Supplementary Legislative Consent Memorandum

Health and Care Bill

Background

1. This memorandum has been lodged by Humza Yousaf, Cabinet Secretary for Health and Social Care, under Rule 9.B.3.1(a) and (c) of the Parliament's standing orders. This memorandum is supplementary to LCM-S6-5¹. The Health and Care Bill was introduced in the House of Commons on 6 July 2021 and the House of Lords on 24 November 2021. The latest version of the Bill can be found at:

https://bills.parliament.uk/publications/44008/documents/1051

Content of the Health and Care Bill

2. The Explanatory Notes² accompanying the Bill set out the UK Government's view of its purpose and main functions. The UK Government describes the principal purpose of the Bill is to give effect to the policies that were set out as part of the NHS's recommendations for legislative reform following the Long Term Plan and in the White Paper 'Integration and Innovation: Working together to improve Health and Social Care for all' published in February 2021 (paragraph 1 of the Explanatory Notes). As health is devolved, the majority of the provisions in the Bill apply to England only.

- 3. The main provisions of the Bill are broadly categorised under four themes:
 - Working together collaboratively and supporting integration;
 - Reducing bureaucracy;
 - Ensuring public confidence and accountability; and,
 - Additional proposals to support social care, public health, and quality and safety.

Provisions which relate to Scotland

4. As set out in LCM-S6-5, the Bill contains provisions that apply to Scotland and the UK Government had initially requested legislative consent in relation to five provisions. It remains, however, the view of the Scottish Government that legislative consent is required for a further provision which has not been recognised by the UK Government: clause 125 of the Bill, as introduced, the advertising of less healthy food and drink.

¹<u>https://www.parliament.scot/-/media/files/legislation/bills/lcms/health-and-care-bill/splcms065.pdf</u>

² https://publications.parliament.uk/pa/bills/cbill/58-02/0140/en/210140en.pdf

5. Details of the provisions relevant to the Scottish Parliament and Scottish Ministers can be found in the original Legislative Consent Memorandum (LCM-S6-5). Additionally, the UK Government tabled an amendment to introduce clauses 126-129 to the Bill, which also require legislative consent.

6. The Scottish Government previously withheld consent to the whole Bill, pending suitable amendments by the UK Government. The Scottish Government can now recommend consent to clauses 87, 136, 142 and 146 of the Bill, as recently published, and recommend consent to clauses 126-129 as tabled on 17 November 2021.

7. It is the view of the Scottish Government that a further supplementary LCM may be required for Part 3 of the Bill, clauses 88-94 (Secretary of State's Power to Transfer or Delegate Functions), as found in the version published on 24 November 2021, when, and if, suitable progress has been made.

8. Clauses 88-94 of the Bill make provision to allow the Secretary of State to transfer health functions between specified Arm's Length Bodies ("ALBs") with the aim of streamlining the health service in England. The clauses are designed to provide the Secretary of State with powers to streamline services but will impact on devolved areas insofar as (a) the exercise of regulation making powers in respect of the transfer of functions which may make provision within legislative competence; and (b) the power to transfer property, rights and liabilities to the Scottish Ministers. The powers are wide ranging and the Secretary of State may modify functions, abolish any ALB affected and modify the funding and constitutional arrangements of the ALB.

9. The Scottish Government, as detailed in the original LCM, requested two amendments to the Bill in relation to these clauses. Discussions with the UK Government are still ongoing and, subject to securing an acceptable outcome, the Scottish Government will bring forward a supplementary LCM upon the tabling of agreed amendments.

Reasons for seeking legislative consent

10. The Bill is a relevant Bill under Rule 9B.1.1 of the Standing Orders, as it makes provision applying to Scotland for purposes within the legislative competence of the Scottish Parliament.

11. The elements of the Bill that make provision for a purpose within the legislative competence of the Scottish Parliament are:

Regulations of healthcare and associated professions

12. Clause 142 of the Bill (previously clause 123) provides the Secretary of State powers to enable reform of the overarching system of healthcare professional regulation. The provisions are consistent with UK-wide consultations on healthcare professional regulatory reform. The provisions will provide the Secretary of State with

a power by secondary legislation to abolish individual health and care professional regulatory bodies where the professions concerned have been deregulated or are being regulated by another body. The Secretary of State will also be provided with a power to remove a profession from regulation where regulation of that profession is no longer required to protect the public. These provisions are consistent with the longstanding principle that healthcare professional regulation be proportionate.

