

HEALTH AND CARE BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Health and Care Bill as introduced in the House of Commons on 6 July 2021 (Bill 140).

- These Explanatory Notes have been prepared by the Department of Health and Social Care in order to assist the reader of the Health and Care Bill and to help inform debate on it. They do not form part of the Health and Care Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Health and Care Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Health and Care Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Health and Care Bill. They are not, and are not intended to be, a comprehensive description of the Health and Care Bill.

Table of Contents

Subject	Page of these Notes
Overview of the Health and Care Bill	10
Policy Background	11
Merging NHS England, Monitor and NHS Trust Development Authority	11
Mandate and financial directions to NHS England	12
Funding for service integration	14
The NHS Payment Scheme	14
Capital spending limits over Foundation Trusts	15
New NHS Trusts	16
Integrated Care Boards and Integrated Care Partnerships	17
Triple Aim	17
Duty to Cooperate	18
Joint Appointments	18
Joint Committees	18
Collaborative Commissioning	18
Secretary of State's duty to report on workforce systems	19
Abolition of LETBs	20
Information	20
Secretary of State power to direct NHS England	24
Power of Direction – Secretary of State Public Health functions	25
Reconfigurations	25
Transfer of functions between Arm's Length Bodies	27
Special Health Authority Time Limits	28
Procurement of clinical healthcare services	29
Competition	29
Patient Choice	30
Health Service Safety Investigation Body	31
International Healthcare	32
Adult Social Care Assurance	34
Hospital Discharge	36

Professional Regulation	36
Medical Examiners	39
Hospital Food Standards	39
Advertising of less healthy food and drink	40
Food information for consumers: power to amend retained EU law	42
Medicine Information Systems	43
Water Fluoridation	45
Territorial extent and application	46
Commentary on provisions of the Bill	47
Part 1: Health Service in England: Integration, Collaboration and Other Changes	47
NHS England	47
Clause 1: NHS Commissioning Board renamed NHS England	47
Schedule 1: Renaming of NHS Commissioning Board	47
Clause 2: Power to Require Commissioning of Specialised Services	47
Clause 3: NHS England Mandate	48
Clause 4: NHS England: Effect of Decisions	48
Clause 5: Public involvement and consultation: carers and representatives	49
Clause 6: Support and Assistance by NHS England	49
Clause 7: Exercise of functions relating to provision of services	50
Clause 8: Preparation of consolidated accounts for providers	51
Clause 9: Funding for service integration	51
Clause 10: Payments in respect of quality	52
Clause 11: Secondments to NHS England	52
Integrated Care Boards	53
Clause 12: Role of Integrated Care Boards	53
Clause 13: Establishment of Integrated Care Boards	53
Schedule 2: Integrated care boards: constitution etc.	54
Clause 14: People for whom integrated care boards have core responsibility	58
Integrated Care Boards: Functions	58
Clause 15: Commissioning hospital and other health services	58
Clause 16: Commissioning primary care services etc.	59
Schedule 3: Conferral of primary care functions on integrated care boards etc.	59

Clause 17: Transfer schemes in connection with transfer of primary care functions	61
Clause 18: Commissioning arrangements: conferral of discretions	62
Clause 19: General functions	62
Integrated Care Partnerships	69
Clause 20: Integrated care partnerships and strategies	69
Integrated Care System: Financial Controls	70
Clause 21: NHS England’s financial responsibilities	70
Clause 22: Expansion of NHS England’s duties in respect of expenditure	72
Clause 23: Financial Responsibilities of integrated care boards and their partners	72
Clause 24: Expansion of financial duties of integrated care boards and their partners	73
Integrated care system: further amendments	73
Clause 25: Integrated Care System: further amendments	73
Merger of NHS bodies etc.	74
Clause 26: Abolition of Monitor and transfer of functions to NHS England	74
Schedule 5: Abolition of Monitor and transfer of its functions	74
Clause 27: Exercise by NHS England of new regulatory functions	74
Clause 28: Modification of standard license conditions	74
Clause 29: Abolition of NHS Trust Development Authority	75
Clause 30: Merger of bodies: consequential amendment	75
Clause 31: Transfer schemes in connection with abolished bodies	75
Clause 32: Transfer schemes under section 31: taxation	75
Secretary of State’s functions	75
Clause 33: Report on assessing and meeting workforce needs	75
Clause 34: Arrangements for exercise of public health functions	76
Clause 35: Power of direction: public health functions	76
Clause 36: Power of Direction: investigation functions	77
Clause 37: General power to direct NHS England	78
Clause 38: Reconfiguration of services: intervention powers	80
Schedule 6: Intervention powers over the reconfiguration of NHS services	80
NHS Trusts	82
Clause 39: NHS trusts in England	82
Clause 40: Removal of power to appoint trust funds and trustees	82

Clause 41: Sections 39 and 40: consequential amendments	82
Schedule 7: NHS trusts in England and removal of power to appoint trustees; consequential amendments	82
Clause 42: Licensing of NHS Trusts	83
Clause 43: NHS Trusts: effect of decisions	83
Clause 44: Oversight and support of NHS trusts	83
Clause 45: Directions to NHS trusts	84
Clause 46: Recommendations about restructuring of NHS trusts	84
Clause 47: Intervention in NHS Trusts	84
Clause 48: NHS Trusts: conversion to NHS foundation trusts and dissolution	85
Clause 49: Appointment of chair of NHS trusts	85
Clause 50: Financial Objectives for NHS trusts	85
NHS Foundation Trusts	86
Clause 51: Licensing of NHS Foundation Trusts	86
Clause 52: Capital Spending Limits for NHS Foundation Trusts	86
Clause 53: Accounts, annual reports, and forward plans	87
Clause 54: NHS foundation trusts: joint exercise of functions	87
Clause 55: NHS foundation trusts: mergers, acquisitions and separations	87
Clause 56: Transfers on dissolution on NHS foundation trusts	88
Clause 57: NHS foundation trusts: wider effect of decisions	88
NHS Trusts and NHS Foundation Trusts: transfer schemes	89
Clause 58: Transfer schemes between trusts	89
Clause 59: Trust special administrators	90
Schedule 8: Trust special administrators: NHS trusts and NHS foundation trusts	90
Joint Working and Delegation of Functions	96
Clause 60: Joint working and delegation arrangements	96
Schedule 9: References to functions: treatment of delegation arrangements etc	98
Collaborative Working	99
Clause 62: Repeal of duties to promote autonomy	100
Clause 63: Guidance about joint appointments	100
Clause 64: Co-operation by NHS bodies etc	100
Clause 65: Wider Effect of decisions: licensing of health care providers	101
NHS Payment Scheme	102

Clause 66: The NHS payment scheme	102
Schedule 10: The NHS payment scheme	102
Patient Choice and Provider Selection	104
Clause 67: Regulations as to patient choice	104
Schedule 11: Patient choice: undertakings by integrated care boards	105
Clause 68: Procurement regulations	106
Clause 69: Procurement and patient choice: consequential amendments etc	106
Competition	107
Clause 70: Duty to provide assistance to the CMA	107
Clause 71: Mergers of providers: removal of CMA powers	107
Clause 72: Removal of functions relating to competition etc.	108
Schedule 12: Removal of CMA functions relating to competition etc	108
Clause 73: Removal of CMA's involvement in licensing etc.	108
Miscellaneous	109
Clause 74: Special Health Authorities: removal of 3 year limit	109
Clause 75: Tidying up etc provisions about accounts of certain NHS bodies	109
Clause 76: Repeal of spent powers to make transfer schemes	110
Clause 77: Abolition of Local Education and Training Boards	111
Clause 78: Hospital Patients with care and support needs: repeals etc	111
Part 2: Health and Adult Social Care Information	111
Clause 79: Information standards	112
Clause 80: Sharing anonymous health and social care information	113
Clause 81: General duties of the Health and Social Care Information Centre etc	114
Clause 82: Collection of information from private health care providers	114
Clause 83: Collection of information about adult social care	115
Clause 84: Enforcement of duties against private providers	116
Clause 85: Medicine Information Systems	117
Part 3: Secretary of State's Powers to Transfer or Delegate Functions	122
Clause 86: Relevant bodies	123
Clause 87: Power to transfer functions between bodies	123
Clause 88: Power to provide for exercise of functions of Secretary of State	124
Clause 89: Scope of powers	124

Clause 90: Transfer schemes in connection with regulations	125
Clause 91: Transfer schemes: taxation	126
Clause 92: Consultation on draft regulations	126
Part 4: The Health Services Safety Investigations Body	127
Introductory	127
Clause 93: Establishment of the HSSIB	127
Schedule 13: The Health Service Safety Investigations Body	127
Investigations	131
Clause 94: Investigation of incidents with safety implication	131
Clause 95: Deciding which incidents to investigate	131
Clause 96: Criteria, principles and processes	132
Reports	133
Clause 97: Final reports	133
Clause 98: Interim reports	134
Clause 99: Draft reports	134
Clause 100: Response to reports	134
Clause 101: Admissibility of reports	135
Investigatory Powers etc	135
Clause 102: Powers of entry, inspection and seizure	135
Clause 103: Powers to require information etc.	137
Clause 104: Voluntary provision of information etc	137
Clause 105: Offences relating to investigations	138
Protection of Material Held by the HSSIB	138
Clause 106: Prohibition on disclosure of HSSIB material	138
Schedule 14: Prohibition on disclosure of HSSIB material: exceptions	139
Clause 107: Exceptions of prohibition on disclosure	141
Clause 108: Offences of unlawful disclosure	142
Clause 109: Restriction of statutory powers requiring disclosure	142
Relationship with other bodies	142
Clause 110: Co-operation	142
Clause 111: Assistance of NHS bodies	143
Clause 112: Investigations relating to Wales and Northern Ireland	144

Oversight of functions	145
Clause 113: Failure to exercise functions	145
Clause 114: Review	145
Offences: supplementary	145
Clause 115: Offences by bodies corporate	145
Clause 116: Offences by partnerships	145
Supplementary	146
Clause 117: Obligations of confidence etc	146
Clause 118: Consequential amendments relating to Part 4	146
Schedule 15: Consequential Amendments relating to Part 4	146
Clause 119: Interpretation of Part 4	146
Part 5: Miscellaneous	147
International Healthcare	147
Clause 120: International Healthcare arrangements	147
Social Care: Regulation and Financial Assistance	148
Clause 121: Regulation of local authority functions relating to adult social care	148
Clause 122: Provision of social care services: financial assistance	150
Professional Regulation	150
Clause 123: Regulation of health care and associated professions	150
Medical Examiners	151
Clause 124: Medical Examiners	151
Food and Drink	152
Clause 125: Advertising of less healthy food and drink	152
Schedule 16: Advertising of less healthy food and drink	153
Clause 126: Hospital Food Standards	159
Clause 127: Food information for consumers: power to amend retained EU law	160
Fluoridation of Water Supplies	161
Clause 128: Fluoridation of water supplies	161
Clause 129: Fluoridation of water supplies: transitional provision	162
Part 6: General	162
Clause 130: Power to make consequential provision	162
Clause 131: Regulations	162

Clause 132: Financial provision	163
Clause 133: Extent	163
Clause 134: Commencement	163
Clause 135: Short title	164
Commencement	165
Financial implications of the Bill	165
Parliamentary approval for financial costs or for charges imposed	166
Compatibility with the European Convention on Human Rights	166
Related documents	169
Annex - Territorial extent and application in the United Kingdom	171

Overview of the Health and Care Bill

- 1 The purpose of the Health and Care Bill is to give effect to the policies that were set out as part of the NHS's recommendations for legislative reform following the Long Term Plan and in the White Paper 'Integration and Innovation: Working together to improve Health and Social Care for all' published in February 2021.
- 2 The Bill aims to support Government in doing the following:
 - Promoting local collaboration;
 - Reforming the NHS Provider Selection Regime;
 - Improving accountability and enhancing public confidence in the health and care system; and
 - Delivering a range of targeted measures to support people at all stages of life.
- 3 The Bill builds on recommendations for reform set out by NHS England in the NHS Long Term Plan published in 2019¹. Enshrining the NHS Long Term Plan in Legislation was also a Government Manifesto Commitment in the 2019 General Election.
- 4 The Bill also contains provisions to support social care, public health and quality and safety in the NHS. These are designed to address specific problems or remove barriers to delivery, maximise opportunities for improvement, and have, in most cases, been informed by the experience of the pandemic.
- 5 The Bill contains 6 parts with 16 Schedules addressing a range of issues relating to health and social care. The Bill makes changes to a number of existing Acts, most notably the National Health Service Act 2006 (the NHS Act 2006) and the Health and Social Care Act 2012 (the 2012 Act).

