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) of the Parliament's Standing Orders. The Health and Care Bill was introduced in the House of Commons on 6 July 2021. This memorandum relates to the Bill as introduced. The Bill can be found at: https://publications.parliament.uk/pa/bills/cbill/58-02/0140/210140.pdf.

Content of the UK Health and Care Bill

2. The Explanatory Notes[1] 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 in Scotland, the majority of the provisions in the Bill apply to England and Wales only. The main provisions of the Bill are broadly categorised under four themes and they are as follows:

Working together collaboratively and supporting integration

3. This is the core theme of the Bill and the legislative proposals are intended to improve how the different parts of the health system in England can best work together. They seek to join up health and care services, local government and NHS bodies and align the common purpose of different professions, organisations and services.

4. None of these provisions extend to Scotland.

Reducing Bureaucracy

5. The provisions under this theme are intended to reform existing legislation to support the workforce by creating the flexibility NHS organisations need – to remove barriers that prevent them from working together and to enable them to arrange services and provide joined up care in the interests of service users. Some of these provisions will make changes to both competition law as it was applied to the NHS in the Health and Social Care Act 2012 and the system of procurement applied to the NHS by that legislation. The changes will enable the NHS and local authorities to reduce bureaucracy in arranging healthcare services while retaining core duties to ensure quality and value.

6. None of these provisions extend to Scotland.

[1] https://publications.parliament.uk/pa/bills/cbill/58-01/0007/en/20007en.pdf

Ensuring public confidence and accountability

7. These provisions are intended to improve accountability in the system in a way that will empower organisations and give the public the confidence that they are receiving the best care from their health and care system. NHS England will merge with NHS Improvement (designated as NHS England) and have accompanying enhanced powers of direction for the government to support better collaboration, information sharing and aligned responsibility and accountability. Further legislation will ensure that the UK Government has the right framework for national oversight of the health system, that national bodies are streamlined with clear roles and responsibilities, and that decision makers can be held to account.

Provisions that extend to Scotland and require an LCM:

- Secretary of State's power to transfer or delegate functions

Additional proposals to support social care, public health, and quality and safety

8. These provisions are intended to support social care, public health and improve quality and safety in the NHS – they have largely been informed by the experience of the pandemic. The proposals are intended to address specific problems, remove barriers to delivery and maximise opportunities for improvement.

Provisions that extend to Scotland and require an LCM:

- International healthcare arrangements
- Food information for consumers: power to amend retained EU law
- Advertising of less healthy food and drinks
- Regulation of healthcare and associated professions
- Medicines Information Systems

Provisions which relate to Scotland and require legislative consent

9. The Bill contains provisions that apply to Scotland and the UK Government has requested legislative consent in relation to the Secretary of State's power to transfer or delegate functions, international healthcare arrangements, food information for consumers: power to amend retained EU law, professional regulation and Medicines Information Systems. However, the view of the Scottish Government is that one of the provisions in relation to the advertising of less healthy food and drinks also requires the legislative consent of the Scottish Parliament.

Secretary of State's Power to Transfer or Delegate Functions

10. Part 3 (clauses 86 to 92) of the Bill makes provisions 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.

11. The UK Government has identified that a legislative consent motion is required here. The Scottish Government agrees that legislative consent is required insofar as the regulation making powers may be used to deal with any devolved purpose (and across any of the six relevant bodies to whom functions may be transferred, acquired, altered or removed), and insofar as these powers could be used to alter the executive competence of the Scottish Ministers. Aside from the fact that legislation which falls within the legislative competence of the Scottish Parliament can be amended by these regulation making powers, most of the relevant bodies listed in Part 3 either carry out functions on behalf of the Scottish Ministers, have a duty to cooperate with the Scottish Ministers in relation to certain matters, or the Scottish Ministers can enter into agreements with them for the provision of goods and services or other functions on their behalf. Clause 92 currently places a requirement on the Secretary of State to consult with the Scottish Ministers if draft regulations are to be made which will make provision within the legislative competence of the Scottish Parliament or for a matter in relation to which functions are exercisable by the Scottish Ministers, including any transfer scheme made in association with those powers. The Scottish Government is of the firm view that the regulations should only be made, if the consent of Scottish Ministers has been obtained in relation to any provision that falls within legislative competence and has requested that the UK Government amend the clause to reflect this.

