

SUPPLEMENTARY LEGISLATIVE CONSENT MEMORANDUM (MEMORANDUM NO 2)

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 the Senedd.

2. The Health and Care Bill ("the Bill") was introduced in the House of Commons on 6 July 2021. On 18 November the UK Government tabled 54 amendments for consideration at Commons Report Stage and 24 of these amendments make provision which falls within the legislative competence of the Senedd. All of these amendments were agreed on 23 November and form part of the Bill which commenced consideration by the House of Lords on 24 November. The Bill as amended can be found at: <https://bills.parliament.uk/publications/44008/documents/1051>

3. It was not possible to lay this Memorandum within the normal two weeks prescribed in SO29, owing to the complexity of the amendments tabled and the on-going discussions with the UK Government on outstanding issues which I had hoped would be resolved and positively covered in this Memorandum. This Memorandum has been laid as soon as possible after the tabling of these amendments allowing for analysis of their effect. However, there remain some outstanding issues which are still the subject of on-going discussions with UK Government.

Policy Objective(s)

4. 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

5. The Bill is sponsored by the Department of Health and Social Care.

6. 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.

Update on position since the publication of the first Legislative Consent Memorandum

7. The Welsh Government laid a Legislative Consent Memorandum in respect of the Bill on 1 September, based on the Bill as introduced to Parliament on 6 July.

8. The Memorandum stated that, as a number of the Bill clauses were of concern to the Welsh Government, despite the merits of some of the clauses, the Welsh Ministers' final position on being able to recommend consent would be subject to the outcome of ongoing discussions with the UK Government regarding amendments to the Bill.

9. Since the publication of the first Memorandum, we have secured amendments from the UK Government which address the majority of our concerns.

10. The UK Government has also amended the Bill in other areas at our request, in order to change existing Bill provisions on behalf of Wales or extend new provisions to Wales. These are set out at paragraphs 36-54 below.

11. These amendments were agreed at House of Commons Report Stage on 23 November 2021.

12. The Senedd will wish to note:

Clauses 88-94 (formerly Clauses 86-92): Arm's Length Bodies Transfer of Functions

13. Constructive discussions between Welsh Government and the Department of Health and Social Care led to the UK Government agreeing amendments which addressed all my areas of concern and which I was fully supportive of. However, an amendment to this provision was not tabled for consideration at Commons Report Stage along with the other amendments tabled, as whilst some aspects of the amendment were agreed by the UK Government and all three Devolved Governments, the UK Government was unable to secure agreement from all the Devolved Governments to further proposed amendments to the provisions.

14. Discussions with the Department for Health and Social Care on this matter are continuing to seek to ensure that an acceptable position for Wales is reached.

15. Until these discussions are resolved I am unable to support these clauses being included in the Bill.

Clauses 149, 144 and 91 (formerly clauses 89, 125 and 130): Consequential Amendments to Senedd Legislation

16. As set out in the first Legislative Consent Memorandum, these clauses provide the Secretary of State with the powers to, by regulation, make provision which is consequential on the Bill. This includes provision that amends, repeals, revokes or otherwise modifies provision made by, or under, an Act or Measure of the Senedd.

17. I and my officials have met with Minister Argar and his officials on a number of occasions to discuss these provisions. The UK Government are of the view that these are standard clauses and that we similarly take powers in Senedd Acts to make consequential amendments to UK Government legislation.

18. UK Government officials have provided examples of how these powers may be used – the amendments likely would be of a minor nature, for example the changing of the name of an English organisation which is referred to in Senedd legislation where a transfer of functions has occurred and Minister Argar has also given a written commitment to making a

Despatch Box statement in relation to Clause 149, the main provision of concern in this regard, on how these powers might be used.

19. Minister Argar has yet to make the Dispatch Box statement.

20. Once that statement has been made I will determine whether, in the light of all the assurances given by the UK Government, the risk presented by the provisions is acceptable.