¹ NHS Long Term Plan, 2019

Policy Background

Merging NHS England, Monitor and NHS Trust Development Authority

- 6 Section 1H of the NHS Act 2006, as inserted by Part 1 of the 2012 Act, established a new Non-Departmental Public Body (NDPB) called the National Health Service Commissioning Board. The NHS Commissioning Board was given broad duties, in conjunction with the Secretary of State, to promote a comprehensive health service and to arrange and secure the provision of services for the purposes of the health service. The NHS Commissioning Board is accountable to the Secretary of State and is now known as NHS England.
- 7 Monitor was established in 2004 by the Health and Social Care (Community Health and Standards) Act 2003 as an executive NDPB of the Department of Health and Social Care (DHSC). It was responsible for regulating NHS Foundation Trusts and in 2012, section 61 of the 2012 Act changed its name to Monitor. Part 3 of the 2012 Act conferred additional functions on Monitor, establishing it as the 'sector regulator' for healthcare. Monitor's overriding duty was to protect and promote the interests of patients by promoting economy, efficiency and effectiveness in the provision of healthcare, whilst maintaining or improving quality.
- 8 The NHS Trust Development Authority (TDA) was a Special Health Authority established by the Secretary of State by order under section 28 of the NHS Act 2006 (see the National Health Service Trust Development Authority (Establishment and Constitution) Order 2012 (SI 2012/901)). The TDA was established to exercise such functions as the Secretary of State may direct in connection with the management of the performance and development of English NHS trusts and other functions as directed by the Secretary of State. The detailed functions of the TDA (which, apart from the patient safety function, are all Secretary of State functions) are set out in directions made by the Secretary of State under section 8 of the NHS Act 2006.
- 9 In 2016, the TDA was directed to work collaboratively with Monitor under a single leadership and operating model to ensure improvement in the quality of care, patient safety and financial sustainability across the health service. As such, Monitor and the TDA came together to operate as a single organisation known as NHS Improvement. NHS Improvement is not itself a statutory body and has no distinct functions of its own.

- 10 More recently, NHS England and NHS Improvement have been working closely together with a view to acting as a single organisation with a single operating model, with an aligned Board and committee arrangements and joint senior executive appointments (the Joint Working Programme). Despite the progress made by the joint working programme to date, as separate statutory bodies, there are limits on the extent to which NHS England and NHS Improvement can collaborate under the current statutory framework. For instance, NHS England and NHS Improvement have been assigned distinctive and non-shareable functions, and legislation requires separate boards including separate chairs, CEOs and non-executive directors for the two organisations.
- 11 The policy intention of DHSC is to merge the functions of the three national statutory bodies responsible for the NHS - the NHS Commissioning Board, Monitor and TDA - into a single body. The aim is to support NHS England and NHS Improvement to provide national leadership, speaking with one voice to set clear and more consistent expectations for providers, commissioners and local health systems; to remove unnecessary duplication; and to use collective resources more efficiently and effectively to support local health systems and ultimately making better use of public money.
- 12 The Bill seeks to achieve this by transferring the functions of Monitor and the TDA to NHS England and abolishing Monitor and TDA, thereby ensuring there is a consistent legislative framework.
- 13 By merging these organisations, including their accountability functions, into a single reporting structure, DHSC will create a more empowered and integrated NHS England, and with it, clearer lines of accountability for the bodies underneath it. It will align a more integrated national landscape with more integrated local systems, bringing commissioning and provision closer together to support strategic decision making.

Mandate and financial directions to NHS England

- 14 Under Section 13A of the NHS Act 2006, the Secretary of State has a duty to lay in Parliament and publish a mandate to NHS England before the beginning of each new financial year. The mandate must include objectives that NHS England has a duty to seek to meet and must also specify the limits on capital and revenue resource use that the Secretary of State has set for the purposes of section 223D. The mandate may also set out the matters the Secretary of State will take into account when assessing progress against the objectives, and may include requirements that NHS England must comply with in order to meet the objectives. Requirements in the mandate only have effect if regulations provide for them to do so.

- 15 NHS England has a legal duty, under section 13T of NHS Act 2006 to set out in its business plan how it intends to meet objectives in the mandate. The Secretary of State also has a duty to keep NHS England's performance against the mandate under review. Having considered NHS England's own annual report, under section 13U of the NHS Act 2006, the Secretary of State must then lay in Parliament and publish an annual assessment of its overall performance during the financial year – including performance against the mandate.
- 16 Currently, a mandate can only be replaced during the financial year it relates to in very limited circumstances. The mandate will remain the primary statutory mechanism for Government to set objectives and requirements for the new NHS England. However, this Bill proposes that the mandate duty should become more flexible, so that a mandate can be set at any time, ensuring there is always a mandate in place, and will remain in force until it is replaced by a new mandate. This flexibility will strengthen the ability of the mandate to set longer-term direction for the NHS, where appropriate, and ensure that each mandate can fully reflect the most up to date strategic priorities and associated Government funding commitments for the NHS even where it is impractical for these to be determined in line with the annual financial cycle. There will continue to be a legal duty, under section 13A(8) for the Secretary of State to consult NHS England, Healthwatch England (representing patients) and any other persons that the Secretary of State considers appropriate before setting objectives in a mandate. Every mandate will also continue to be laid in Parliament with any requirements that may be included requiring underpinning through negative resolution regulations. Should the Government replace a mandate within its first year, NHS England will not be required to revise its own business plan for that year but will need to set out in its annual report the progress it has made on any mandates in force for the relevant year.
- 17 The Secretary of State will continue, under section 13U of the NHS Act 2006 to have a duty to keep performance against the mandate under review and continue to lay in Parliament and publish an assessment of NHS England's overall performance against any mandate in force on an annual basis.
- 18 As a consequence of removing the statutory link between the mandate and the annual financial cycle, it is proposed that NHS England's annual limits on capital and revenue resource use are given statutory force through the financial directions. 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.

Funding for service integration

- 19 The Better Care Fund (BCF) is the national policy driving forward the integration of health and social care in England. The BCF requires Integrated Care Boards (ICBs) (formerly NHS Clinical Commissioning Groups (CCGs)) and local authorities to make joint plans and pool budgets for the purposes of integrated care, providing a context in which they can work together, as partners, towards shared objectives.
- 20 The Bill will put in place stand-alone powers for directions to be given to NHS England and to ICBs to use a specified sum of their financial allocation for the purposes of service integration, known as the BCF, which does not rely on the NHS mandate.
- 21 Currently, the legal basis for the allocation of the BCF relies on ministers setting a requirement each year in the NHS mandate to ringfence funding from ICB budgets.
- 22 Replacing this with a stand-alone power will ensure that the BCF can continue to function as it currently does should mandates be set on anything other than a financial year basis. It is a technical change and will not have any impact on the operation or policy intention of the BCF.

The NHS Payment Scheme

- 23 The national tariff ("the tariff") sets out the prices, and rules for those prices, that NHS commissioners (such as CCGs) pay to providers (such as hospitals) for providing NHS-funded healthcare. The tariff is published by Monitor (which is part of NHS Improvement), although the proposals for each tariff must be agreed with NHS England.
- 24 Not all treatments are covered by the tariff, but there are over 2,300 mandatory tariffs which represent around 60% of payments made to hospitals and other acute providers.
- 25 The tariff sets out national prices, but there is also flexibility for local systems to alter the prices and the rules to support different ways of delivering care, and to agree local prices for services not covered by national prices. This allows local providers and commissioners to agree to some local payment approaches to support more integrated care. For example, agreeing a local price for a "one-stop shop" where several tests or investigations are done at once rather than bringing the patient back for a separate appointment for each test or investigation (each with its own tariff).
- 26 The measures in the Bill on tariff are designed to meet the NHS request for changes to give the NHS more flexibility in how tariff prices and rules are set, to help support the delivery of more integrated care at local levels.

27 To reflect that the new measures on tariff mean that there may not be any national tariffs, the Bill therefore proposes to revoke the national tariff and replace it with a new NHS payment scheme. The scheme will be published by NHS England, who will consult with ICBs as the new commissioner of most NHS services, as well as relevant providers (both NHS providers and those from the independent or voluntary sector). The NHS payment scheme will set rules around how commissioners establish prices to pay providers for healthcare services for the purposes of the NHS, or public health services commissioned by an ICB or NHS England, on behalf of the Secretary of State (known as section 7A and section 7B services).

Capital spending limits over Foundation Trusts

28 DHSC is allocated a capital funding budget by Parliament and the Treasury, which covers all capital spending by DHSC, including the NHS (e.g. buildings, equipment and IT). DHSC and the NHS are obliged not to spend above this limit.

29 From 1 April 2020, a major part of the NHS capital budget has been allocated to voluntary partnerships of NHS commissioners, providers and local authorities known as Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICs), in system-wide envelopes. These envelopes are derived directly from the NHS' share of DHSC's total departmental capital budget. They are set for all NHS provider organisations within an ICS footprint for their annual business as usual operational investments (e.g. routine maintenance and replacing equipment), as distinct from the specific nationally led programmes such as major new hospital builds. It is the role of the ICB to ensure system capital expenditure is affordable within these envelopes and to prioritise its spending plans in accordance with the system wide health needs between each of the system providers. The Bill will establish, a joint duty between the ICB and its partner Trusts and Foundation Trusts to prepare a plan setting out their use of planned capital resources.

30 NHS Trusts are currently set statutory annual capital expenditure limits by the TDA in accordance with their capital expenditure plans. Future capital expenditure limits will be set by NHS England once it has been merged with the TDA and Monitor. At present there is no limit set on NHS Foundation Trusts, who also have additional freedoms to borrow from commercial lenders and spend their own surpluses to fund capital projects. Capital expenditure by Foundation Trusts still counts against the ICS capital envelope and DHSC's overall capital departmental expenditure limit (CDEL). Under current statutory powers, there is a risk that a Foundation Trust may go ahead with an individual scheme/s using its own cash to invest in capital without considering the overall impact on the local system ICB capital envelope, or on the national capital

budget. This is an issue of equity as well as proper financial management. Uncertainty about Foundation Trust capital spending plans, and the risk of breaching the capital limit, could lead to capital spending in one or more NHS providers having to be reduced to ensure the NHS lives within its allotted capital resources.

31 The Bill will give a new power to allow NHS England to set capital spending limits for Foundation Trusts. The Foundation Trust limit 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. 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.

32 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.

33 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.

New NHS Trusts

34 When the 2012 Act was passed, it was expected that all NHS Trusts would develop Foundation Trust status and once there were no NHS Trusts left, NHS Trusts could be abolished along with the ability to create new NHS Trusts. However, NHS Trusts remain an important part of the provider landscape in the NHS, making up around a third of providers. We do not expect the provider landscape to drastically change and, to ensure flexibility in that landscape, the Bill provides for the repeal of the provisions for the abolition of NHS Trusts and the continuation of the legislative provisions governing such Trusts, including the power to establish new Trusts.

35 We expect this will be done on application from an ICB to the Secretary of State, with further guidance to be published in due course. As part of creating new NHS Trusts, we are also creating transfer schemes to allow NHS Trusts and Foundation Trusts to

transfer assets, property and liabilities between themselves, subject to the approval of NHS England.

Integrated Care Boards and Integrated Care Partnerships

- 36 Under current arrangements, CCGs are responsible for the planning and commissioning of health care services in local areas. Since 2016, health and care organisations have increasingly been working together in every part of England to coordinate services and to plan in a way that improves population health and reduces inequalities between different groups. The formation of non-statutory Integrated Care Systems (ICSs) has accelerated this change.
- 37 The Bill will establish statutory Integrated Care Boards (ICBs) and statutory Integrated Care Partnerships (ICPs).
- 38 The ICB will take on the commissioning functions of the CCGs as well as some of NHS England’s commissioning functions. However, an ICB will not simply be a larger CCG and is expected to work differently in practice – its governance model reflects the need for integration and collaboration across the system. It will have the ability to exercise its functions through place-based committees (while remaining accountable for them) and it will also be directly accountable for NHS spend and performance within the system.
- 39 The ICB will, as a minimum, include a chair, Chief Executive Officer, and representatives from NHS Trusts and NHS Foundation Trusts, general practice, and local authorities. Beyond that, local areas will have the flexibility to determine any further representation in their area. ICBs will also need to ensure they have appropriate clinical advice when making decisions.
- 40 Each ICB and its partner local authorities will be required to establish an ICP, bringing together health, social care, public health (and potentially representatives from the wider public space where appropriate, such as social care providers or housing providers).
- 41 The ICP will be tasked with developing a strategy to address the health, social care and public health needs of its system. The ICB and local authorities will have to have regard to that plan when making decisions.

Triple Aim

- 42 We are proposing to introduce a new duty on NHS organisations to consider the effects of their decisions on the better health and wellbeing of everyone, the quality of care for all patients, and the sustainable use of NHS resources - the policy referred to in the White Paper “Working together to improve health and social care for all” as the “Triple Aim”.

- 43 The current legislative framework can lead organisations to work primarily in the best interest of their own organisations and their own immediate patients - but this does not support the delivery of integrated, patient-centred care.
- 44 This new duty will require organisations to think about the interests of the wider system and will provide common, system-wide goals that need to be achieved through collaboration.

Duty to Cooperate

- 45 The Bill introduces a new power that allows the Secretary of State to issue guidance on cooperation between NHS bodies, and between NHS bodies and local authorities.
- 46 New guidance will give organisations greater clarity about what the duties to cooperate mean in practice, helping DHSC to build on the innovation, working relationships and positive behaviours that have been seen over the past year, in particular.