12. It is also the view of the Scottish Government that where the powers are being exercised in a way which relates to reserved matters, including conferring, altering or removing functions which the Scottish Ministers may exercise in relation to a reserved matter, consultation with the Scottish Ministers should be required. The Scottish Government has requested that amendments are made to the clauses to make provision for such consultation.

13. The Scottish Government has also requested that a Memorandum of Understanding (MoU) underpins the consent requirement and the consultation requirement already included in the Bill (which the Scottish Government considers should apply to the exercise of functions within reserved matters). The view of the Scottish Government is that the MoU should outline the principles for engagement between administrations, including the timescales for consultation, and that the detail can be finalised at a later date.

14. Furthermore, the Scottish Government considers that meaningful and early engagement should be practised in relation to the changes that are made across any of the relevant bodies. However, it is particularly important that there is early engagement and that Scottish Ministers' views are taken into account in relation to any proposed changes to the Human Fertilisation and Embryology Authority. The Scottish Government has therefore requested an undertaking, at Ministerial level, that full, meaningful and early engagement will be provided and Scottish Ministers' views taken into account. The underlying principles for that engagement should be established through the MoU.

15. Given that the Scottish Government has identified, and has requested, that amendments are required, the Scottish Government cannot recommend that consent is granted at this time. Subject to the response from the UK Government, a supplementary Memorandum may be submitted.

International Healthcare

16. Clause 120 amends the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (HEESAA) and gives the Secretary of State powers to implement reciprocal healthcare agreements with countries outside the EEA and Switzerland, by removing the territorial restrictions of the HEESAA. The Secretary of State will also have a regulation-making power to make provision for discretionary payments for healthcare not under an agreement, but only in countries with which the UK has a reciprocal healthcare agreement, and where the Secretary of State considers that exceptional circumstances justify the payment. An LCM is required in respect of clause 120 as the Scottish Government has certain powers to give effect to health agreements under the NHS (Scotland) Act 1978 and the regulation making power may also be used to confer functions on the Scottish Ministers. The power may therefore be exercised so as to make provision falling within legislative competence and may be used to alter the executive competence of the Scottish Ministers.

17. By virtue of these proposed amendments to the HEESAA, the exchange of data between the UK and other rest of world (RoW) countries will be possible (expanding the current powers which relate to EEA and Switzerland), which facilitates the administration of reimbursement arrangements of a reciprocal healthcare agreement between the UK and other countries, and support effective monitoring of the agreement.

18. However, section 5 of the HEESAA sets out that before making regulations under section 2 that contain provision which is within the legislative competence of a devolved legislature, the Secretary of State must consult the relevant devolved authority on that provision. The Scottish Government made representations about this issue when the HEESAA was making its parliamentary passage as a Bill, and remains of the view that the Scottish Ministers should not only be consulted, but should be required to consent before regulations are made in such circumstances. The UK Government has already declined this request, favouring an agreed governance structure in the form of a memorandum of understanding, agreed at ministerial level by all four nations, to enable Devolved Administration cooperation and influence. The Scottish Government, however, stands firm in the view that the consent of Scottish Ministers must be obtained where the UK Government proposes the introduction of regulations, under Section 5 of the HEESAA, that impinge on devolved competence.

19. The Scottish Government has also identified that there is an amendment to the HEESAA that contains a power to make regulations to confer functions on “public authorities”. This has brought devolved administrations within scope of the power without an associated requirement to obtain the consent of Scottish Ministers before exercising the power. The UK Government proposed an amendment that excludes Scottish Ministers from the definition of ‘’public authorities’’ in clause 120 of the Bill. However the Scottish Government has concerns as to the impact on existing functions

for Ministers to determine applications for planned healthcare. In addition the power extends beyond Scottish Ministers to other public authorities in Scotland, for example NHS Boards. The position of the Scottish Government is that this is unacceptable and supports the view that there should be a consent requirement attached to provisions that would be within legislative competence. More generally, the Scottish Government has identified that replacing section 2 of HEESAA could remove devolved functions from Scottish Ministers as regards to determining applications for planned healthcare.

20. If the UK Government is prepared to amend the Bill to fully address the above issues, the Scottish Government would be able to recommend consent to these provisions, but at the moment it cannot.

Food information for consumers: power to amend retained EU law

21. 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. Food labelling is accepted as a devolved subject-matter and the UK Government, in its Explanatory Notes to the Bill, recognises that this provision requires the legislative consent of the Scottish Parliament. The Scottish Government agrees with this view. However, at this point, the Scottish Government does not recommend that legislative consent is granted, due to the number of outstanding amendment requests that have been made for other clauses within the Bill. Subject to the response from the UK Government, a supplementary Memorandum may be submitted.

