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12 July 2021

The Health and Care Bill [Bill 140 of 2021-22]

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Summary

The Health and Care Bill 2021-22 [Bill 140 of 2021-22] was introduced in the House of Commons on 6 July 2021. The second reading is scheduled for Wednesday 14 July 2021.

The Bill would enact policies set out in the NHS's recommendations for legislative reform, following the NHS Long Term Plan (January 2019), and the White Paper, Integration and Innovation: working together to improve health and social care for all (February 2021).

The Government says the Bill builds on the NHS's own proposals for reform, aiming to make it less bureaucratic, more accountable, and more integrated, and that it has incorporated lessons learnt from the pandemic.

What does the Bill do?

Several provisions in the Bill were originally proposed by NHS England, such as establishing existing Integrated Care Systems (ICSs) on a statutory footing, formally merging NHS England and NHS Improvement, and making changes to procurement and competition rules relating to health services.

The Bill also includes proposals from the February 2021 White Paper to give the Secretary of State for Health and Social Care powers to direct NHS England and to decide how some other health services are organised. It gives the Secretary of State powers to transfer functions between some of the 'Arm's Length Bodies' that lead, support and regulate healthcare services in England, and to intervene in proposed changes to the way health services are delivered.

The Bill doesn't cover wider reforms of the social care and public health systems, although it does provide for some changes in these areas (and ICSs are intended to improve coordination between the NHS and local authority services).

Social care and public health provisions

For social care, the Bill provides for the Care Quality Commission (CQC) to assess how local authorities deliver their adult social care functions and it aims to improve data sharing.

There are also measures to streamline how people with ongoing care needs are discharged from hospitals. Public health measures in the Bill relate to food advertising and water fluoridation.

Safety investigation and other measures

The Bill would establish the Healthcare Safety Investigation Branch as a statutory body, and make changes to the system of medical examiners.

These measures were previously introduced in the Health Services Safety Investigations Bill [HL Bill 4] in October 2019 and earlier draft legislation in 2017.

Other matters covered by the Bill include the regulation of health and care professionals, the collection and sharing of data (including measures to support the development of new medicine registries), international healthcare, and hospital food standards.

The Bill contains 135 clauses (grouped into six parts), with 16 Schedules, and makes changes to several existing Acts, most notably the National Health Service Act 2006 and the Health and Social Care Act 2012.

Reaction to the Bill

NHS England

The NHS England Chief Executive, Sir Simon Stevens, said the Bill's proposals for integrated care were "widely supported":

> They go with the grain of what our staff and patients can see is needed, by removing outdated and bureaucratic legal barriers to joined-up working between GPs, hospitals, and community services.

The Chief Executive said the reforms would "undoubtedly both help tackle health inequalities and speed the recovery of care disrupted by the covid pandemic."

The Health and Social Care Committee

The Health and Social Care Committee's report on the White Paper proposals summarises a wide range of responses to the Government's planned reforms. Overall, it supported the direction of travel set out in the White Paper.

The Committee noted that the creation of ICSs could improve the delivery of care services for patients if proper accountability mechanisms are put in place, particularly relating to the safety and quality of care. However, the Committee also concluded that several areas in the White Paper required further clarity or revision, such as the addition of new powers for the Secretary of State.

The new Secretary of State, Sajid Javid, has written the Health and Social Care Committee to explain how its report's recommendations informed the drafting of the legislation.

More powers for the Secretary of State

While there has been widespread support for better integrated care, the proposals to extend the Secretary of State's powers have been controversial. Dr Jennifer Dixon, Chief Executive of the Health Foundation, said that the new powers are" politically driven and risks taking healthcare backwards."

NHS Providers has said it will seek appropriate safeguards to balance new ministerial powers. It also stresses that an excessively top-down approach to ICS structures could hinder effective local collaborative working.

While noting its concerns about the additional powers for the Secretary of State, the NHS Confederation has said its membership of NHS organisations are relieved that the Bill has been brought forward before the summer recess. They describe the timetable for ensuring that ICSs can take on statutory responsibilities by April 2022 as "incredibly tight".

Private sector involvement

There are mixed views about what changes to competition rules might mean for the level of private sector involvement in the NHS. The King's Fund has welcomed the Bill's removal of "cumbersome" competition rules under the Health and Social Care Act 2012. But the Labour party, the British Medical Association and anti-privatisation campaigners have warned that the Bill could allow contracts to be awarded to private healthcare providers without proper scrutiny.

What about other pressures on the NHS?

There are concerns that the Bill does not sufficiently address the greatest challenges facing the NHS, namely the impact of the pandemic on staff and patients, waiting lists for non-Covid treatment, wider reform of adult social care, and workforce pressures.

A wide range of groups representing NHS staff and organisations have called for the Bill to include further measures to require a long-term workforce strategy. This has been backed by think tanks and the Health and Social Care Committee.

The Shadow Health Secretary, Jonathan Ashworth, questioned the timing of the Bill, asking why the Government was embarking on reorganising the NHS rather than "...resourcing the NHS sufficiently to bring down the record waiting lists for surgery, mental health and cancer care or giving our NHS workers the proper pay rise they deserve."

1 Background to NHS reform and integrated care

1.1 The NHS Long Term Plan (January 2019) and the Health and Care White Paper (February 2021)

The White Paper, Integration and Innovation: working together to improve health and social care for all (February 2021), set out the Government's plans for a Health and Care Bill. The Government's intention to introduce this legislation was confirmed in the Queen's speech on 11 May 2021.

The White Paper included a number of measures that were originally proposed by NHS England to support the NHS Long Term Plan (January 2019). The NHS Long Term Plan set objectives for improving public health and clinical outcomes in areas such as preventing infant mortality, improving cancer survival rates, and better mental health services. To enable these changes, the Plan set out actions on workforce, technology, innovation and efficiency. It also proposed changes to the 'system architecture' of the NHS to increase the coordination of services through the creation of Integrated Care Systems. This was seen as a move away from some of the competition-based reforms introduced by the Health and Social Care Act 2012.[1]

The Long Term Plan included recommendations for changes to the legislative framework and said amendments to primary legislation "…would significantly accelerate progress on service integration, on administrative efficiency, and on public accountability".[2]

Proposals for legislation in the Long Term Plan were followed by the Health and Social Care Committee's report NHS Long-term Plan: legislative proposals (HC2000, 24 June 2019). The December 2019 Queen's speech included plans for draft legislation to support the Long Term Plan.[3]

1 Further background can be found in the Library briefing paper on The structure of the NHS in England (June 2020)

2 NHS Long Term Plan, January 2019, page 10

3 Further background can be found in the Library briefing paper on The structure of the NHS in England (June 2020)

The latest proposals from NHS England were set out in a consultation, Integrating care: next steps to building strong and effective integrated care systems across England, published in November 2020.[4]

The White Paper (February 2021) confirmed NHS England proposals to:

- establish Integrated Care Systems as statutory bodies and other measures to support integration of health and care;
- formally merge NHS England and NHS Improvement; and
- make changes to procurement and competition rules relating to health services.

The White Paper also set out several proposed changes to the legislation relating to the Secretary of State, including powers to direct NHS England, to make changes to Arm's Length Bodies, and to intervene in health service reconfigurations.

The White Paper detailed a wide range of other proposals for inclusion in the Bill, including the following areas:

- social care (relating to payments, CQC assessments and data sharing)
- public health (water fluoridation and food and drink advertising)
- the collection and sharing of health and social care data
- international healthcare (enabling more comprehensive reciprocal healthcare arrangements outside the EEA),
- to require the Secretary of State to produce a workforce assessment every 5 years
- to enable greater changes to the regulation of health and care professionals through secondary legislation

The White Paper confirmed the Health and Care Bill would incorporate measures that were previously introduced in the Health Services Safety Investigations Bill in October 2019, and earlier draft legislation in 2017 to establish the Healthcare Safety Investigation Branch as a statutory body, and changes to the system of medical examiners.[5]

While many responses to the White Paper supported the overall aims of better integrated care, there were concerns about areas not covered, notably wider social care reform. There were calls for further detail and scrutiny on some of the proposed measures, such as additional powers for the Secretary of State.

4 See also NHS England's Legislating for Integrated Care Systems: five recommendations to Government and Parliament, frequently asked questions on ICS legislative recommendations and consultation on proposals for the NHS Provider Selection Regime (all published in February 2021).

5 Health Service Safety Investigations Bill [HL] Session 2019

1.2 The Health and Social Care Committee's report on the White Paper

The Secretary of State for Health and Social Care wrote to the Chair of the Health and Social Care Committee inviting the Committee to scrutinise the White Paper in advance of the Bill's introduction to help inform Government thinking. The Health and Social Care Committee took oral evidence on the White Paper, including sessions with the Secretary of State on 16 March 2021,[6] and NHS Chief Executive Sir Simon Stevens on 9 March 2021.[7]

A session took place with some of the health think tanks and other stakeholders on 2 March 2021.[8]

Written evidence was submitted to the Health and Social Care Committee's inquiry. This evidence included detailed submissions from most of the organisations giving oral evidence on 2 March 2021, including the King's Fund, the Nuffield Trust, the Health Foundation, NHS Providers, the NHS Confederation and the Local Government Association.

The Health and Social Care Committee's report on the White Paper proposals was published on 14 May 2021. Given time constraints, the Committee focussed on the purpose of the reforms, patient choice and potential implementation (Chapter 2), Integrated Care Systems (Chapter 3), social care (Chapter 4), workforce planning (Chapter 5), additional powers for the Secretary of State (Chapter 6), public health (Chapter 7) and proposals to reduce bureaucracy and increase innovation (Chapter 8).

Overall, the Committee said it supported the proposals and welcomed the "direction of travel."[9] The Committee observed the creation of ICSs had potential to improve the delivery of care services for patients provided proper countability mechanisms are put in place, particularly relating to safety and quality of care. However, the Committee identified areas in the White Paper which required further clarity or revision - and noted some concerning omissions, such as wider reform of adult social care.[10]

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[6] The Committee took evidence from the then Secretary of State for Health and Social Care Matt Hancock, and Jason Yiannikkou, the Director of NHS Legislation Programme at the Department of Health and Social Care (DHSC).

[7] Sir Simon Stevens gave evidence alongside Amanda Pritchard, Chief Operating Officer of NHS England and NHS Improvement.

[8] On 2 March 2021 the Committee took evidence from Richard Murray, Chief Executive of the King's Fund; Hugh Alderwick, Head of Policy at the Health Foundation; Nigel Edwards, Chief Executive of the Nuffield Trust; Danny Mortimer, Chief Executive of the NHS Confederation; Sarah Pickup, Deputy Chief Executive of the Local Government Association; Sir Robert Francis, Chair of Healthwatch England; and Chris Hopson, Chief Executive of NHS Providers.

[9] Health and Social Care Committee, The Government's White Paper proposals for the reform of Health and Social Care, 14 May 2021, HC 20 2021-22, para 13, page 5

[10] Ibid, chapter 4

The Committee's report on the White Paper proposals recommended the Government include in the Bill a more detailed framework that sets out the roles and responsibilities of what are now referred to as the Integrated Care Board (ICB) and the Integrated Care Partnership. To ensure that ICS are "…not dominated by the views of the NHS" the Committee recommend that a duty be placed on ICBs to ensure that:

- the composition of boards includes representatives with experience and expertise in the views and needs of patients, carers and the social care sector.
- where an ICS's decision-making affects carers and the social care sector, that the ICS undertake formal consultation with the groups and sectors affected.[11]

The Committee welcomed the former Secretary of State's commitment to include in the Bill, at the Committee's suggestion, provisions to enable the Care Quality Commission (CQC) to undertake ratings of Integrated Care Systems. They further recommended that the CQC's assessment of ICSs should include consultation with patient groups and consideration of patient outcomes.[12]

Other Committee recommendations related to the appointment of board members to the statutory ICS bodies. These included calls for greater voice within ICSs for carers, transparency around the criteria by which the Secretary of State will use powers to appoint and veto appointments, and the introduction of a "fit and proper person test" for board members.[13]

The Committee said it did not believe the proposal to introduce a duty for the Secretary of State to publish a workforce assessment once every five years was an adequate response to NHS staff shortages. The Committee welcomed proposals from the Kings Fund, Health Foundation and Nuffield Trust to place a duty in the Bill to produce annual workforce projections (similar proposals were submitted by the Academy of Medical Royal Colleges and Royal College of Nursing). The Committee recommended the Government include provisions in the Bill to require Health Education England to publish objective, transparent and independent annual reports on workforce shortages and future staffing requirements to cover the next five, ten and twenty years and to include an assessment of whether sufficient numbers are being trained. They further recommended that such workforce projections cover social care as well as the NHS, given the close links between the two systems, and that workforce reports be undertaken in consultation with the Devolved Administrations.

On 14 April 2021, the Health Foundation, Nuffield Trust and The King's Fund wrote a joint letter to Matt Hancock and Jeremy Hunt calling for the proposed

[11] Ibid, para 52
[12] Ibid, para 24, pages 7-8
[13] Ibid, para 52-54, page 15

Bill to put in place a system to support better workforce planning. Specifically, they called for a new clause to require Health Education England to publish annual, independently verified projections of the future supply of the health care workforce in England, and set out how those projections compare to projected demand for the healthcare workforce over a 15-year period (consistent with the long-term projections of health care spending produced by the Office for Budget Responsibility).[14]

On 6 July 2021 the new Secretary of State, Sajid Javid, sent a letter to the Health and Social Care Committee to confirm new powers for the CQC to assess ICSs would be introduced as an amendment to the Bill. The letter went on to outline several areas where the Committee had informed the Government's approach to drafting the legislation and its plans for statutory guidance. However, the letter said the Government did not agree that a requirement in primary legislation to publish long-term workforce projections was needed in order to continue to invest in the workforce.[15]

Integrated Care Systems

By bringing local health and care leaders together to plan around the long-term needs of residents, Integrated Care Systems (ICSs) aim to make practical improvements, such as making it easier for patients to access and navigate different health and care services. They also aim to help people live healthier lives for longer, and to stay out of hospital when they do not need to be there, for example by joint working with councils and others such as the voluntary sector.

The King's Fund provides the following background on how ICS form a key part of the future direction for the NHS as set out in the NHS Long Term Plan, to achieve greater integration of health and care services; improve population health and reducing inequalities:

> ICSs are part of a fundamental shift in the way the health and care system is organised. Following several decades during which the emphasis was on organisational autonomy, competition and the separation of commissioners and providers, ICSs depend instead on collaboration and a focus on places and local populations as the driving forces for improvement. They have grown out of sustainability and transformation partnerships (STPs) – local partnerships formed in 2016 to develop long-term plans for the future of health and care services in their area.[16]

[14] Joint letter to the Rt Hon Matthew Hancock MP and Rt Hon Jeremy Hunt MP from the Health Foundation, Nuffield Trust and The King's Fund, 14 April 2021

[15] Letter from the Secretary of State for Health and Social Care, Sajid Javid, to the Chair of the Health and Social Care Committee, Jeremy Hunt, 6 July 2021; HSJ, Exclusive: CQC to get new powers through Health and Care Bill amendment, 8 July 2021

[16] The King's Fund, Integrated Care Systems explained, 11 May 2021

NHS England and NHS Improvement (NHSEI) published FAQs on their legislative recommendations on ICSs on 11 February 2021. This included a section 'How will a statutory ICS be different from a CCG?', set out below:

> Although we propose the ICS takes on many of the CCG functions, its remit will be much broader and have a much greater system role. NHS trusts, FTs or local authorities will be full and active partners in the leadership of the ICS and could also delegate some of their functions into the collaborative arrangements in the system.

The design of ICSs

The King's Fund briefing Integrated Care Systems explained (11 May 2021) noted that there was a relatively permissive approach in the early stages of their development. The aim was that the development of ICSs should be locally led, and "in contrast to many previous attempts at NHS reform" there was no blueprint for developing an ICS.[17] NHS England did subsequently provide guidance for a more consistent approach to the design of ICS governance, including Designing Integrated Care Systems in England and the NHS Long-Term Plan, both published in 2019.

Designing Integrated Care Systems in England highlighted three important levels at which decisions are made within ICSs:

- Neighbourhoods (populations circa 30,000 to 50,000 people) - served by groups of GP practices working with NHS community services, social care and other providers to deliver more coordinated and proactive services, including through primary care networks.
- Places (populations circa 250,000 to 500,000 people) - served by a set of health and care providers in a town or district, connecting primary care networks to broader services including those provided by local councils, community hospitals or voluntary organisations.
- Systems (populations circa 1 million to 3 million people) - in which the whole area's health and care partners in different sectors come together to set strategic direction and to develop economies of scale.[18]

NHS planning and contracting guidance for 2020/21 (January 2020) set out some further guidance on the development of ICS structures. This included the streamlining of commissioning arrangements, including typically moving to just one clinical commissioning group (CCG) per ICS, with formal mergers expected to have taken place by 1 April 2021.

Further information is available from the NHSEI webpage: Integrated Care Systems.

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[17] Ibid.

[18] NHS England Designing Integrated Care Systems in England, June 2019, page 2

ICS boundaries

NHS England's Designing Integrated Care Systems in England (2019) noted that the ICS 'place level' may match local council boundaries or the "natural geographies" at which services are delivered.