Joint Appointments

- 47 In the Bill we are proposing to introduce the ability to issue guidance on joint appointments between types of NHS bodies; NHS bodies and local authorities; and NHS bodies and Combined Authorities. In this provision, references to NHS bodies means NHS England, ICBs, NHS Trusts and NHS Foundation Trusts. This will ensure that there is a clear set of criteria for organisations to consider when making joint appointments.
- 48 Ahead of publishing any guidance, NHS England would consult with appropriate organisations.

Joint Committees

- 49 Legislation does not currently allow NHS providers (NHS Trusts and Foundation Trusts) and CCGs (which will become ICBs) to come together to formally take joint decisions. We are therefore proposing to create a new legal mechanism that will allow ICBs and NHS providers to form joint committees, or indeed two or more providers, to make joint arrangements and pool funds.
- 50 These joint committees could include representation from other bodies such as primary care networks (PCNs), GP practices, community health providers, local authorities or the voluntary sector.

Collaborative Commissioning

- 51 Existing NHS legislative mechanisms make it difficult for the health and care system to work collaboratively and flexibly across different geographical footprints, forcing local systems to adopt complex workarounds to be able to take align their decisions and pool budgets. In practice, these arrangements can be cumbersome, difficult to manage and can slow decision-making processes.
- 52 DHSC wants to make a number of technical legislative changes that will remove barriers and bureaucracy which staff say get in the way of delivering high-quality care to patients.
- 53 The proposed Bill provisions will make it easier for ICBs to commission services collaboratively with other ICBs and other system partners by permitting a wider set of arrangements for joint commissioning, pooling of budgets and delegation of functions.

Secretary of State's duty to report on workforce systems

- 54 Section 1 of the NHS Act 2006 gives the Secretary of State a duty to promote a comprehensive health service in England. Section 1F of the NHS Act 2006 gives the Secretary of State a further duty to secure an effective system for the planning and delivery of education and training to individuals who are employed or are considering becoming employed as healthcare workers. This duty is delegated to Health Education England (HEE) through Section 97(1) of the Care Act 2014. However, other bodies (currently including the NHS Commissioning Board, TDA and individual employers, and, following changes made by the Bill, the newly merged NHS England and ICBs) also have responsibilities for workforce planning and supply.
- 55 However, no one document exists or captures how the workforce planning and supply system operates at national, regional and local level. The Bill will set out a duty on the Secretary of State to publish, at least once every five years, a report describing the system in place for assessing and meeting the workforce needs of the health service in England. It will also place a duty on HEE and NHS England to assist in the preparation of the report, if asked to do so by the Secretary of State.
- 56 The scope of the report will include workforce planning and supply for healthcare workers, including those working in the NHS, public health, regulated healthcare professions working in social care (e.g. nurses and occupational therapists) and other sectors (including criminal justice).
- 57 The report will provide clarity and transparency as to how the workforce planning and supply system operates, by describing the workforce planning and supply roles of relevant national bodies – including DHSC, HEE and NHS England, ICBs and

individual employers - and how they work together in practice at national, regional and local levels. It will not set out workforce targets or give any bodies new functions.

58 The report will be published at a minimum of every five years but can be reviewed by the Secretary of State before then, if the Secretary of State considers appropriate.

Abolition of LETBs

59 Local Education and Training Boards (LETBs) are statutory sub-committees of HEE. The roles of HEE and their LETBs are set out in Chapter 1 of Part 3 of the Care Act 2014. Sections 103 – 107 and Schedule 6 of the Care Act 2014 make provision for the appointment, constitution and functions of LETBs.

60 LETBs, working within the national framework set by HEE, 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.

61 There are seven LETBs covering England, with each of the geographical footprints matching that of NHS England's regional directorates.

62 The activities of LETBs are carried out as part of regional people boards, which are dually accountable to NHS England and NHS Improvement's and HEE's regional leadership teams and the National People Board. However, the LETBs report to the HEE Board and LETB chairs are appointed by and accountable to the chair of HEE.

63 The policy intention is to abolish LETBs as a statutory sub-committee and to enable HEE to develop and adapt its own flexible regional operating model to best deliver its objectives over time.

Information

64 The data provisions in the Bill are intended to work, collectively, to enable increased sharing and more effective use of data across the health and adult social care system. The provisions are informed by extensive work done by DHSC and its partners to identify barriers to - and solutions to ensure - the secure, appropriate, and proportionate use of data to benefit individuals, populations, and the health and social care system.

65 Key to this has been learning from the Government's response to COVID-19 which has shown how data can be used effectively and securely to improve the services individuals receive and the operation of the health and care system.

Information standards

- 66 For the health and social care system to work efficiently and effectively, data needs to flow through the system in a standardised way, so that when it is accessed by or provided to an organisation for any purpose it can be read, be meaningful to, and be easily understood by the recipient and/or user of the data. This relies on data being collected, processed, and shared in a consistent way.
- 67 Information standards set standards relating to processing information, including standards about how information is shared, and which make it easier to compare data, across the publicly funded health and social care system. They are prepared and published by the Secretary of State (in relation to health services and adult social care) and by NHS England in relation to NHS services. They apply to the Secretary of State and NHS England as well as to bodies involved in the provision of publicly arranged health or adult social care services in England.
- 68 The Health and Social Care Information Centre (operating as NHS Digital) maintains a list of information standards, for example in relation to the NHS Number. This standard is about how the NHS Number is used to identify people receiving health and social care services, and in locating and communicating their health and care records and other information pertaining to the planning and provision of their care. It also sets standards for how information systems accept, store, process, display and transmit the NHS Number, and standards to ensure correct use of the NHS number by organisations. It applies to bodies involved in the provision of publicly funded or arranged health or adult social care services in England, including those that commission or provide such services.
- 69 There is a desire to further improve the consistency with which information systems used by health and adult social care providers (which are provided by a range of commercial suppliers) adopt a standardised approach to the collection, storage and processing of data. This legislation aims to enable DHSC, and NHS England to publish mandatory standards. Providers of health or adult social care to whom such standards apply will have to comply with them, rather than merely having regard to them. It is also intended to extend the potential application of information standards to include private providers of health and adult social care.

Improving sharing of information

- 70 There is a need to ensure greater certainty among health and social care organisations about what information they can share and when, so that information is shared appropriately for the benefit of the health and adult social care sector and those using services.

- 71 The processing of personal data (that is, information which identifies an individual or enables them to be identified) is subject to UK data protection legislation. The legislation does not impose restrictions on the sharing of information that is not personal data. If the information does not relate to identified or identifiable individuals, it may be shared without the need for rigorous safeguards to ensure privacy and confidentiality.
- 72 DHSC is introducing 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 requirement will only apply to information that is in a form that does not identify any individual or enable the identity of any individual to be ascertained, i.e. it is anonymous. This information is not subject to the retained version of the General Data Protection Regulation (EU 2016/679) (UK GDPR), the Data Protection Act 2018 or the common law duty of confidentiality. This means that pseudonymised or de-identified data, which enables individuals to be identified, will not fall under the requirement. In addition, the Bill provides powers to make regulations that will enable the introduction of exceptions to the duty, which would allow further safeguards to be introduced, for example, where the information requested is publicly available, or to ensure that the duty does not apply to commercially sensitive information.
- 73 The duty to share anonymous information will complement the existing duty on certain health or social care organisations to share information about an individual with certain persons where this is likely to facilitate the provision to the individual of health services or adult social care and is in the individual's best interests (section 251B of the 2012 Act). The objective is to increase the sharing of anonymous data for the benefit of the health and adult social care sector.
- 74 The intention is to require organisations to share anonymous information they already hold if required to do so by a relevant organisation; organisations are not required to undertake any process of anonymisation for the purpose of complying with the requirement.
- 75 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, including ICBs, requiring them to have regard to the effects of their decisions on the health and well-being of the people of England, the quality of services and the efficiency and sustainability in relation to the use of resources.

The Health and Social Care Information Centre

76 The Health and Social Care Information Centre (known as NHS Digital) (“HSCIC”) was established and given functions under the 2012 Act. It is the national information and technology partner to the health and social care system in England. There is a need to ensure that it has the right powers and duties to enable it to collect, share and otherwise process data proportionately, appropriately and with due regard to protecting privacy, to benefit the health and social care system and the individuals served by it.

Adult Social Care

77 Adult social care is governed by a national regulatory framework but is generally delivered at a local level by local authorities. Under normal circumstances, (prior to the COVID-19 crisis), aggregated adult social care data is collected from local authorities once a year and is published by NHS Digital. There is no mechanism to collect data from private social care providers and, due to the frequency with which data is collected from public providers and local authorities, it is not always complete, accurate or up to date. This has resulted in gaps in the information available to inform policy decisions or to identify and respond to emerging issues and risks. Social care reform is a priority for the Government and access to reliable data is key to achieving this aim.

78 The lack of information available to the Government to effectively manage the response to COVID-19 became a significant concern at the start of the pandemic. As a result, some new data streams were established, such as the Capacity Tracker tool, which adult social care providers complete regularly. Completion of the tracker is a prerequisite to access the Infection Control Fund which has resulted in high compliance. Under normal circumstances and without an incentive it is unlikely that providers would provide regular information voluntarily.

79 In future, DHSC will need data more frequently than it was receiving before the pandemic. The Government considers that data showing details relating to care received by individuals is more useful than aggregate data in enabling it to link and use data across health and adult social care to improve services and to monitor people’s journeys through the whole care system. The Government has also identified the need for consistency of data whether care is publicly arranged or arranged privately by individuals.

80 Alongside client data, information from, and about, providers will enable effective oversight and management of the social care market by improving the understanding of capacity and risk in the system, enabling identification of when and how to target direct support to providers and enabling identification of and responses to social care workforce needs including recruitment, retention and equality policies. This

information would continue to be subject to restrictions under the Data Protection Act 2018, the UK GDPR and the common law duty of confidentiality (although the provision of the information to DHSC would not itself breach the common law duty of confidentiality).

Secretary of State power to direct NHS England

- 81 The Secretary of State has responsibility for ensuring that NHS England, Monitor and the TDA are effectively carrying out their functions and retains ultimate responsibility for securing provision of services through the exercise of their functions, such as their powers to set objectives for commissioners (for example by setting the mandate under section 13A of the 2012 Act), to oversee the effective operation of the health service and to intervene in the event of significant failure (under section 13Z2 of the 2012 Act).
- 82 As explained above, the Bill will abolish Monitor and the NHS TDA and transfer their functions to NHS England. In recognition of the expanded powers and responsibilities of NHS England, the Bill seeks to introduce an additional accountability mechanism to support the Secretary of State in their democratic oversight of NHS England.
- 83 The Bill amends the NHS Act 2006 by inserting new sections 13ZC, 13ZD, 13ZE, and 13ZF which provide the Secretary of State with powers to give directions to NHS England in relation to their functions. The powers apply only to functions of NHS England and will sit alongside the existing accountability mechanisms and processes for ensuring NHS England fulfil their duties to promote a comprehensive health service and deliver Government priorities. The policy intention is that the Secretary of State will be able to use these powers to ensure that NHS England continues to work effectively with other parts of the system for which he has responsibility including social care and public health, to support integration and tackle broader priorities such as health inequalities.
- 84 The powers conferred by this new section are not intended to be powers that the Secretary of State would use frequently to intervene in the affairs of NHS England. NHS England will remain an Arm's Length Body and will therefore continue to exercise the majority of its functions as it does now. The Mandate will remain the primary mechanism through which the Secretary of State will set out the priorities that NHS England should be seeking to achieve. The Framework Agreement between DHSC and NHS England will continue to set the parameters within which NHS England should operate and how DHSC and NHS England will interact with each other. The new power is designed to supplement these mechanisms by giving the Secretary of State the ability, where he deems it appropriate, to set direction and to intervene in relation to NHS England's functions. Directions could be issued on specific matters or on a

standing basis. This will be done in a transparent way. Any directions made by the Secretary of State must be made in the public interest, in writing, and published.

Power of Direction – Secretary of State Public Health functions

- 85 Section 7A of the NHS Act 2006 enables the making of arrangements for the delegated exercise of the Secretary of State’s public health functions by agreement.
- 86 NHS England currently commissions a range of services, including national immunisation and screening programmes, under such a delegation as set out in an NHS Public Health Functions Agreement with the Secretary of State.
- 87 However, the Secretary of State cannot require NHS England, or any other NHS body to take on a delegated public health function. This potentially exposes the Secretary of State to a position where he is unable to effectively deliver an aspect of his public health duties. The proposal is therefore to create a power for the Secretary of State to require, via directions, NHS England (or an ICB) to discharge public health functions delegated by the Secretary of State.
- 88 This is intended to provide for greater speed, agility, certainty and clarity to keep in step with challenges presented to public health, and to strengthen the Secretary of State’s ability to play the role in the system that Parliament expects of him.
- 89 It is expected that the delegation of public health functions will continue to be on the basis of agreement in most circumstances. However, consistent with other changes in the Bill, it is considered appropriate to adopt an approach which bolsters the Secretary of State’s ability, via the flexibility of a direction making power, to ensure the system can respond rapidly to emerging issues as they arise, or where the additional clarity and certainty of directions is otherwise desirable. Power to give directions to NHS England as to the exercise of public health functions, once delegated, will be covered by the more general power of direction in new section 13ZC.
- 90 To ensure transparency, the Secretary of State will need to provide directions in writing, stating that he is satisfied that they are in the public interest, and to publish these as soon as is practicable.