Advertising of less healthy food and drinks

22. Clause 125 includes provisions to introduce, on 1 January 2023: a) a 5.30am to 9pm TV advertising watershed for “less healthy food or drink” products (in effect categories of foods high in fat, sugar or salt (HFSS foods)); b) a similar advertising restriction for on-demand programme services which are under the jurisdiction of the UK (and regulated by Ofcom); and c) a restriction of paid-for HFSS foods advertising online. The aim of the policy broadly aligns with the position advocated in the Scottish Government’s 2018 Diet and Healthy Weight Delivery Plan.

23. The UK Government considers all of the above matters to be reserved as the television advertising provisions and the restrictions on on-demand programme services (items ‘a’ and ‘b’ above) relate to reservation K1 of schedule 5 of the Scotland Act 1998 (broadcasting) and the online advertising provisions (item ‘c’ above) relate to reservation C10 of schedule 5 of the Scotland Act (specifically “internet services”). The UK Government explained that it considers the primary purpose of the relevant provisions to be targeting advertisers on the internet; the focus being on the content of the advertisement and the media format on which the advert is being displayed. It considers the purpose of the provisions to be to regulate online advertising (which they equate to internet services).

24. The Scottish Government does not accept that provisions in relation to online advertising are reserved, as the purpose of the provisions is to reduce the purchase and thereby consumption of HFSS foods to reduce population health harm and to protect public health, which is a devolved matter. The primary purpose is to tackle childhood obesity by preventing children's exposure to paid-for HFSS advertising online. It is not the purpose of the provisions to regulate the provision of internet services and the provisions do not target the service providers.

25. The Scottish Government is therefore of the view that the online advertising provisions do engage the legislative consent process, as the purpose of these provisions falls within legislative competence of the Scottish Parliament. The Scottish Government has requested that amendments should be made to the relevant provisions to require the Secretary of State to obtain the consent of the Scottish Ministers before exercising their powers to make secondary legislation in relation to them. The Scottish Government does not consider that the online advertising provisions respect the devolution settlement, and cannot recommend that the Scottish Parliament gives its consent to the Bill at this time. The Scottish Government will continue to press the UK Government to recognise the devolved purpose of these provisions and may provide a supplementary Memorandum to the Parliament in due course.

Regulation of healthcare and associated professions

26. Clause 123 of the Bill 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.

27. The Secretary of State will be provided with a power to enable the delegation, through subordinate legislation, of previously restricted functions of a regulatory body to other regulatory bodies. Furthermore, the Secretary of State will be provided with a power to regulate groups of workers concerned with health and care whether or not they are generally considered to be a profession. The UK Government recognises that these provisions require the legislative consent of the Scottish Parliament insofar as they affect existing groups of healthcare professions brought into regulation after the commencement of the Scotland Act 1998, and groups regulated which are within devolved competence. The Scottish Government agrees with this view. However, due to the number of outstanding amendment requests for other clauses with the Bill, the Scottish Government cannot recommend that the Parliament grants legislative consent at this stage. Subject to a positive response from the UK Government to the request for amendments to the Bill, a supplementary Memorandum may be provided.

Medicines Information Systems (Medicines Registries) and Medical Devices Information Systems (MDIS)

28. Clause 85 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 the Health and Social Care Information Centre (commonly called "NHS Digital"). The Secretary of State may specify in those regulations the information which must be provided to NHS Digital, the form in which information is to be provided, and, the person who must provide information. This delegated power can be used to create information systems for the purposes of enabling information on human medicines to be analysed and tracked. The information system can be established and operated for purposes relating to (a) the safety, quality and efficacy of human medicines, and (b) the improvement of clinical decision-making in relation to human medicines. The clause also includes a direction making power which could allow the Secretary of State to issue a written direction setting out the type of information to be provided to NHS Digital.

29. The establishment of medicines registries in this context is intrinsically linked to Medicines and Healthcare products Regulatory Agency's (MHRA's) role as the sole regulatory body for medicines and medical devices for Great Britain.

