February 2022



1. Background

The UK Government's Health and Care Bill

1. The UK Government's Health and Care Bill¹ (the Bill) was introduced into the House of Commons on 6 July 2021. It is sponsored by the Department of Health and Social Care.

2. The Bill completed its passage through the House of Commons on 22 November 2021 and first reading in the House of Lords took place on 24 November. The Bill is currently at Committee Stage in the House of Lords.

The Welsh Government's Legislative Consent Memorandum

3. Standing Orders 29.1 and 29.2 provide that a Legislative Consent Memorandum is required when a relevant UK Bill makes provision in relation to Wales for any purpose within the legislative competence of the Senedd or which modifies the Senedd's legislative competence.

4. On 1 September 2021 Eluned Morgan MS, the Minister for Health and Social Services (the Minister), laid before the Senedd a Legislative Consent Memorandum² (the Memorandum) in respect of the Bill.

5. Paragraphs 7 to 67 of the Memorandum set out the Welsh Government's assessment, at the time, of the provisions in the Bill that it considered required the consent of the Senedd, namely clause 75 (Tidying up etc provisions about accounts of certain NHS bodies), clause 78 (Hospital patients with care and support needs: repeals etc), clause 85 (Medicines information systems), clauses 86 to 92 (Secretary of State's powers to transfer or delegate functions), clause 120 (International healthcare arrangements), clause 123 (Regulation of health care and associated professions), clause 125 and Schedule 16 (Advertising of less healthy food and drink), clause 127 (Food information for consumers: power to amend retained EU law), and clause 130 (Power to make consequential provision). The UK Government disagreed that clauses 75, 123, 125 and 130 require consent.

6. Paragraphs 68 to 71 of the Memorandum set out the Welsh Government's position on the Bill, and that the Minister was not in a position to recommend to the Senedd that consent be granted to the relevant provisions in the Bill.

¹ Health and Care Bill, as introduced (HC Bill 140 2021-22)

² Welsh Government, Legislative Consent Memorandum, Health and Care Bill, September 2021

7. In the Memorandum, the Minister also noted that a supplementary Legislative Consent Memorandum may be required, because of issues relating to clauses in the Bill which enable the Secretary of State to consequentially amend Senedd legislation, and clauses in the Bill which could negatively impact on NHS bodies in Wales.

8. The Minister, in the Memorandum, told the Senedd that there remained disagreement between UK Government and the Welsh Government on some of these issues and further work with the UK Government to resolve these concerns would continue during the Bill's passage through Parliament and a supplementary Legislative Consent Memorandum would be brought forward if required.³

Summary of our first report

9. We reported on the Memorandum (first report) on 3 December 2021.⁴

10. Paragraphs 15 to 94 of our first report set out in detail our consideration of the Memorandum.

11. In our first report, we acknowledged the difference in Welsh and UK Government views about the clauses (and Schedules) of the Bill for which the consent of the Senedd should be sought.

12. We also highlighted that the Welsh Government was recommending, at that point in time, that consent be withheld by the Senedd.

13. Our first report made specific observations and conclusions regarding clauses 75, 85, 86 to 92, 120, 123, 125 (and Schedule 16), and 130. We also discussed, in detail, the provisions in the Bill that would enable regulations made by the Secretary of State and Lord Chancellor to amend Senedd Acts and Measures and also the *Government of Wales Act 2006* (the 2006 Act).

14. In total, our first report included four formal conclusions and eight recommendations.

15. The Minister responded to our first report on 2 February 2022.⁵

³ Welsh Government, Memorandum, paragraph 71

⁴ Legislation, Justice and Constitution Committee, <u>The Welsh Government's Legislative Consent Memorandum on</u> <u>the Health and Care Bill</u>, December 2021

⁵ Letter from the Minister for Health and Social Services, 2 February 2022

The Welsh Government's Supplementary Legislative Consent Memoranda (Memorandum No. 2 and Memorandum No. 3)

Memorandum No. 2 and Memorandum No. 3

16. On 17 December 2021 the Minister laid before the Senedd a Supplementary Legislative Consent Memorandum⁶ (Memorandum No. 2) in respect of amendments made to the Bill on 23 November 2021 during Report Stage in the House of Commons. Clause (and Schedule) numbering referred to in Memorandum No. 2 relates to the version of the Bill as introduced into the House of Lords.⁷

17. At paragraph 3 of Memorandum No. 2 the Minister stated that "It was not possible to lay this Memorandum within the normal two weeks prescribed in [Standing Order] 29, owing to the complexity of the amendments tabled and the on-going discussions with the UK Government on outstanding issues".

18. The Minister also noted that "there remain some outstanding issues which are still the subject of on-going discussions with UK Government".⁸

19. On 28 January 2022 the Minister laid before the Senedd a further Supplementary Legislative Consent Memorandum⁹ (Memorandum No. 3) in respect of amendments tabled to the Bill on 24 January 2022 during Committee Stage in the House of Commons. Clause (and Schedule) numbering referred to in Memorandum No. 3 also relates to the version of the Bill as introduced into the House of Lords.