13. Clause 142 requires legislative consent insofar as it affects new and existing groups of healthcare professions brought into regulation after the commencement of the Scotland Act 1998, as making provision in relation to these regulated groups for Scotland is within devolved competence. However, this applies only to a small number of groups, with the vast majority of regulators and the groups they regulate remaining within reserved competence. Ministers have committed to a four country approach to health professional regulation, to maintain a consistent understanding for patients, employers and professionals, and to prevent practitioners with problems from working across administrative boundaries. As the primary powers will apply equally to all regulated health professional groups, and enactment of the provisions requires subordinate legislation subject to appropriate scrutiny of the Scottish Parliament, it is pragmatic for the UK Parliament to legislate for devolved interests.

14. The Scottish Government agrees with this assessment and, owing to satisfactory amendments made elsewhere in the Bill, can now recommend that the Scottish Parliament grants legislative consent.

Food information for consumers: power to amend retained EU law

15. Clause 146 of the Bill (previously clause 127) includes provisions to amend section 16 of the Food Safety Act 1990 to give relevant Ministers, including Scottish Ministers, powers to amend the retained EU Food Information to Consumers (2011/1169) Regulation (EU FIC) through secondary legislation. Since the end of the EU Exit Implementation Period, this Regulation has been retained EU law in the UK. Existing powers in the Food (Scotland) Act 2015 would enable enforcement sanctions in Scotland for any new labelling regulations introduced by amending the retained EU FIC.

16. The UK Government intends to use these powers to implement policies such as changes to the front-of-pack nutrition labelling scheme and mandatory alcohol calorie labelling, following a UK-led four nations consultation. The clause will give the Scottish Ministers an equivalent power to that which the Secretary of State will have.

17. Clause 146 requires legislative consent insofar as the clauses have the devolved purpose of food labelling. The Scottish Government agrees with this assessment and, on account of satisfactory amendments made elsewhere in the Bill, can now recommend that the Scottish Parliament grants legislative consent.

International healthcare arrangements

18. Clause 136 of the Bill (previously clause 120) requires legislative consent insofar as the implementation of healthcare agreements may be exercised within devolved competence and the Scottish Ministers have certain powers to give effect to health agreements under the NHS (Scotland) Act 1978.

19. Clause 120 of the Bill, as originally drafted, allowed the Secretary of State to confer functions on public authorities and provided for the delegation of functions to public authorities, without requiring the consent of Scottish Ministers. In Scotland 'public authorities' include Scottish Ministers and NHS Boards. That position was clearly unacceptable to the Scottish Government.

20. Amendments to Clause 136 (previously clause 120) were tabled by the UK Government on 18 November. The amendments grant concurrent powers to the devolved administrations to allow them to make their own regulations on the implementation of reciprocal healthcare agreements in their respective countries. The original regulation making power for the Secretary of State to implement healthcare agreements on a UK wide basis is retained (but, importantly, it is now restricted by the amendments so the power can no longer be used to confer functions on the Scottish Ministers). This clause requires legislative consent because it will confer a new function on the Scottish Ministers to make regulations and those powers will be capable of being used to make provision or amendments that will fall within devolved competence, to implement international healthcare agreements. It has been decided that the power in relation to discretionary payments outside healthcare agreements in exceptional circumstances should remain with the Secretary of State, given that the UK Government will fund reciprocal healthcare with rest of world countries, although protocols will be developed across the four nations as exceptional circumstances arise.

21. This addresses the Scottish Government's concern, as outlined in the original LCM, around the extent of the powers and the exercise of those powers by UK Ministers to implement healthcare agreements without the consent of the Scottish Ministers (as Section 5 of The Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 only requires consultation, rather than consent, before regulations under section 2 that contain provision which is within the legislative competence of a devolved legislature may be made). Accordingly the Scottish Government can now recommend that the Scottish Parliament grants legislative consent.