Reconfigurations

- 91 Reconfiguration is the term used to describe the management of service change in the NHS that has an impact on patients. Reconfigurations involve changing the way NHS

- services are delivered to patients, such as the closure of several stroke units being replaced with a single centralised hyper acute unit.
- 92 Most service changes are delivered and implemented locally – planned reconfigurations are developed at local or regional levels by commissioners. The current system for reconfigurations works well for the majority of changes, and this will be left in place for many day-to-day transactions.
- 93 The aim of this policy is to address the minority of cases which are complex, a significant cause for public concern, or where Ministers can see a critical benefit to taking a particular course of action. Cases such as these can lead to difficult debate and lengthy processes.
- 94 The Secretary of State is currently only able to intervene in such cases upon receiving a local authority referral. Following a referral, the Secretary of State typically asks the Independent Reconfiguration Panel to provide advice and recommendations. After receiving these, the Secretary of State will communicate his final decision. Whilst this can help with difficult cases, referrals can often come very late in the process meaning Ministers must account for service changes in Parliament without often having been meaningfully engaged on them themselves.
- 95 These provisions will add a new discretionary power to the NHS Act 2006 for the Secretary of State to give a direction to NHS bodies or providers requiring a reconfiguration to be referred to him instead of being dealt with locally. The Secretary of State will be able to use this call-in power at any stage of the reconfiguration process. To support this intervention power, the current Local Authority referral power, which is set out in regulations under the NHS Act 2006 will be amended to reflect the new process. This does not remove the local Health Oversight and Scrutiny Committee (HOSC) role or the requirement to involve them in reconfigurations.
- 96 Where a reconfiguration has been called in by the Secretary of State, there will be a duty on NHS commissioning bodies or providers to provide all information relevant to the reconfiguration to the Secretary of State. This will include any representations that a HOSC, stakeholder, patient group or any other interested party have made, if applicable.
- 97 The NHS commissioning bodies or providers who are subject to a direction from the Secretary of State under this section must refer the reconfiguration decision to the Secretary of State, provide all relevant information and take no further action in progressing the reconfiguration without the Secretary of State's agreement. They will be

able to make representations to the Secretary of State in support of their preferred option at this stage.

- 98 Once a direction has been given, the Secretary of State should also be able to request specific information from, and address specific questions to, the relevant organisations to assist him in scrutinising the reconfiguration.
- 99 The Secretary of State will be required to seek appropriate advice in advance of their decision to meet the legal duties placed on them, including in relation to value for money, and subsequently publish it in a transparent manner.
- 100 The new process means that the Independent Reconfiguration Panel role will adapt to the new process, including getting involved earlier in the process which will be similar to what it did when first set up in 2003.
- 101 The Secretary of state will publish guidance for NHS commissioning bodies, NHS trusts and NHS foundation trusts about how they should be exercising their functions under this new process as well as how Secretary of State may exercise their functions during this new process. NHS must have regard to any guidance provided by Secretary of State at all stages of the process of reconfigurations of NHS services.
- 102 Guidance will clarify NHS bodies' duty to notify Secretary of State of reconfigurations and clarify how Secretary of State may use expert advice, including the Independent Review Panel.
- 103 The Secretary of State will be able to exercise the call-in power at any stage of a reconfiguration process, but also be able to be the catalyst for a reconfiguration where he thinks appropriate. This might occur before NHS England, an ICB or provider has notified the Secretary of State of a proposed reconfiguration but where the Secretary of State is aware of an emerging issue following stakeholders raising the issue with the Secretary of State or information from within DHSC.

Transfer of functions between Arm's Length Bodies

- 104 Arm's Length Bodies (ALBs) are bodies which have a role in the processes of national Government, but are not a part of it, and which accordingly operate to a greater or lesser extent at Arm's Length from ministers. The health and social care ALBs landscape is made up of a mix of Executive Agencies (EAs) which are legally part of DHSC; Special Health Authorities (SpHAs) which are created by secondary legislation and are subject to direction by the Secretary of State; Executive Non-Departmental Public Bodies (NDPBs) which operate at arm's length and are legally separate from DHSC and ministers, though a minister will be responsible to Parliament; Advisory NDPBs and

expert committees, which form part of the core of the Department, and non-ministerial departments, which are currently only represented by the Food Standards Agency.

105 This configuration of ALBs has remained largely unchanged since the 2012 Act reforms. As the challenges facing the health system have changed over the last decade, the statutory nature of this configuration has made it harder for ALBs to change their role.

106 This power will allow the transfer, by regulations, of functions from one of a list of relevant Non-Departmental Public Bodies (NDPB) to another. It will also enable the Secretary of State, by regulations, to provide for the Secretary of State's functions to be exercised by any of the NDPBs. (This power will not allow the Secretary of State's functions to be transferred to a Non-Departmental Public Body, merely the exercise of those functions).

107 There will be a full and transparent process throughout, including a formal consultation before laying, this will involve the ALBs affected and, where relevant, the devolved administrations, and approval secured from both Houses of Parliament by way of an affirmative SI process.

108 SpHAs exercise functions of the Secretary of State. The Secretary of State already has the power to provide for a function that is currently exercised by a SpHA to be exercised instead by a different SpHA (Section 7 of the NHS Act 2006, amended in Section 21 of the 2012 Act).

109 Executive Agencies are legally indistinguishable from the Secretary of State and, as such, there is no need for them to be included in this power.

110 The following NDPBs, CQC, NICE and HSSIB (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.

Special Health Authority Time Limits

111 Existing legislation sets automatic expiry dates on Special Health Authority (SpHAs) set up after 2012, which requires DHSC to formally extend their existence every three years. This proposal will remove the three-year time limit on all SpHAs.

112 Formally extending a SpHA's existence every three years is a time consuming and bureaucratic process that creates unnecessary administration costs for the SpHAs and the Department of Health and Social Care. The removal of the time limit only affects NHS CFA, as the other SpHAs have been in existence prior to the introduction of a time limit. Therefore, the need to renew NHS CFA every three years is an anomaly. By

removing this time limit, as well as removing a duplicative process, we are ensuring all SpHAs are treated equally in legislation.

113 Another consequence of this policy is that, because the NHS CFA and any future SpHAs will not be subjected to being reviewed/potentially closed every three years, staff should be reassured of the stability of their posts.

Procurement of clinical healthcare services

114 The procurement reforms within the Bill will enable the removal of the current procurement 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, which will include removing the procurement of health care services for the purposes of the health service from scope of the Public Contracts Regulations 2015. The Bill provisions also repeal Section 75 of the 2012 Act and the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

115 The Bill will enable the development of a new procurement regime for the NHS and public health procurement, informed by public consultation, to reduce bureaucracy on commissioners and providers alike, and reduce the need for competitive tendering where it adds limited or no value.

116 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 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.

117 NHS England have previously consulted on the proposal to replace the current legislation with a new provider selection regime, and 76% of respondents either agreed or strongly agreed with this proposal.

Competition

118 The 2012 Act gave Monitor (now operating as NHS Improvement) and the Competition and Markets Authority (“the 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.

- 119 The NHS Long Term Plan called for a stronger emphasis on collaboration between organisations and a less central role for competition in the system.
- 120 DHSC are therefore proposing to remove Monitor's competition duties rather than moving them to NHS England as part of the merger, to allow NHS England to focus more on improvement in the quality of care and use of NHS resources, and on the development of integrated care.
- 121 DHSC are also proposing to remove the CMA's ability to review NHS foundation trust mergers. Instead NHS England, as the national body responsible for the NHS, will review mergers of NHS providers to ensure they are in the best interests of patients and the taxpayer.
- 122 DHSC will remove Monitor's ability to refer contested licence conditions and tariff prices to the CMA. Instead, NHS England will make its own decisions on how to operate the licencing regime and the NHS Payment Scheme, in consultation with local leaders.
- 123 The CMA will retain its functions in relation to regulating competition within the private healthcare market. This is a very different landscape compared to the NHS provider landscape, and we see a clear benefit of the CMA continuing this role.

Patient Choice

- 124 Currently, regulations regarding patient choice can be made under Section 75 of the 2012 Act. Section 75 also covers procurement and is being repealed as part of this Bill, which means the regulations covering patient choice would also be revoked. However, patient's rights to choice will continue to be protected, and the Bill will add similar powers including those relating to guidance and enforcement of the 'standing rules' in the NHS Act 2006. The power to make guidance and enforcement of patient choice will be held by NHS England, following the planned merger with NHS Improvement, under the Bill. As NHS Improvement currently has, NHS England will have powers to resolve any breaches of patient choice.
- 125 There are a wide range of choices that people should expect to be offered in the NHS services they use; for example, choosing a GP and GP practice and choosing where to go for your appointment as an outpatient (with some exceptions). The Bill will allow for these, and other aspects of patient choice, to be preserved under the new powers added to the 'standing rules'.

126 The intention is to preserve the existing requirements for patient choice, which are a tool for improving waiting times and people's experience of care.

Health Service Safety Investigation Body

127 The existing Healthcare Safety Investigation Branch ("the Investigation Branch") was set up on 1 April 2017. The Investigation Branch is currently operational under Secretary of State Directions as an organisational arm of the TDA. 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

128 The policy is to establish the HSSIB as a new Executive NDPB, with powers and independence to conduct investigations into "qualifying incidents". These are incidents that occur in England during the provision of health care services which have, or may have, implications for the safety of patients. Independence is fundamental to the HSSIB as it will help ensure that patients, families and staff have trust in its processes and judgements.

129 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.

130 The Bill creates a 'safe space' within which participants can provide information to the HSSIB for the purposes of an investigation without fear that it will be disclosed to others. It prevents the HSSIB, or any individual connected with the HSSIB from disclosing "protected material" held by the HSSIB in connection with its investigatory function. In this context, protected material includes any information, document, equipment or other item which is held by the HSSIB (or a connected individual) for the purposes of the HSSIB's investigation function. Information held in safe space will only be disclosed by the HSSIB in certain limited circumstances. The policy to establish the 'safe space' provision is comparable to similar legal provisions for bodies that investigate air, rail and marine accidents. These investigation branches look to use 'safe space' principles to improve safety, by promoting learning and not attributing blame, and this is a founding principle behind establishing a 'safe space' for investigating qualifying incidents.

131 The HSSIB will look to encourage the spread of a culture of learning within the NHS through promoting better standards for local investigations and improving their quality

and effectiveness. To this end, the HSSIB may provide advice, guidance and training to organisations in connection with an investigation upon request.

132 HSSIB's remit will cover healthcare provided in by the independent sector as well as by the NHS.

133 These proposals align with the recommendations in the report *Learning not blaming: the Government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS' and the Morecambe Bay Investigation* (July 2015)².

International Healthcare

134 Reciprocal healthcare agreements can support people from the UK to obtain access to healthcare in other countries (and vice versa for people from other countries who visit the UK). Reciprocal healthcare agreements support UK residents to access necessary healthcare when they travel abroad and can also facilitate co-operation on planned treatment or other areas of healthcare policy.

135 In 2019 Parliament enacted the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 ("HEEASAA") to establish a legal basis for the Secretary of State to fund and implement reciprocal healthcare, and share necessary data, after the UK left the EU. The Act contained powers to implement new bilateral agreements with individual Member States and to establish detailed unilateral arrangements to support certain people to access healthcare in an EEA state or Switzerland if no bilateral arrangement was in place.

136 On 20 December 2020, the UK signed the Trade and Cooperation Agreement (TCA) with the EU. The TCA contains a Protocol on Social Security Coordination which provides UK Nationals with access to a range of social security benefits, including reciprocal healthcare cover when they are in the EU.

137 The Government is now looking to strengthen the UK's relationships with countries across the globe and improve international healthcare cooperation.

138 The reciprocal healthcare provisions in this Bill amend HEEASAA to enable the Secretary of State to implement comprehensive reciprocal healthcare agreements with

² Learning not blaming: the Government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS' and the Morecambe Bay Investigation, 2015

Rest of World (ROW) countries. No reciprocal healthcare arrangements are made or changed as a direct result of this legislation.

139 Currently, the Secretary of State only has powers under HEEASAA to implement comprehensive reciprocal healthcare agreements within the European Economic Area (EEA) and Switzerland. The limited territorial scope of the powers in HEEASAA mean that the Secretary of State does not have the necessary powers to implement reciprocal healthcare agreements with ROW countries, including, for example, British Overseas Territories and Crown Dependencies, other than the ability to exempt individuals from charges for relevant NHS services.

140 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. For example, under the terms of reciprocal healthcare agreements the UK has with ROW countries, UK nationals are able to access emergency treatment should they require it, however, access to haemodialysis for kidney patients is restricted or not included within the scope of these agreements. Adult Social Care Provider Payments

141 The Health and Social Care Act 2008 allows the Secretary of State to provide financial assistance to ‘qualifying bodies’ who are providing health and social care services, or to those providing related services to providers of health and social care services.