Changes to the Bill for which consent is sought since the publication of the Memorandum

20. In Memorandum No. 2, the Minister informed the Senedd that, since the publication of the Memorandum in August 2021, the Welsh Government had secured amendments from the UK Government which "address the majority our concerns".¹⁰

⁶ Welsh Government, <u>Supplementary Legislative Consent Memorandum (Memorandum No. 2), Health and Care</u> <u>Bill</u>, December 2021

⁷ Health and Care Bill, as introduced (HL Bill 71)

⁸ Welsh Government, Memorandum No. 2, paragraph 3. See also paragraphs 55 to 57 and 60 to 62.

⁹ Welsh Government, <u>Supplementary Legislative Consent Memorandum (Memorandum No. 3), Health and Care</u> <u>Bill</u>, January 2022

¹⁰ Welsh Government, Memorandum No. 2, paragraph 9

21. The Minister, in paragraph 10 of Memorandum No. 2, also said:

"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."

22. Paragraphs 13 to 54 in Memorandum No. 2 set out changes made to the Bill since the publication of the Memorandum, and the Welsh Government's view on each of these changes.

23. Paragraphs 7 to 50 in Memorandum No. 3 set out changes made to the Bill since the publication of Memorandum No. 2, and again include the Welsh Government's accompanying views.

Clause 87 (formerly clause 85)

24. Clause 87 (formerly clause 85) relates to medicines information systems. The Minister had concerns regarding the availability to the Welsh Ministers of data for purposes within devolved competence such as clinical decision-making.

25. Paragraphs 22 to 25 in Memorandum No. 2, and paragraphs 14 and 15 in Memorandum No. 3 provide details as regards amendments to clause 87 and corresponding changes to the Welsh Government's position.¹¹

26. In summary, Memorandum No. 2 noted:

- the concerns of the Welsh Government were addressed by amendments agreed at Report Stage in the House of Commons, specifically:
- i. amendment 116 which "limits the scope of the purposes for which medicine information systems regulations can be made under clause 87",¹²
- ii. amendment 118 which "requires that secondary legislation made under [clause 87] must provide for information to be collected by the Welsh Ministers or a person designated by them... subject to specified exceptions in that secondary legislation",¹³ and

¹¹ See also Letter from the Minister for Health and Social Services, 2 February 2022

¹² Welsh Government, Memorandum No. 2, paragraph 22

¹³ Welsh Government, Memorandum No. 2, paragraph 23

- iii. amendments 117 and 121 which "require that the Welsh Ministers be consulted on any regulations or directions relating to medicine information systems which relate to Wales";¹⁴
- the Minister can now support this clause of the Bill.¹⁵

27. Paragraphs 14 and 15 in Memorandum No. 3 note that clause 87 is one of three areas in the Bill where currently the UK Government is required to consult with the Welsh Ministers before making regulations. At paragraph 15 the Minister states:

"The Memorandum of Understanding concerning Medicines Information Systems is yet to be drafted by UK Government. We have communicated to the UK Government the need to develop this Memorandum as soon as possible with a view to it being in place before the provisions come into force."

Clauses 88 to 94 (formerly clauses 86 to 92)

28. Clauses 88 to 94 provide the Secretary of State with regulation-making powers to transfer functions between relevant arm's length bodies and to delegate certain health functions of the Secretary of State to them.

29. Paragraphs 13 to 15 in Memorandum No. 2, and paragraphs 14, 16, and 19 to 28 in Memorandum No. 3 provide details about amendments to clauses 88 to 94 and corresponding changes to the Welsh Government's position.¹⁶

30. Memorandum No. 2 noted that:

- discussions between the Welsh Government and the Department of Health and Social Care led to the UK Government agreeing amendments which addressed all of the Minister's areas of concern and which the Minister fully supported;
- an amendment to the clauses providing the Secretary of State with regulationmaking powers was not tabled for consideration at Report Stage in the House of Commons along with the other amendments tabled, as the UK Government was

¹⁴ Welsh Government, Memorandum No. 2, paragraph 24

¹⁵ Welsh Government, Memorandum No. 2, paragraph 25

¹⁶ See also Letter from the Minister for Health and Social Services, 2 February 2022

unable to secure full agreement from all the devolved governments to further proposed amendments to the provisions;

 until "an acceptable position for Wales" was reached, the Minister would not support these clauses being included in the Bill.¹⁷

31. Paragraphs 14 and 16 in Memorandum No. 3 note that clauses 88 to 94 are the second of three areas in the Bill where currently the UK Government is required to consult with the Welsh Ministers before making regulations. At paragraph 16 the Minister states that a Memorandum of Understanding concerning arm's length bodies will no longer be required if an amendment (amendment 231C) is agreed which provides the Welsh Ministers with a consenting role before the Secretary of State can make regulations under clauses 89 or 90.¹⁸

32. Memorandum No. 3 also notes that:

- the UK Government has tabled amendments removing the Welsh Ministers, Welsh NHS Trusts and Welsh Special Health Authorities from the list of "appropriate persons" in clause 92 "thus fully addressing the concerns of the Welsh Government in this area";¹⁹
- the Minister's concerns with the power given to the Secretary of State in clause 91 to make regulations which make provision consequential on clauses 88 or 90 have now been addressed (see below under 'Clauses 149, 144 and 91' for details);²⁰
- the Minister can now support these clauses of the Bill.²¹

Clauses 91, 144 and 149 (formerly clauses 89, 125 and 130)

33. Clauses 91, 144 and 149 confer Henry VIII powers on the Secretary of State to, by regulations, make provision which is consequential on the Bill. Such regulations may repeal, revoke or amend Senedd legislation (an Act or Measure of the Senedd, or secondary legislation made by the Welsh Ministers). This can be done without recourse to the Senedd or to the Welsh Ministers.