Changes to the Bill since the publication of the first Legislative Consent Memorandum for which consent is required

21. The following clauses, which make provision in relation to Wales and are within the legislative competence of the Senedd, have been amended by the UK Government during House of Commons Report Stage:

Clause 87 (formerly Clause 85): Medicines information systems

22. In relation to inappropriate use of data, amendment 116 limits the scope of the purposes for which medicine information systems regulations can be made under clause 87. The amendment provides that provision in the regulations for a purpose in relation to clinical decision making can only be made where there is a connection with the safety of such decisions relating to human medicines.

23. The concerns of the Welsh Government regarding the availability of data to Welsh Ministers for purposes within devolved competence such as clinical decision making, and further concerns regarding the overlap of data collection for the purposes of the Registry with existing data gathering in Wales have been addressed by amendment 118, as well as the commitment to consult on provisions made in regulations made under the provisions. Amendment 118 requires that secondary legislation made under it must provide for information to be collected by the Welsh Ministers or a person designated by them such as Digital Health and Care Wales (DHCW), subject to specified exceptions in that secondary legislation. The amendment ensures where appropriate, data remains available for use by Welsh Ministers.

24. Finally, in addition to the safeguards agreed on the face of the Bill as introduced, amendments 117 and 121 require that the Welsh Ministers be consulted on any regulations or directions relating to medicine information systems which relate to Wales.

25. Taken together I am content that the amendments made to these provisions address the key concerns of Welsh Government and consequently I can now support this Bill clause.

Clause 136 (formerly Clause 120): International healthcare arrangements

26. We had two concerns regarding this clause as introduced.

27. Firstly the provision to allow the Secretary of State to confer functions on and/or delegate functions to Welsh Ministers and public authorities in Wales, when making regulations to make provision for the purpose of giving effect to healthcare agreements.

28. To resolve this, Amendment 124 amends the definition of a “relevant public authority” to which the Secretary of State can confer or delegate functions to when making regulations about international healthcare agreements under the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (“HEEASA”), by excluding both the Welsh Ministers and other devolved Welsh authorities from that definition. Amendments 122 and 123 bring Welsh Local Health Boards into the scope of the Secretary of State’s regulation making power to ensure that existing functions already conferred on them regarding planned healthcare applications remain.

29. Our second concern was the proposal to only consult with the Welsh Ministers on draft regulations giving effect to international healthcare agreements, meaning that should the Welsh Government have concerns regarding unreasonable or unfunded pressures on the NHS in Wales arising from such agreements, those concerns may not always be taken into account.

30. Amendment 125 will amend HEEASA to confer a power on the Welsh Ministers enabling them to make regulations in devolved areas for the purpose of giving effect to international healthcare agreements, which includes the power to delegate functions to, and/or confer functions on, all devolved Welsh authorities. The regulations will be subject to the negative procedure. Should the Welsh Ministers fail to exercise this power to confer relevant functions onto the Local Health Boards regarding healthcare agreements, the Secretary of State may confer those functions, as set out in the previous paragraph. I am of the view that this amendment addresses Welsh Government concerns about the Secretary of State for Health legislating in relation to devolved areas.

31. I am mindful of the fact that the ability of the Welsh Ministers to have the power to place reciprocal healthcare function on Local Health Boards and other devolved Welsh authorities in Wales does not remove the ability for the UK Government to enter into reciprocal healthcare agreements that could lead to additional pressures on the Welsh NHS. However I am of the view that the amendments are a significant shift from the position of the Bill as introduced and together with the Memorandum of Understanding on the engagement of the Devolved Administrations in the development of new and revised reciprocal healthcare agreements – which I will forward to the Committee in due course - provide sufficient protection of the devolution settlement.

32. Consequently I can now support this Bill clause.

Clause 142 (formerly Clause 123): Regulation of health care and associated professions

33. While the regulation of health professionals is reserved, the regulation of persons who are not professionals but who are groups of workers concerned with the physical or mental health of

individuals falls within devolved competence. The clause as introduced in the Bill would have extended the power of the Secretary of State to regulate these additional groups of workers.

