provision of food information is therefore a devolved area.

## **Clause 130: Power to make consequential provision**

64. Clause 130 of the Bill provides the Secretary of State with a power to, by regulations, make provision that is consequential on this Bill. This may include provision that amends, repeals, revokes or otherwise modifies any provision within the Bill or any provision made by, or under, an Act or Measure of Senedd Cymru.
65. This is a Bill-wide provision, meaning that the Secretary of State could exercise this consequential power in relation to any aspect of the Bill so as to amend Senedd legislation without recourse to the Welsh Ministers. This clause is similar to clauses 89(6) and 125.
66. The UK Government has not identified this as a clause which requires the legislative consent of Senedd Cymru.
67. However, the Welsh Government considers that this provision falls within Senedd Cymru legislative competence and therefore requires the legislative consent of Senedd Cymru.

## **Reasons for making these provisions for Wales in the Health and Care Bill**

68. The Welsh Government considers that although some of the provisions in the Bill have merit, for example in relation to obesity, food information for consumers and repealing redundant enactments (relating to patients' needs for care and support to be assessed before discharge from

hospital), several of its provisions would have deleterious effects on the devolution settlement.

### **Welsh Government Position on the Bill as introduced**

69. The Welsh Government is not in a position to recommend consent to the Bill as introduced.

70. This is on the basis that, despite some of the clauses being helpful to Wales, there are a number of clauses of concern:

- clauses in the Bill which enable the Secretary of State to consequentially amend Senedd legislation;
- clauses in the Bill which could negatively impact on NHS bodies in Wales (for example the clauses concerning Medicines Information Systems, International Healthcare Arrangements and regulation of healthcare professions).

71. There remains disagreement between UK Government and the Welsh Government on some of these issues and further work with the UK Government to resolve these concerns will continue during the Bill's passage through Parliament and a supplementary Legislative Consent Memorandum will be brought forward if required.

### **Financial implications**

72. The provisions of the Bill give rise to potential financial implications for the Welsh Government and Welsh health bodies. For example, in the area of patients visiting Wales for treatment under international healthcare agreements. However it is impossible to assess these until decisions are taken by the UK Government on implementation.

### **Conclusion**

73. As set out above, the legislative consent of Senedd Cymru is required for a number of clauses of the Health and Care Bill 2021-2022. A number of these clauses are of constitutional concern to the Welsh Government. Thus, despite the merits of some of the clauses, the Welsh Ministers' final position on being able to recommend consent is subject to the outcome of ongoing discussions with the UK Government regarding amendment to the Bill.

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**31 August 2021**