¹⁷ Welsh Government, Memorandum No. 2, paragraphs 13 to 15

¹⁸ See also Welsh Government, Memorandum No. 3, paragraphs 22 and 23

¹⁹ Welsh Government, Memorandum No. 3, paragraph 25

²⁰ Welsh Government, Memorandum No. 3, paragraphs 26 and 27

²¹ Welsh Government, Memorandum No. 3, paragraph 28

34. Paragraphs 16 to 20 in Memorandum No. 2, and paragraphs 29 to 37 in Memorandum No. 3 provide details as regards intergovernmental discussions on clauses 91, 144 and 149, and corresponding changes to the Welsh Government's position.²²

35. Memorandum No. 2 notes that the UK Government is of the view that these are standard clauses and the Welsh Ministers similarly take such powers in Acts of the Senedd to make consequential amendments to UK legislation. Memorandum No. 2 also notes that UK Government officials had provided examples of how these powers may be used, and that while Edward Argar MP, Minister of State for Health, had given a written commitment to make a Despatch Box statement on how the power in clause 149 may be used, such a statement had not yet been made.²³

36. In paragraph 20 of Memorandum No. 2 the Minister states:

"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."

37. Paragraphs 31 to 36 of Memorandum No. 3 provide an updated position; in particular, paragraph 31 notes that Minister Argar's Despatch Box statement would cover clause 91 in addition to clause 149. However, given that the UK Government does not consider that clause 144 requires the Senedd's legislative consent, this clause will not be included in the wording of the statement. The Welsh Government has agreed the wording of the statement, and the UK Government has committed to making the statement "prior to the Legislative Consent Motion debate in the Senedd".

38. At paragraphs 33 and 36 of Memorandum No. 3 the Minister states:

"...on the basis of the assurances provided by the UK Government on the possible use of the powers, we accept the consequential amendments which might arise from Clause 144 as **an acceptable and minor constitutional risk**.

(...)

On the basis of the statement being made, and in the light of all the assurances given by the UK Government, I regard the risk presented by the provisions to be acceptable." (Emphasis added)

²² See also Letter from the Minister for Health and Social Services, 2 February 2022

²³ Welsh Government, Memorandum No. 2, paragraphs 17 to 19

Clauses 122 to 125

39. Clauses 122 to 125 are new clauses added to the Bill which relate to virginity testing. These clauses make carrying out virginity testing, as well as offering to or aiding or abetting a person to carry it out, an offence.

40. Paragraphs 40 to 45 in Memorandum No. 2 provide details as regards clauses 122 to 125 and the Welsh Government's position.

41. In Memorandum No. 2 the Minister states:

"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. (...)

I support this amendment as it has been extended to Wales at the request of the Welsh Government."²⁴

Clause 135

42. Clause 135 is also a new clause added to the Bill at House of Commons Report Stage and it relates to reimbursement to community pharmacies.

43. Paragraphs 46 to 54 in Memorandum No. 2 provide details as regards clause 135 and the Welsh Government's position.

44. Memorandum No. 2 notes that clause 135 amends section 88 of the *NHS (Wales) Act 2006* (the 2006 NHS Act), creating an exemption where pharmacy contractors do not need to be reimbursed for medicinal products that are used for vaccines and immunisation of for the prevention and treatment of disease that could become a pandemic, where those products have been procedure centrally.²⁵

45. Memorandum No. 2 also notes that consequential amendments to clause 153 (commencement) provide the Welsh Ministers with regulation-making powers to bring into force the amendments to the 2006 NHS Act and to make transitional provisions in connection

²⁴ Welsh Government, Memorandum No. 2, paragraphs 43 and 45

²⁵ Welsh Government, Memorandum No. 2, paragraph 46

with the coming into force of those amendments. Such regulations will not be subject to any Senedd scrutiny procedure.²⁶

46. At paragraphs 52 and 54 of Memorandum No. 2 the Minister states:

"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. (...)

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

Clause 136 (formerly clause 120)

47. Clause 136 (formerly clause 120) amends the *Healthcare (European Economic Area and Switzerland Arrangements) Act 2019* (HEEASA) to enable the UK Government to implement international healthcare agreements with countries, territories and international organisations outside the European Economic Area and Switzerland. Clause 136 will also rename HEEASA to the *Healthcare (International Agreements) Act 2019*.

48. Clause 136 widens the scope of existing powers conferred on the Secretary of State relating to reciprocal healthcare, by removing these territorial restrictions. It broadens the geography of, and makes permanent, existing temporary powers which currently enable the UK Government to authorise payments in European Economic Area countries and Switzerland for five years after EU exit. This arrangement was established on the grounds of the need for speed and flexibility as the UK withdrew from the EU.

49. Paragraphs 26 to 32 in Memorandum No. 2, and paragraphs 14 and 17 in Memorandum No. 3 provide details as regards amendments to clause 136, further intergovernmental discussions, and corresponding changes to the Welsh Government's position.²⁷

²⁶ Welsh Government, Memorandum No. 2, paragraph 47

²⁷ See also Letter from the Minister for Health and Social Services, 2 February 2022

50. In Memorandum No. 2, the Minister confirmed that the Welsh Government had two concerns with this clause. First, that it enabled the Secretary of State to confer functions on and/or delegate functions to the Welsh Ministers and public authorities in Wales when making regulations that would give effect to healthcare agreements. Second, that the UK Government would only consult with the Welsh Ministers on draft regulations giving effect to international healthcare agreements.