The Government's February 2021 White Paper said that joined up approaches should be "coterminous with local authorities". This has been reported by the Health Service Journal (HSJ) and others as meaning that ICSs "…will generally not be allowed to cross the boundaries of upper-tier local authorities." The HSJ has noted that at least 18 of the 42 ICS are not currently entirely coterminous with local authority boundaries.[19]

PQ responses have noted that ICSs "…which are not aligned with local authority boundaries are being reviewed to ensure future arrangements can support effective partnership working between the National Health Service and local government."[20]

A number of MPs raised concerns about possible changes to ICS boundaries in their areas during an Adjournment debate on 29 June 2021. The Minister responding, Edward Argar, noted that Sajid Javid, as the newly appointed Secretary of State, "…will want to consider carefully the background to this issue, the options before him and, indeed, the views of right hon. and hon. Members before any decision is made."[21]

[19] See HSJ, 'Retrograde' white paper rule will spark '18 months of arguments over ICS boundaries', 19 February 2021, and HSJ, ICS boundary changes will worsen patient care, Hancock warned, 21 June 2021.

[20] PQ183122, Integrated Care Systems, 22 April 2021

[21] Hansard, NHS Integrated Care System Boundaries, 29 June 2021, c240

2 Part 1: Provisions to support integration and collaboration

2.1 Background

The Health and Care White Paper, Integration and Innovation: working together to improve health and social care for all (February 2021), set out the Government's plans to put Integrated Care Systems (ICSs) on a statutory footing.[22] It proposed that statutory ICSs would be made up of an ICS NHS Body (referred to as an 'Integrated Care Board' in the Bill) and a Health and Care Partnership (referred to as 'Integrated Care Partnership' in the Bill). The Integrated Care Board (ICB) will focus on integration between NHS bodies and the Integrated Care Partnerships (ICP) will focus on integration between the NHS, local government, and other providers.

The White Paper said ICS collaboration would be supported by a number of other legislative provisions, including: a duty to collaborate across the NHS and local government; a shared duty on all NHS bodies to pursue the 'triple aims' of the NHS Long Term Plan (better health and wellbeing, better quality health care and ensuring the financial sustainability of the NHS); and a duty on NHS trusts and foundation trusts to have regard to the system's financial objectives. The legislation proposed by the White Paper would enable decisions to be taken by joint committees and facilitate increased 'collaborative commissioning' across different footprints, for example, by enabling NHS England to share some of its direct commissioning functions with ICSs.

The introduction to the White Paper provided the following information on establishing ICSs as statutory bodies, including how they would work with other measures to support the integration of health and care:

> We will also bring forward measures for statutory Integrated Care Systems (ICSs). These will be comprised of an ICS Health and Care Partnership, bringing together the NHS, local government and partners, and an ICS NHS Body. The ICS NHS body will be responsible for the day to day running of the ICS, while the ICS Health and Care Partnership will bring together systems to support integration and

[22] This was originally proposed by NHS England, to support the NHS Long Term Plan (January 2019), with the latest proposals from NHS England set out in a consultation, Integrating care: next steps to building strong and effective integrated care systems across England, published in November 2020 (see also Legislating for Integrated Care Systems: five recommendations to Government and Parliament, published in February 2021).

> develop a plan to address the systems' health, public health, and social care needs. Both bodies will need to draw on the experience and expertise of front-line staff across health and social care. The legislation will aim to avoid a one-size-fits-all approach but enable flexibility for local areas to determine the best system arrangements for them. A key responsibility for these systems will be to support place-based joint working between the NHS, local government, community health services, and other partners such as the voluntary and community sector.[23]

The King's Fund's The health and social care White Paper explained (9 March 2021) outlines the importance of 'place level' footprints within ICSs, which they say will be expected to do "much of the heavy lifting of integration":

> The [White Paper] also recognises the importance of 'place', which is a smaller footprint than that of an ICS, often that of a local authority. Experience suggests that much of the heavy lifting of integration and improving population health is driven by organisations collaborating at this level, and successful ICSs have therefore often concentrated their efforts on developing the places within their footprint. The Department states that it has decided against giving place a statutory underpinning although it is explicit that there will be an expectation that ICS NHS bodies delegate 'significantly' to place level as well as to provider collaboratives. The development of place-based partnerships will therefore be left to local determination, building on existing arrangements where these work well. ICSs will be expected to work closely with health and wellbeing boards and required to 'have regard to' the joint strategic needs assessments and joint health and wellbeing strategies produced by health and wellbeing boards.[24]

Under the Government's proposals, ICS Integrated Care Boards (ICBs) will take on the commissioning functions of clinical commissioning groups (CCGs) as well as some of NHS England's commissioning functions. NHS England will allocate a single system financial envelope to each ICB using the existing CCG allocation formula.[25]

The February 2021 White Paper sets out the duties for ICS and NHS providers with regard to system financial objectives, noting that a duty would be placed on the ICS to deliver financial balance. While the ICS will not have the power to direct providers, the White Paper says "…these arrangements will be supplemented by a new duty to compel providers to have regard to the

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[23] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, para 1.14, pages 10-11. Further detail on the Government's proposals for ICSs is set out at Annex B of the White Paper, encompassing both the legislative and the non-legislative arrangements they intend to put in place.

[24] The King's Fund, The health and social care White Paper explained (9 March 2021)

[25] PQ289, Integrated Care Systems: Finance, 18 May 2021

system financial objectives so both providers and ICS NHS Bodies are mutually invested in achieving financial control at system level."[26]

2.2 Merging NHS England and NHS Improvement (Clauses 1, 26-32 and Schedules 1 and 5)

Background

NHS England is the operational name for the NHS Commissioning Board, which was established by the Health and Social Care Act 2012. It is an executive non-departmental public body which leads and oversees the funding, planning and delivery of healthcare in England. Currently, NHS England allocates most of the funding it receives from the Department of Health and Social Care to NHS clinical commissioning groups (CCGs), and supports them to commission services based on local need. NHS England directly commissions some healthcare services including specialised services, and screening and immunisation programmes.

Since 2016 NHS Improvement has been the operational name for the two different bodies (Monitor and the Trust Development Authority) that support and oversee NHS Trusts and Foundation Trusts, as well as independent providers that provide NHS-funded care.

NHS England and NHS Improvement, currently known as NHSEI, have seven regional directorates that give support to NHS organisations on the ground.

NHS England and NHS Improvement are accountable through their boards to the Secretary of State for Health and Social Care, and through the Secretary of State to Parliament.

Since 1 April 2019, NHS England and NHS Improvement have worked together as a single organisation (known as NHSEI), although they remain legally distinct under the Health and Social Care Act 2012. Proposals to formally merge them into one body known as 'NHS England' were published by NHSEI in September 2019. This would combine their respective responsibilities for provider and commissioner performance, finance and care transformation. Plans for this merger were confirmed in the Government's February 2021 White Paper.

Clause 1 of the Bill would formally merge NHS England and NHS Improvement. There are additional provisions to abolish the two statutory

[26] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, para 5.12. The King's Fund's The health and social care White Paper explained (9 March 2021) provides some further background on these financial duties.

bodies that currently make up NHS Improvement and transfer most of their functions to NHS England.[27]

Clause 1 and Schedule 1: changing the name of the NHS Commissioning Board

Clause 1 changes the legal name of the National Health Service Commissioning Board to NHS England. **Schedule 1** contains consequential amendments which seek to amend other legislation to change any references to the NHS Commissioning Board to NHS England.

Clauses 26-32 and Schedule 5: Merging functions of Monitor and the Trust Development Authority into NHS England

Clause 26 abolishes Monitor, which was first established in 2004 as the independent regulator of NHS Foundation Trusts and later became the economic regulator for the health service under the Health and Social Care Act 2012.

Schedule 5 makes consequential amendments relating to the transfer of Monitor's functions to NHS England. **Clause 27** places a duty on NHS England to minimise the risk of conflict between its regulatory and other functions, and to manage any conflicts that arise. Relating to Monitor's current licensing of providers, **Clause 28** would require NHS England to produce an impact assessment before a modification of the standard licence conditions that apply to all NHS Foundation Trusts and most other providers of NHS services (but not NHS Trusts).[28] **Clause 29** transfers powers from the Trust Development Authority (TDA) to NHS England and abolishes the TDA.

2.3 The Triple Aim (Clauses 4, 15, 43 and 56)

The 2019 NHS Long Term Plan proposed a 'triple aim' for the NHS of better health and wellbeing, better quality health care and ensuring financial sustainability. The February 2021 White Paper committed to creating a shared duty on all NHS bodies to pursue this triple aim.

Clause 4 requires NHS England to have regard to the 'triple aim' duty, which will also apply to Integrated Care Boards (under **clause 15**), NHS trusts (**clause 43**) and NHS Foundation Trusts (**clause 56**).

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[27] NHS England/NHS Improvement, The NHS's recommendations to Government and Parliament for an NHS Bill, September 2019

[28] NHS Improvement, using Monitor's statutory powers to act as a sector regulator for health services in England, sets and enforces a framework of rules for providers; implemented in part through licences issued to NHS-funded providers.

Comment

NHS Providers say this clause seeks to legislate for decision-making which balances health and wellbeing, the quality of services, and efficiency and sustainability within a constrained resource envelope. While in many ways this reflects the status quo, NHS Providers state that this clause offers a new legal basis for decisions and could be used to justify greater expenditure on some services rather than others.[29]

2.4 NHS England and Integrated Care Board requirements to involve and consult patients and carers (Clauses 5 and 19)

Clause 5 amends the existing requirement for NHS England to involve and consult the public when exercising its commissioning functions to specify consultation and involvement with carers and patient representatives.

Clause 19, which provides a number of duties for Integrated Care Boards, requires that, in the exercise of their functions, they promote the involvement of patients and their carers and representatives in decisions about the provision of health services to patients (through the insertion of new section 14Z36 in the NHS Act 2006).

2.5 Other provisions relating to the exercise of functions by NHS England (Clauses 6-8 and 10-11)

Clause 6 broadens the powers of NHS England to give assistance and support to any provider of NHS services or any body carrying out the functions of the NHS. This could include Integrated Care Boards (ICBs) and non-NHS bodies providing NHS services.

Clause 7 allows NHS England to direct an ICB to exercise any of NHS England's relevant functions, and to make payments or give directions regarding the exercise of these functions. The Explanatory Notes provide details of what these NHS functions are for the purposes of these provisions. They include functions relating to primary medical services, primary dental services, primary ophthalmic services or pharmaceutical services, and any of the Secretary of State's public health functions delegated to NHS England. The Secretary of State will have power to make regulations to specify any

[29] NHS Providers, Briefing on the Health and Care Bill, 6 July 2021

limits or conditions on the functions that NHS England may delegate to ICBs under this clause.[30]

Clause 8 places duties on NHS England relating to consolidated accounts for NHS trusts and NHS foundation trusts. This replaces duties imposed on Monitor and the Trust Development Authority (which operate as NHS Improvement), and which are being abolished under the merger of NHS England and NHS Improvement.

Clause 10 removes the Secretary of State's powers to make regulations about payments by NHS England in respect of quality. **Clause 11** amends provisions relating to secondments to NHS England.

2.6 Functions and duties of Integrated Care Systems (Clauses 12-25 and Schedules 2 and 3)

General functions and governance of Integrated Care Boards (ICBs)

Clause 12 sets out that any ICB established under the Bill has the function of arranging for the provision of services for the purposes of the health service in England.

Clause 13 insert new sections (14Z25 to 14Z28) into the NHS Act 2006 relating to the establishment of ICBs and the abolition of CCGs.

Key new sections include 14Z25, which requires NHS England to establish ICBs, and new section 14Z26, which sets out the process for establishing initial ICBs. For example, new section 14726 sets out the process for CCGs to develop initial ICBs and their constitutions, and NHS England's role in approving and providing guidance. Under new section 14Z27, all CCGs will be abolished on an appointed day, which will be the same day NHS England's duty to establish ICBs commences. The appointed day will be specified in regulations.

New section 14Z28 contains provision about schemes for the transfer of staff, property, rights and liabilities in connection with the establishment of ICBs and the abolition of CCGs.

New Section 14Z28(3) specifies that NHS England is required to ensure that all property, rights and liabilities (except criminal liabilities) of CCGs are transferred either to an ICB or to NHS England. The Explanatory Notes state that these:

> ...include rights and liabilities relating to contracts of employment. Subsection (5) contains a list of things a transfer scheme may do,

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[30] Bill 140 EN 2021-22, paras 239-241

> including to make provision which is the same as or similar to the Transfer of Undertakings (Protection of Employment) Regulations 2006, which includes certain protections of employment rights for transferred staff.[31]

New section 14Z29 requires each ICB to publish its constitution, including when it is updated or varied. New section 14Z30(1) concerns the management of conflicts of interest, and requires each ICB to maintain and publish a register of any interests of its board members, committee or sub-committee members, and its employees. The Explanatory Notes state that each ICB "…must ensure that any potential conflicts of interest that may affect the board's decision-making when commissioning services are declared promptly (subsection (3)) and managed effectively (subsection 4))."[32]

Schedule 2 of the Bill inserts a new Schedule 1B into the NHS Act 2006 which sets out further detail about ICBs, their constitutions and minimum governance requirements, as well as consequential amendments. This Schedule provides that the composition of an ICB will, at a minimum, consist of a chair, chief executive and at least three other members, known as 'ordinary members'. Schedule 1B specifies that the chair of the ICB must be appointed by NHS England, with the approval of the Secretary of State. It further states that only NHS England may remove the chair from office, and that this must be subject to the approval of the Secretary of State. The ICB chief executive must be appointed by the chair, with the approval of NHS England. The constitution should set out that the chief executive must be an employee of the ICB.

Schedule 2 provides that the ordinary members of the ICB, at a minimum, must include one member jointly nominated by NHS Trusts and NHS Foundation Trusts, one jointly nominated by general practice, and one jointly nominated by the local authorities who provide services within the ICB area. It provides that the ICB constitution must detail how the process of nominating representatives should operate. The ICB must have regard to any NHS England guidance about this process. The ICB constitution must provide for committees or sub-committees of the ICB to be formed. The Explanatory Notes mention that sub-committees may be established at 'place' level, at a smaller footprint within the ICS, often aligning with local authority boundaries.[33]

Clause 14 provides that NHS England must publish rules for determining the people for whom ICBs have responsibility. It sets out that, at a minimum, an ICB must be identified as responsible for a) everyone who is provided with NHS primary medical services (i.e. anyone who is, for example, registered with a GP in the ICB area) and b) everyone who is usually a resident in England and living in the geography of the ICB, even if they are not provided with NHS primary medical services.

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[31] Bill 140 EN 2021-22, para 260

[32] Bill 140 EN 2021-22, para 262

[33] Bill 140 EN 2021-22, para 269

Clause 15 provides ICBs with duties and powers to commission hospital and other health services for those persons for whom they are responsible. **Clause 16** gives ICBs responsibility for medical, dental and ophthalmic primary care functions.

Schedule 3 sets out the specific functions conferred on ICBs in relation to primary care services and contains related amendments. Statutory responsibility for primary care services currently sits with NHS England. The Explanatory Notes say "The intention is that ICBs will hold the majority of these functions at an agreed point in the future" and that "NHS England will retain a limited role in oversight and discharging functions that can be most effectively exercised at a national level."[34]

Clause 17 provides for schemes to transfer property, rights and liabilities in connection with the transfer of primacy care functions from NHS England to ICBs. The Explanatory Notes confirm that this includes provision for employees to be transferred to the ICB, under terms which are the same as, or similar to, those provided for by the Transfer of Undertakings (Protection of Employment) Regulations 2006, which includes certain protections of employment rights for transferred staff.[35] **Schedule 3** also provides that NHS England may direct an ICB to exercise any of NHS England's primary care functions.

The Explanatory Notes say that **clause 18** "…allows persons with whom NHS England and ICBs have entered into commissioning arrangements to also determine the means by which services will be delivered."[36]

Clause 19: Duties of Integrated Care Boards (ICBs)

Clause 19 sets out a number of duties that ICBs will be subject to in carrying out their responsibilities. These are similar to some of the duties placed on NHS England and CCGs under the Health and Care Act 2012 Act and include:

- promoting the NHS Constitution;
- securing continuous improvements in the quality of services commissioned;
- reducing inequalities;
- promoting education and training;
- enabling choice;
- promoting patient involvement;
- securing integration; and
- promoting innovation and research.

As noted previously, **clause 19** provides ICBs with the 'triple aim' duty, to have regard to all likely effects of their decisions on 1) the health and well-being of

[34] Bill 140 EN 2021-22, para 296
[35] Bill 140 EN 2021-22, para 309
[36] Bill 140 EN 2021-22, para 310

the people of England 2) the quality of services provided or arranged by relevant bodies, and 3) the efficiency and sustainability of resources used by the relevant bodies.

Clause 19 also provides requirements for ICBs to involve the public (whether by consultation or otherwise) and patients in the commissioning process, which appear to be broadly similar to existing CCG duties.

Other ICS functions provided for in **clause 19** include:

- The Joint exercise of functions with Local Health Boards in Wales
- Powers to make grants and raise additional income
- The need to have regard to NHS England guidance
- The need to prepare accounts and produce an annual report

Clause 19 and **Schedule 2** set out that the ICB and its partner NHS Trusts and NHS Foundation Trusts must prepare a five-year forward plan setting out how they will exercise a number of their statutory duties. The Explanatory Notes say "…it is expected that this plan will set out how an ICB will meet the health needs of its population and this will include primary, community and acute care." It "…must also reference how the plan implements any relevant joint local health and wellbeing strategies", to which the ICB is required to have regard.[37] **Clause 19** provides for the consultation and revision process for forward plans.