142 Section 150 of the Health and Social Care Act 2008 and the Health and Social Care (Financial Assistance) Regulations 2009 prescribe conditions for a ‘qualifying body’, and this excludes providers who operate for profit. Social care in England is largely delivered by private providers operating on a profit-making basis as an ordinary business. As such, the Secretary of State is unable to make direct payments under this existing statutory power to much of the social care provider sector. Regular funding for social care is delivered funded via CCGs (soon to be Integrated Care Boards) or local authorities.

143 This Bill seeks to address this by making changes to sections 149-156 of the Health and Social Care Act 2008, expanding existing powers so that payments can be made to providers delivering social care services or delivering services relating to that provision of social care.

144 These proposals do not amend the powers in these sections regarding the ability of the Secretary of State to make payments to health service providers. The type of payment that can be made and any terms on which a payment is made, to health service providers will also not be changed.

Adult Social Care Assurance

- 145 Part I of the Care Act 2014 sets out a wide range of care and support responsibilities and functions (functions relate to the processes, activities or broader responsibilities that local authorities perform), for which local authorities are responsible. These include the direct provision or commissioning of adult social care services.
- 146 The Bill will introduce a new legal duty for the CQC to review and make an assessment of the performance of local authorities in discharging their ‘regulated care functions’ under Part 1 of the Care Act 2014. These are the specific adult social care functions, which will be set out in secondary legislation, that will be subject to review by the CQC, with the aim of assessing the effectiveness of services put in place to achieve high quality care outcomes for local populations.
- 147 The CQC will publish the findings of their reviews with the intention of helping people see and understand how their local authority is performing in the delivery of its adult social care duties, and thus support transparency and local accountability. This new level of insight will support local authorities to understand what they are doing well and help them to identify what they could do better. It will also help DHSC understand what is happening in the provision of adult social care at a local level as well as forming an overarching national picture, gaining insight into issues such as regional variation. This will provide a platform from which DHSC and Government partners can work with local authorities to promote best practice, provide support, and act to secure improvement in the event of substantial issues being identified.
- 148 The CQC is the regulator of health and social care in England and has a statutory duty to undertake a variety of functions, including conducting reviews and performance assessments of adult social care providers, as set out under section 46 of the Health and Social Care Act 2008. Under section 48 of the Health and Social Care Act 2008, the CQC has undertaken local strategic reviews of how well health and care systems work together to care for people.
- 149 The exact functions in Part 1 of the Care Act 2014 in scope for review under the new duty will be set out in secondary legislation. The reviews undertaken by the CQC under the new section 46A will be by reference to objectives and priorities set for the CQC by the Secretary of State. This will help focus reviews of regulated care functions on areas of particular concern or in alignment with future key priorities for adult social care policy. Review by the CQC will also be by reference to a set of quality indicators determined by the CQC and approved by the Secretary of State.

- 150 The CQC must devise a methodology for assessing and evaluating local authorities including the frequency by which it will undertake its performance reviews, which it must then set out in a statement to be approved by the Secretary of State. For example, in developing the methodology for assessment, the CQC may wish to undertake reviews at different intervals or make a case for alternative methodologies depending on the specific case presented. The CQC may also consider that it wishes to review local authorities that perform above a certain threshold less frequently.
- 151 The new duty for the CQC will sit alongside their existing powers and duties to undertake special reviews or investigations under section 48 of the Health and Social Care Act 2008. Section 48 of the Health and Social Care Act 2008 provides that the CQC may, or must when requested by the Secretary of State, conduct a ‘special review’ or investigation into a range of matters, including the provision of adult social care services. The CQC must first gain the approval of the Secretary of State before undertaking a review of how local authorities arrange for the provision of adult social services. Section 48 will be amended so that there is a clear distinction between these ‘special reviews’ or investigations, and the reviews to be carried out by the CQC under a new section 46A, of the Health and Social Care Act 2008.
- 152 Section 50 of the Health and Social Care Act 2008 sets out the steps which the CQC may or must take following a review under section 46 (or a special review or investigation under section 48) of the Health and Social Care Act 2008, where it is considered that a local authority is failing to discharge its adult social services functions. Section 50 will be amended to also apply to reviews conducted by the CQC under the new section 46A.
- 153 Under section 50 of the Health and Social Care Act 2008 in circumstances where the CQC considers that the local authority is failing to discharge any of its adult social services functions to an acceptable standard, it must inform the Secretary of State of this and recommend any ‘special measures’ that it considers should be undertaken by the Secretary of State. However, where the CQC considers that the failings are not substantial, it may instead choose to give notice to the local authority about what it considers the local authority is failing to do, the action that the CQC thinks should be taken to remedy failings and a timeframe within which the CQC thinks the action should be taken. The CQC must notify the Secretary of State that it has taken this action.
- 154 Section 60 of the Health and Social Care Act 2008 enables the CQC to conduct inspections for the purposes of its regulatory functions, including functions carried out under sections 46, 48 and 50. Section 60 will be amended so that the CQC may carry out inspections for the purposes of its reviews under new section 46A.

155 These proposals form part of a wider assurance framework being developed by the department, which aims to increase transparency and accountability across the Adult Social Care sector and in doing so, help people achieve the outcomes that matter to them in their life.

Hospital Discharge

156 This clause revokes the procedural requirements in the Care Act 2014 which require local authorities to carry out social care needs assessments, in relevant circumstances, before a patient is discharged from hospital. It does not change existing legal obligations on NHS bodies to meet health needs, and local authorities are still required to assess and meet people's needs for adult social care.

157 This clause introduces flexibility for local areas to adopt the discharge model that best meets local needs, including an approach known in England as 'discharge to assess' – a model which allows individuals to recover in an environment that is familiar to them, while they receive care and reablement support in the community. Individuals are then assessed at a point of optimum recovery, allowing a more accurate evaluation of their needs.

158 The policy intention is that guidance on hospital discharge will set out the requirements and expectations of health and social care partners during the discharge process. This will enable people to be discharged safely from hospital to the most appropriate place, and to receive the care and support they need.

159 Since the Care Act 2014 came into force, the requirement to carry out assessments before discharge has resulted in some individuals experiencing delayed hospital discharge as they wait for their assessment to be carried out, meaning the appropriate transfer of care cannot take place when a patient is ready to leave a hospital. Delayed discharges can result in poorer patient outcomes, such as loss of independence or functional decline such as muscle deterioration in patients who are elderly or have dementia; additional expense to the NHS as patients occupy beds without a clinical need; pressure on hospital beds so it is harder to give in-patients the healthcare they may need; and more complex or higher levels of care on discharge due to the loss of function described above.

160 Discharging patients as soon as they no longer meet the criteria to reside in hospital – and therefore no longer need acute hospital care – is increasingly recognised as the most effective way to support patient outcomes.

161 Amendments to secondary legislation will also separately be required to ensure all legislation accurately reflects the amendments being made to the Care Act 2014.

Professional Regulation

162 The 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

163 Section 60 of the Health Act 1999 provides powers to make changes to the professional regulatory landscape through secondary legislation. This clause extends the scope of the existing powers in section 60 of the Health Act 1999 regulating health and social care professions by means of Orders in Council to make further changes to the professional regulation system.

164 Section 60 provides powers to amend legislation in relation to nine health and care regulatory bodies which operate across the UK. Any use of the extended powers will be subject to Ministerial approval across the devolved administrations. 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).

165 These additional powers will widen the scope of section 60 and enable the Secretary of State to make additional changes.

166 The powers will enable:

- the abolition of an individual health and care professional regulatory body where the professions concerned have been deregulated or are being regulated by another body;
- the removal of a profession from regulation where regulation is no longer required for the protection of the public;
- the delegation of previously restricted functions to other regulatory bodies through legislation; and
- the regulation of groups of workers concerned with health and care, whether or not they are generally regarded as a profession i.e. senior managers and leaders.

167 Secondary legislation made using the new powers would be subject to the existing provision in Schedule 3, namely, a public consultation and the affirmative parliamentary procedure.

168 In 2017, the UK Government and the devolved administrations consulted on high-level principles for reform of professional regulation and set out their five objectives, to:

- i. improve the protection of the public from the risk of harm from poor professional practice;
- ii. support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future;
- iii. deal with concerns about the performance of professionals in a more proportionate and responsive fashion;
- iv. provide greater support to regulated professionals in delivering high quality care; and
- v. increase the efficiency of the system.

169 The 2017 consultation *Promoting professionalism, reforming regulation* included questions relating to the provisions in the Bill.³ The Government response set out the proposals that were welcomed by key stakeholders, including professional organisations, regulatory bodies and employers.⁴

170 The consultation response also highlighted the case for broader changes to the regulatory landscape including reducing the number of regulatory bodies. The Secretary of State further committed to reviewing the number of health and care professional regulatory bodies in the November 2020 *Busting Bureaucracy* policy paper.⁵ The review will consider whether the current make-up of the regulatory landscape might be simplified to provide better public protection in a more efficient way.

171 In March 2021, the UK Government published a further consultation *Regulating healthcare professionals, protecting the public* that sets out proposed reforms to the regulator's legislation in four key areas: Governance and Operating Framework; Education and Training; Registration; and Fitness to Practise, starting with the General Medical Council.⁶ The Government will also commission a review of the professions that are currently regulated in the UK, to consider whether statutory regulation remains appropriate for these professions.

172 The powers included in the Bill form another strand to the overall reform programme. The powers take into consideration the Government response to the Law Commission's

³ Regulatory Reform Consultation FINAL FOR PUBLICATION.pdf

⁴ Promoting professionalism reforming regulation consultation response (publishing.service.gov.uk)

⁵ Busting bureaucracy: empowering frontline staff by reducing excess bureaucracy in the health and care system in England - GOV.UK (www.gov.uk)

⁶ Regulating healthcare professionals, protecting the public (publishing.service.gov.uk)

review of UK law relating to the regulation of healthcare professionals,⁷ and, the recent review of the fit and proper persons test.⁸

Medical Examiners

173 The Bill will amend the Coroners and Justice Act 2009 in England to set out a power for English NHS bodies to appoint Medical Examiners and a duty on 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 to identify and deter poor practice, and to ensure that their performance is monitored.

174 The purpose of the amendment is to introduce a statutory scheme of medical examiners within the NHS rather than Local Authorities in England. Following a death that is not being referred to a coroner, medical examiners, who will be registered medical practitioners, will scrutinise the cause of death stated by the attending medical practitioner on the Medical Certificate of Cause of Death and hold discussions with families.

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

Hospital Food Standards

176 In the summer of 2019, the Secretary of State for Health announced a “root and branch” review of food served and sold in hospitals. The scope of the review included the safety, nutrition, quality and production methods of food for patients, staff and visitors in NHS hospitals.

177 The Independent Review of NHS Hospital Food⁹ - published on 26 October 2020 – made a series of recommendations across a range of areas to improve standards for food served to patients and staff, including:

- Catering staff support
- Nutrition and hydration

⁷ Regulation of Health and Social Care Professionals | Law Commission

⁸ Kark review of the fit and proper persons test - GOV.UK (www.gov.uk)

⁹ Report of the Independent Review of NHS Hospital Food (publishing.service.gov.uk)

- Food safety
- Facilities
- Technology
- Enforcing standards
- Sustainability and waste

178 As well as recommendations on the above areas, the Hospital Food Review recommended for improved NHS food and drink standards for patients, staff and visitors to be put on a statutory footing to ensure a level playing field and compliance across the sector so far as nutritional standards in hospitals are concerned.

179 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.

180 This is in line with the recommendations of the Independent Review of NHS Hospital Food.

181 Any regulations made under the provisions of this Bill will be enforced by the Care Quality Commission (CQC) pursuant to their existing statutory powers of enforcement under the Health and Social Care Act 2008. The CQC may consider compliance with any regulations made under this power when undertaking routine inspections of hospitals. The CQC only has the power to inspect hospital premises who are providers of regulated activities as defined in Section 8 of the Health and Social Care Act 2008. The clause will not therefore apply to premises that are not within its regulatory remit.

Advertising of less healthy food and drink

182 Obesity is one of the greatest long-term health challenges this country faces. Today, around two-thirds (63%) of adults are above a healthy weight and of these, half are living with obesity. Obesity is associated with reduced life expectancy and is a risk factor for a range of chronic diseases, including cardiovascular disease, type 2 diabetes, cancer and respiratory disease. It can also impact upon mental health.

183 In July 2020, the Government published their obesity strategy, 'Tackling obesity: empowering adults and children to live healthier lives'. This was in response to emerging evidence that people who are overweight or living with obesity are at greater risk of long-term health conditions and being seriously ill and dying from COVID-19.

184 The intention of this Bill is to reduce children’s exposure to the advertising of less healthy food and drink products on TV and online. This Bill will introduce a 9pm watershed for less healthy food or drink advertising on TV and a prohibition of paid-for less healthy food or drink advertising online, simultaneously, at the end of 2022. All On Demand Programme Services (ODPS) under the jurisdiction of the UK, and therefore regulated by OFCOM, will be included in the TV watershed. Other ODPS will be subject to the online prohibition because they are not defined in the Communications Act, so are considered as ‘internet services’.