51. As regards the first concern, at paragraph 28 of Memorandum No. 2, the Minister stated that the Bill had been amended so that 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 HEEASA, excludes both the Welsh Ministers and other devolved Welsh authorities. Memorandum No. 2 also notes that Welsh Local Health Boards have been brought 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.²⁸

52. In relation to the Minister's second concern with clause 136, Memorandum No. 2 notes that an amendment agreed at Report Stage amended 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. Such regulations would be subject to the negative scrutiny procedure in the Senedd.²⁹

53. At paragraphs 30 to 32 of Memorandum No. 2 the Minister states:

"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.

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

²⁸ Welsh Government, Memorandum No. 2, paragraph 28

²⁹ Welsh Government, Memorandum No. 2, paragraph 30

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.

Consequently I can now support this Bill clause."

Clause 142 (formerly clause 123)

54. Clause 142 (formerly clause 123) makes a number of amendments to the *Health Act 1999* (the 1999 Act) relating to the regulation of health professions. As outlined in Memorandum No. 2, while the regulation of health professionals is a reserved matter, 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 in the Bill as introduced would have extended the power of the Secretary of State to regulate these additional groups of workers.

55. Paragraphs 33 to 35 in Memorandum No. 2 provide details as regards amendments to clause 142 and corresponding changes to the Welsh Government's position.³⁰

56. At paragraph 34 of Memorandum No. 2 the Minister notes that an amendment to the clause means that the consent of the Welsh Ministers will now be needed before an Order in Council can be made under section 60 of the 1999 Act that is within the legislative competence of the Senedd. The Minister adds:

"I am content that this amendment address[es] the concerns of Welsh Government in respect of this provision and consequently I can now support this Bill clause."³¹

Clause 143

57. Clause 143 relates to medical examiners.

³⁰ See also Letter from the Minister for Health and Social Services, 2 February 2022

³¹ Welsh Government, Memorandum No. 2, paragraph 35

58. Paragraphs 36 to 39 in Memorandum No. 2 provide details as regards amendments to clause 143 and corresponding changes to the Welsh Government's position.

59. An amendment to clause 143, agreed at Report Stage, inserts a new section 18B into the *Coroners and Justice Act 2009* (the 2009 Act) in England and Wales, which sets out a power for Welsh NHS bodies to appoint medical examiners. Memorandum No. 2 notes that 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 ensure that their performance is monitored.³²

60. In Memorandum No. 2 the Minister states:

"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.

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."³³

New clause – Criminalisation of hymenoplasty

61. Paragraphs 38 to 43 in Memorandum No. 3 provide details as regards amendments tabled to the Bill at Committee Stage in the House of Lords relating to the criminalisation of hymenoplasty³⁴, and the Welsh Government's position.

62. The amendments tabled to the Bill by the UK Government make carrying out, as well as offering to carry out or aiding or abetting a person to carry out, hymenoplasty an offence.

³² Welsh Government, Memorandum No. 2, paragraph 36

³³ Welsh Government, Memorandum No. 2, paragraphs 37 and 38

³⁴ Hymenoplasty, also called 'hymen repair', is a surgical intervention which involves reconstructing the hymen. Hymenoplasty is a form of Female Genital Cosmetic Surgery.

63. At paragraphs 41 and 43 of Memorandum No. 3 the Minister states:

"We have agreed for this provision to extend to and apply in 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; if these offences did not extend to Wales it would mean that women and girls in Wales have fewer protections than their counterparts in England. (...)

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

New clause – Mandatory reporting

64. Paragraphs 44 to 50 in Memorandum No. 3 provide details as regards amendments tabled to the Bill at Committee Stage in the House of Lords which make provision for the Secretary of State to make regulations which require manufacturers or commercial suppliers of health care products (or persons connected) to publish information about payments or other benefits made by them to health care providers, or provide such information to the Secretary of State for publication. These paragraphs also set out the Welsh Government's position.

65. At paragraphs 46 to 50 of Memorandum No. 3 the Minister states:

"I am of the view that it is important the policy of recording information on payments or other benefits applies across the UK. (...)

Following negotiations with the Devolved Governments, UK Government has agreed that the Secretary of State must seek the consent of the Welsh Ministers before making provision in Regulations which would be within the legislative competence of the Senedd.

Should the consent of the Welsh Ministers not be forthcoming, the amendment also provides that the Secretary of State can in regulations make different provision for different parts of the UK in this area, which could allow for arrangements to exclude Wales-based manufacturers from reporting if necessary.

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

Update on the Welsh Government's overall position since the publication of the Memorandum

66. As of December 2021, as set out in Memorandum No. 2, the majority of the concerns of the Welsh Government had been addressed by amendments made to the Bill at Report Stage in the House of Commons.³⁵

67. At paragraph 61 of Memorandum No. 2 the Minister states:

"... 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."

68. In Memorandum No. 3, laid before the Senedd on 28 January 2022, the Minister states:

"... we have reached agreement with the UK Government regarding the remaining areas of concern, namely Arm's Length Bodies Transfer of Functions and Consequential Amendments to Senedd Legislation. (...)