ICBs and their partner NHS Trusts and NHS Foundation Trusts must prepare a joint plan setting out their planned capital resource use for a period specified by the Secretary of State.

The NHS Providers briefing on the Bill summarises how NHS England will assess and manage the performance of ICBs under powers in **clause 19**:

> NHS England will conduct a performance assessment of each ICB each financial year. If NHS England deems an ICB to be failing or at risk of failure, NHS England will have powers of direction over the ICB (including prohibiting or restricting the ICB from delegating functions) and may terminate the appointment of the chief executive and direct others to exercise the ICB's functions.[38]

Comment

The NHS Providers briefing on the Bill notes their concerns that "collective confidence" in an ICB could be undermined by an excessively top down approach. In particular, they highlight the requirements relating to the membership of ICBs in Schedule 2 of the Bill. They also note concerns about the potential lack of involvement of ICBs and system partners in the

[37] Bill 140 EN 2021-22, para 334

[38] NHS Providers, Briefing on the Health and Care Bill, 6 July 2021, page 7

appointment and removal of ICB chairs (these powers would be held by NHS England alone, with approval from the Secretary of State):

> Schedule 2 states that an ICB chair will be appointed by NHS England with approval from the secretary of state and no involvement of the ICB members or wider system partners. This is concerning as the chair needs to have the confidence of the ICB and system partners. We urge the government to ensure a significant role for these bodies in the recruitment of the chair, even if powers of appointment lie elsewhere.
>
> The Bill provides for NHS England alone, with approval of the secretary of state, to remove the chair from office. However, it seems probable in the medium term, as local arrangements develop and get underway, that an ICB chair may lose the confidence of the ICB and/or the organisations within the system. Where this happens there must be a role for the ICB board in initiating the removal of the chair and this needs to be addressed in the constitution. If the ICB cannot initiate the removal of the chair, this will potentially lead to conflict, a stalemate and potential disruption to services.[39]

Clause 20: Integrated Care Partnerships

As noted by the NHS Providers briefing on the Bill, ICBs and relevant LAs must establish a statutory joint committee for the ICS – known as Integrated Care Partnerships (ICPs) – which will bring together health, social care, public health, and wider partners. NHS Providers set out some of the ICP provisions specified in the Bill:

> The ICP membership will include one member appointed by the ICB, one member appointed by each of the relevant LAs, and any other members appointed by the ICP. The ICP will be able to determine its own procedures locally. The ICP must prepare an 'integrated care strategy', building on the relevant joint strategic needs assessments (JSNAs) and considering the effectiveness of establishing section 75 arrangements. The ICP must have regard to guidance issued by the secretary of state. An ICP may include in this strategy a statement of its views on how the provision of health-related services could be more closely integrated with health and social care services. The strategy must detail how it will be delivered by the ICB, NHS England or LAs. There is a requirement for LAs and the ICB, in response and with regard to the integrated care strategy, to create a joint local health and wellbeing strategy.[40]

Clause 20 amends the Local Government and Public Involvement in Health Act 2007 to account for the transition from CCGs to Integrated Care Boards

[39] NHS Providers, Briefing on the Health and Care Bill, 6 July 2021, page 7
[40] NHS Providers, Briefing on the Health and Care Bill, 6 July 2021

and makes amendments to provide for the Integrated Care Partnership (ICP) and its integrated care strategy.

Clause 25 inserts **Schedule 4** which makes minor and consequential amendments relating to ICBs and ICPs.

Comment on Integrated Care Partnerships

While the Health and Social Care Committee's report on the White Paper highlighted concerns from the King's Fund and other think tanks about the risk that Integrated Care Partnerships may lack the powers to drive change and that ICSs could be too narrowly focused on the NHS.[41]

Responding to the publication of the Health and Care Bill, Cllr David Fothergill, Chairman of the Local Government Association's Community Wellbeing Board, said: "The requirement for NHS integrated commissioning boards and local authorities to establish a health and care partnership with responsibility for producing an integrated care strategy is helpful." He also noted that "It is good to see recognition of the importance of Health and Wellbeing Boards and the health and wellbeing strategies and joint strategic needs assessment they produce, to improve the health and wellbeing of their populations."[42]

2.7 Financial controls on NHS England and ICBs (Clauses 21-24)

These clauses set out the financial responsibilities of NHS England and ICBs.

Clauses 21 and 22 provide that NHS England must exercise its functions with a view to ensuring that total resource and capital expenditure does not exceed the amount the health service receives each year, and related matters.

Clauses 23 and 24 provide that ICBs and their partner NHS Trusts and NHS Foundation Trusts must operate with a view to ensuring that the capital and revenue resources they use do not exceed the limits specified by direction from NHS England in that financial year, and related matters.

[41] Health and Social Care Committee, The Government's White Paper proposals for the reform of Health and Social Care, 14 May 2021, HC 20 2021-22, para 37, page 12
[42] LGA, LGA responds to publication of Health and Care Bill, 6 July 2021

2.8 Additional powers for the Secretary of State and the relationship with NHS England

Background to proposed powers of direction for the Secretary of State

The White Paper, Integration and Innovation: working together to improve health and social care for all (February 2021), said the Government would bring forward measures to improve accountability and enhance public confidence. It set out several proposals to achieve this, including additional powers for the Secretary of State:

1. To direct a newly merged NHS England and NHS Improvement.
2. To intervene in health service reconfigurations.
3. To transfer the functions of Arm's Length Bodies (ALBs).[43]

Further detail can be found in section 3 and Annex B of the White Paper. The Executive Summary provides an overview of the rationale for the new powers of direction, which it says will improve accountability:

> The de facto development in recent years of a strongly supportive national NHS body in the form of a merged NHS England and NHS Improvement will be placed on a statutory footing and will be designated as NHS England. This will be complemented by enhanced powers of direction for the government over the newly merged body which will support great collaboration, information sharing and aligned responsibility and accountability.[44]

The White Paper proposed that Ministers should have powers to determine service reconfigurations earlier in the process than is presently possible.[45] It also set out plans for greater flexibility in setting the Department of Health and Social Care's Mandate to NHS England, and in transferring functions between Arm's Length Bodies.

The Government says these measures will "…further ensure the NHS is able to respond to changes and external challenges with agility as needed."[46]

Clause 2: specialised services

Clause 2 relates to the existing power of the Secretary of State to require NHS England to commission certain specialised services that are not appropriate

[43] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, Section 3

[44] Ibid. para 1.16, page 11

[45] Ibid. para 1.16, page 12

[46] Ibid. para 1.16, page 12

for commissioning by CCGs (or, in future, Integrated Care Boards). The Explanatory Notes to the Bill provides examples, including services for patients with rare cancers, genetic disorders or other complex medical or surgical conditions.

Under **Clause 2(2)** the test for the Secretary of State to prescribe a service to be commissioned by NHS England is amended to clarify that the Secretary of State can prescribe a service if they deem it appropriate for NHS England, or someone acting on NHS England's behalf, to commission it. **Clause 2(3)** removes the requirement for Secretary of State to consider the financial implications for CCGs if they were required to arrange for the provision of the service or facility. **Clause 2(4)** requires the Secretary of State to explain to NHS England his reasoning, if he refuses a request to revoke provisions made in regulations specifying which services NHS England may commission.

Clause 3: The Mandate to NHS England

The Health and Social Care Act 2012 established a duty for the Secretary of State to provide a Mandate to NHS England before the beginning of each new financial year, to set its strategic direction.

The Mandate must include objectives that NHS England has a duty to seek to meet and must specify the limits on capital and revenue resource use. The Mandate may set out matters the Secretary of State will take into account when assessing progress against objectives, and may include requirements that NHS England must comply with in order to meet the objectives. The White Paper said that greater flexibility in setting the Mandate was required as the current annual cycle does not align with NHS annual planning timescales or other strategic decisions. It proposed that the Bill should allow the Mandate to set direction over a longer term and in a more strategic way.

Clause 3 removes the requirement for a Mandate to be set before the start of each financial year. Instead, Secretary of State will be able to set a Mandate at any time. The Bill would ensure there is always a Mandate in place which will remain in force until replaced by a new Mandate.

The White Paper said this change would not impact on Parliament's ability to scrutinise the Mandate as each new Mandate will have to be laid in Parliament. NHS Mandate requirements would continue to be underpinned by negative resolution regulations.

As a consequence of removing the statutory link between the Mandate and the annual financial cycle, the Explanatory Notes say it is proposed that NHS England's annual limits on capital and revenue resource use are given statutory force through financial directions. The Explanatory Notes explain:

> It will become a legal duty for the Secretary of State to give such directions, and to both publish them and lay them in Parliament, to ensure continued transparency to Parliament for the financial

allocations within which NHS England is expected to deliver mandate objectives and requirements, as well as its wider functions.[47]

Clause 9

Currently, the legal basis for the allocation of the Better Care Fund (a pooled NHS and local authority budget for integrated care) relies on ministers setting a requirement each year in the NHS Mandate to ringfence this funding. As the Mandate will no longer have to be set on an annual basis, **Clause 9** of the Bill creates a stand-alone power to ensure the Better Care Fund (BCF) can continue to function as it currently does. The Explanatory Notes describe this as a technical change which "will not have any impact on the operation or policy intention of the BCF".[48]

Clause 33 places a duty on the Secretary of State to publish, at least once every five years, a report describing the system for assessing and meeting the workforce needs of the health service in England.

Clauses 34-38 and Schedule 6

The Bill provides the Secretary of State with several new or extended powers of direction and intervention.

On public health, **clause 34** would allow the Secretary of State's public health functions to be exercised by an ICB, a local authority that has duties to improve public health, a combined authority, or any other body specified in regulations. **Clause 35** would allow the Secretary of State to direct NHS England to take on specific public health functions. **Clause 36** provides powers of direction for the Secretary of State over NHS England, or any other public authority, in relation to safety investigations.

Clause 37 provides the Secretary of State with a general power of direction over NHS England. The Explanatory Notes state that the provision is designed to give the Secretary of State the ability, if required, to intervene and to set direction for NHS England, and ensure that it is working effectively with other parts of the system including social care and public health.

The Explanatory Notes say the intention is for NHS England to continue to exercise its functions as an Arm's Length Body as it does now, with the Mandate remaining the primary mechanism through which the Secretary of State will set out the priorities that it should be seeking to achieve.[49] This clause provides some exceptions to this power, specifying that it cannot be used in relation to the appointment of individuals by NHS England (including to NHS Trusts and Foundation Trusts); individual clinical decisions; or in relation to the funding of particular drugs or treatments by the NHS.

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[47] Bill 140 EN 2021-22, para 18

[48] Bill 140 EN 2021-22, para 22

[49] Bill 140 EN 2021-22, para 421-422

Clause 38 and Schedule 6: Health service reconfigurations

Clause 38 inserts **Schedule 6** which gives the Secretary of State power to give a direction to the NHS calling in any proposal for a local NHS service reconfiguration. The Schedule allows the Secretary of State to take on the decision-making role of the relevant NHS body with regard to the proposed service change.

The Explanatory notes set out the variety of decisions the Secretary of State may choose to take when giving a direction for the reconfiguration of NHS services. This includes the power to decide whether a proposal should, or should not, proceed, or should proceed in a modified form; the power to decide particular results to be achieved by the NHS in taking decisions in relation to the proposal; the power to decide the procedural or other steps that should, or should not, be taken in relation to the proposal; and the power to retake any decision previously taken by the relevant NHS body.

Schedule 6 provides that the Secretary of State must publish guidance to outline the expectations for NHS bodies when a reconfiguration is called in. The guidance must outline the process the Secretary of State will follow, including how they will adhere to their existing duties, including the Secretary of State's duty as to improvement in the quality of services.

Comment

The chief executive of the Nuffield, Nigel Edwards, has raised concerns about the new power for the Secretary of State to intervene at any stage of changes to NHS services, warning that "It risks gridlock and a lack of innovation, and ministers themselves might come to feel it as a millstone around their necks."[50]

The Local Government Association has said that the power of the Secretary of State to call in NHS reconfiguration proposals should not undermine the role of local authority health overview and scrutiny committees. Local authorities' current powers to review and scrutinise the planning, provision and operation of local health services derive from the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013. The Department of Health and Social Care guidance Local Authority Health Scrutiny: Guidance to support Local Authorities and their partners to deliver effective health scrutiny provides further information on current arrangements.

The Health and Social Care Committee called for clear criteria to be set out in the Bill on the use of the Secretary of State's powers to intervene in reconfigurations. In his letter to the Committee on 6 July, Sajid Javid said that "Whilst the scope of the power as drafted is broad, we intend to set out further detail of how the process will work in practice and what is expected of

[50] Nuffield Trust, Nuffield Trust response to Health and Care Bill, 6 July 2021

all parties." The Secretary of State also confirmed the Independent Reconfiguration Panel will be maintained, and "will help to ensure that Ministers receive the necessary advice and information before making decisions."[51]

Further information about the role of the Independent Reconfiguration Panel (IRP) in reviewing proposals for changes to NHS services that are being contested, and advising the Secretary of State for Health and Social Care can be found on the IRP website (see also the IRP webpage How we advise the Secretary of State).

2.9 NHS Trusts and NHS Foundation Trusts

Clauses 40-50 and Schedule 7: NHS Trusts

The Explanatory Notes state that when the Health and Social Care Act 2012 was passed, it was expected that all NHS Trusts would develop Foundation Trust status and so the 2012 Act provided for the abolition of NHS Trusts and powers to create new Trusts. However, NHS Trusts remain an important part of the NHS, making up around a third of providers, and the Government does not expect the provider landscape to drastically change. Although the section of the 2012 Act relating to the abolition of NHS Trusts was never commenced, **clause 39** of the Bill provides for the repeal of these provisions and the continuation of the legislative provisions governing such Trusts, including the power to establish new Trusts.

Clauses 40 and 41, and **Schedule 7** include further measures relating to NHS Trusts, principally to remove the Secretary of State's powers to appoint NHS Trust funds and trustees, and consequential amendments.

Clause 42 removes the exemption on NHS trusts to hold a licence from Monitor (in future NHS England), bringing NHS Trusts in line with the licensing arrangements for NHS Foundation Trusts.

Clause 43 relates to the application of the 'Triple Aim' duty to NHS Trusts.

Clauses 44-47 ensure the Trust Development Authority's functions to monitor, support, and direct NHS Trusts are carried over to NHS England following the abolition of the TDA. Similarly, **clauses 49 and 50** carry over provisions in relation to the appointment of NHS Trust chairs and the setting of financial objectives for NHS Trusts. **Clause 48** amends provisions relating to the conversion of NHS Trusts to NHS Foundation Trusts, and the dissolution of NHS Trusts, to provide authorising powers for NHS England, having taken on the role of regulator from Monitor.

[51] Letter from the Secretary of State for Health and Social Care, Sajid Javid, to the Chair of the Health and Social Care Committee, Jeremy Hunt, 6 July 2021

Clauses 51-57: NHS Foundation Trusts

Clause 52 gives NHS England power to set a capital expenditure limit on an NHS Foundation Trust. The Explanatory Notes state that, unlike NHS Trusts, Foundation Trusts are not currently subject to statutory annual capital expenditure limits. NHS Foundation Trusts also have additional freedoms to borrow from commercial lenders and spend their own surpluses to fund capital projects.

The Explanatory Notes say that because capital expenditure by Foundation Trusts still counts against the ICS capital envelope and the Department of Health and Social Care's overall capital departmental expenditure limit (CDEL), there is a risk that a Foundation Trust's capital spending may impact on the overall local system ICB capital envelope, or on the national capital budget. The Bill therefore introduces a power for NHS England to set capital spending limits for Foundation Trusts. The Explanatory Notes say that limits would be set on an individual basis in respect of a named Foundation Trust for a specified period (expected to be a financial year), and the limit would automatically cease at the end of that period. It further explains that the power would be "used proportionately and in a limited way":

> [...] The power is intended to only be used on a Foundation Trust where there is a clear risk of an ICS breaching its system capital envelope as a result of non-cooperation by a Foundation Trust, and other ways of resolution have been unsuccessful.
>
> NHS England will produce guidance on the use of the power which will set out the circumstances in which it is likely to make an order to set a capital limit. The guidance will show that the power would be used proportionately and in a limited way and will outline the process before an order is established, including notifications and consideration of views from the Foundation Trust and the ICB. The guidance will also set out the publication of the order so there is transparency in the process.
>
> The limit applies solely to capital expenditure (e.g. investment in new building and equipment etc.) and not to revenue expenditure (e.g. staff costs and consumables). Foundation Trusts will continue to operate as autonomous organisations, legally responsible for maintaining their estates and providing healthcare services, with their boards continuing to decide what investments they make. They will retain their freedoms around commercial borrowing or reinvesting their surpluses.[52]

Clause 54 would allow an NHS Foundation Trust to form a joint committee with other providers to pool funds and to carry out their functions together.

Additional clauses relating to NHS Foundation Trusts amend legislation to enable the new NHS England to take on the role of Monitor (this role has been

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[52] Bill 140 EN 2021-22, paras 31-33

carried out under the operational name NHS Improvement since 2016). For example, **clause 53** provides that NHS Foundation Trusts submit their forward plans to NHS England rather than Monitor. **Clause 53** introduces some additional flexibilities around the preparation of accounts by Foundation Trusts. **Clauses 51** amends the process for NHS England to grant licences to NHS Foundation Trust, and **Clauses 55 and 56** amend the process for approving the merger and dissolution of NHS Foundation Trusts. **Clause 57** applies the new 'Triple Aim' duty to NHS Foundation Trusts.