185 This Bill will amend the Communications Act 2003 to enable OFCOM to introduce restrictions prohibiting advertising of less healthy food or drink between the hours of 0530h to 21:00h on broadcast TV, and on ODPS¹⁰ that are subject to Part 4A of the Communications Act 2003. This Bill will also introduce a prohibition of paid-for HFSS advertising online by inserting a new section into the Communications Act 2003 after Part 4B.

186 TV Broadcasters and ODPS - defined in the Communications Act 2003 will be liable for breaches of the TV watershed. Advertisers will be liable for breaches of the paid-for online prohibition. For ODPS not subject to UK regulation, the advertiser will be liable for breaches of the paid-for online prohibition on these platforms.

187 OFCOM will be appointed as the appropriate regulatory authority. OFCOM will then be able to appoint a day-to-day regulator to carry out frontline regulation. The frontline regulator will use informal powers (e.g. reputational sanction, such as naming and shaming) and takedown requests in the first instance. For serious breaches or where these sanctions have had no effect, the frontline regulator can refer the relevant liable party to the backstop regulator (OFCOM).

188 The responsibility for monitoring and regulating broadcast advertising is co-regulated by the Advertising Standards Authority (ASA) and OFCOM. The content and standards for broadcast advertising on TV and ODPS are set out in the Communications Act 2003.

189 Advertising on the internet is not currently subject to statutory regulation.

¹⁰ On Demand Programme Services differ from live TV because they allow viewers to watch programmes at a time of their choosing and on a device of their choosing. However, many broadcast TV channels also have On Demand Programme Services. There are also On Demand Programme Services that are available as paid-for subscriptions. On Demand Programme Services are different from Video Sharing Platforms because viewers can only view content, they cannot create content.

Food information for consumers: power to amend retained EU law

- 190 Existing EU regulations were converted into domestic law by the European Union (Withdrawal) Act 2018. This Bill enables technical changes to be made to food labelling and presentation requirements to reflect our withdrawal from the EU.
- 191 The retained Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers ('Regulation (EU) No. 1169/2011') was incorporated into domestic law, carried forward and modified according to the EU (Withdrawal) Act 2018. It sets out requirements on the provision of food information to consumers which includes the labelling of prepacked food and drink in the UK. Due to its status as retained direct principal EU legislation, primary legislation is often required to amend or otherwise, modify the provisions contained within Regulation (EU) No. 1169/2011. The Bill provides Secretary of State and Ministers of Scotland and Wales to amend and modify retained EU legislation, Regulation (EU) No. 1169/2011 using secondary legislation, via an affirmative process. This clause therefore allows the Government (and/or, where appropriate, a devolved authority) to make regulations to implement any new policies regarding food information and labelling.
- 192 The Bill confers a power on the Secretary of State and Ministers of Scotland and Wales to amend and modify by regulations parts of retained direct principal EU legislation, set out in Regulation (EU) No. 1169/2011. The intention of the power is to broaden the reach for any modifications to Regulation (EU) No. 1169/2011 to those matters that fall within the scope of section 16 (1) (e) of the Food Safety Act 1990. Regulations made under the new power are subject to the affirmative process. This clause therefore allows the Secretary of State and Ministers in Scotland and Wales to implement new policies regarding food information and labelling applicable to their relevant territories.
- 193 The new power to amend retained direct principal EU legislation, Regulation (EU) No. 1169/2011 will enable the Secretary of State and Ministers in Scotland and Wales to amend food labelling requirements so they meet the needs of their respective nations. For example, the Government's obesity strategy: 'Tackling obesity: empowering adults and children to live healthier lives' included a commitment to consult on front of pack nutrition labelling and whether to mandate alcohol calorie labelling to help support consumers make healthier choices. If consultations indicate that changes to food and drink labelling and/or presentation is required, this provision will enable Ministers to introduce key policies, whilst retaining a level of scrutiny on any proposed changes. It

will also support the alignment of labelling policies across the three nations, by allowing each nation to make changes applicable to their relevant territories.

Medicine Information Systems

- 194 The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of DHSC. It acts on behalf of the UK's licensing authority¹¹, and is responsible for overseeing the regulatory regime for human medicines in the UK as set out in the Human Medicines Regulations 2012. The regime provides a comprehensive scheme for regulating human medicines that covers licensing, manufacture, importing, brokering, labelling, distribution, advertising, and pharmacovigilance.
- 195 The MHRA's pharmacovigilance activities are a key way that the safety of medicines on the market is monitored. This includes assessing the risk and benefits of medicines so that necessary steps may be taken to improve their safe use, monitoring the everyday use of medicines to identify new, or changes in existing patterns of adverse events and providing information to healthcare practitioners and patients to promote safe and effective use of medicines.
- 196 Comprehensive, UK-wide registries have the potential to be an important tool in improving post marketing surveillance of the use of medicines, and in turn improving patient safety, as they are a valuable source of evidence on the use, safety, and effectiveness of medicines. Registries consolidating prescribing data for specific medicines and linking it with data from clinical care and other social administrative databases with additional bespoke patient-focussed data capture, enable the exploration of trends in prescribing and associated patient experiences and the identification of issues that may impact on patient safety. The need for the establishment of registries was recommended in the Independent Medicines and Medical Devices Safety (IMMDS) Review published on 8 July 2020.
- 197 The evidence generated through medicines registries can be used to inform regulatory decision making, support local clinical practice and provide patients and prescribers with the evidence they need to make better informed decisions.
- 198 UK-wide obligations to capture data, potentially through a registry, can already be placed on companies or other legal entities that have the authorisation to market a medicine (also known as Marketing Authorisation Holders) in the UK by the MHRA, through post-authorisation commitments detailed in a medicine's approved Risk

¹¹ The licensing authority consists of the Secretary of State and the Northern Ireland Minister acting jointly or separately.

Management Plan. However, Marketing Authorisation Holders cannot oblige healthcare providers to share information with them, which in many circumstances leads to the incomplete capture of evidence. These types of registries have not consistently delivered the required evidence in reasonable timeframes, partly due to a lack of trust from clinicians and patients but also partly due to the way in which they are set up, placing burdens on healthcare providers for additional data entry, meaning that they have often failed to recruit sufficient patients to meet the required objectives.

199 To improve the existing monitoring of the use, benefits, and risks of medicines and to improve patient safety, the Bill create powers through which one or more medicines information system(s) can be established and operated to allow for the creation of centrally held UK-wide medicine registries. The core of these registries would be made up of existing routinely collected data which would be supplemented with bespoke data extracts from other systems to minimise the burden on healthcare professionals to input additional information.

200 The central vehicle through which the health service in England collects and disseminates health service information and data is the Health and Social Care Information Centre, known as NHS Digital. NHS Digital is a statutory corporation established under s. 252 of the 2012 Act. The 2012 Act sets out the general functions of NHS Digital, such as collecting, analysing and presenting national health and social care data, setting up and managing national IT systems as well as publishing rules around the handling and management of personal confidential information of patients.

201 The Bill will 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 system(s). The MHRA would be able to then use the information held in an information system to establish and maintain comprehensive UK-wide medicines registries. This would improve post-market surveillance on the use medicines. For example, where a safety issue has led to the introduction of measures to minimise risk to patients, registries would facilitate the early identification and investigation of potential non-compliance so that additional action can be taken by regulators in conjunction with health service providers at a national, local, or individual patient level.

202 It is not the intention to create a registry for every medicine used in the UK. A registry 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. A similar power to establish and operate one or more information systems for medical devices is found in

the Medicines and Medical Devices Act 2021 (section 19). This Bill amends that Act, this will ensure both powers are set out in the same piece of legislation.

Water Fluoridation

- 203 Research shows that both children and adult benefit from water fluoridation by improving oral health and reducing oral health inequalities. Around 10% of the population of England currently receive fluoridated water. If five-year-olds with the most tooth decay drank fluoridated water, they would have 28% less tooth decay and be 45-68% less likely to need teeth removed in hospital.
- 204 Since 2013 local authorities have had the power, through the Water Industry Act 1991, to propose, and consult on, new fluoridation schemes and variations or terminations to existing schemes. Local authorities, and the NHS who had responsibility for water fluoridation schemes before them, have faced difficulties with implementing water fluoridation schemes, including most recently the fact that local authority boundaries are not coterminous with water flows, which requires the involvement of several authorities in these schemes, in a way which is complex and burdensome.
- 205 In light of these challenges, the purpose of the clauses within the Bill that relate to water fluoridation is to give Secretary of State for Health and Social Care the power to directly introduce, vary or terminate water fluoridation schemes. This removes the burden from local authorities and will allow DHSC to streamline processes and take responsibility for proposing any new fluoridation schemes, which will be subject to consultation and funding being agreed.

Territorial extent and application

- 206 Clause 133 sets out the territorial extent of the Bill, which describes the jurisdictions in which the Bill will form part of the law.
- 207 Largely the provisions in the Bill extend to England and Wales only and apply to England, as health is largely a matter for devolved competence.
- 208 There are some provisions in the Bill which extend UK-wide. As the extent of the Bill can be different from its application and application is about where an Act produces a practical effect. A small number of these provisions will also apply UK-wide. An amendment, repeal or revocation made by this Bill has the same extent as the provision amended, repealed or revoked.
- 209 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.
- 210 To the extent that the provisions of the Bill fall within the legislative competence of devolved legislatures, the legislative consent procedure would be appropriate.
- 211 See the table in the Annex for a summary of the position regarding territorial extent and application in the United Kingdom. The table also summarises the position regarding legislative consent motions and matters relevant to Standing Orders Nos. 83J to 83X of the Standing Orders of the House of Commons relating to Public Business.

Commentary on provisions of the Bill

Part 1: Health Service in England: Integration, Collaboration and Other Changes

NHS England

Clause 1: NHS Commissioning Board renamed NHS England

212 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.

Schedule 1: Renaming of NHS Commissioning Board

213 This schedule amends a number of enactments to reflect the name change of the National Health Service Commissioning Board to NHS England. All references in the relevant enactments to either “the National Health Service Commissioning Board”, “The National Health Service Commissioning Board”, “the National Health Service Commissioning Board (“the Board”)”, “The Board” or the Board are substituted for “NHS England”. Any references to “The Board’s” are substituted for “NHS England’s”

Clause 2: Power to Require Commissioning of Specialised Services

214 Clause 2 amends section 3B of the NHS Act 2006. This clause relates to the power of the Secretary of State to require NHS England to commission certain specialised services that are not appropriate for commissioning by CCGs (or, in future, Integrated Care Boards)– for example, patients with rare cancers, genetic disorders or complex medical or surgical conditions.

215 Under subsection (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.

216 Subsection (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.

217 Subsection (4) requires the Secretary of State to explain to NHS England his reasoning, if he refuses a request from NHS England to revoke provisions made in regulations that specify which services NHS England may commission.

Clause 3: NHS England Mandate

- 218 Clause 3 amends sections 13A 13B, 13T and 13U of the NHS Act 2006. Clause 3 (2)(a) removes the requirement for a mandate to be set before the start of each financial year, providing flexibility on when a mandate may be set, and how long it may continue to have statutory force.
- 219 Clause 3(2)(c) omits subsections (3) and (4) from section 13A, removing the requirement on the Secretary of State to specify in the mandate the financial limits set for the purposes of section 223D.
- 220 Clause 3(2)(d) amends section 13A(5) to allow the Secretary of State to specify the matters which the Secretary of State proposes to assess NHS England's performance against, and removes the limit for this to apply for only the first financial year to which the mandate relates.
- 221 Clause 3(2)(e) inserts new subsections (6A) and (6B) into section 13A, providing that the Secretary of State may revise the mandate and making clear that any revised mandate must be published and laid before Parliament.
- 222 Clause 3(3) amends section 13B, omitting subsections (2) to (5). This removes the requirement for the mandate to be revised where the Secretary of State varies financial directions given under section 223D. It also removes the limitations as to when the Secretary of State may revise the mandate.
- 223 Clause 3(4) inserts new subsection (3A) into section 13T, making clear that NHS England is not required to revise its business plan should the mandate be revised during the period that the plan relates to.
- 224 Clause 3(5) substitutes subsection (2) of section 13U to require NHS England to set out in its annual report the extent to which it met any objectives or requirements set out in any mandates covering the relevant financial year.

Clause 4: NHS England: Effect of Decisions

- 225 *Duty to have regard to effect of decisions* – this provision, which is to be inserted in the NHS Act 2006 as the new section 13N, sets out a new duty, which also applies to the other 'relevant bodies'. The 'relevant bodies' are integrated care boards (new section 14Z43), NHS Trusts in England (new section 26A) and NHS Foundation Trusts (new section 63A), for NHS England.
- 226 This duty has been described by DHSC operationally as the 'triple aim' duty.