I welcome the amendments the UK Government has made to the Bill to address the remaining areas of concern of the Welsh Government and the further amendments regarding the introduction of Criminalisation of Hymenoplasty and Mandatory Reporting provisions which, at our request, are to extend to Wales.

Subject to the tabled amendments being passed by the House of Lords and the making of the agreed Dispatch Box Statement, I am able to recommend consent to all of the clauses in the Bill which relate to areas within devolved competence as it is currently constituted."³⁶

³⁵ Welsh Government, Memorandum No. 2, paragraph 60

³⁶ Welsh Government, Memorandum No. 3, paragraphs 51, 55 and 56

2. Committee consideration

69. We considered Memorandum No. 2 at our meeting on 10 January 2022,³⁷ and Memorandum No. 3 at our meeting on 7 February 2022.³⁸ We also agreed our report on 7 February.

Our view

General comments

70. In our first report, we highlighted concerns with the timeliness of Welsh Government legislative consent memoranda being laid before the Senedd and how delays to laying such memoranda place Senedd committees at a disadvantage as they attempt to scrutinise what are, ever increasingly, complicated matters.

71. The Minister's swift action to lay Memorandum No. 3 before the Senedd only a few days after relevant amendments had been tabled in the House of Lords is very much welcomed. However, almost a month passed between the tabling of amendments at Report Stage in the House of Commons and the Minister laying Memorandum No. 2 before the Senedd.

72. In Memorandum No. 2, the Minister offers an explanation that the delay was caused by the complexity of the amendments which required analysis for their full effect.³⁹ While we acknowledge the Minister's comments that there were also discussions on-going with the UK Government on further outstanding issues, given that a number of these amendments were tabled at the request of the Minister, their full effect would have been known at the point of tabling.

73. We are mindful of the work involved in preparing legislative consent memoranda. Nonetheless, we remind the Welsh Government that it is important that the Senedd is provided with accurate and timely legislative consent memoranda, not least because the Senedd is, in the first place, being denied the opportunity to fully scrutinise the primary legislation to which the memoranda relate.

³⁷ Legislation, Justice and Constitution Committee, 10 January 2022

³⁸ Legislation, Justice and Constitution Committee, 7 February 2022

³⁹ Welsh Government, Memorandum No. 2, paragraph 3

74. We note the position of the Welsh Government as set out in Memorandum No. 2 and Memorandum No. 3 with regards to its reasons for making provision for Wales in the Bill. These matters are discussed below as part of our consideration of specific clauses in the Bill.

Clause 87 (formerly clause 85)

75. Paragraphs 28 to 34 and recommendation 1 in our first report dealt with clause 87 of the Bill (referred to as clause 85 in that report) which relates to medicines information systems.

76. We note the information provided in Memorandum No. 2 and Memorandum No. 3 regarding amendments made to clause 87, including the amendments which now mean that Welsh Ministers will be consulted on any regulations or directions made under the clause relating to medicine information systems which relate to Wales.

77. We further note the Minister's response to recommendation 1 in our first report, and the Minister's updated position that she will now support the inclusion of this clause in the Bill.

78. We also note that there is to be a Memorandum of Understanding concerning Medicines Information Systems, which is yet to be drafted by the UK Government. We acknowledge the Minister's statement that she has "communicated to the UK Government the need to develop this Memorandum as soon as possible with a view to it being in place before the provisions come into force".

Conclusion 1. The Memorandum of Understanding between the Welsh and UK Governments concerning Medicines Information Systems should be finalised and put in place before the relevant provisions in the Bill (if and once enacted) come into force.

Recommendation 1. The Minister should, before or during the debate on the relevant consent motion, provide an update to the Senedd on progress being made by the Welsh and UK Governments to finalise the Memorandum of Understanding concerning Medicines Information Systems, and confirm whether it will be in place before the relevant provisions in the Bill (if and once enacted) come into force.

Clauses 88 to 94 (formerly clauses 86 to 92)

79. Paragraphs 35 to 46 and recommendations 2 and 3 in our first report dealt with clauses 88 to 94 of the Bill (referred to as clauses 86 to 92 in that report) which relate to the transfer of functions between relevant arm's length bodies.

80. In our first report we said that we were unclear why the Minister was satisfied with reassurances given by the UK Government regarding clause 89 as opposed to a legislative

commitment on the face of the Bill. Recommendation 3 in our first report said the Minister should seek an amendment to the Bill to address her concerns about this clause to the effect that the Secretary of State cannot use the powers therein to transfer and/or delegate functions in relation to Special Health Authorities where those functions were directed by the Welsh Ministers in relation to Wales.

81. We note the information provided in Memorandum No. 2 and Memorandum No. 3 regarding amendments made (or proposed) to clauses 88 to 94 of the Bill, and the Minister's response to recommendations 2 and 3 in our first report. We also acknowledge the Minister's updated position that she will now support the inclusion of these clauses in the Bill.

82. We note that the UK Government has tabled an amendment (amendment 231C) providing for a statutory consent requirement, whereby the consent of the Welsh Ministers is needed before the Secretary of State can make regulations under clauses 89 or 90 where those regulations contain provision which would be within the legislative competence of the Senedd if contained in an Act of the Senedd (and is not merely incidental to, or consequential on, provision which would be outside that legislative competence) or which modifies the functions of the Welsh Ministers (i.e. modifies their executive competence).