Other clauses related to NHS Trusts and Foundation Trusts

Clause 58 allows for NHS England to make one or more schemes to transfer property, rights and liabilities between NHS Trusts and Foundation Trusts.

Clause 59 introduces **Schedule 8** of the Bill relating to Trust Special Administrators (TSAs), who can be appointed to make recommendations to secure sustainable and high quality services where an NHS provider has been placed into administration. **Schedule 8** outlines changes to the process and authorisation for the appointment of TSAs, which align with NHS England taking on the role of appointing TSAs.

Comment on NHS Foundation Trust capital limits

The NHS Providers Parliamentary briefing for the Bill's Seconding Reading debate recognises the need, in the move to system working and given the overall national constraints on capital spending, for NHS England to have a "reserve, backstop, power" to set individual Foundation Trusts capital spending limits. However, they also note that the use of powers to limit Foundation Trust capital investment should be carefully controlled: "It is absolutely right that foundation trusts and trusts retain their current accountability for the delivery of safe care and having sufficient freedom over capital expenditure is central to this task."[53]

2.10 Joint working, delegation, and collaboration (Clauses 60-65 and Schedule 9)

Clauses 60 and 61 and Schedule 9 provide for NHS England, ICBs, NHS Trusts and Foundation Trusts to arrange for their functions to be exercised by or jointly with one of the other bodies, or with local authorities. **Clause 60** allows the establishment of joint committees and pooled funds and provides for NHS England to publish guidance for NHS bodies in relation to joint working and delegation arrangements.

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[53] NHS Providers, Parliamentary briefing: Health and Care Bill Second Reading, 8 July 2021

Clause 62 removes the Secretary of State and NHS England's duties to promote autonomy, which were introduced by the Health and Social Care 2012. This relates to provisions in the Bill giving the Secretary of State powers of direction over NHS England. The Explanatory Notes say that removing these duties will also "…ensure that they do not conflict with duties for system partners to cooperate and think more broadly about the interests of the wider health system."[54]

Clause 63 gives NHS England the ability to issue guidance concerning joint appointments between NHS bodies, and between NHS bodies and local authorities.

Clause 64 amends the existing duties on NHS bodies and local authorities in England and Wales to co-operate with each other. It provides for the Secretary of State to issue guidance on how this duty is discharged. It imposes a duty on NHS bodies and local authorities, except for Welsh NHS bodies and local authorities, to have regard to this guidance.

Clause 65 amends provisions relating to licence conditions on NHS providers to include further purposes for which NHS England may set conditions in light of the creation of the 'Triple Aim' duty for NHS Foundation Trusts and NHS Trusts.

2.11 NHS payment systems (Clause 66 and Schedule 10)

The NHS national tariff sets out the prices, and rules for those prices, that NHS commissioners pay to providers (such as NHS Trusts and Foundation Trusts) for the provision of NHS-funded healthcare. The tariff is currently published by Monitor (which is part of NHS Improvement), with the proposals for each tariff agreed with NHS England.

Clause 66 inserts **Schedule 10** and replaces the national tariff with a new NHS payment scheme and makes provisions relating to the new system. The Explanatory Notes say these measures are designed to give the NHS more flexibility in how tariff prices and rules are set and to help support the delivery of more integrated care at local levels.[55]

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[54] Bill 140 EN 2021-22, para 572

[55] Bill 140 EN 2021-22, para 26

2.12 Patient choice and competition (Clauses 67-73 and Schedules 11 and 12)

Clauses 67 and Schedule 11: Patient choice

The Explanatory Notes set out that, currently, regulations regarding patient choice can be made under Section 75 of the 2012 Act. Section 75 also covers procurement and will be repealed by the Bill, which means the regulations covering patient choice would also be revoked. However, given the Government intention that patients' rights to choice should continue to be protected, the Bill will add similar powers relating to guidance and enforcement of the 'standing rules' on patient choice.[56]

As summarised by the NHS Providers briefing on the Bill, **Clause 67** strengthens the current rules around patient choice by making it mandatory for regulations to contain provisions about how NHS England and ICBs will allow patients to make choices about their care.[57] **Clause 67 and Schedule 12** provide for NHS England to take on powers to make guidance, and to resolve breaches of patient choice rules which are currently exercised by NHS Improvement.

Clause 68 and 69, and Schedule 12: Procurement and provider selection

The Explanatory Notes describe the procurement reforms within the Bill which will enable the removal of the current rules which apply for NHS and public health service commissioners when arranging clinical healthcare services, e.g., hospital or community services. The Bill provides a power to create a separate procurement regime for these services. This will include removing the procurement of health care services for the purposes of the health service from the scope of the Public Contracts Regulations 2015.

The Bill repeals section 75 of the 2012 Act and the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013. The Explanatory Notes say that a new procurement regime for NHS and public health services (also known as the 'provider selection regime') is being developed "...to reduce the need for competitive tendering where it adds limited or no value." The Explanatory Notes provide some further background on the scope of these reforms:

> These reforms will only apply to the procurement of clinical healthcare services, and the procurement of non-clinical services, such as professional services or clinical consumables, will remain subject to the Public Contract Regulations 2015 rules, until these are replaced by Cabinet Office procurement reforms. The power does

[56] Bill 140 EN 2021-22, para 124

[57] NHS Providers, Briefing on the Health and Care Bill, 6 July 2021

however provide an ability to make provision for mixed procurements in the regime, where a contract involves a mixture of health care and other services or goods, for example if a health service is being commissioned but in the interests of providing joined up care some social care services are also commissioned as part of a mixed procurement.[58]

Clause 68 enables the Secretary of State to make regulations in relation to the procurement of health care services in England and the procurement of health care services as part of mixed procurements e.g. with social care services.

Clause 69 removes the reference to existing regulation making powers on procurement, patient choice and competition from section 12E of the NHS Act 2006 and replaces this with the new procurement regulations in **clause 68** (12ZB). **Clause 69** would remove the existing regulation making powers on procurement, patient choice and competition from the Health and Social Care Act 2012, and revokes the current regulations on procurement, patient choice and competition (sometimes known as the section 75 regulations).

Background on proposals to reform procurement and competition rules

The February 2021 White Paper set out plans for legislative changes relating to competition and procurement in the NHS. It builds on previous NHS England proposals to repeal the Procurement, Patient Choice and Competition Regulations 2013, and section 75 of the Health and Social Care Act 2012.[59]

The Health and Social Care Committee's report NHS Long-term Plan: legislative proposals (HC2000, 24 June 2019) supported the intent behind NHS England's proposals to ensure that commissioners can exercise greater discretion over when to conduct a procurement process. However, the Committee also noted that the way the NHS in England operates may mean the proposals to change how procurement rules apply could face legal difficulties. The Committee's report noted varied views about the extent and impact of competitive tendering within the English NHS.[60]

The White Paper also states that "Where competitive processes can add value they should continue, but that will be a decision that the NHS will be able to make for itself."[61]

[58] Bill 140 EN 2021-22, para 116

[59] NHS England and NHS Improvement, The NHS's recommendations to Government and Parliament for an NHS Bill, September 2019

[60] Health and Social Care Committee, NHS Long-term Plan: legislative proposals, June 2019, HC 2000 2017-19, paras 42 to 48

[61] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, February 2021, para 5.46

The powers within the Bill are intended to enable the development of a new provider selection regime that will provide a framework for NHS bodies and local authorities to follow when deciding who should provide healthcare services. The consultation on the NHS Provider Selection Regime was published in February 2021.

Further information on NHS procurement and competition policy is available in section 8 of the Library briefing on The Structure of the NHS in England (June 2020).

Comment

The King's Fund has said the Bill will remove "cumbersome" competition rules and make it simpler for health and care organisations to work together to deliver more joined-up care to the increasing numbers of people who rely on multiple different services.[62]

The British Medical Association (BMA) briefing said it believed "the proposed reforms are insufficient to fully protect the NHS from unnecessary private sector involvement and could, under the Provider Selection Regime, allow contracts to be awarded to private providers without proper scrutiny or transparency." The BMA commented that in order to protect the NHS and prevent fragmentation of services "…the NHS should be made the default option for NHS contracts, with competitive tendering used only where an NHS provider cannot provide a given service."[63]

Clauses 70-73 and Schedule 12: competition and the role of the Competition and Markets Authority

The Explanatory Notes explain how the Health and Social Care Act 2012 gave Monitor (now operating as NHS Improvement) and the Competition and Markets Authority (CMA) formal roles to provide regulatory oversight of competition issues within the NHS. Monitor currently has a concurrent duty to promote competition in the NHS, whilst the CMA has specific functions to investigate mergers between NHS Foundation Trusts. The CMA can also investigate contested licence conditions should significant numbers of providers and/or commissioners object to them.[64]

Clause 70 requires NHS England to give the CMA regulatory information it may need to exercise its functions, or which would assist in carrying out its functions.

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[62] The King's Fund response to the Health and Care Bill, 6 July 2021
[63] BMA Member briefing: Health and Care Bill, July 2021
[64] Bill 140 EN 2021-22, para 118

Clause 71 introduces an exemption from Part 3 of the Enterprise Act 2002, removing CMA powers over NHS Foundation Trust mergers. Instead, NHS England will review NHS provider mergers and acquisitions to ensure there are clear patient benefits.

Private healthcare providers will still be in scope of the CMA's merger control regime. **Clause 72** removes Monitor's concurrent competition duties alongside the CMA. **Clause 72** provides for **Schedule 12**, which contains consequential amendments. **Clause 73** removes the CMA's involvement in contested licence conditions.

3 Part 2: Health and adult social care information

The data provisions in the Bill are intended to enable increased sharing and more effective use of data across the health and adult social care system. Specifically, the legislation aims to enable the Department of Health and Social Care and NHS England to publish mandatory information standards to ensure providers of health and adult social care adopt a standardised approach to the collection and processing of data. These provisions extend the potential application of information standards to include private providers of health and adult social care.

The Explanatory Notes state that requiring, enabling, facilitating, and encouraging more effective use of data will support other key provisions in the Bill, for example provisions strengthening the duty to cooperate across the health and care system.[65]

Clause 79 amends powers to publish information standards under the Health and Social Care Act 2012, including to make these standards mandatory for any person to whom they apply unless there is waiver.

Clause 80 relates to the sharing of anonymous health and social care information. This clause introduces a power for relevant health or social care public bodies in England to require the sharing of information, other than personal information, for purposes related to their functions in connection with the provision of health services or adult social care in England. The Explanatory Notes say that pseudonymised or de-identified data, which enables individuals to be identified, will not fall under the requirement.[66]

Clause 81 amends the general duties of the Health and Social Care Information Centre (known as NHS Digital), as established under the Health and Social Care Act 2012. It includes an amendment to clarify that NHS Digital may only share information for purposes connected with the provision of health care or adult social care or the promotion of health. The Explanatory Notes set out that this could include the following examples:

- commissioning,
- planning,
- policy analysis and development,
- population health management,

[65] Bill 140 EN 2021-22, para 75
[66] Bill 140 EN 2021-22, para 72

- assessment of the quality of services and individuals' experiences of them,
- workforce planning,
- research for purposes which benefit or are relevant to the provision of health or adult social care, and
- developing innovative approaches to the delivery of health and adult social care.[67]

Clause 81 would require NHS Digital to have regard to the need to promote the effective and efficient planning, development, and delivery of health services and of adult social care in England when exercising its functions. It further requires that NHS Digital balances the need to have regard to matters set out in its statutory functions so far as they compete.

Clause 82 amends NHS Digital's powers to require and request the provision of information under the Health and Social Care Act 2012. The effect of the amendment is to enable NHS Digital to require private providers of health services to provide it with any information it requires to comply with a direction from the Secretary of State under the 2012 Act to establish an information system.[68] **Clause 84** provides for the enforcement of these duties on private providers.

Clause 83 amends the Health and Social Care Act 2012 to enable the Secretary of State to require providers of adult social care to provide information to the Secretary of State about themselves, their social care activities, or the people to whom they have provided adult social care.[69] The Explanatory Notes explain there is currently no mechanism to collect data from private social care providers. This has resulted in gaps in information available to inform policy decisions or identify and respond to risks. It adds that the lack of data available to the Government to manage the response to Covid-19 "became a significant concern at the start of the pandemic."[70]

The February 2021 White Paper said the ability to collect more data will "enable the Department to better understand the system to inform future policy developments and ultimately help facilitate the care of individuals across the care system."[71]

Clause 85 amends the Medicines and Medical Devices Act 2021 to enable NHS Digital to collect a range of information about the use of medicines and their effects in the UK and hold this data in one or more information systems. The Explanatory Notes say the Medicines and Healthcare products Regulatory

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[67] Bill 140 EN 2021-22, para 700

[68] The Explanatory Notes (Bill 140 EN 2021-22, para 701) state that this does not include information which NHS Digital requires in order to comply with requests under section 255 of the 2012 Act.

[69] Further information on the detailed provisions, including around data protection, is provided in the Bill 140 EN 2021-22, pages 115-6

[70] Bill 140 EN 2021-22, para 334, page 23

[71] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, page 55

Agency (MHRA) would be able to use the information to establish and maintain comprehensive UK-wide medicines registries to improve post-market surveillance on the use of medicines. It also notes that medicine registries will only be established where there is a clear public health need and after the Commission on Human Medicines (CHM), the independent expert advisory body to the MHRA, has made a formal registry-specific recommendation.[72]

Comment

The BMA has broadly welcomed efforts to improve information standards, but has said clarity on powers given to the Secretary of State to enforce information standards may need to be established, particularly regarding what this could mean for healthcare providers and staff. The BMA has also said it "…will be carefully considering the impact of the legislation to ensure that the appropriate safeguards for patient confidentiality are not undermined."[73]

Information sharing: the legal framework

The Explanatory Notes acknowledge that some of the information sharing provisions in Part 2 of the Bill engage the legal framework governing the sharing and disclosure of personal data. This box provides an overview of that framework to put the Bill's provisions in context.

The Data Protection Act 2018

The Data Protection Act 2018 (the '2018 Act') and the UK General Data Protection Regulation (UK GDPR) set out the data protection framework in the UK which governs the processing and sharing of personal information.

Processing of personal data is prohibited unless there is a lawful basis for it, such as consent; compliance with a legal obligation; or the performance of a task in the public interest. Any sharing of personal data must also be accountable, lawful, fair, and secure.

Additional conditions apply in relation to 'special category data', which is data that is likely to be more sensitive, including data on racial or ethnic origins, religious views, and health data. This type of data is treated with greater care because collecting and using it is more likely to interfere with fundamental rights.

The data protection framework applies to data that relates to an identified or identifiable individual. It does not apply to personal data that has been

[72] Bill 140 EN 2021-22, paras 200-201

[73] BMA Member briefing: Health and Care Bill, July 2021

anonymised, meaning that the individual to whom it relates can no longer be identified.

Data protection is regulated by the Information Commissioner who has the power to issue fines. The 2018 Act also contains several criminal offences which can be committed in relation to personal data, including unlawfully obtaining data.

Further information is available on the Information Commissioner's Office website.

Duty of confidentiality

The courts have also developed a principle known as the common law duty of confidentiality. This means that when someone shares personal information in confidence, there may be a duty not to disclose it without some form of legal authority or justification.

4 Part 3: Secretary of State powers to transfer functions

4.1 Arm's Length Bodies: transferring and delegating functions (Clauses 86-92)

Part 3 of the Bill allows the transfer, by regulations, of functions from one of a list of relevant Non-Departmental Public Bodies (NDPB) to another. It will enable the Secretary of State, by regulations, to provide for the Secretary of State's functions to be delegated to an NDPB. These powers cannot be used to formally transfer any of the Secretary of State's functions to a NDPB.[74]

The Explanatory Notes say there will be a "full and transparent process" in making regulations to transfer or delegate functions, including a formal consultation before laying. Consultation will involve the affected Arm's Length Bodies (ALBs) and, where relevant, the devolved administrations. The Bill provides that these regulations will be subject to approval by the Commons and Lords, under the affirmative SI process.

The Secretary of State already has powers to transfer functions between Special Health Authorities or Departmental executive agencies. The Explanatory Notes say that the Care Quality Commission (CQC), National Institute for Health and Care Excellence (NICE) and Health Service Safety Investigation Branch (once it is created as a NDPB through this Bill) are to remain out of scope given their particular, technical, regulatory functions and the need for them to be independent.[75]

Clause 86 sets out the following "relevant bodies" to which the Secretary of State's powers to transfer will apply:

- Health Education England
- The Health and Social Care Information Centre (known as NHS Digital)
- The Health Research Authority
- The Human and Embryology Authority.
- The Human Tissue Authority
- NHS England

As well as conferring power to transfer ALB functions on the Secretary of State through regulations, **clause 87** sets out the conditions which will need to be

[74] Bill 140 EN 2021-22, para 107

[75] Bill 140 EN 2021-22, para 110

met in order for these regulations to be made. For example, such regulations can only be made when the Secretary of State considers it will improve the exercise of these functions with regard to:

- efficiency;
- effectiveness;
- economy; and
- securing appropriate accountability to Ministers.