227 Subsection 13NA(1) provides that NHS England will be under a duty, in making a decision about the carrying out of their functions, to have regard to all likely effects of their decisions on three areas: the health and well-being of the people of England (subsection (a)), the quality of services provided or arranged by relevant bodies (subsection (b)) and the efficiency and sustainability of resources used by the relevant bodies (subsection (c)).

228 The reference in the subsection to “all” likely effects means that NHS England will have to consider, under subsections (b) and (c), the effects of the decision both on its own quality of services and resource use and those of other relevant bodies.

229 Subsection 13NA(2) excludes decisions relating to services provided to a particular individual (e.g. Individual clinical decisions or highly specialist commissioning decisions concerning an individual patient) from this duty.

230 Subsection 13NA(3) provides that NHS England must have regard to guidance on the discharge of this duty that it publishes (13NB).

231 Section 13NB gives NHS England a power to publish guidance on the discharge of this duty and requires NHS England to consult those who they view as appropriate when producing or revising it.

Clause 5: Public involvement and consultation: carers and representatives

232 Clause 5 amends section 13Q of the NHS Act 2006, which requires NHS England to involve and consult individuals to whom health services are provided when exercising its commissioning functions. Following this amendment to subsection (2), NHS England is required to also consult and involve carers and representatives of those individuals to whom health services are provided when exercising its commissioning functions.

Clause 6: Support and Assistance by NHS England

233 Clause 6 inserts a new section 13YA. New subsection (1)(a) gives NHS England the power to provide assistance or support to any person providing or proposing to provide services as part of the health service. Subsection (1)(b) will also give NHS England the power to give other support to providers of services for the purposes of the health service (equivalent to the Secretary of State’s power in section 254A of the NHS Act 2006).

234 Subsection (2) clarifies that any assistance provided under subsection (1)(a) includes making available the services, employees and other resources of NHS England.

235 Subsection (3) clarifies that any assistance provided under subsection (1)(a) or under subsection (1)(b) to an integrated care board, includes making financial assistance. The

insertion of this provision extends the support functions provided by NHS England, placing in statute a provision allowing NHS England to provide direct financial support to providers within the scope of the provisions, and support and assistance to all those providers of services within the health service.

236 Subsection (4) gives NHS England the ability to set the terms on which support under this section is provided.

Clause 7: Exercise of functions relating to provision of services

237 This clause amends the NHS Act 2006 to insert new provisions (13YB) that allow NHS England to direct an integrated care board to exercise any of its relevant functions. In other words, even where there is no agreement between NHS England and integrated care boards to enter into section 65Z5 arrangements, NHS England can nevertheless delegate relevant functions to integrated care boards.

238 Subsection 13YB(2) sets out that, for the purposes of these provisions, these NHS England functions are:

- Any commissioning function that NHS England has been given by virtue of section 3B(1);
- Any function beyond those given to NHS England under section 3B(1) that relates to providing primary medical services, primary dental services, primary ophthalmic services or pharmaceutical services specified under Part 7;
- Any function delegated to NHS England by virtue of section 7A or section 7B, which relate to Secretary of State's public health functions; and
- Any other function that may be exercised in connection with the above functions. This last category is designed, for example, to cover NHS England's power to provide assistance or support under section 13YA.

239 The Secretary of State will be able to make regulations under subsection 13YB(3) which can specify any limits or conditions on the functions that NHS England may delegate to integrated care boards under this clause.

240 Subsection 13YB(4) gives NHS England powers, when delegating functions to integrated care boards under this clause, to limit the ability of integrated care boards to arrange for other bodies to carry out these functions.

241 NHS England may also make payments to an integrated care board in relation to the exercise of the relevant function (subsection 13YB(6)) and give directions regarding the exercise of that function (subsection 13YB(7)).

242 Subsection 13YB(8) requires NHS England to publish any directions which delegated functions to integrated care boards under subsection (1). This is so that it is clear who is exercising which of these relevant functions – NHS England or integrated care boards. An integrated care board that has been directed to exercise a function as part of these arrangements is liable for the exercise of that function (subsection (9)).

Clause 8: Preparation of consolidated accounts for providers

243 Clause 8 amends the NHS Act 2006 inserting new section 65Z4 ‘Consolidated Accounts for NHS Trusts and Foundation Trusts’. This section places into primary legislation the duties imposed on Monitor and the TDA to prepare, in respect of each financial year, consolidated accounts of NHS trusts and Foundation Trusts through directions from the Secretary of State in the Consolidated Provider Accounts Directions 2018. Those directions will be revoked as a result of the abolition of Monitor and the TDA.

244 Subsection (2) gives the Secretary of State the power, with approval of the Treasury, to give directions to NHS England on the content and form of the consolidated accounts, and the methods and principles to be applied in preparing them. The Secretary of State can direct that the accounts must be accompanied by any reports or information. Under subsection (3) NHS England must send a copy of the consolidated accounts to the Secretary of State and the Comptroller and Auditor General.

245 Under subsection (5), the Comptroller and Auditor General must examine, certify and report on the consolidated accounts and send copies of the report to the Secretary of State and to NHS England. Under subsection (6) NHS England have a duty to lay copies of the consolidated accounts and the related report before Parliament.

Clause 9: Funding for service integration

246 Clause 9 makes amendments to section 223B (‘Funding of NHS England’) and 223GA (‘Expenditure on integration’) of the NHS Act 2006 to make provision for a fund for the integration of care and support with health services, known as the Better Care Fund. Section 223B places a duty on the Secretary of State to make an annual payment to NHS England which is attributable to the exercise of its functions for that year, and the amendment allows for the Secretary of State to provide directions requiring NHS England to use a specified amount of this annual payment for purposes relating to service integration. Amended section 223GA provides that, where the Secretary of State has given a direction about the use by NHS England of the annual amount paid to them for purposes relating to service integration, that NHS England may direct integrated care boards (‘ICBs’) that a designated amount of the annual payment is to be used for purposes of service integration.

247 Clause 9(2)(a) substitutes subsection (6) of 223B to allow the Secretary of State to direct

NHS England to use a sum paid under that section for purposes relating to service integration in respect of a financial year. This power to direct NHS England replaces the requirement to specify this sum in the mandate to NHS England under section 13A.

248 New subsection (6)(b) provides that the Secretary of State may direct NHS England as to how this sum should be used.

249 Clause 9(2)(c) inserts new subsections (7A) and (7B). Subsection (7A) provides that the power to direct NHS England about the use of the sum includes the power to direct them as to the exercise of any of its functions under or by virtue of 223GA (this includes directions requiring consultation with the Secretary of State or other specified persons). New subsection (7B) requires the Secretary of State to publish any direction that is given under subsection (6) of 223B.

250 Clause 9(3)(a) substitutes section 223GA(1) and (2) to provide that where the Secretary of State has given NHS England a direction under 223B(6) about sums paid to it for service integration purposes, NHS England may direct ICBs that a designated amount of their financial allocation must be used for purposes relating to service integration. This replaces the requirement for the mandate to specify service integration objectives before NHS England can exercise this power.

251 Clause 9(3)(c) omits subsection (7) of 223GA which provided that requirements in the mandate relating to service integration could also include requirements to consult the Secretary of State or other specified persons. This has been recreated by inserting (7A) into section 223B.

252 'Service integration' means the integration of health services with health-related or social care services.

Clause 10: Payments in respect of quality

253 Clause 10 repeals subsections (4) and (5) in section 223K of the NHS Act 2006, removing the Secretary of State's powers to make regulations about payments by NHS England in respect of quality.

Clause 11: Secondments to NHS England

254 Clause 11 inserts paragraph 9A in Schedule A1 of the NHS Act 2006 and amends section 272 of the NHS Act 2006 as a consequence. Subsection (3) of this clause, which inserts new paragraph 9A, allows NHS England to make arrangements for secondees to NHS England to serve as members of their staff. Through paragraph 9A(3), secondees from a prescribed list of NHS bodies (see paragraph 9A(4)) can be considered as employees of NHS England and can exercise functions of NHS England. Under 9A(5), the Secretary of State may by regulations amend this list to include other references.

Integrated Care Boards

Clause 12: Role of Integrated Care Boards

255 *General functions of integrated care boards* - This clause replaces section 1I of the National Health Service Act 2006 and sets out that any integrated care board established under Chapter A3 of Part 2 of this Act has the function of arranging for the provision of services for the purposes of the health service in England.

Clause 13: Establishment of Integrated Care Boards

256 *Establishment of integrated care boards (including by re-purposing clinical commissioning groups)*. This clause inserts new clauses into the NHS Act 2006 before Chapter 3 of Part 2. New sections 14Z25 to 14Z28 make provision for the abolition of CCGs and the establishment of integrated care boards. New section 14Z29 concerns the publication of an integrated care board's constitution. New section 14Z30 concerns the management of conflicts of interest.

257 *Duty to establish integrated care boards*. New section 14Z25 requires NHS England to establish integrated care boards (subsection (1)) by issuing an establishment order for each relevant area in England (subsection (2)). Under subsection (3), the geographical boundaries of each integrated care board may not coincide or overlap. Under subsection (4), all areas of England must have an integrated care board on, and after, the day of commencement for these provisions, which will be set out in regulations (subsection (9)). Under subsection (5), the establishment order referred to in subsection (2) must either include the integrated care board's constitution, or reference where the integrated care board's constitution is published. Under subsection (7), NHS England is required to consult with any integrated care board that might be affected before varying or revoking an establishment order. Further information about the requirements for integrated care board constitutions can be found in Schedule 1B.

258 *Process for establishing initial integrated care boards*. New section 14Z26 subsection (1) requires NHS England to publish a list of the areas where integrated care boards are to be established. Under subsection (2), the existing CCG or CCGs in those areas are required to propose a constitution for the new integrated care board to be established in their area, for consideration by NHS England. Under subsection (3), in developing a constitution, CCGs must consult with any persons they consider it appropriate to consult with. Under subsection (4), NHS England must give effect to a proposed constitution unless NHS England consider the proposal inappropriate. NHS England is required to determine the terms of an integrated care board's constitution if a CCG or group of CCGs propose an inappropriate constitution or fail to consult appropriately on the terms of the constitution. Under subsection (6), NHS England can publish guidance

for CCGs concerning the process for establishing initial integrated care boards, to which CCGs are required to have regard under subsection (7).

- 259 *Abolition of clinical commissioning groups.* Under new section 14Z27, all CCGs will be abolished on an appointed day (subsection (1)), which will be the same day NHS England's duty to establish integrated care boards commences and will be defined in regulations (subsection (2)).
- 260 *Transfer schemes in connection with integrated care boards.* New section 14Z28 contains provision about schemes for the transfer of staff, property, rights and liabilities in connection with the establishment of integrated care boards and abolition of CCGs. NHS England can also make transfer schemes in connection with the variation of the constitution of an integrated care board, or the abolition of an integrated care board, by order under section 14Z25. Under subsection (3), NHS England is required to ensure that all property, rights and liabilities (except criminal liabilities) of CCGs are transferred either to an integrated care board or to NHS England. Rights and liabilities include rights and liabilities relating to contracts of employment. Subsection (5) contains a list of things a transfer scheme may do, 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.
- 261 *Duty for integrated care board to publish constitution.* Under new section 14Z29, each integrated care board is required to publish its constitution, including when it is updated or varied.
- 262 *Register of interests and management of conflicts of interests.* New section 14Z30 subsection (1) requires each integrated care board to maintain and publish a register of any interests of its board members, committee or sub-committee members, and its employees. Each integrated care board 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)).

Schedule 2: Integrated care boards: constitution etc.

- 263 Clause 13 also inserts a new schedule 1B into the NHS Act 2006, which sets out further detail about integrated care boards, their constitutions and minimum governance arrangements as well as consequential amendments

Part 1

- 264 Part 1 concerns the constitutions of integrated care boards. Every integrated care board must have a constitution (paragraph (1)) that specifies its name and the area for which it is established (paragraph (2)). Under paragraph (3), the constitution must also set out

the minimum requirements for membership of the board of the integrated care board, which must include a chair, a chief executive and at least three other members, known as “ordinary members”.

265 Under paragraph (4), the chair of the integrated care board will be appointed by NHS England, with the approval of the Secretary of State. Under paragraph (5), the constitution must not provide for anyone other than NHS England to remove the chair from office. The power for NHS England to remove the chair from office must be subject to the approval of the Secretary of State.

266 Under paragraph (6), the 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 integrated care board.

267 Under paragraph (7), the constitution must detail by whom the ordinary members of the integrated care board will be appointed and state that the chair must approve the appointments of the ordinary members (sub- paragraph (1)).

The ordinary members of the integrated care board must, at a minimum, include:

- One member jointly nominated by NHS trusts and NHS foundation trusts that provide services within the area of the integrated care board (sub- paragraph (2a));
- One member jointly nominated by persons who provide primary medical services within the area of the integrated care board (sub- paragraph (2b)); and
- One member jointly nominated by the local authorities within the area of the integrated care board (sub- paragraph (2c)).

These members are to be appointed by the chair. The constitution must detail how the process of nominating representatives should operate (sub- paragraph (3)). NHS England may publish guidance about this process, to which the persons involved must have regard (sub- paragraph (4)).