83. We also acknowledge the Minister's statement that a Memorandum of Understanding concerning arm's length bodies will no longer be required if amendment 231C is agreed.

84. We further note that the UK Government has tabled amendments removing the Welsh Ministers, Welsh NHS Trusts and Welsh Special Health Authorities from the list of "appropriate persons" in clause 92 which the Minister considers to have fully addressed the Welsh Government's concerns in this area.

85. While we also note the Minister's explanation that her concerns with the power given to the Secretary of State in clause 91 to make regulations which make provision consequential on clauses 88 or 90 have now been addressed in intergovernmental negotiations regarding clauses 91, 144 and 149, we are not content with the position and our concerns are outlined in further detail below.

Clauses 91, 144 and 149 (formerly clauses 89, 125 and 130)

86. Clauses 91, 144 and 149 all contain Henry VIII powers.

87. Paragraphs 78 to 85 and recommendation 7 in our first report dealt with clause 144 of the Bill (referred to as clause 125 in that report). Paragraphs 86 to 90 in our first report dealt with clause 149 of the Bill (referred to as clause 130 in that report).

88. Paragraphs 91 to 94, conclusion 4 and recommendation 8 in our first report dealt with the issue of Henry VIII regulation-making powers in the Bill that would permit the Secretary of State and Lord Chancellor to amend Senedd Acts and Measures as well as the 2006 Act.

89. As indicated in our first report, the UK Government does not consider that the Senedd's consent is required for clauses 144 and 149.

Conclusion 2. Our views on clauses 144 and 149 have not changed. We remain of the view that the relevant provisions in clause 144 (and Schedule 16) and 149 fall within a devolved purpose as provided for by Standing Order 29(i).

Conclusion 3. Our views on the provisions in the Bill that would enable the Secretary of State or Lord Chancellor to amend Senedd Acts and Measures as well as the *Government of Wales Act 2006* have not changed. As regards the amendment of the 2006 Act, our consistent view has been and will be that the legislative competence of the Senedd should not be modified by regulations made by UK Ministers.

90. We note the information and views provided by the Minister in both Memorandum No. 2 and Memorandum No. 3 as regards the intergovernmental discussions that have continued as regards these provisions in the Bill. We also note the Minister's response to recommendations 7 and 8 in our first report.

91. We are disappointed with the reasoning provided by the Minister as to why she is now content with these clauses of the Bill.

92. While we acknowledge that both the Welsh and UK Governments have worked on addressing the issues with these clauses, the Minister is aware that despatch box commitments – despite being a tool of government – are not binding on any future Government and neither do they provide a role for the legislature.

93. While such a commitment may seem an appropriate compromise for the Welsh Ministers, we do not share that view. The use of despatch box commitments do not equate to an appropriate provision within a Welsh Government Bill, and is not an approach to be welcomed.

94. The Minister has stated that the agreed outcome of negotiations between the governments has resulted in a "minor constitutional risk". This outcome, and the Minister's acceptance of it, is unacceptable: elements of the Welsh devolution settlement should not be put at risk because a UK Bill is being used to legislate in a devolved area.

Recommendation 2. The Minister, should in advance of the Senedd's debate on the relevant legislative consent motion, explain and quantify the risk she describes in paragraph 33 of Memorandum No 3.

95. As regards recommendation 8 in our first report regarding the provisions in the Bill enabling UK Ministers to amend the 2006 Act via regulations, we are disappointed and concerned that the Minister has not addressed this matter in her letter to us dated 2 February 2022.

96. While her letter addresses the matter of broad Henry VIII powers that would enable the Secretary of State to use regulations to amend Senedd Acts and Measures, the Minister has not provided a response to our recommendation that she should seek an amendment to the Bill to the effect that the powers therein cannot be used by UK Ministers to amend the 2006 Act.

Conclusion 4. Our views on the powers in the Bill that would enable the legislative competence of the Senedd to be modified by regulations made by UK Ministers have not changed.

Recommendation 3. The Minister should seek an amendment to the Bill to the effect that the powers in the Bill cannot be used by UK Ministers to make regulations that amend the *Government of Wales Act 2006.* The Minister should, in advance of the Senedd's debate on the relevant consent motion, confirm that she has sought such an amendment and provide an update to the Senedd on the latest position.

Clauses 122 to 125

97. We note the information provided in Memorandum No. 2 regarding new clauses added to the Bill which relate to virginity testing.

98. We further note, and draw to the Senedd's attention, the Minister's statement that the extension of these provisions to Wales was actioned at the request of the Welsh Government and, as such, the Minister supports the inclusion of these clauses in the Bill.

Clauses 135 and 153

99. We note the information provided in Memorandum No. 2 regarding new clause 135 added to the Bill which relates to reimbursement to community pharmacies.

100. We further note, and draw to the Senedd's attention, the Minister's statement that the extension of these provisions to Wales was actioned at the request of the Welsh Government and, as such, the Minister supports the inclusion of these clauses in the Bill.