The clause sets out that through secondary legislation, the Secretary of State can modify the functions, constitution or funding of a "relevant body" and to abolish an ALB if it has become redundant as a consequence of the transfer of functions. However, **clause 87(3)** provides an exemption in relation to the transfer of functions of NHS England to prevent the Secretary of State from using the new power to make it redundant and to abolish it.

Clause 88 relates to the delegation of functions by the Secretary of State to an ALB. Specifically, subsection 87(1) confers a power on the Secretary of State to provide, through regulations, for a relevant body to exercise specified functions of the Secretary of State on their behalf.

Clause 89 relates to the detailed scope of these powers, and **clause 90** relates to the making of schemes for the transfer of property, rights or liabilities. **Clause 91** refers to taxation arrangements in relation to assets and liabilities transferred under a scheme made under **clause 90**.

Clause 91 sets out who the Secretary of State must consult on draft regulations, including devolved administrations, where relevant.

Comment

The NHS Providers' briefing for Members published ahead of the debate on Second Reading says the exercise of powers to transfer ALB functions must not threaten the operational independence of key parts of the NHS. In particular, where these powers could be used by the Secretary of State to abolish a body, or to transfer the majority of its powers to other bodies, there should be proper parliamentary scrutiny, and that should require primary legislation.[76]

Matthew Taylor, chief executive of the NHS Confederation, said that "In their current form, these plans also bring with them the risk that arm's-length bodies, including NHS England and NHS Improvement, could be split up or abolished without any real scrutiny."[77]

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[76] NHS Providers, Parliamentary briefing: Health and Care Bill Second Reading, 8 July 2021

[77] NHS Confederation, NHS Bill 'right direction of travel' but concerns remain, 6 July 2021

5 Part 4: The Health Services Safety Investigations Body

5.1 Background

Since April 2017 the Healthcare Safety Investigation Branch (HSIB) has conducted independent investigations of patient safety concerns in NHS-funded care across England. It was set up following recommendations from the House of Commons Public Administration Committee, and a subsequent expert advisory group. Both recommended the establishment of a body focused on investigating and learning from incidents affecting patient safety.

The HSIB was set up to investigate incidents in the NHS and to improve patient safety through recommendations based on these investigations. The HSIB can investigate patient safety concerns across any NHS-funded service in England. From 1 April 2018, it became responsible for patient safety investigations of certain maternity incidents occurring in the NHS.

The HSIB is a non-statutory body, operational under Secretary of State directions as an organisational arm of the Trust Development Authority (TDA) which is part of NHS Improvement.

Further information on the HSIB's responsibilities is available on its website at 'About us' and in the House of Lords Library briefing on the Health Service Safety Investigations Bill [HL].

Part 4 of the Health and Care Bill would replace the current non-statutory HSIB (Investigation Branch) with a new statutory, independent, arm's-length investigating body called the Health Service Safety Investigations Body (HSSIB). The Explanatory Notes to the Health and Care Bill state:

> The Bill will establish a new statutory body which will largely replace the Investigation Branch. There will be transitional arrangements to transfer the Investigation Branch's function to NHS England for an interim period following the abolition of the TDA and prior to the establishment of the HSSIB.
>
> [...]

> Establishing the HSSIB as a new independent body aligns with the Department's drive to improve patient safety and reflects the commitment given when the Investigation Branch was established.[78]

The Health Service Safety Investigations Bill

The draft Bill

Provisions to create a new statutory body to investigate NHS safety incidents were proposed by the Government in a draft Health Service Safety Investigations Bill on 14 September 2017. The draft Bill was published in response to a number of high-profile inquiries and reviews into the investigation of patient safety incidents. They included:

- The Mid Staffordshire NHS Foundation Trust Public Inquiry Report, chaired by Robert Francis QC, February 2013
- Freedom to Speak Up report, Sir Robert Francis, February 2015
- Keogh Mortality Review, July 2013
- Berwick review into patient safety, August 2013
- Report of the Morecambe Bay Investigation by Dr Bill Kirkup, March 2015
- Investigating Clinical Incidents in the NHS, Public Administration Select Committee, March 2015.

The reports highlighted the often, poor quality of NHS incident investigations, the pressures that deter healthcare professionals from being frank about failings in patient care, and the factors that might contribute to them. The reviews emphasised the importance of moving away from a culture of individual blame to one of learning, to give healthcare professionals the confidence to be honest and candid when things go wrong.

In its response to the reviews, the Government committed to the introduction of a new independent patient safety investigation service to conduct independent, expert-led investigations into patient safety incidents.[79]

The draft Health Service Safety Investigations Bill, published in September 2017, made provision for the new investigative body - the Health Service Safety Investigations Body (HSSIB).[80] In the Foreword to the draft Bill the Government said:

> Building on the Healthcare Safety Investigation Branch – in operation since April 2017 – this draft Bill will create a statutory Health Service Safety Investigations Body, independent of the NHS and at arm's length from Government, with new powers that will enable it to discharge its investigation functions fully and effectively. The body

[78] Bill 140 EN 2021-22, paras 127-129

[79] Department of Health, Learning not blaming, July 2015, Cm 9113, page 39

[80] Department of Health, Draft Health Service Safety Investigations Bill, Cm 9497, September 2017

> will play a pivotal role in safety improvement using established investigative methods. Importantly, it will investigate for the sole purpose of learning, not to attribute blame or individual fault, providing a safe space for staff and patients to be open and candid when things go wrong. The new body will be an exemplar of healthcare safety investigative practice and will help embed a culture of learning across the NHS in England.[81]

Pre-legislative scrutiny

A joint Committee of the House of Commons and the House of Lords was tasked with conducting pre-legislative scrutiny of the draft Bill. In its August 2018 report of recommendations to the Government, the Committee welcomed many aspects of the draft Bill, including the need for the new statutory health safety body to be independent of the NHS and the Government and to have statutory investigative powers to make it fully effective.[82] It recommended that, in order for the HSSIB to carry out comprehensive investigations, its remit should be extended to cover privately funded care.[83]

The Committee raised several concerns in relation to the HSSIB's powers of disclosure and the effect those provisions may have on compromising the 'safe space' protection for investigations. It did not agree with the provision to allow the HSSIB to accredit other NHS trusts to carry out 'safe space investigations' into their own and other trusts.[84]

The Committee expressed further concern about the HSSIB's remit to undertake maternity investigations and other non-safe space investigations on the basis that they could lead to confusion about its role and undermine support and cooperation from other bodies for investigations. The Committee recommended the provision for maternity investigations and for other non-'safe space' investigations should not be included in the Bill and should not be allocated to the HSSIB. It believed that maternity investigations should instead be recognised as a duty of NHS Improvement.[85]

A Government's response to the joint Committee's recommendations was published in December 2018. The Government accepted many of the recommendations, including concerns over the accreditation of 'safe space' investigations and committed to remove them from the Bill.[86]

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81 Department of Health, Draft Health Service Safety Investigations Bill, Cm 9497, September 2017

82 Joint Committee on the Draft Health Service Safety Investigations Bill, Draft Health Service Safety Investigations Bill: A New Capability for Investigating Patient Safety Incidents, HL Paper 180 2017–19, 2 August 2018

83 ibid, para 179

84 ibid, chapter 3

85 ibid, p50

86 Department of Health and Social Care, Government Response to the Report of the Joint Committee on the Draft Health Service Safety Investigations Bill, December 2018, Cm 9737, p8.

In respect of the Committee's recommendation that the HSSIB's remit be extended to investigate independently funded care, the Government agreed to give this further consideration and consult with stakeholders.[87]

The Government did not, at that stage, accept the Committee's recommendation to remove the statutory duty of cooperation and maternity investigations from the Bill on the basis that it believed the best way to improve maternity investigations was to allow the current programme under the HSIB to continue so that learning and benefits could be gained.

Further analysis of the joint Committee's inquiry, the Government's response and changes made to the subsequent Bill as a result of its recommendations can be found in the House of Lord's Library note Health Service Safety Investigations Bill [HL]: Briefing for Lords Stages.

Health Service Safety Investigations Bill 2019

The Health Services Safety Investigations Bill 2019 was introduced in the House of Lords on 15 October 2019. The factsheet accompanying the Bill said its main objectives were to:

- establish the Health Service Safety Investigations Body (HSSIB) as a new independent arm's-length body with powers to conduct investigations into patient safety incidents that occur during the provision of NHS-funded services;
- create a 'safe space' whereby participants can provide information to the HSSIB safe in the knowledge the information will not be shared with others, and only disclosed under certain limited circumstances as set out in legislation; and
- amend the Coroners and Justice Act 2009 to allow for NHS bodies, rather than local authorities, to appoint medical examiners; and place a duty on the Secretary of State to ensure the system is properly maintained.

Under the Bill, the HSSIB would take over the duties of the current non-statutory Healthcare Safety Investigation Branch (HSIB). It would effectively put this body on a statutory footing, giving it full independence and statutory powers. However, the Government said the maternity investigations programme currently led by HSIB had been not been added to HSSIB's remit and was not included in the Bill. As noted above, concerns about this aspect of the body's duties were raised by the joint Committee set up to consider the draft Bill published in September 2017. Although the Government initially rejected the Committee's concerns, it subsequently decided that maternity investigations would not transfer to the statutory body upon its establishment.

[87] Ibid. para 2.17

The House of Lords Library briefing note written for the second reading debate provides further information on the changes made to the legislation following pre-legislative scrutiny and consultation.

As a result of the dissolution of Parliament for the December 2019 General Election, the Bill progressed no further than its second reading stage in the House of Lords. Legislative provisions to establish HSSIB were reintroduced under Part 4 of the Health and Care Bill on 6 July 2021.

Further background on the genesis of the HSSIB and the HSSI Bill is set out in the following reports, briefing papers and factsheets:

Report of the Joint Committee on the Draft Health Service Safety Investigations Bill, 2 August 2018

The Government response to the Report of the Joint Committee on the Draft Health Service Safety Investigations Bill, December 2018

Health Service Safety Investigations Bill [HL]: Briefing for Lords Stages, 24 October 2019

Factsheets on the Draft Health Service Safety Investigations Bill

5.2 The Bill (Clauses 93-119 and Schedule 13)

Part 4 of the Bill would establish the Health Service Safety Investigations Body (HSSIB) as an independent body corporate with responsibility to conduct investigations into patient safety incidents occurring during the provision of health services in England. Schedules 13 and 14 to the Bill contain further provisions relating to the HSSIB and its functions.

Clauses 93–94 and Schedule 13: HSSIB and its investigatory functions

Clause 93 of the Bill would establish a new statutory patient safety investigating body to replace the current Healthcare Safety Investigations Branch (HSIB).[88] Schedule 13 makes provision for the new body's governance arrangements, including its status and membership.

The new Health Service Safety Investigation Body (HSSIB) would be an independent non-departmental body responsible for investigating "qualifying incidents", set out in **clause 94(1)** as incidents that:

(a) occur in England during the provision of health care services, and

(b) have or may have implications for the safety of patients.

[88] Clause 93 and Schedule 13

Clause 94 of the Bill would extend the scope of current HSIB's powers and those set out in the previous HSSI Bill to allow the HSSIB to investigate non-NHS funded services in England. This change was implemented in response to recommendations made by the joint Committee on the draft Bill and to questions raised during the debate on second reading of the HSSI Bill in the House of Lords on the omission of private healthcare investigations.[89]

Clause 94 makes it clear that the purpose of an investigation is not to assess or determine blame or liability, but to identify risks to patients and address those risks by facilitating improvements in health service systems and practices.

Clauses 95 and 96: Investigatory procedures

Clause 95 makes clear that the HSSIB's functions under **clause 94** include the power to determine which "qualifying incidents" to investigate. This is subject to a power of the Secretary of State to direct the HSSIB to investigate a particular qualifying incident. **Clause 95** also makes provision for the procedures that apply when the HSSIB decides to begin, to discontinue or not to investigate a qualifying incident.

Clause 96 would require the HSSIB to develop and publish:

- the criteria it will use to determine the incidents it will investigate;
- the principles governing investigations;
- the processes to follow when carrying out investigations; and
- the processes for ensuring that patients and their families are involved in investigations.

Publications concerning the processes for patient and family involvement in investigations are required to be easily accessible and capable of being easily understood by patients and families.

Clause 96 also specifies that the HSIBB must review its criteria, principles and processes three years after first publication, and then every five years. It must consult with the Secretary of State (and any other person it considers relevant) when developing or revising its criteria, principles and processes.

Clauses 97-101: Incident reports

The HSSIB would be required to publish a final report into any incidents it investigates. This report must contain the facts of the investigation and an analysis of the findings, together with any recommendations as to the action to be taken by any person(s) specified. Where applicable, the report must also set out the HSSIB's conclusions in respect of improvements to NHS systems and practices.

[89] See HL Deb, 29 October 2019, c892 on the Health Service Safety Investigations Bill [HL], Lord Hunt of Kings Heath

The focus of the final report must be on ascertaining risks to the safety of patients and on making recommendations on actions to address those risks. The function of the final report is not to make an assessment of, or to determine, blame. This is made explicit on the face of the Bill in **clauses 97(3)-(4)**.

Clause 97(6) prohibits the naming of individuals providing information to the HSSIB or involved in an incident under investigation unless they have consented to being named.

Under **clause 98**, the HSSIB would have power to publish interim reports into investigations, subject to the same requirements for final reports.

Clause 99 states that before publication, drafts of interim and final reports must be circulated to those who may be adversely affected by it and may be circulated to other potentially interested parties. Such persons must be notified of the opportunity to comment on the draft before a specified deadline.

Clause 100 outlines the procedure for when a report from the HSSIB makes recommendations for future action. The HSSIB must make a report available to a person to whom its recommendations apply. Under **clause 100(4)** HSSIB's recommendations would require a written response from any addressee(s) (unless specifically exempt).

Clause 101 provides that the HSSIB's draft, interim and final reports are not admissible in certain court, tribunal or regulatory body proceedings set out in **clause 101(2)**. The high court may however, make an order admitting those reports following an application to do so from a person in those proceedings.

Clause 102: Inspection and seizure

Clause 102 makes provision for powers of entry, inspection and seizure of documents by HSSIB investigators for the purposes of investigations. Clause 102(1) would allow investigators to:

- enter and inspect premises in England (that are not used as private dwellings);
- inspect and take copies of documents;
- inspect equipment or items at the premises; and
- seize and remove documents, equipment, or items.

Items seized by an investigator may be retained by the HSSIB for so long as is necessary for the purposes of the investigation.[90]

The explanatory notes to the Bill say the powers of entry, inspection and seizure are intended to be used where consent to do so has not been given. The Explanatory Notes say:

[90] Clause 102(3)

> In carrying out its function of investigating incidents, the HSSIB will engage with those under investigation and those managing the organisations where the investigation is taking place. It is expected that in most cases, the staff and organisation will co-operate with the HSSIB investigators, consent to the investigators' entry to premises and provide relevant documents. However, where consent is not given, clause 102(1)(a) gives the HSSIB powers to enter and inspect premises in England.
>
> These are similar powers to investigatory bodies in other safety-critical industries, such as the Air Accident Investigations Branch (AAIB). [91]

Clauses 103 and 104: Powers to require information

Clauses 103 and 104 contain provisions for how the HSSIB should give notice to individuals requiring them to provide information or items or to be interviewed regarding investigations. Under **clause 103(3)** a person given notice to provide information or items would not be required to do so where there is a risk to a patient's safety or it may incriminate the person. A person would be also entitled to refuse to provide information if they would be entitled to do so in legal proceedings on the grounds that it is subject to legal professional privilege.

Clause 103 allows the HSSIB to retain any document, equipment or other item provided to an investigator, for as long as is necessary, for the purposes of an investigation unless its retention would risk the safety of any patient.

Clause 105: Offences

Clause 105 would create new criminal offences of obstructing an investigator in the performance of functions conferred under clause 102 or failing to comply with a notice under clause 103 without a reasonable excuse. It would be a criminal offence to knowingly provide false or misleading information to a HSSIB investigator.

Clauses 106 – 109 and Schedule 14: Disclosure of information

Clause 106 prohibits the disclosure of "protected material" to any person.

The Government has said the aim of the provision is to create a 'safe space' for participants during the investigation, enabling them to "speak openly and candidly with the HSSIB". The Explanatory Notes add:

> The safe space applies both to protected material obtained before the HSSIB decided whether to investigate as well as to material held in connection with an investigation already underway or completed.[92]

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[91] Bill 140 EN 2021-22, paras 854-855

[92] Bill 140 EN 2021-22, para 877

Subject to certain exemptions, the prohibition on the disclosure of protected materials would encompass any information, document, equipment or other items held by the HSSIB in connection with its investigations; relates to a qualifying incident; or has not been lawfully made available to the public.

Exemptions to the prohibition are set out in **Schedule 14** to the Bill. They include if disclosure is:

- necessary for the purposes of carrying out the HSSIB's investigation function;
- necessary for the prosecution or investigation of an offence
- believed to be necessary to address a serious and continuing risk to the safety of a patient or the public;
- ordered by the High Court; and
- required by a coroner.

The Secretary of State would be able to authorise further exceptions to clause 106 by virtue of a regulation-making power under **clause 107(c)**.

Clause 108 would make it a criminal offence for a person to knowingly or recklessly disclose protected material when they know or suspect that disclosure is prohibited.

Clause 109 would prevent the use of powers in other legislation being used to require the disclosure, or seizure of protected material from the HSSIB. The power is subject to the provisions in Schedule 14 to allow disclosure to coroners.