30. The proposed registries will support the MHRA's regulatory functions and while Scotland-only registries could be established (and already exist for some disease conditions on a voluntary basis), the MHRA note that a UK-wide registry 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 registries mandatory, improving the ability to reduce harm. The Scottish Government has been working and continuing to engage with the MHRA and others across Scotland to ensure that work to support the development of medicines registries by the MHRA is relevant to and captures Scottish interests and will be practically feasible to implement across Scotland.

31. Clause 85 also makes technical amendments to section 19 of the Medicines and Medical Devices Act 2021 which are intended to align with the proposed Medicines Information System (MIS) and which will enable NHS Digital to share information they receive which comes from data linkage; and to contain commercially sensitive technical information about devices. The Scottish Parliament indicated consent to the Medicines and Medical Devices Bill on 12 November 2020[2]. The Bill was enacted in February 2021.

32. In addition, Clause 85 includes amendments to section 43 of the Medicines and Medical Devices Act 2021. Section 43 is being amended to allow regulations made under the provision outlined above and the existing section 19 of the Medicines and Medical Devices Act 2021 (which relates to medical devices information systems) to amend the part of the Health and Social Care Act 2012 which establishes NHS Digital and sets its remit and powers.

[2] Legislative consent for the Medicines and Medical Devices Bill - https://archive2021.parliament.scot/parliamentarybusiness/bills/115811.aspx

33. The Explanatory Notes to the Bill set out the UK Government's view that the legislative consent of the Scottish Parliament is required for the provisions in Clause 85. The Scottish Government agrees with this view.

34. In particular, the Scottish Government considers that legislative consent is required because regulations made under clause 85 may make provision relating to "the improvement of clinical decision-making in relation to human medicines". The Scottish Government considers that the purpose of collecting or analysing information relating to clinical decision-making in this context would relate to decisions by clinicians about which medicines to prescribe or supply to patients in Scotland. In addition, the purpose of collecting or analysing data relating to these decisions would be to improve the medical treatment provided to patients in Scotland and patient outcomes. More broadly, this would relate to the health of patients in Scotland.

35. The Scottish Government notes 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. It is the opinion of the Scottish Government that clause 85 confers a delegated power which could be used for devolved purposes. This also applies to the direction making power in clause 85 which could allow the Secretary of State to issue a written direction setting out the type of information to be provided to NHS Digital.

36. The amendments to section 43 of the Medicines and Medical Devices Act 2021 at clause 85 allow regulations made under the medicines registries provision 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) 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. Regulations made under these expanded powers would be the first information services functions which NHS Digital will perform outside of England and Wales without being specifically invited by a Scottish public body to carry out work in Scotland.

37. The Scottish Government is concerned that these amendments to section 43 could allow an extension of the NHS Digital remit into Scotland in relation to the regulations for medicines registries and medical devices information systems but without the Scottish Ministers' consent. The Scottish Government has therefore requested that requirements are included in the Bill that regulations can only be made by UK Ministers using these new provisions with the consent of the Scottish Ministers and that directions made under these new provisions are also subject to the consent of the Scottish Ministers.

38. Given these aspects of the provisions have a devolved purpose that falls within legislative competence, the Scottish Government has requested that these provisions are amended so that the Scottish Ministers may choose whether Scottish providers will participate in any particular registry or medical devices information system.

39. Furthermore, Scottish Ministers and NHS in Scotland have the primary responsibility for the confidentiality and security of Scottish patient data. The Scottish

Government has therefore requested that the clause is amended to require that regulations to establish a medicines registry or medical devices information system must prescribe circumstances in which persons who are required to provide information for a registry or information system, may provide information to the Information Centre (NHS Digital) in pseudonymised form.

40. The Scottish Government cannot recommend that the Scottish Parliament gives its consent to this clause at this time. Discussions regarding the requested amendments are on-going and the Scottish Government will provide an updated recommendation to Parliament at the conclusion of those discussions.

Consultation

41. The primary vehicle for public consultation on the Health and Care Bill has been the engagement exercise undertaken to support NHS England in the NHS's recommendations to Government and Parliament for an NHS Bill, published in 2019. These recommendations were made as a result of a public consultation involving patients, staff and other health and care organisations and received over 190,000 individual responses. These legislative recommendations were themselves a product of NHS England's Long Term Plan, published in 2019. NHS England's original proposals were scrutinised through an inquiry by the Health and Social Care Committee in 2019, and the proposals contained in the Department of Health and Social Care (DHSC) White Paper were scrutinised by the UK Parliament's Health and Social Care Committee this year.