101. We also wish to highlight three specific matters regarding this new clause.

102. First, we note and draw to the Senedd's attention, that consequential amendments to clause 153 as a result of new clause 135 provide the Welsh Ministers with new regulation-making powers to bring into force the amendments to the 2006 NHS Act and to make transitional provisions in connection with the coming into force of those amendments. Such regulations will not be subject to any Senedd scrutiny procedure. While such commencement powers are often not accompanied by a formal scrutiny procedure, given that Members of the Senedd have not had the opportunity to formally scrutinise the primary legislative provision enabling such a delegated power, we consider this to be unsatisfactory.

103. Second, and in relation to the consequential amendments to clause 153 as a result of new clause 135, it is unclear to us why the Minister has not listed clause 153 as a provision requiring the consent of the Senedd given the amendments made to it which provide the Welsh Ministers with the power to bring into force the new provisions regarding reimbursement to community pharmacies.

Conclusion 5. We believe the consent of the Senedd should be sought for clause 153 of the Bill, as we consider the clause makes provision in relation to Wales for a purpose within the legislative competence of the Senedd or which modifies the Senedd's legislative competence.

Recommendation 4. The Minister should, in advance of the Senedd's debate on the relevant consent motion, explain in full why she is not seeking the Senedd's consent for clause 153 of the Bill.

104. Finally, there is an interesting choice of words used in paragraph 52 of Memorandum No. 2, namely that "officials consider it is prudent and timely to agree to the UK Government making these amendments via the Bill". While we recognise that government officials provide necessary and required advice to the Welsh Ministers, final decisions should be and are made by the Welsh Ministers themselves.

Clause 136 (formerly clause 120)

105. Paragraphs 47 to 72 and recommendations 4 and 5 in our first report dealt with clause 136 of the Bill (referred to as clause 120 in that report) which relates to the implementation of international healthcare agreements.

106. In our first report we concluded that clause 136 of the Bill would:

- constitute a departure from constitutional convention of implementing international agreements requiring changes to domestic legislation via primary legislation, with its accompanying scrutiny;
- provide broad scope to the Secretary of State to make healthcare payments for healthcare that falls outside of an international healthcare agreement in "exceptional circumstances", which is not defined by the Bill, and we noted that there are no limits on the amount or type of healthcare funded;
- reduce the UK Parliament's current limited role in the scrutiny of international agreements and accompanying primary legislation;
- place additional limitations on the involvement of the devolved legislatures in the scrutiny process of UK international agreements, including those in areas of devolved competence.

107. We note that amendments have been made to the face of the Bill which are supported by the Minister. We further note the Minister's response to recommendations 4 and 5 in our first report.

108. First, we acknowledge that 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 HEEASA has been amended so that the Welsh Ministers and other devolved Welsh authorities are excluded from that definition. We also note that other amendments now 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.

109. Second, we acknowledge that HEEASA has been amended to give the Welsh Ministers a new regulation-making power enabling them to make regulations in devolved areas for the purpose of giving effect to international healthcare agreements. This includes the power to delegate functions to, and/or confer functions on, all devolved Welsh authorities. We also acknowledge that, 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.

Conclusion 6. The Welsh Ministers should make any necessary regulations in devolved areas for the purpose of giving effect to international healthcare agreements. Where they do not do so, and the power to confer relevant functions onto the Local Health Boards regarding healthcare agreements is instead exercised by the Secretary of State, the Welsh Ministers must

provide full detail and an explanation to the Senedd in advance of such regulations being made by the Secretary of State.

110. We note that if regulations are made by the Welsh Ministers under this provision, they would be subject to the negative procedure in the Senedd. As a result of these amendments to the Bill, we acknowledge that the Senedd will retain its ability to have sight of and scrutinise regulations made in relation to international healthcare agreements, albeit those regulations will be subject to the negative scrutiny procedure. Given that this clause previously gave such regulation-making powers exclusively to the Secretary of State to implement healthcare agreements for Wales, which would not have offered the Senedd the same opportunity for scrutiny as regulations made by the Welsh Ministers, we acknowledge that this is an improved position.

111. Recommendation 5 in our first report said that the Minister should seek an amendment to the Bill to the effect that a clear and proportionate test for what qualifies as an 'exceptional circumstance' for the purpose of this clause is included on the face of the Bill. We note the Minister's response to our recommendation, but it does not fully satisfy our concerns.

112. The Minister's letter to us dated 2 February included examples of how the UK Government has previously used powers under HEEASA to fund healthcare treatment which had not otherwise been covered by a reciprocal agreement. The Minister also told us:

"Exceptional circumstances are likely to be those in which the refusal to fund healthcare treatment would result in unjustifiably harsh consequences for the individual such that the refusal of an application for funding would not be proportionate. Determining whether a payment is justified by exceptional circumstances will necessarily require a balance to be struck between any competing public and individual interests involved. Attempting to define this further in primary legislation by reference to an amount or type of healthcare that can be funded would unduly restrict the Secretary of State's ability to exercise this discretion and hinder the ability to assist British residents when they most need it.

It is therefore my view that it is not appropriate to put a clear and proportionate test on the face of the Bill for what would qualify as an 'exceptional circumstance' for the purposes of the amount or type of healthcare that can be funded outside of an international healthcare

agreement as this could have a detrimental or limiting impact to provide support when needed."40

113. Given that there are examples available to the governments on how such similar powers have been used, we are unclear why the broad tests that would have been previously met in order for funding to be put in place with those examples could not be set out on the face of the Bill.