Medicine Information Systems (MIS)

22. Clause 87 of the Bill (originally clause 85) requires legislative consent insofar that the improvement of patient outcomes and the improvement of the health of the people of Scotland are devolved purposes, which are within the legislative competence of the Scottish Parliament. Clause 87 confers a delegated power on the Secretary of State to make regulations providing for an information system in relation to human medicines, to be established and managed by NHS Digital; it is the view of the Scottish Government that the delegated power could be used for devolved

purposes. This also applies to the direction making power in clause 87, which could allow the Secretary of State to issue a written direction setting out the type of information to be provided to NHS Digital.

23. Clause 87 also makes amendments to section 43 of the Medicines and Medical Devices Act 2021. The amendment will allow for regulations that are made under the MIS regulation making powers (outlined above), and the existing section 19 of the Medicines and Medical Devices Act 2021 (which confers a similar delegated power to make regulations providing for a Medical Devices Information System(MDIS)) to amend the part of the Health and Social Care Act 2012 which establishes NHS Digital and sets its remit and powers. This expressly includes the power to extend the geographical area in which NHS Digital can perform its functions, which includes expanding to Scotland, and insofar as this power is used for a devolved purpose, it requires legislative consent.

24. The Scottish Government, as outlined in the original LCM, requested that the Bill was amended to reflect that both the regulation making and direction making powers are subject to the consent of Scottish Ministers. The Scottish Government also felt it was appropriate to allow Scottish Ministers to choose which MIS or MDIS to participate in and requested an amendment to make provision for this. Furthermore, the Scottish Government raised concerns about the confidentiality and security of Scottish patient data and requested an amendment to require that information may be provided to NHS Digital in pseudonymised form.

25. The Scottish Government is of the view that the requested amendments reflected the devolved purpose of the provisions that fall within the legislative competence of the Scottish Parliament; and were necessary to allow compliance with existing, and fundamental, safeguards and processes already in place within Scotland to protect Scottish patient data.

26. Amendments to clause 87 were tabled by the UK Government on 18 November and provide the following: (1) require the UK Government to consult with the Scottish Ministers before making Medicine Information Systems regulations or issuing a direction setting out the type of information to be provided to NHS Digital; (2) narrow the purposes for which the information system can be used such that there are fewer devolved purposes for which the system could be used; and (3) allows for NHS bodies in Scotland to supply their data to the information system via an intermediary body, which will allow for a single response on behalf of NHS Scotland as a whole.

27. The proposed information systems will support the Medicines and Healthcare products Regulatory Agency's (MHRA) regulatory functions and while Scotland-only information systems could be established, the MHRA note that a UK-wide information system is more robust for pharmacovigilance reasons. The Scottish Government is supportive of this position with regards to high risk medicines as there is the potential to make the completion of these information systems mandatory, improving the ability to reduce harm.

28. The Scottish Government is of the view that the amendments provide an acceptable degree of reassurance to the concerns around Scottish patient data.

Although they differ from the requested amendments, the Scottish Government is of the view that the consequences of not being included in the Medicine Information Systems would, on balance, outweigh any other concerns. Moreover, the Scottish Government recognises the benefits of UK-wide participation in monitoring the use, safety, benefits and risks associated with medicines.

29. Accordingly, the Scottish Government can now recommend that the Scottish Parliament grants legislative consent.

Virginity Testing Offences: Scotland

30. Part 5 of the Bill introduces criminal offences relating to the carrying out of virginity testing in England and Wales, in Scotland and in Northern Ireland; with clauses 126-129 making provision for those offences in Scotland. This is a new provision which was added to the Bill, via an amendment tabled by the UK Government on 17 November, and voted through during the House of Commons Report Stage on 23 November.

31. The UK Government has sought agreement from all devolved administrations to take action to criminalise the practice across all four nations. In addition to seeking a unified stance on the issue, the request from the UK Government also relates to their decision to attach extra-territorial jurisdiction to their offence of virginity testing. This would mean that should a UK National, or person who lives in the UK, carry out a virginity test abroad, they could be prosecuted under this new offence upon their return to the UK. It also means it is an offence to take a UK national, or person who lives in the UK, abroad for testing.