Clauses 110-112: Relationship with other bodies

Clause 110 would impose a duty on the HSSIB and specified listed persons to co-operate with each other when investigating the same or related qualifying incident. Listed persons include NHS bodies, health authorities and regulators specified in **clause 110(3)**.

Under **clause 111**, the HSSIB would be required to comply with requests from NHS bodies and NHS England to give assistance to an NHS body with carrying out investigations into incidents involving NHS services. The assistance includes:

- disseminating information about best practice in carrying out investigations;
- developing standards to be adopted in carrying out investigations; and
- providing advice, guidance, or training (where practical).

The HSSIB could also provide assistance to unspecified bodies if requested,[93] as long as it would not interfere with the exercise of its main functions.[94] It would be able to charge for this provision.[95]

Although under **clause 94** the HSSIB's investigatory functions apply to health care incidents occurring in England, the Bill would allow the HSSIB to support investigations by NHS bodies in other areas of the United Kingdom. Under **clause 112** the HSSIB could enter into agreements to carry out investigations connected to incidents with implications for patient safety occurring in the United Kingdom during the provision of Welsh or Northern Irish NHS services. **Clause 112(4)** would allow the HSSIB to charge for these services; it would not be permitted to enter into an agreement to provide services if doing so would significantly interfere with its main functions.

The **clause 112** would not enable the HSSIB to provide assistance in connection with Scottish NHS services, but it could offer assistance in investigations if requested to do so under the provision in **clause 111(5)**.

Clauses 113 and 114: Oversight of functions by the Secretary of State

Clause 113 provides for intervention by the Secretary of State should the HSSIB fail significantly to carry out its functions or fail to carry them out properly.

Clause 114 requires the Secretary of State to publish a review of the effectiveness of the HSSIB in carrying out its investigative functions four years after being formally established and lay that report before Parliament.

Clause 115-119: Supplementary provisions

Clauses 115 to 119 contain supplementary provisions relating to: offences under Part 4 by bodies corporate (**clause 115**) and partnerships (**clause 116**); obligations of confidence and data protection in respect of disclosure of information (**clause 117**) ; consequential amendments (**clause 118**) and definitions in Part 4 of the Bill (**clause 119**).

Comment

The NHS Providers' briefing on the Bill reiterates a number of concerns raised by the joint Committee on the draft HSSI Bill concerning the independence of the HSSIB. It recommends the addition of "balancing provisions" in order for the HSSIB to be able to determine, without interference, when it undertakes investigations.[96]

Further concerns are raised in relation to the exceptions on the prohibition on disclosure which it argues "are wide ranging, discretionary and unreasonably open to external applications for access".[97] It recommends the Bill be

[93] Clause 111(5)

[94] Clause 115(6)

[95] Clause 115(8)

[96] NHS Providers, Briefing on the Health and Care Bill, 9 July 2021, page 10

[97] ibid, p11

amended to put beyond any possible doubt that the 'safe space' cannot be compromised save in the most exceptional circumstances and that the prohibition on disclosure applies equally to disclosure to coroners.[98] In addition, it calls on the test for an application to disclose protected material be tightened to "ensure that disclosure is only sought in extremis".[99]

[98] ibid

[99] ibid

6 Provisions relating to adult social care

While the Bill's provisions regarding health and social care integration are clearly of importance for adult social care, the Bill also contains several other provisions directly related to the sector.

6.1 Hospital discharge and social care assessments (Clause 78)

Background

Under Schedule 3 of the Care Act 2014, local authorities are required, in certain circumstances, to carry out an assessment of a person's social care needs before they are discharged from hospital.[100]

This requirement has been disapplied during the Covid-19 pandemic during which time the NHS has operated a "Discharge to Assess" model, whereby social care needs assessments can take place after an individual has been discharged from hospital.[101] Additional funding has been provided to cover the follow-on care costs of patients discharged under this model. Further information is provided in section 5 of the Library Briefing: Coronavirus: Adult social care key issues and sources.

Models of "Discharge to Assess" or "Home First" were being used before the pandemic, with some pilots starting in 2016. This was part of work between the Department of Health and Social Care, NHS England, NHS Improvement, and local government to provide support to help local areas improve transfers out of hospital and reduce delays.[102]

Clause 78 of the Bill revokes the requirement for social care needs assessments to be carried out prior to a person's discharge from hospital.[103] It is intended that guidance on hospital discharge will set out the requirements of health and social care partners during the discharge process.[104]

The Explanatory Notes to the Bill say the requirement to carry out assessments prior to discharge can lead to delays when people are ready to

[100] Care Act 2014, Section 74 & Schedule 3.
[101] Coronavirus Act 2020, section 14(8) & Schedule 12, paragraph 14; DHSC, Hospital discharge and community support: policy and operating model, last updated 5 July 2021.
[102] For more information, see: DHSC, ADASS, NHS England, QUICK GUIDE: DISCHARGE TO ASSESS.
[103] Health and Care Bill, Clause 78; Bill 140 EN 2021-22, pages 36 & 111.
[104] Bill 140 EN 2021-22, p36.

leave hospital. In turn, this can lead to poorer patient outcomes and can add to pressure on hospital beds. They add that the change provided for by the Bill will allow local areas to adopt the most suitable discharge model for local needs, including the "discharge to assess" model.[105]

The February 2021 White Paper added that the change "will help to embed good practice guidelines which have been followed over the past few years."[106]

Comment

In its response to the Bill, the Local Government Association said "the repeal of legislation related to delayed discharges is good news and paves the way for the continuation of discharge arrangements which have worked well during the pandemic."[107]

In evidence to the Health and Social Care Committee, Age UK said it was "very supportive of the policy intentions and aspirations of the Discharge to Assess model", but added that appropriate safeguards are needed "to ensure that the standards of care older people can expect are clearly articulated and no one falls through the gaps."[108]

In its evidence to the Committee, Carers UK expressed concern about the Discharge to Assess model and said it must be ensured that "before someone is discharged from hospital, their carer is willing and able to care for that person."[109] However, in its response to the Bill, it noted that the hospital discharge guidance had now been updated to reflect carers' rights during the process.[110]

6.2 CQC assessment of local authority social care functions (Clause 121)

Clause 121 of the Bill provides for the Care Quality Commission (CQC) to be placed under a duty to assess local authorities' delivery of their adult social care functions under Part 1 of the Care Act 2014. The exact functions in scope for review will be set out in regulations. Under the Bill's provisions, there will be certain steps that the CQC may or must take if it considers that a local authority is failing in the discharge of its adult social care functions. If the failings are considered substantial, this includes informing the Secretary of

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[105] Bill 140 EN 2021-22, para 157

[106] DHSC, Integration and Innovation: working together to improve health and social care for all, February 2021, page 57.

[107] LGA, LGA responds to publication of Health and Care Bill, 6 July 2021

[108] HSC0986,

[109] HSC0942

[110] Carers UK, Carers UK responds to introduction of Health and Care Bill, 6 July 2021

State and recommending any special measures it considers the Secretary of State should take.[111]

The February 2021 White Paper said accountability for social care services has become increasingly important as more people access social care as a result of demographic change. It added that it was therefore "only reasonable for Government to want to ensure the [adult social care] system is delivering the right kind of care, and the best outcomes, with the resources available." The White Paper added that the Government understood that the proposals come "following an extraordinarily challenging time for adult social care" and that the focus initially would be on improving data collection [see above] with the assessment element "introduced over time."[112]

Comment

The Health and Social Care Committee's report on the Government's White Paper (14 May 2021) said the proposal "received a mixed response from our witnesses." While a number of witnesses broadly welcomed the proposal, they also noted that it would not solve the main issues in the sector, including around funding. The Committee's report concluded that the proposal would "shine a much-needed light on local variation in the provision of social care" but that, for it to be successful, "the social care system needs to have in place a fully funded 10-year plan to sit alongside the NHS's own 10-year plan."[113]

In its response to the Bill, published on 6 July 2021, the Local Government Association said it was working closely with the CQC and the Department of Health and Social Care to "ensure the assurance process is proportionate, includes a clear and continuous role for existing sector-led improvement work, and takes account of the significant financial pressures facing adult social care."[114]

6.3 Financial assistance (Clause 122)

Clause 122 of the Bill amends the Health and Social Care Act 2008 to provide the Secretary of State with power to provide financial assistance to adult social care providers. Currently, while the Secretary of State may provide financial assistance to "qualifying bodies" delivering adult social care, this does not include providers operating for profit, and thus excludes much of the adult social care provider market.

[111] Bill 140 EN 2021-22, pages 148-50

[112] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, page 56

[113] Health and Social Care Committee, The Government's White Paper proposals for the reform of Health and Social Care, 14 May 2021, HC 20 2021-22, pages 19-20.

[114] LGA, LGA responds to publication of Health and Care Bill (6 July 2021)

The February 2021 White Paper said the Covid-19 pandemic had demonstrated "the need for speed and flexibility in providing support to the social care sector." It added that, while the Bill would not prescribe the circumstances when the power can be used, the Government is clear that it will only be used in "exceptional circumstances" and "will not be used to amend or replace the existing system funding of adult social care."[115]

6.4 Comment on wider reform of adult social care

Most of the commentary on the adult social care elements of the Bill and the February 2021 White Paper have focused on what isn't included – namely, more fundamental reform of the adult social care sector.

For example, in its response to the Bill, the Nuffield Trust stated

> The social care reforms in this Bill do not solve any of the problems that have brought this sector to a point of crisis, where hundreds of thousands of people needing care cannot get it. It's all very well to hold local councils to account for delivering, but at the moment they are operating within a system that all political parties agree is fundamentally broken. The hope that the NHS will cooperate more with social care services will also come to nothing without proper reform so that more people receive help, more staff join the sector, and stability is restored after years of desperation.[116]

The King's Fund response to the Bill emphasised the "pressing need" for more fundamental reform of adult social care and said "reforming health services while leaving the social care sector in crisis would be a recipe for failure."[117]

The Association of Directors of Adult Social Services (ADASS) similarly noted in its response that it had "called on the Government to urgently publish its promised plans for Adult Social Care ahead of the parliamentary recess later this month, so that we can collectively ensure that they dovetail with and complement the provisions in the Health and Care Bill."[118]

The Health and Social Care Committee's report on the Government's White Paper also noted a "significant number of submissions to our inquiry pointed out that the White Paper did not address the urgent need for a long-term plan for social care." The report expressed concern that the "White Paper did not set out a long-term plan for social care" and stated that "the absence of a fully funded plan for social care has the potential to destabilise Integrated Care Systems and undermine their success." In order to give reassurance to

[115] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 February 2021, page 56

[116] Nuffield Trust, Nuffield Trust response to Health and Care Bill (6 July 2021)

[117] King's Fund, 'Important reforms could be undermined by plans for ministerial interference': The King's Fund response to the Health and Care Bill (6 July 2021)

[118] ADASS, ADASS Responds: Health and Care Bill

the sector that the wider financial and structural issues will be addressed, the report recommended that the Bill include a duty for the Secretary of State to publish a 10-year plan within six months of the Bill receiving Royal Assent.[119]

The Government has committed to bring forward proposals for adult social care reform by the end of the year. Further information is provided in Library Briefing (CBP8001), Reform of adult social care funding: developments since July 2019 (England).

Further information on the broader funding of adult social care, is available in Library Briefing (CBP7903), Adult Social Care Funding (England).

[119] Health and Social Care Committee, The Government's White Paper proposals for the reform of Health and Social Care, 14 May 2021, HC 20 2021-22, pages 16-19

7 Restrictions on TV and online advertising of less healthy food and drink

7.1 Background

Currently, responsibility for monitoring and regulating broadcast advertising is co-regulated by the Advertising Standards Authority (ASA) and Ofcom. Permitted content and standards for broadcast advertising on television and on demand programme services (ODPS) are set out in the Communications Act 2003. Advertising on the internet is not currently subject to statutory regulation.

The Government believes that obesity is one of the greatest long-term health challenges the UK faces, with 1 in 3 children leaving primary school already overweight or living with obesity.[120] In addition, around two-thirds (63%) of adults are above a healthy weight and of these, half are living with obesity.[121] Evidence suggests that people who are overweight, or are living with obesity are at greater risk of long-term health conditions and being seriously ill and dying from Covid-19.[122]

Following public consultations in 2019 and 2020 on proposals for new restrictions on the advertising of High Fat Salt and Sugar (HFSS) food and drink[123], the Government published its response on 24 June 2021.[124] It announced that new advertising restrictions would be implemented as part of its ongoing commitment to tackle childhood obesity. Specifically, a 9pm watershed for advertisements of HFSS foods, applicable to television and UK on-demand programmes.[125] In addition, a prohibition on paid-for advertising of HFSS foods online. Both restrictions are legislated for in the Bill (**clause 125** and **Schedule 16**).

[120] NHS Digital, "National Child Measurement Programme, England 2018/19 School Year [National Statistics]", 10 October 2019

[121] NHS Digital, "Statistics on Obesity, Physical Exercise, and Diet, England 2020", 5 May 2020

[122] DHSC, "Policy Paper: Tackling obesity: government strategy", 27 July 2020

[123] "HFSS products" are food and soft drink products that are high in fat, salt or sugar as identified using nutrient profiling. The Government uses "Nutrient Profiling Technical Guidance" published by the Department of Health on 1 January 2011

[124] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[125] DHSC, New Advertising rules to help tackle childhood obesity, press release, 24 June 2021

Detailed information on the background to both measures and the policy rationale is outlined in Section 7 of a separate briefing paper, "Obesity".[126] That paper also provides an overview of the current regulation of advertising in the UK by the ASA (i.e. content of advertising, sales promotions, and direct marketing across all media, including marketing on websites).

A second briefing paper, Advertising to children, provides further information and government statistics on children's media habits and HFSS online advertising.[127]

7.2 The Bill (Clause 125 and Schedule 16)

An important aim of the Bill is to reduce children's exposure to the advertising of "less healthy food and drink" products on TV and online. For the purposes of the Bill, a food or drink product is "less healthy" if:

- it falls within a description specified in regulations made by the Secretary of State, and
- it is "less healthy" in accordance with the relevant guidance.

The relevant guidance is "Nutrient Profiling Technical Guidance" published by the Department of Health on 1 January 2011. The Government has said that to keep the restrictions proportionate, the new advertising restrictions would only apply to food and drink products of most concern to childhood obesity (i.e. HFSS products).[128]

Clause 125 and **Schedule 16** of the Bill would amend the Communications Act 2003 (CA 2003) to restrict advertising of certain food and drink products. The restrictions are as follows:

- A 9pm television watershed before which adverts for HFSS products could not be shown.
- Paid-for advertising for HFSS products online would be banned.
- All on demand programme services (ODPS) under UK jurisdiction, and therefore regulated by Ofcom, would be included in the TV watershed.[129]
- Other ODPS not UK regulated would be subject to the online advertising prohibition (since they are not defined in the CA 2003 they are considered "internet services").

[126] House of Commons Library briefing, Obesity (CBP 9049), 8 July 2021

[127] House of Commons Library briefing, Advertising to children (CBP 8198), 9 July 2021

[128] This is consistent with the approach that will be used for the promotions restrictions on price and volume policy, part of the Tackling Obesity Strategy

[129] On demand programme services (ODPS) differ from "live" television because they allow viewers to watch programmes at a time of their choosing and on a device of their choosing. It is the case that may broadcast TV channels also have ODPS, there are also ODPS available as paid-for subscriptions..

The television and online restriction is to be introduced simultaneously.

In respect of broadcast television and ODPS subject to Part 4A of the CA 2003, Schedule 16 would amend the CA 2003 to enable Ofcom to introduce restrictions prohibiting HFSS advertising between the hours of 5.30am to 9:00pm on broadcast TV. The Bill would also introduce a prohibition on paid-for HFSS advertising online by inserting a new section into the CA 2003 after Part 4B. In effect, a person must not pay for advertisements for an "identifiable" less healthy food or drink product to be placed on the internet.

Significantly, the online ban would be limited to "paid-for" advertising[130] of HFSS products; it would not apply to "owned media". This means that brands could continue to advertise within owned media spaces online (e.g. a brand's own blog, website, app, or social media channel).[131] The Government's consultation response[132] said this is to ensure that:

- brands can continue to talk about their products in the spaces they own,
- adults are not prevented from accessing owned media online spaces,
- and factual information can be shared on a brand's own online spaces (e.g. allergen ingredients).

The Bill's prohibition on paid-for advertising for HFSS products online would also not cover adverts:

- published online by a person who does not carry on business in the UK
- not intended to be accessed principally by persons in any part of the UK.[133]

Schedule 16 also provides for other exemptions, including:

- Businesses would be able to continue to promote online their products or services to other businesses (in other words, the Bill would allow marketing communications online targeted exclusively business-to-business).
- Audio online content which is streamed (e.g. podcasts and online only radio) would also be exempt, because the Government thinks that the impact of HFSS advertising in this media is unclear.[134]

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[130] Paid-for space online is any space where a third party has had to pay the owner to display content

[131] Owned media is any online property owned and controlled, usually by a brand. For owned media the brand exerts full editorial control and ownership over content

[132] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[133] This approach is the same as that taken in the Tobacco Advertising and Promotions Act 2002

[134] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

In respect of both a prohibition on paid-for advertising of HFSS products online and the 9pm TV watershed, Schedule 16 contains two important exemptions, namely:

- Brand advertising would still be permitted provided there were no "identifiable" HFSS products in the adverts. The reason given for this exemption is to give brands the opportunity to change and "move towards offering healthier products".[135]
- The advertising restrictions would only apply to businesses with 250 or more employees that make and/or sell HFSS products.