Conclusion 7. We remain concerned at the extensive and limitless scope of the power provided in clause 136 as regards the ability of the Secretary of State to make payments for healthcare that fall outside of an international healthcare agreement. Our preferred approach remains to amend the face of the Bill as set out in recommendation 5 in our first report.

Recommendation 5. In the absence of amendments being tabled to the face of the Bill in line with recommendation 5 in our first report, we believe that the Secretary of State should make information publicly available regarding the broad tests and criteria that will be used in determining what is an 'exceptional circumstance' for the purpose of clause 136. The Minister should pursue this matter directly with the Secretary of State.

114. We note the Minister's 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... provide sufficient protection of the devolution settlement."

115. Recommendation 4 in our first report asked that the Minister, in advance of the Senedd's debate on the relevant consent motion, provide us and all Members of the Senedd with a copy of the final Memorandum of Understanding (MoU) in place between the Welsh and UK Governments in relation to HEEASA, and confirm that the text of that existing MoU reflected the final, limited scope of the Bill as agreed by the UK Parliament.

116. The MoU was only made available to us on 2 February 2022, therefore limiting the potential for full and effective scrutiny before the Senedd is asked whether or not to consent to clause 136.

117. In responding to recommendation 4 in our first report, the Minister said:

"The MOU has been agreed by all four nations. The Committee will wish to note that the wider linkages in relation to the new intergovernmental

⁴⁰ Letter from the Minister for Health and Social Services, 2 February 2022

relations (IGR) governance arrangements have not yet been included in the MOU but are being considered. The MOU will be updated to reflect the new IGR arrangements in due course."⁴¹

118. We acknowledge that the MoU will be updated to reflect the new intergovernmental relations arrangements agreed (as announced on 13 January 2022⁴²).

Recommendation 6. The Minister should work proactively with the UK Government and other devolved governments to ensure that the Memorandum of Understanding in respect of the consultation process for international healthcare agreements and their implementation is updated as soon as possible to reflect the new intergovernmental relations arrangements (including dispute resolution processes) agreed and announced on 13 January 2022.

Recommendation 7. Further to recommendation 6, the Minister must provide to the Senedd the updated version of the Memorandum of Understanding in respect of the consultation process for international healthcare agreements and their implementation as soon as it is agreed and finalised.

Recommendation 8. As the Committee responsible for the scrutiny of non-trade international agreements, the Minister should commit to notify us of any forthcoming international agreements which will fall within the remit of the Memorandum of Understanding in respect of the consultation process for international healthcare agreements and their implementation.

Clause 142 (formerly clause 123)

119. Paragraphs 73 to 77 and recommendation 6 in our first report dealt with clause 142 of the Bill (referred to as clause 123 in that report) which relates to the regulation of health professions.

120. We note the information provided in Memorandum No. 2 regarding amendments made to clause 142, and that such amendments mean that the consent of the Welsh Ministers will now be needed before an Order in Council can be made under section 60 of the 1999 Act when it is within the legislative competence of the Senedd.

121. We further note that the Minister is now content that her concerns have been addressed and she now supports the inclusion of clause 142 in the Bill.

⁴¹ Letter from the Minister for Health and Social Services, 2 February 2022

⁴² UK Government, **Review of intergovernmental relations**, 13 January 2022

Clause 143

122. We note the information provided in Memorandum No. 2 and Memorandum No. 3 regarding amendments made to clause 143 which relates to medical examiners.

123. We also note, and draw to the Senedd's attention, the Minister's statement that the extension of these provisions to Wales was actioned at the request of the Welsh Government and, as such, the Minister supports the inclusion of this clause in the Bill.

New clause – Criminalisation of hymenoplasty

124. We note the information provided in Memorandum No. 3 regarding amendments tabled to the Bill which relate to criminalising hymenoplasty.

125. We further note, and draw to the Senedd's attention, the Minister's statement that the extension of these provisions to Wales was actioned at the request of the Welsh Government and, as such, the Minister supports the inclusion of these clauses in the Bill.

New clause – Mandatory reporting

126. We note the information provided in Memorandum No. 3 regarding amendments tabled to the Bill which relate to the Secretary of State making regulations which require manufacturers or commercial suppliers of health care products (or persons connected) to publish information about payments or other benefits made by them to health care providers, or provide such information to the Secretary of State for publication.

127. We also note that, following negotiations with the devolved governments, the amendments proposed require the Secretary of State to seek the consent of the Welsh Ministers before making regulations under these clauses which would be within the legislative competence of the Senedd. We further note that the amendments will enable the Secretary of State to proceed with regulations that make different provision for other parts of the UK in this area should the consent of the Welsh Ministers not be forthcoming.

128. We draw to the Senedd's attention the Minister's statement that the extension of these provisions to Wales was actioned at the request of the Welsh Government and, as such, the Minister supports the inclusion of these clauses in the Bill.

Final observations

129. As we highlight above, many of the provisions in the Bill have been included at the request of the Welsh Government. Moreover, while we have made recommendations in this report to address our overall concerns in some areas, they are no substitute for the ability of

Members of the Senedd to test and improve legislation by means of tabling amendments to Welsh Bills introduced to the Senedd. We are aware of the challenges the Welsh Government face (and which we are investigating) but that should not overshadow the constitutional risk to the devolution settlement that arises from the continued use of UK Bills in devolved areas to deliver Welsh Government policy objectives.