32. If these offences did not apply in Scotland then, as well as not protecting those who live in Scotland, and preventing those who live here from committing the offence, it would mean that it may be possible for a UK national or resident to come to Scotland and legally conduct a virginity test. Furthermore, it may be possible for a person from elsewhere in the UK (or the rest of the world) to be taken to Scotland and be tested without breaking the law. This position applies similarly to the other proposed offences of offering to test and to helping, arranging or encouraging this practice.

33. It is the view of the Scottish Government that virginity testing in Scotland may already be captured under existing laws on assault. However, as this is untested by case law, the Scottish Government cannot say for certain that an offence of virginity testing could be successfully prosecuted.

34. An LCM is required because the provisions relating to virginity testing fall within the legislative competence of the Scottish Parliament. The Scottish Government recognises virginity testing as a form of gender based, and honour based, violence. The Scottish Government also supports the notion of having a joined up approach to this issue across all four nations in the UK. Furthermore, the UK Government's legislation provides for extra-territorial jurisdiction to the offence of virginity testing which means that, if Scotland does not criminalise this practice, a potential loophole may occur in its legislation. Lastly, should the Scottish

Government not consent to this amendment, Scotland may become the only nation in the UK where virginity testing is not expressly illegal.

35. Accordingly, the Scottish Government recommends that the Scottish Parliament grants legislative consent to the provisions.

Consultation

36. Full details of consultation for clauses 87, 136, 142 and 146 can be found in the original Legislative Consent Memorandum (LCM-S6-5).

37. In relation to clauses 126-129, the Scottish Government has taken forward significant stakeholder consultation on the issue of virginity testing, including open discussions regarding potential options for addressing the issue in Scotland. This engagement has included representation from key organisations, including Police Scotland, NHS Scotland, Public Health Scotland and Education Scotland; as well as several third sector partners with expertise in issues relating to violence against women and girls and honour based violence. This engagement has included individual discussions with these groups, as well as two roundtable discussions held in March and October 2021.

38. The overall consensus is that a new criminal offence of virginity testing should be introduced in order to set a precedent that it is a form of violence against women and girls; and to send a message to perpetrators that it will not be tolerated.

Financial implications

39. The amended Bill does not create immediate financial requirements beyond what is needed for ongoing Scottish Government engagement on the Bill. As outlined in LCM-S6-5, it is difficult to fully ascertain any possible financial implications that may materialise in relation to clause 87.

40. In relation to virginity testing, the creation of a new criminal office may result in costs for Police Scotland, the Scottish Courts and Tribunals Service, and the Crown Office and Procurator Fiscal Service should cases of virginity testing be investigated and prosecuted.

41. There is no evidence of virginity testing taking place in Scotland and the Scottish Government does not anticipate that there will be a high number of cases per annum to be investigated and prosecuted; therefore, any costs related to this new criminal offence will be minimal.

Conclusion

42. As set out in LCM-S6-5, the Scottish Government noted most aspects of the Bill are not contentious but that it considered it fundamental that amendments were made to the Bill to provide reassurance on the intent and scope of the powers, most notably with the Medicine Information Systems provision. The Scottish Government

is content with the amendments tabled by the UK Government, and can now recommend that the Scottish Parliament gives its consent to:

- Medicine Information Systems
- International healthcare arrangements
- Regulations of healthcare and associated professions
- Food information for consumers: power to amend retained EU law
- Virginity testing offences: Scotland

Draft Legislative Consent Motion

43. The draft motion, which will be lodged by the Cabinet Secretary for Health and Social Care, is:

"That the Parliament agrees that the relevant provisions of the Health and Care Bill, introduced in the House of Commons on 6 July 2021, relating to regulation of healthcare and associated professions; food labelling for consumers; international healthcare arrangements; Medicine Information Systems; and virginity testing offences: Scotland; so far as these matters fall within the legislative competence of the Scottish Parliament and alter the executive function of the Scottish Ministers, should be considered by the UK Parliament."

Scottish Government December 2021

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