34. Amendment 127 requires the consent of the Welsh Ministers to an Order in Council made under section 60 of the Health Act 1999 that is within the legislative competence of the Senedd and brings into regulation a group of workers who are not professionals, but who are concerned with the physical or mental health of individuals.

35. I am content that this amendment address the concerns of Welsh Government in respect of this provision and consequently I can now support this Bill clause.

Clause 143: Medical Examiners

36. Amendment 128 amends Clause 143 of the Bill to insert a new section 18B into the Coroners and Justice Act 2009 in England and Wales, which sets out a power for Welsh NHS bodies to appoint medical examiners. A duty will also be imposed on the Welsh Ministers to ensure that enough medical examiners are appointed in the healthcare system in Wales, that enough funds and resources are made available to medical examiners to enable them to carry out their functions of scrutiny to identify and deter poor practice, and to ensure that their performance is monitored.

37. This amendment has been made at our request to enable appointment of medical examiners by a range of Welsh NHS bodies rather than only Local Health Boards in Wales (as is set out in the current provision of the 2009 Act). This will enable more collaborative working across Welsh NHS bodies to ensure the effective delivery of the medical examiners scheme and bring provisions broadly in line the position in England.

38. While the subject matter of Part 1 of the 2009 Act, which is where this provision will be inserted, is reserved by paragraph 167 of Schedule 7A to the Government of Wales Act 2006, consent is nonetheless required because the amendment imposes a reserved function on Welsh NHS bodies and places duties on Welsh Ministers.

39. I support this amendment as it has been made at our request.

Clauses 122-125: Virginity Testing

40. Virginity testing is the examination of female genitalia for the purpose, or purported purpose, of determining virginity.

41. The World Health Organisation and the Royal College of Obstetricians and Gynaecologists position is that virginity tests have no scientific merit or clinical indication, as it is not possible to tell whether a woman has had intercourse through this type of examination. The procedure is not carried out on the NHS as it is not recognised as a medical procedure. Virginity testing seems to predominantly take place in private healthcare settings and to be carried out by healthcare professionals. However, it can also take place in other settings such as the home, where family members or community leaders may perform the test.

42. Amendments 36-39 make carrying out virginity testing, as well as offering to carry out virginity testing or aiding or abetting a person to carry out virginity testing, an offence. The penalty for the offence is:

- on summary conviction, to imprisonment for a term not exceeding the maximum summary term for either-way offences or a fine (or both);
- on conviction on indictment, to imprisonment for a term not exceeding 5 years or a

fine (or both).

43. We have agreed this provision extends to Wales as to not do so would risk Wales being left behind on this important issue. Our Programme for Government commits to making Wales the safest place in Europe to be a woman and this would mean that women and girls in Wales have fewer protections than their counterparts in England.

44. The amendment falls within the legislative competence of the Senedd. The purpose underpinning the amendment is safeguarding and protecting the health and welfare of women and girls. Both safeguarding and health and welfare are within the legislative competence of the Senedd.

45. I support this amendment as it has been extended to Wales at the request of the Welsh Government.

Clause 135: Reimbursement to Community Pharmacies

46. Amendment NC62 amends section 88 of the NHS (Wales) Act 2006, creating an exemption where pharmacy contractors do not need to be reimbursed for medicinal products that are used for vaccines and immunisation or for the prevention and treatment of disease that could become a pandemic, where those products have been procured centrally.

47. Amendment 129 provides the Welsh Ministers with a regulation making power to bring into force the amendments to section 88 of the 2006 Act. Amendment 132 confers a power on the Welsh Ministers to make transitional provision in connection with the coming into force of the amendments. A statutory instrument made in the exercise of these powers is not subject to any Senedd procedure.