This final exemption is important. It means that small and medium sized enterprises (SMEs) who employ 249 employees or less, would be able to continue advertising online and before the 9pm TV watershed. In its June 2021 consultation response, the Government explained the reasons for this exception:

> The government recognises these companies may be some of the hardest hit by the pandemic and rely on online media as the sole way to communicate with their customers.
>
> [...]
>
> Furthermore, advertising restrictions could mean SMEs are less able to compete with larger brands who can use their brand recognition and resources to mitigate the effects of the proposed HFSS restrictions.[136]

Some stakeholders are calling on the Government to reconsider this exemption amid fears that it creates a "loophole" that might be exploited by multinationals. It is argued that multinationals selling their HFSS products in the UK and employing fewer than 250 staff could be exempt from the advertising restrictions, meaning they could advertise freely before the TV watershed and online.[137]

In respect of liability for non-compliance with the HFSS advertising restrictions, Schedule 16 of the Bill stipulates:

- Television Broadcasters and UK regulated ODPS (as defined in the CA 2003) would be liable for any breaches of the HFSS TV watershed.
- Advertisers would be liable for any breaches of the paid-for online prohibition.

[135] Ibid

[136] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[137] "Row over 'loophole' that could let foreign firms dodge junk food advert ban", Telegraph, 6 July 2021

- For non-UK ODPS, the advertiser would be liable for any breaches of the paid-for online prohibition on these platforms.

As outlined in the Government's response,[138] this approach aligns with the current enforcement frameworks across TV, online and ODPS advertising:

> It will provide greater regulatory coherence for broadcasters, platforms, advertisers and regulators as the liable parties for HFSS advertising breaches will be the same as for other breaches of the advertising codes.[139]

It is significant that under the provisions of the Bill, online platforms would not be made expressly liable for breaches. In its response the Government states that the extent of platforms' liability for unlawful advertising generally would be considered as part of its "Online Advertising Programme".[140] It would be for the regulators to determine whether an online platform should be treated as an advertiser.

In respect of enforcement of the new HFSS advertising restrictions, Ofcom would be the statutory regulator. However, under the Bill, Ofcom could appoint a day-to-day regulator to carry out frontline regulation; the expectation is that the ASA will carry out this function. The day-to-day regulator would use powers contracted out by Ofcom to promote compliance with, and understanding of, the new HFSS advertising restrictions.

In effect, day-to-day responsibility for applying the new advertising restrictions, considering complaints, and providing guidance would be with the frontline regulator. It is envisaged that, in the first instance, the frontline regulator would use informal powers to insist on a non-complying advert being removed (e.g. reputational sanction, such as naming and shaming) and takedown requests. However, for serious or repeated breaches or where these sanctions have had no effect, the frontline regulator could refer the case to Ofcom. To enforce the new advertising restrictions, Ofcom could use fines and other civil sanctions (the maximum fines would be in line with those found in broadcasting, for parity between broadcast and online). In effect, Ofcom would act as the backstop regulator. In the Government's view, this approach would make enforcement "both rigorous and proportionate within the changing online media landscape".[141]

If enacted, the measures contained in Schedule 16 of the Bill would come into force on **1 January 2023**. As with all other advertising restrictions, the rules would apply to the whole of the UK. The Government has already made a

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[138] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[139] Ibid.

[140] Ibid.

[141] Ibid.

commitment to work with regulators to ensure guidance is made available to businesses before the implementation of the new restrictions.[142]

7.3 Views of stakeholders

The Government summarises respondents' feedback to the March 2019 and autumn 2020 consultations in its response published on 24 June 2021.[143] It states that:

- 81% of individuals, 73% of organisations and 13% of businesses supported a watershed for television HFSS adverts.
- 75% of individuals, 85% of organisations and 23% of businesses supported an online ban for HFSS adverts.

According to the Government, one respondent to its 2019 consultation drew attention to the fact that current rules already require advertisers to use multiple evidence sources where possible to ensure they are compliant with the Advertising Codes, and to exercise caution in cases where robust evidence is not available. Another respondent said that dynamically served advertising online is not strictly automated, and that "humans make conscious decisions about when and where adverts are shown online, control the buying process, and specify how ads should be targeted, with numerous points in the process where regulatory compliance is checked before, during and after a campaign".[144]

Responding to these specific points the Government said:

> We do not consider that this addresses fundamental concerns about flaws in the system by which advertising is targeted, which are magnified as children spend more time online, and further undermined by a lack of transparency.
>
> A solution building on existing audience-based restrictions is therefore too dependent on an opaque and potentially porous system, over which the advertiser may sometimes have limited control, and applied to an advertising category which is unique in being age restricted in advertising but not otherwise (unlike, for example, alcohol which is age restricted for purchase and consumption).

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[142] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[143] Department for Digital, Culture, Media & Sport (DCMS) and the Department of Health and Social Care (DHSC), "Introducing further advertising restrictions on TV and online for products high in fat, salt and sugar: government response", 24 June 2021

[144] Department of Health and Social Care and the Department for Digital, Culture, Media and Sport, "Total restriction of online advertising for products high in fat, sugar and salt (HFSS)", 10 November 2020

> In addition, an approach where compliance relies on the quality and reliability of targeting information and the ability to target certain advertisements away from children, may engage issues of competition. Effective and widespread targeting tools and methods would be necessary to ensure a level playing field. Some platforms may be better disposed to implement time-based targeting already, which may confer an advantage over those facing operational or practical burdens in implementing a time-based restriction. Measures to enable compliance would have to be universally accessible and compatible in order to minimise potential risks of market distortion and competitive advantage.[145]

On 10 June 2019, the ASA, the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) published their response to the Government's March 2019 consultation. They questioned the evidence base for the proposed 9pm watershed for TV advertising of HFSS products and asked whether the existing controls in the BCAP and CAP Codes might be further developed instead. An extract from this response is reproduced below:

> In relation to the pre-9pm option, CAP and BCAP raise concerns on the basis of practicality and proportionality and invite a further assessment of the relative merits of timing-based restrictions (proposed in the consultation) and audience-based restrictions, which are currently in place. CAP, BCAP and legacy ad regulators have historically favoured audience-based restrictions (combined with content rules) as the most effective and efficient means to achieve the necessary protection afforded to children while avoiding disproportionate intrusion into adults' TV viewing and adults' online engagement.
>
> [...]
>
> If, following its consideration of consultation responses, Government is inclined to consider alternative adjustments to the current framework of restrictions, we think there is an opportunity for it to work with all parties to identify a wider range of options that may better address any harms that are not adequately addressed by the current restrictions, which continue to be effective.[146]

The Internet Advertising Bureau (IAB UK), the industry body for digital advertising, was part of a group[147] that came together to respond to the Government's autumn 2020 consultation paper and its proposal to implement

[145] Ibid.

[146] Letter to the Department of Health and Social Care from the Advertising Standards Authority, the Committee of Advertising Practice and the Broadcast Committee of Advertising Practice, 10 June 2019

[147] This group, organised by the Advertising Association, included the ISBA, the IPA (Institute of Practitioners in Advertising) and food and drink manufacturers

a ban of HFSS adverts online. The IAB published the Ad industry's reaction, an extract is reproduced below:

> Trade bodies across the ad industry have condemned the Government's proposed ad ban as "unwarranted" and "draconian" and called for the Government to be led by the evidence, which doesn't show that a ban would address obesity. Industry bodies including IAB UK, Advertising Association, ISBA, IPA, AOP, PPA and the NMA sent a joint letter to the Prime Minister expressing these views and calling for a proportionate approach to the issue based on robust evidence. You can read IAB UK's full statement, which was also sent to the Government, here.
>
> Following the launch of the Government's consultation on how to implement a total ban online in November 2020, IAB UK issued a joint statement with the Advertising Association, ISBA and the IPA, plus run an editorial piece in The Times that calls on the Government to base their decision on evidenced policies that deliver the greatest benefit for the least economic cost. We are holding meetings with Government ministers and the Prime Minister's advisors, and have written jointly with the AA, ISBA and the IPA to backbench MPs highlighting our concerns.[148]

On 10 November 2020, the Advertising Association also published online a "Joint Ad Industry Comment on HFSS Advertising".[149] It urged ministers to "develop evidenced solutions that are targeted at the problem they wish to address, appropriate to digital media fit for the 21st century".[150] The Advertising Association also criticised the Government for beginning the consultation during the coronavirus pandemic:

> If this policy of an outright ban goes ahead, it will deal a huge blow to UK advertising at a time when it is reeling from the impact of Covid-19. This consultation has landed just as we have entered another period of lockdown, with all the heightened uncertainty this creates for people and businesses right across the country. Businesses that should be devoting their time and energy to surviving this economically unpredictable situation will now have to devote precious resources to responding to the Government and working out whether they will even be able to advertise their products in the future.[151]

Conversely, the RSCPH (Royal College of Paediatrics and Child Health) published a response developed in collaboration with the Obesity Health Alliance (OHA) (a coalition of over 40 health charities, medical royal colleges and campaign groups working together to influence Government policy to

[148] Internet Advertising Bureau (IAB UK) "Q&A: What does an online HFSS ad ban mean?", 17 November 2020

[149] Advertising Association, Joint Ad Industry Comment on HFSS Advertising, 10 November 2020

[150] Ibid.

[151] Ibid.

reduce obesity).[152] While supporting the introduction of new restrictions on the advertising of HFSS products on TV and online, the RSCPH suggested that similar restrictions should be applied to other types of media:

> We also think restrictions should apply to packaging, and to sponsorship, including sponsorship of TV channels, programmes, websites, sports events, and school-based activities. Sponsorship is currently regulated separately, and we need a level playing field to avoid a loophole where HFSS could be shown at the start and end of advertising breaks.[153]

The OHA published "An analysis of adverts shown during a week of 'Britain's Got Talent' live shows".[154] Among its key findings was that more than one in five (23%) of all adverts shown before 9pm was for an HFSS food or drink. In addition, "a child who watched all six episodes up to 9pm would see over 22 minutes of unhealthy food and drink adverts – which could lead to them eating over 300 additional calories".[155] The OHA made the following recommendation:

> Despite comprehensive evidence showing the harmful effect of unhealthy food and drink advertising and Government acknowledgment of the issue, unhealthy food and drink adverts continue to be shown heavily during children's favourite TV programmes. This analysis provides real-world evidence that hundreds of thousands of children are being exposed to unhealthy food advertising at a level that leads to excess calorie consumption.
>
> We want to see the Government commit to introducing a comprehensive 9pm watershed on unhealthy food and drink adverts on TV and online with no exemptions. This would provide broad protection for children and is supported by over 70% of the public.[156]

In its autumn 2020 consultation document the Government cites Cancer Research UK analysis.[157] Cancer Research UK found that almost half of all food adverts shown on ITV, Channel 4, Channel 5 and Sky One were for HFSS products, rising to almost 60% between 6pm and 9pm when they are deemed most likely to be viewed by children.[158]

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[152] A list of full members is available on the OHA (Obesity Health Alliance) website

[153] Royal College of Paediatrics and Child Health, "Department of Health and Social Care: Further advertising restrictions for products high in fat, sugar and salt", June 2019

[154] Obesity Health Alliance, "Britain's Got a Problem with Junk Food Adverts: An analysis of averts shown during a week of "Britain's Got Talent' live shows", May 2019

[155] Ibid.

[156] Ibid.

[157] Cancer Research UK, "Analysis of revenue for ITV1, Channel 4, Channel 5 and Sky One derived from HFSS TV advertising spots in September 2019", by Dominic Ng, Alizee Froguel and Malcolm Clark, July 2020

[158] Ibid.

8 Other provisions

8.1 International healthcare (Clause 120)

On 26 March 2019, legislation to enable the implementation of new reciprocal healthcare arrangements received Royal Assent: the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019. The legislation was introduced as the Healthcare (International Arrangements) Bill on 26 October 2018. During the Lords stages there were significant changes to limit the global scope of regulations and to confine the Bill to arrangements with EEA countries and Switzerland. To reflect these changes at Report stage on 12 March 2019, the Lords amended the title to the Healthcare (European Economic Area and Switzerland Arrangements) Bill. Further information on the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019, including Explanatory Notes and Impact Assessments, can be found on the Parliament website.

The Explanatory Notes to the Bill explain that the limited territorial scope of the powers in 2019 Act mean that the Secretary of State does not have necessary powers to implement reciprocal healthcare agreements with countries outside of the EEA, including, for example, British Overseas Territories and Crown Dependencies, other than the ability to exempt individuals from charges for relevant NHS services.[159]

As a result, although the UK has a number of reciprocal healthcare agreements with countries outside the EU, such as Australia and New Zealand, "they are limited in scope because of the absence of financial reimbursement or data sharing powers". Broadly, they allow UK nationals to access emergency treatment while in the other country, but access to services such as haemodialysis for kidney patients is restricted or not included within the scope of existing agreements.[160]

Clause 120 amends the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 to enable the Government to implement comprehensive reciprocal healthcare agreements with countries outside the EEA and Switzerland. The Explanatory Notes state that the exact arrangements which will be provided for under any future reciprocal healthcare agreements is a matter for negotiations.[161] Unlike most other

[159] Bill 140 EN 2021-22, para 139
[160] Bill 140 EN 2021-22, para 140
[161] Bill 140 EN 2021-22, para 923

provisions in the Bill, the territorial extent and application of this clause includes Wales, Scotland and Northern Ireland, as well as England.

8.2 Professional regulation (Clause 123)

The Explanatory Notes state that powers sought through this Bill "...form part of a wider programme aiming to create a more flexible and proportionate professional regulatory framework that is better able to protect patients and the public."[162]

Section 60 of the Health Act 1999 provides powers to make changes to the professional regulatory landscape through secondary legislation. **Clause 123** extends the scope of the existing powers in section 60 and Schedule 3 of the Health Act 1999 to enable a number of significant changes to be made to the professional regulation system through secondary legislation. The Explanatory Notes say these powers could be used so that:

- where it appears that a regulated healthcare profession no longer requires regulation for the purposes of public protection it can be deregulated by an order in council;
- a regulatory body can be abolished by an order in council where the profession(s) concerned have been deregulated as above or will continue to be regulated by another regulatory body;
- groups of workers, whether or not they are generally regarded as a profession, can be brought into regulation;
- reserved functions of regulatory bodies can be delegated to other regulatory bodies by an order in council. These reserved functions are maintaining a register of members, determining standards of education and training and giving advice about standards of conduct and performance, and administering the fitness to practise function.[163]

The Explanatory Notes clarify that the new powers could be used to bring senior NHS managers and leaders within the scope of professional regulation, irrespective of whether they are part of a healthcare profession.[164]

As with all Section 60 orders, secondary legislation using these new powers would be subject to public consultation and the affirmative parliamentary procedure.[165]

[162] Bill 140 EN 2021-22, para 162
[163] Bill 140 EN 2021-22, para 949
[164] Bill 140 EN 2021-22, para 166
[165] This requires the approval of both Houses of Parliament.

The nine regulatory bodies for health and care professions operate across the UK, and the Explanatory Notes state that any use of the extended powers "would be subject to Ministerial approval across the devolved administrations."[166] Orders will always require the approval of the Northern Ireland Assembly where professional regulation is a transferred matter and may require the approval of the Scottish Parliament (where they concern professions brought into regulation after the Scotland Act 1998) or the Welsh Assembly (where the order concerns social care workers).

The Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, regarding the Health and Care Bill, provides the following rationale for **clause 123**:

> The legislation governing the regulation of health care professions is best amended by means of secondary legislation in order to allow regulatory bodies to be flexible and responsive to the changing needs of the healthcare environment, to support the development of a diversifying workforce and to protect the public effectively.[167]

On 24 March 2021 the Government published Regulating Healthcare Professionals, Protecting the Public, a consultation setting out detailed policy proposals for reforming the legislation of healthcare regulators. This consultation closed on 16 June 2021.

8.3 Medical examiners (Clause 124)

Clause 124 of the Bill would amend the Coroners and Justice Act 2009 to introduce a statutory medical examiner system within the NHS rather than local authorities in England, for the purpose of scrutinising all deaths which do not involve a coroner. It would require the Secretary of State to ensure that enough medical examiners are appointed in the healthcare system in England, that enough funds and resources are made available to medical examiners to enable them to carry out their functions of scrutiny, and to ensure that their performance is monitored.

The Explanatory Notes to the Bill state:

> Medical examiners will introduce an additional level of scrutiny to those deaths not reviewed by a coroner, improve engagement with the bereaved in the process of death certification and offer them an opportunity to raise any concerns as well as improving the quality and accuracy of Medical Certificates of Cause of Death. Independent scrutiny of deaths will reduce the potential for malpractice by doctors to go unchecked. The level of scrutiny will be proportionate

[166] Bill 140 EN 2021-22, para 164

[167] Health and Care Bill Delegated Powers Memorandum from DHSC to the Regulatory Reform Committee, 6 July 2021

> so as not to impose undue delays on the bereaved or undue burdens on medical practitioners and others involved in the process.[168]

Further information can be found in the Library Briefing paper, Death certification and medical examiners (CBP9197, 12 July 2021).