42. For development of policy on Integrated Care Systems, which build on proposals set out in NHS England's initial document, NHSE published an engagement document Integrating Care – The next steps to building strong and effective integrated care systems across England[3] - endorsing these changes. More than 7,000 written responses to this document were received by the UK Government from individuals and organisations, including patient groups and staff representatives. These informed NHS England's subsequent response Legislating for Integrated Care Systems: five recommendations to Government and Parliament[4].

43. DHSC has undertaken further engagement with stakeholders representing all parts of the health and care system through roundtables and smaller discussions, and has told us they engaged with approximately 100 organisations from across the health and care system. A list of organisations supplied to us with representation beyond England has been provided:

- Academy of Medical Royal Colleges – coordinates UK and Ireland's 23 medical Royal Colleges and Faculties
- Age UK
- British Dental Association
- British Medical Association

[3] https://www.england.nhs.uk/wp-content/uploads/2021/01/integrating-care-next-steps-to-building-strong-and-effective-integrated-care-systems.pdf

[4] https://www.england.nhs.uk/wp-content/uploads/2021/02/legislating-for-integrated-care-systems-five-recommendations.pdf

- British Red Cross
- Carers UK
- Faculty of General Dental Practice UK
- NHS Confederation – membership organisation representing the healthcare system in England, Wales and Northern Ireland
- UK Home Care Association

44. DHSC has informed the Scottish Government that engagement with stakeholders was undertaken on specific proposals in the Bill. NHS England consulted on the Provider Selection Regime and DHSC consulted on the data proposals as part of the Government's draft data strategy. Health Service Safety Investigation Body (HSSIB) was subject to pre-legislative scrutiny by a House of Lords and House of Commons joint committee[5] in 2018 and the UK Government published a response to this report.

45. On the professional regulation proposals, the Law Commission published[6] proposals to reform the regulatory framework which the Scottish Government, and the other DAs, responded to in 2014. The four UK Governments were then consulted on high level policy proposals to reform the regulatory framework for health professionals in 2019, and the UK Government consulted again on this earlier this year. The UK Government plans to consult on the process for considering how decisions are made on which professions should be subject to statutory regulation later this year, and has commissioned an Independent Review, which will be taken forward by KPMG, to consider the number and make-up of the professional regulators.

Financial Implications

46. Consenting to the Bill would have no immediate financial implications although these may materialise in the future through certain provisions within the Medicines Information Systems (MIS) and the Arm's Length Bodies (ALB) clauses. It is difficult to ascertain any possible financial implications until decisions have been reached on the funding model of new registries that are created through the MIS clause, and the extent of the powers within the ALB clause.

Conclusion

47. At this time, the Scottish Government cannot recommend to the Scottish Parliament that it gives its consent to the Bill. While aspects of the Bill are not contentious (section 2 on pages 1 and 2), there are several that impinge on the legislative competence of the Scottish Parliament and the executive competence of the Scottish Ministers: these are Medicines Information Systems; Secretary of State's Power to Transfer or Delegate Functions; International Healthcare; Regulations of healthcare and associated professions; Advertising of less healthy food and drink; Food information for consumers; and power to amend retained EU law. The Scottish Government has requested that the UK Government make amendments that would respect devolved competence by requiring the statutory consent of the Scottish

[5] https://publications.parliament.uk/pa/jt201719/jtselect/jthssib/1064/1064.pdf
[6] https://www.lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/

Ministers is sought before new powers in these areas are exercised. The Scottish Government has made this request as the new powers have implications for how policy is delivered in Scotland and for the transfer of Scottish patient data to another jurisdiction, where the Scottish Government's and NHS Scotland's ability to act in accordance with their responsibility for rights and freedoms of the population of Scotland (including confidentiality and security of such data) would be lost.

48. The Scottish Government's position, which has been explained to the UK Government, is that, if satisfactory amendments should be made to the Bill to respect the devolution settlement, the Scottish Government may be able to recommend that the Scottish Parliament consents to the Bill. If, during the remaining stages of the Bill, appropriate amendments are provided which address concerns, a supplementary memorandum with a final position on consent may be lodged.

SCOTTISH GOVERNMENT
August 2021

This Legislative Consent Memorandum relates to the Health and Care Bill (UK legislation) and was lodged with the Scottish Parliament on 31 August 2021

HEALTH AND CARE BILL – LEGISLATIVE CONSENT MEMORANDUM

Produced and published in Scotland by the Scottish Parliamentary Corporate Body.

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