48. When there is a health emergency (such as the current global pandemic) the current supply and reimbursement arrangements for specific products are not fit for purpose. There is no real 'competition' in the supply chain as there is not enough product for global demand and prices rise as health organisations worldwide try to source the same product. To ensure continuity of supply protecting UK stock intended for UK patients, the government may centrally purchase some stock. In these scenarios the Welsh Government wants to have the option to be able to supply the product 'directly' to pharmacies, without needing to sell into the supply chain. Welsh Government may use the typical pharmaceutical supply chain as a logistic service provider to deliver the medicine (the Welsh Government would need to pay them for this service) but the Welsh Government would retain title of the medicine.

49. This may involve supplying to pharmacies free of charge. In these circumstances the Welsh Government does not want to have to reimburse pharmacies, otherwise the government has to pay twice for the product - once to buy it in the first place and again in reimbursing the pharmacy.

50. We do not want to sell these centrally secured medicines as if it were a manufacturer into the supply chain to sell onto pharmacies in the usual way, as this would give rise to the opportunity for wholesalers, once they own the stock, to export it or sell at a much higher price than is usually paid.

51. Amendment 129 provides the Welsh Ministers with a regulation making power to bring into force the amendments to section 88. Amendment 132 confers a power on the Welsh Ministers to make transitional provision in connection with the coming into force of the amendments. A statutory instrument made in the exercise of these powers is not subject to any Senedd procedure.

52. I have agreed these amendments in the Bill are extended to Wales because, whilst the amendment relates to Welsh legislation, officials consider it is prudent and timely to agree to the UK Government making these amendments via the Bill, given the Bill already contains several provisions relating to medicines and devolved matters, and there is a need to ensure Wales' legislation does not preclude supply without reimbursement. The powers to commence the provisions that apply in Wales enable these amendments to be commenced in line with our own timeframes.

53. These amendments fall within the legislative competence of the Senedd. Whilst medicinal products, including manufacture, authorisations for use and regulation of prices is reserved under paragraph 147 of Schedule 7A to GOWA, the purpose of the proposed amendments relates to health and remuneration for pharmaceutical services, both of which are devolved matters.

54. I support these amendments as they have been extended to Wales at our request.

Welsh Government position on the Bill as amended

55. As set out above, we have secured agreement with the UK Government regarding the majority of areas of concern. In addition the UK Government has at the request of the Welsh Government amended the Bill to reflect the situation in Wales with regard to Medical Examiners, and extended UK Government amendments regarding Virginit Testing and Reimbursement to Community Pharmacies to Wales. I support consent in respect of all these provisions.

56. However, the agreed amendment with regard to Arm's Length Bodies was not tabled and in addition, Minister Argar has to date not made the Dispatch Box statement with regard to powers to make consequential amendments.

57. Until the above matters are resolved, I am unable to recommend consent to all of the clauses in the Bill which relate to areas within devolved competence as it is currently constituted.

Financial implications

58. There have been continuing discussions with UK Government regarding costs, and I have received some assurances. Broadly, Minister Argar has confirmed that the Barnett Formula will apply to additional costs arising from provisions in the Bill impacting on Wales as set out in the Statement of Funding Policy.

59. In relation to reciprocal healthcare specifically, the UK Government has confirmed that it will continue to fund the costs of treatment provided overseas to Wales' residents under any new healthcare agreements.

Conclusion

60. I welcome the amendments the UK Government has made to the Bill to address the majority of the areas of concern of the Welsh Government and the further amendments made at our request to reflect the situation in Wales with regard to Medical Examiners and to extend UK Government amendments regarding Virginit Testing and Reimbursement to Community Pharmacies to Wales.

61. However, until the concerns regarding Arm's Length Bodies and the powers to make consequential amendments are resolved I am unable to recommend consent to all of the clauses in the Bill which relate to areas within devolved competence as it is currently drafted. I will set out more detail on the Welsh Government's position as the situation develops and further information becomes available.

62. A further Supplementary Legislative Consent Memorandum will be brought forward if required.

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Minister for Health and Social Services