8.4 Hospital food (Clause 126)

The Independent Review of NHS Hospital Food published in October 2020 recommended improved NHS food and drink standards for patients, staff and visitors be put on a statutory footing. The Bill would grant the Secretary of State for Health and Social Care powers to adopt secondary legislation that will implement the national standards for food across the NHS. The Explanatory Notes provide the following:

> This Bill amends section 20 of the Health and Social Care Act 2008 to provide the Secretary of State for Health and Social Care powers to make regulations imposing requirements in connection with the provision of food or drink provided on hospital premises in England relating to food or drink provided or sold to patients, staff, visitors or anyone else on hospital premises. Such requirements include the power to specify nutritional standards, or other nutritional requirements, such as to specify descriptions of food or drink that are not to be provided or made available.[169]

8.5 Food labelling requirements (Clause 127)

Clause 127 introduces a power to amend retained EU law relating to food information for consumers.

Regulation (EU) No 1169/2011 (the Regulation) makes provision regarding food information, including the labelling of prepacked food and drink for consumers in the UK, and brings together EU rules on general food labelling and nutrition into a single piece of legislation. Article 7 of the Regulation sets out a general principle that food information should not be misleading.

The Regulation was converted into domestic law and retained under the European Union (Withdrawal) Act 2018. The retained version of Regulation (EU) No 1169/2011 applies to food businesses in Great Britain, whereas EU food law, including Regulation (EU) No 1169/2011 continues to apply in Northern Ireland.

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[168] Bill 140 EN 2021-22, para 175

[169] Bill 140 EN 2021-22, para 179

Guidance from the Food Standards Agency provides further information about the legal requirements for food packaging and labelling in the UK.

Section 16 of The Food Safety Act 1990 makes provisions regarding food safety and consumer protection and enables the Government to make regulations on various aspects of food safety. Section 16(1)(e) of the Act enables the Government to introduce regulations which make provision for:

> ...imposing requirements or prohibitions as to, or otherwise regulating, the labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food;

The Bill would give the UK, Scottish and Welsh Governments the power to amend Regulation (EU) No 1169/2011, by amending an existing power in the Food Safety Act 1990. This is set out in clause 127, section 16(3A):

> (3A) Regulations under subsection (1)(e) may amend Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

Amendments to Regulation (EU) No 1169/2011 would be made using secondary legislation and an affirmative process.

The Department of Health and Social Care acknowledged the breadth of the power proposed in the Bill, and measured this against safeguards:

> The power is a broad one but is subject to a number of safeguards; regulations are to be made via the affirmative procedure and there is a general duty to consult in matters concerning food law. Article 9 of Regulation (EU) 178/2002 (which is retained EU law) places a statutory requirement to consult on changes to food law.[170]

Why has the Government proposed the new powers?

The Government has said that **clause 127** of the Bill would enable it to respond appropriately to the needs of domestic consumers and changing scientific opinion:

> A delegated power enables the Secretary of State (where he deems appropriate) to adapt the existing regime concerning the provision of food information to consumers in response to the specific needs of domestic consumers (for example, nutritional information to support public health needs of the population) and in response to feedback from stakeholders concerning operating within the restrictions.
>
> [...]

[170] Health and Care Bill, Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, 6 July 2021, para 795

> Food safety law and the requirements around food labelling can be a fast developing area and it is the Department's view that it is desirable that requirements in relation to the labelling of food should be able to adapt appropriately to evolving scientific opinion and other developments in the area.[171]

The Bill is intended to simplify the legislative process for amending the Regulation.

Owing to its status as retained direct principal EU legislation, changes to Regulation (EU) No 1169/2011 would need to be made via primary legislation, as per the European Union (Withdrawal) Act 2018. The new Bill would enable these changes to be made with secondary legislation.

The Government has also suggested that "the level of technical detail involved in amendments to the retained legislation in [Regulation (EU) No 1169/2011] is deemed too high for inclusion in in primary legislation".[172]

Referring to an overlap in the provisions of the Regulation and the Food Safety Act 1990, the Department of Health and Social Care proposed that regulations made using the powers set out in the Food Safety Act 1990 should now have the ability to amend the provisions under Regulation (EU) No 1169/2011.[173]

Developing Government policy on food labelling

The Bill would contribute to the Government's wider policy on food, and in particular, the Government's obesity strategy. In a policy paper setting out the proposals for the Health and Care Bill, the Government said that the new powers would enable it to introduce key policies from its obesity strategy:

> 5.129 We are proposing to amend section 16 of the Food Safety Act 1990 to give ministers the power to amend the EU Food Information to Consumers (2011/1169) regulations that have been transposed into UK law. This will allow ministers to introduce new strengthened labelling requirements that best meet the needs of the consumer to make more informed, healthier choices subject to approval by Parliament.
>
> 5.130 This power will enable the swift introduction of key obesity strategy policies such as changes to our front-of-pack nutrition labelling scheme and mandatory alcohol calorie labelling, following consultation. We are considering the impact of this clause with the

[171] Health and Care Bill, Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, 6 July 2021, paras 790 and 793

[172] Health and Care Bill, Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, 6 July 2021, para 790

[173] Health and Care Bill, Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee, 6 July 2021, para 791

> devolved administrations and will continue to engage them on our current and any future policy proposals.[174]

As part of its obesity strategy, the Government has committed to a range of work on food labelling.

In a July 2019 prevention Green Paper, Advancing our health: prevention in the 2020s, the Government said that it would:

- Explore how the marketing and labelling of infant foods can be improved
- Consult on how the success of the current front-of-pack nutritional labelling scheme could be built on following the UK's departure from the EU

In a July 2020 policy paper, Tackling obesity: empowering adults and children to live healthier lives, the Government said that it would:

- Publish a 4-nation public consultation to gather views and evidence on the current "traffic light" food labelling system
- Introduce legislation to require large out-of-home food businesses to add calorie labels to the food they sell
- Consult on the intention to make companies provide calorie labelling on alcohol

For a detailed discussion of the Government's obesity policy, please see the Library's July 2021 briefing on obesity.

Aside from obesity policy, the Government has also indicated that it will give consideration to addressing other matters related to food labelling. Defra Minister Victoria Prentis said on 7 July 2021 that the Government plans to consult later in 2021 on "what can be done through labelling to promote high standards of animal welfare across the UK market".[175]

8.6 Water fluoridation (Clauses 128 and 129)

Clauses 128 and 129 of the Bill would amend the Water Industry Act 1991 so that the Secretary of State has powers to directly introduce, vary or terminate water fluoridation schemes in England. These changes would mean that the Secretary of State would no longer need to be directed by a local authority to establish a water fluoridation scheme.

The Explanatory Notes to the Bill highlight difficulties with the current process, such as discrepancies between water flow boundaries and local authority boundaries. It explains that the amendments would remove "the

[174] DHSC White Paper, Integration and Innovation: working together to improve health and social care for all, 11 Feb 2021
[175] PQ 24280, 7 July 2021

burden from local authorities and will allow the Department of Health and Social Care to streamline processes and take responsibility for proposing any new fluoridation schemes, which will be subject to consultation and funding being agreed."[176]

Background

Fluoride is a naturally occurring mineral, that can help to prevent tooth decay, and improve oral health. Since the mid-20th century, fluoride has been added to drinking water through water fluoridation schemes to reduce the risk of tooth decay in the population.[177] Currently, around six million people in England live in areas with fluoridation schemes.[178] In other areas of England, the water naturally contains fluoride at the required level.

The water fluoridation process is the responsibility of the water company providing the supply in the area. It is controlled through a series of legislative and regulatory measures and companies are required to exercise their responsibilities in accordance with a technical code of practice published by the Drinking Water Inspectorate (DWI), the body responsible for assuring the quality of public water supplies in England.[179] The DWI is also responsible for monitoring the levels of fluoride in water that occur both naturally and as a result of fluoridation schemes.[180] More information about the fluoridation process and the regulation of fluoride in water is provided in the Public Health England guidance, Improving oral health: A community water fluoridation toolkit for local authorities

Public Health England (PHE) has a duty to monitor (on behalf of the Secretary of State) the health effects of water fluoridation schemes under Section 90A of the Water Industry Act 1991[181] and is required to produce reports on this at least every four years. The most recent report, Water fluoridation: health monitoring report for England 2018, was published in March 2018. It concluded that "water fluoridation is an effective and safe public health measure to reduce the prevalence and severity of dental caries, and reduce dental health inequalities."[182]

Water fluoridation is widely supported by medical organisations such as the British Medical Association,[183] the British Dental Association,[184] and the Royal College of Paediatrics and Child Health.[185] However, there has been some controversy around the introduction of water fluoridation schemes, and

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[176] Bill 140 EN 2021-22, para 205

[177] NHS, Fluoride, August 2018

[178] Public Health England, Water fluoridation: health monitoring report for England 2018, March 2018

[179] DWI, Code of Practice on Technical Aspects of Fluoridation of Water Supplies 2016, January 2016

[180] DWI, Fluoridation of drinking water, June 2016

[181] Section 90, Water Industry Act 1991

[182] Public Health England, Water fluoridation: health monitoring report for England 2018, March 2018

[183] BMA, BMA response to 'Advancing our health: prevention in the 2020s', 2 October 2019, page 5.

[184] BDA, Dentists: Fluoridation offers 'theoretical' benefits without up-front investment, 11 February 2021

[185] RCPCH, The State of Child Health, Oral health, [accessed 12 July 2021]

significant local opposition to their introduction in some areas.[186] Concerns have been raised by some organisations that there may be negative health impacts associated the fluoridation of drinking water.[187] The NHS website reports that reviews of the risk so far have "found no convincing evidence to support these concerns." It does note that dental fluorosis (mottling of the teeth) can occur in children's teeth where they are exposed to too much fluoride when developing but states that it is uncommon for severe fluorosis to occur in the UK because fluoride levels are carefully monitored.[188]

The 2018 Public Health England monitoring report of the health effects of water fluoridation provided the following conclusions:

> The reduction in the number of five-year-olds experiencing caries and the decrease in the severity of this dental disease was significant in those receiving a fluoridated water supply, and most clearly so in more deprived areas, narrowing differences in dental health between more and less deprived children. The effect of fluoridation on admission for tooth extraction was also substantial. A larger number of the most deprived children and young people benefited, again lessening differences in dental health between more and less deprived children and young people.
>
> We have also been able to explore associations with potential adverse health effects in more detail: despite some suggestion of associations between water fluoridation and certain health effects, the overall results of our analysis, and weight of wider evidence means causal associations are unlikely.[189]

Current legislative framework and proposed amendments

Currently, under the amended Water Industry Act 1991, local authorities have the powers to introduce, consult on and end water fluoridation schemes in their local areas. Under this Act, the Secretary of State for Health and Social Care is responsible for making, varying or terminating fluoridation agreements with water companies only in accordance with the proposals of the affected local authority.

Government proposals

The February 2021 White Paper, Integration and Innovation: working together to improve health and social care for all, set out proposals to give the Secretary of State greater power with regard to water fluoridation schemes in

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[186] BBC, Southampton's fluoridation decision 'unlawful', 19 January 2011; BBC, Southampton council votes to oppose fluoride water plan, 15 September 2011; BBC, Southampton water fluoridation plans scrapped, 28 October 2014.

[187] See for example, UK Freedom From Fluoride Alliance

[188] NHS, Fluoride, August 2018

[189] Public Health England, Water fluoridation: health monitoring report for England 2018, March 2018

the Health and Care Bill. It explained some of the difficulties that local authorities have faced under the existing arrangements:

> Local authorities have reported several difficulties with this process including the fact that local authority boundaries are not co-terminous with water flows, which requires the involvement of several authorities in these schemes, in a way which is complex and burdensome. In addition, local authorities are responsible for the oversight of revenue and costs associated with new proposals, including feasibility studies and consultations, while having no direct financial benefit from any gains in oral health.[190]

The White Paper set out that, in response to these challenges, the Government was proposing to give the Secretary of State the power to directly introduce, vary or terminate water fluoridation schemes. It noted that the Secretary of State already has power to decide on whether proposals for water fluoridation should be approved, and responsibility for the administration of schemes. The White Paper said that the proposal would "remove the burden from Local Authorities" and allow the Department to "streamline processes" and take responsibility for proposing new fluoridation schemes, which would remain subject to public consultation.[191] Central government would become responsible for associated work and costs.

In the report on its inquiry on the Government's White Paper proposals for the reform of Health and Social Care, the Commons Health and Social Care Select Committee noted that it had received mixed responses to the Government's plans on fluoridation in the White paper.[192] Health organisations had expressed support for the proposals, but some had highlighted the need for consultation with local areas. The Local Government Association had also said that fluoridation schemes should not be imposed on local areas and that local decision makers were "best placed to take into account locally-expressed views and to balance the perceived benefits of fluoridation with the ethical arguments and any evidence of risks to health". Some organisations in opposition to water fluoridation also submitted evidence to the committee. The UK Freedom From Fluoride Alliance said that whilst it remained in opposition to fluoridation generally, if this continued it should remain in the hands of local authorities where it said, local people could be more easily involved in the decision. The Committee drew the Governments attention to the submissions and said that "the Secretary of State will recognise the long-standing debate on fluoridation, and we look to him to set out a balanced response to both sides of the argument during the debates on the Bill."[193]

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[190] DHSC White Paper, Working together to improve health and social care for all, 11 February 2021, page 58

[191] DHSC White Paper, Working together to improve health and social care for all, 11 February 2021

[192] Commons Health and Social care Select Committee, Department's White Paper on health and social care, 14 May 2021, HC 20 2021–22

[193] Commons Health and Social care Select Committee, Department's White Paper on health and social care, 14 May 2021, HC 20 2021–22

8.7 Miscellaneous provisions (Clauses 75-77)

Clause 74 disapplies the existing legislative provisions that currently impose a three year time limit on any new Special Health Authority (SpHA). The three year limit was introduced by the Health and Care Act 2012, and only applies to SpHAs that came into force after 2012. Currently this requirement applies to the NHS Counter Fraud Authority, which has to have its existence formally extended every three years. **Clause 75** sets out requirements for SpHAs in relation to their accounts and auditing.

Clause 76 relates to the repeal of spent powers of the Secretary of State, under the Health and Social Care Act 2012 to make a property transfer scheme or a staff transfer scheme in connection with the establishment or abolition of a body by that Act, or the modification of the functions of a body or other person by or under that Act.

Clause 77 abolishes Local Education and Training Boards (LETBs), which are statutory sub-committees of Health Education England (HEE). HEE and their LETBs were established under the Care Act 2014. The Explanatory Notes state that LETBs "…exercise HEE's functions at local level to plan and commission education and training, quality assure the education and training commissioned for their areas, and act as a forum for local workforce development in the NHS and public health system." There are seven LETBs covering England, with each of the geographical footprints matching that of NHS England's regional directorates. The policy intention is to abolish LETBs as a statutory sub-committee "…to enable HEE to develop and adapt its own flexible regional operating model to best deliver its objectives over time."[194]

8.8 Part 6: Consequential provisions, regulations, commencement, extent and short title (Clauses 130-135)

Clause 130 gives the Secretary of State some general regulation making powers consequential on the Bill. In particular, the power may be used to amend, repeal, revoke or otherwise modify any provision within this Bill or any provision made by or under primary legislation passed or made either before this Act is passed or later in the same Parliamentary session. The Explanatory Notes say "Where regulations modify primary legislation, the affirmative

[194] Bill 140 EN 2021-22, para 63

procedure must be used. Otherwise, the regulations can be made under the negative procedure."[195]

Clause 131 makes some further provision relating to regulations made under the Bill. In particular it sets out that, in addition to any regulations that amend primary legislation, regulations laid under the following clauses must be subject to the affirmative parliamentary procedure:

- **Clause 14(4)** regarding Integrated Care Board responsibility.
- **Clause 87 and 88** regarding the power to transfer functions between Arm's Length Bodies.
- **Clause 107** regarding exceptions to the Health Service Safety Investigation Body's prohibition on disclosure.[196]

Clause 132 deals with the further financial provision necessary as a result of the Bill.

Clause 133 sets out the territorial extent of the Bill, providing that it extends to England and Wales only with the exception of the following sections and subsections that extend to England, Wales, Scotland and Northern Ireland:

- Schedule 1 part 1, paragraph 1(3) or (4) (renaming of NHS Commissioning Board).
- Part 3 (Secretary of State's powers to transfer or delegate functions).
- Part 4, section 109 (restriction of statutory powers requiring disclosure).

The provisions extending to England and Wales apply to England only, as health is largely a matter for devolved competence.

There is a convention that Westminster will not normally legislate with regard to matters that are within the legislative competence of the Scottish Parliament, Senedd Cymru or the Northern Ireland Assembly without the consent of the legislature concerned. The Explanatory Notes provide, in the annex, a summary of the position on territorial extent and application in the UK.[197]

Clause 134 provides that Part 6 of the Bill come into force on the day the Act is passed. These are the general provisions (dealing with consequential amendments, regulations, extent, commencement and the title). **Clause 125** and **Schedule 16** (advertising of less healthy food and drink) come into force on 1 January 2023. The remaining provisions would come into force on the day or days specified by the Secretary of State in regulations. There is a power to make regulations which include transitional or saving provisions in connection with the coming into force of any provision of the Bill.

[195] Bill 140 EN 2021-22, paras 1014-1015
[196] Bill 140 EN 2021-22, para 1019
[197] Bill 140 EN 2021-22, Annex, pages 173-174

Clause 135 states the Bill's short title as 'The Health and Care Act 2021'.

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