268 Under paragraph (8), the constitution may include further details concerning how members are to be appointed and the conditions of membership (e.g. tenure, remuneration, eligibility for re-appointment). Under paragraph (9), further requirements in relation to the constitution may be set out in regulations, which the integrated care board must adhere to.

269 Under paragraph (10), the constitution must detail how the integrated care board will discharge its functions and may provide for committees or sub-committees of the integrated care board to be formed in order to exercise the board’s functions – for

example, exercising budgets and functions to 'place'-level committees of the integrated care board as is locally appropriate. These committees and sub-committees may include members who are not board members or employees of the integrated care board.

270 Under paragraph (11), the constitution must also detail where the integrated care board will make decisions and how the board will ensure that decisions are made transparently. Paragraph (12) requires the consultation to include detail about how any conflicts of interest will be identified and managed (paragraph (12)). The constitution should also detail how the integrated care board will fulfil its duties to involve and consult the public in decision-making (under paragraph (13)).

271 Under paragraph (14), the constitution must detail the process for how the constitution can be amended. This should include provision allowing NHS England to approve any amendments to the constitution as well as provision for NHS England to amend the constitution on its own initiative. NHS England will issue a model constitution to assist integrated care boards in developing their own. Paragraph (15) sets out that the constitution may make further provision to those matters already listed in Part 1.

Part 2

272 Part 2 sets out further details about integrated care boards.

273 Paragraph (16) sets out that an integrated care board is a body corporate, [which means it has its own legal rights and responsibilities]; it, and its property, is not to be considered as an agent, or property, of the Crown.

Staff

274 Under paragraph (17), the integrated care board can appoint employees. The integrated care board may determine the terms and conditions of employment, including details concerning remuneration, and make payments to employees in relation to pensions, allowances or gratuities.

275 Under paragraph (18), an integrated care board may arrange for individuals to be seconded to the board to serve as a member of staff (sub- paragraph (1)). This should not affect the continuity of a person's employment with the employer from whom they are seconded (sub- paragraph (2)). Secondees may exercise functions of the integrated care board and be paid by the board (sub- paragraph (3)). For the purposes of paragraph 6(2) (the requirement for the chief executive to be an employee) an individual on secondment from the organisations listed is to be considered an employee of an integrated care board. Secondees acting as a chair of the integrated care board may be considered an employee if they are a Civil Servant or employed by any of the following bodies: NHS

England, an NHS trust, an NHS foundation trust, the Care Quality Commission, the Health and Social Care Information Centre, the Health Services Safety Investigations Body, the Human Tissue Authority, the Human Fertilisation and Embryology Authority or NICE (sub- paragraph (4)). Regulations may amend this list of bodies (sub- paragraph (5)).

Additional powers in respect of payment of allowances

276 Under paragraph (19), an integrated care board may pay appropriate allowances to members of committees or sub-committees of the board, should it consider this to be appropriate.

Externally financed development agreements

277 Under paragraph (20), an integrated care board may enter into externally financed development agreements. Such agreements for third party funding can be used, for example, for the development of premises for use for the purposes of the health service. This must be approved in writing by the Secretary of State (sub- paragraph (1)). The Secretary of State may approve this if the main purpose of the agreement is to exercise a function of an integrated care board and a person proposes to make a loan or provide finance in relation to the agreement to another party, other than the integrated care board.

Accounts and audits

278 Under paragraph (21), an integrated care board must keep proper accounts and records of the accounts. It must also prepare annual accounts in respects of each financial year. NHS England, with the approval of the Secretary of State, may direct an integrated care board to prepare accounts for a specified period, by a specified date, and specify how the accounts must be prepared. The Comptroller and Auditor General may examine any annual accounts or accounting reports of an integrated care board.

Incidental powers

279 Under paragraph (22) integrated care boards can enter into agreements, acquire and dispose of property, and accept gifts (including property) for purposes related to their functions.

Seal and evidence

280 Where used, the integrated care board's seal must be authenticated by the signature of an authorised person.

Clause 14: People for whom integrated care boards have core responsibility

281 *People for whom integrated care board has responsibility* – This clause inserts 14Z31 in the National Health Service Act 2006. New 14Z31 provides that NHS England must publish rules for determining the people for whom integrated care boards have responsibility. It is expected that the basis of NHS England’s general rule for ICB responsibility will continue to be in relation to GP registration to ensure operational continuity. 14Z31(2) ensures that, at a minimum, under the rules published by NHS England, 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) 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. Subsection (5) defines “NHS primary medical services” for the purposes of subsection (2). Under 14Z31(3), regulations may create exceptions to these rules. Under 14Z31(4), the Secretary of State may, with regulations, change the definition of the people for whom integrated care boards are responsible, inserting a substituted version of 14Z31.

Integrated Care Boards: Functions

Clause 15: Commissioning hospital and other health services

282 This clause amends section 3 of the NHS Act to require integrated care boards to commission hospital and other health services for those persons for whom the integrated care board is responsible.

283 *Duties of integrated care boards as to commissioning certain health services*. New section 3 requires integrated care boards to commission the specified hospital and other health services for those persons for whom the integrated care board is responsible. Integrated care boards are responsible for those people specified in the rules to be published by NHS England under section 14Z31 and any other people who may be prescribed in regulations. Under subsection (4), in exercising this function, integrated care boards must act in accordance with Secretary of State and NHS England’s duty to promote a comprehensive health service and any objectives or requirements specified in the NHS mandate published under section 13A.

284 *Power of integrated care boards to commission certain health services*. New section 3A allows integrated care boards to arrange services or facilities that relate to improving people’s physical or mental health, or preventing, diagnosing and treating illness in those people. Under subsection (2), integrated care boards are responsible for those people specified under section 14Z31 and any other people who may be prescribed in regulations. Under subsection (3), an integrated care board may not arrange for the provision of services that NHS England is required to arrange under sections 3B or 4. Under subsection (4), in exercising this function, integrated care boards must act in accordance with Secretary of

State and NHS England's duty to promote a comprehensive health service and any objectives or requirements specified in the NHS mandate published under section 13A.

Clause 16: Commissioning primary care services etc.

285 Clause 16 inserts Schedule 3 which amends the NHS Act 2006 to give integrated care boards responsibility for medical, dental and ophthalmic primary care functions. It contains other amendments relating to primary care services.

Schedule 3: Conferral of primary care functions on integrated care boards etc.

286 Schedule 3 confers functions on integrated care boards in relation to primary care services and contains related amendments. It makes amendments to the NHS Act 2006 and consequential amendments to related legislation for the conferral of medical, dental and ophthalmic primary care functions on Integrated Care Boards (ICBs). Currently, the functions associated with arranging these services sit with NHS England. The intention is that Integrated Care Boards will hold the majority of these functions at an agreed point in the future. NHS England will retain a limited role in oversight and discharging functions that can be most effectively exercised at a national level.

Part 1 - Conferral of functions etc.

287 Part 1 of this Schedule is referring to amendments made to the NHS Act 2006. Power to require NHS England to continue to exercise certain primary care functions.

288 Under section 3B of the 2006 NHS Act, the Secretary of State can make regulations requiring NHS England to arrange certain services. New paragraphs (za) and (aa) enables the Secretary of State to also require NHS England to commission primary medical services and primary ophthalmic services. This is an addition to the current list of: (a) dental services of a prescribed description; (b) services or facilities for members of the armed forces or their families; (c) services or facilities for persons who are detained in a prison or in other accommodation of a prescribed description; (d) such other services or facilities as may be prescribed.

Primary Medical services

289 New section 82B of the NHS Act 2006 requires integrated care boards to make the necessary arrangements to secure the provision of primary medical services to meet the reasonable requirements of the persons for whom they are responsible (as defined in 14Z31). Regulations under section 82A may set out how primary medical services should be defined for the purposes of this Act.

290 New section 83 provides a general power for integrated care boards and NHS England to make arrangements for the provision of primary medical services to fulfil their section 82B and section 3B(1) obligations respectively.

291 Section 83A stipulates that each integrated care board and NHS England must publish information about such matters as may be prescribed in relation to the primary medical services provided under this Act.

292 New section 98A allows the Secretary of State to direct NHS England to exercise any of the Secretary of State's functions relating to the provision of primary medical services.

293 New section 98B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under this Part.

Dental services

294 New section 99 requires integrated care boards to make the necessary arrangements to secure the provision of primary dental services to meet the reasonable requirements of the persons for whom it is responsible (as defined in 14Z31). Regulations under section 98C may set out how primary dental services should be defined for the purposes of this Act.

295 Section 99A provides a general power for integrated care boards and NHS England to make arrangements for the provision of primary dental services to fulfil their section 99 and section 3B(1) obligations respectively.

296 When referring to dental services in the context of NHS England's section 3B(1) responsibilities, it includes both primary and secondary dental services. This is different from primary medical and primary ophthalmic services because section 3B(1) only refers to those services provided in a primary care setting.

297 New section 99B stipulates that each integrated care board and NHS England must publish information about such matters as may be prescribed in relation to the primary dental services provided under this Act.

298 New section 114A allows the Secretary of State to direct NHS England to exercise any of the Secretary of State's functions relating to the provision of primary dental services.

299 New section 114B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under this Part.

Ophthalmic services

300 New section 115 requires integrated care boards to make the necessary arrangements to secure the provision of primary ophthalmic services to meet the reasonable requirements of the persons for whom it is responsible (as defined in 14Z31). Regulations under section 114C may set out how primary ophthalmic services should be defined for the purposes of this Act.

301 Section 116A provides a general power for integrated care boards and NHS England to make arrangements for the provision of primary ophthalmic services to fulfil their section 115 and section 3B(1) obligations respectively.

302 New section 116B stipulates that each integrated care board and NHS England must publish information about such matters as may be prescribed in relation to the primary ophthalmic services provided under this Act.

303 New section 125A allows the Secretary of State to direct NHS England to exercise any of the Secretary of State's functions relating to the provision of primary ophthalmic services.

304 New section 125B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under this Part.

Pharmaceutical services

305 New section 168A allows the Secretary of State to direct NHS England to exercise any of the Secretary of State's functions relating to services that may be provided as pharmaceutical services, or as local pharmaceutical services, under this Part.

306 The provision of pharmaceutical services and local pharmaceutical services under Part 7 are also capable of being delegated from NHS England to integrated care boards via the mechanisms in sections 65Z5 (by agreement) or section 13YB(2)(b)(iv) (by direction).

Part 2 – Consequential amendments

307 Part 2 of this Schedule makes consequential amendments to various legislation relating to primary care to ensure the wider statute book reflects the conferral of medical, dental and ophthalmic primary care functions to integrated care boards. The amendments relate to the following pieces of legislation: *Dentists Act 1984, Access to Health Records Act 1990, Trade Union and Labour Relations (Consolidation) Act 1992, Health Service Commissioners Act 1993, Freedom of Information Act 2000, NHS Act 2006, National Health Service (Wales) Act 2006, Health Act 2009 and the Domestic Abuse Act 2021.*

Clause 17: Transfer schemes in connection with transfer of primary care functions

308 This clause allows NHS England to make one or more schemes for the transfer of property, rights and liabilities to an integrated care board in connection with the transfer of primary care functions from NHS England to an integrated care board.

309 Subsection (2) outlines what is transferrable under a transfer scheme. This includes property, rights and liabilities that could not otherwise be transferred; property acquired, and rights and liabilities arising, after the making of the scheme; and criminal liabilities. This includes provision for employees to be transferred to the integrated care board, 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.

Clause 18: Commissioning arrangements: conferral of discretions

310 Clause 18 amends section 12ZA of the NHS Act 2006. Section 12ZA makes provision about commissioning arrangements made by NHS England and CCGs. 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.

Clause 19: General functions

311 *Duty to promote the NHS Constitution.* New section 14Z32 imposes a duty upon integrated care boards both to act in the exercise of its functions (for example through their commissioning functions) with a view to securing that health services are provided in a way that promotes the NHS Constitution and to promote awareness of it among staff, patients and the public. This means that not only must integrated care boards act in accordance with the NHS Constitution, but they should ensure that people are made aware of their rights enumerated in it. They may also do this by contributing, as far as possible, to the advancement of the Constitution's principles, rights, responsibilities and values, through their actions.

312 *Duty as to effectiveness, efficiency etc.* Under new section 14Z33, each integrated care board must exercise its functions effectively, efficiently and economically.

313 *Duty as to improvement in quality of services.* New section 14Z34 places integrated care boards under a duty to exercise their functions with a view to securing continuous improvement in the quality of services provided to individuals, as part of the health service. Under 14Z34(3) Integrated care boards should, in particular, look to continuously improve effectiveness of services, safety of services and patient experience.

314 *Duties as to reducing inequalities.* New section 14Z35 sets out that integrated care boards must, in the exercise of their functions, have regard to the need to reduce inequalities between patients in relation to their ability to access health services and in the outcomes achieved from health services.

315 *Duty to promote involvement of each patient.* Section 14Z36 requires integrated care boards to, in the exercise of their functions, promote the involvement of patients and their carers and representatives in decisions about the provision of health services to patients.

316 *Duty as to patient choice.* Section 14Z37 imposes a duty on integrated care boards, in the exercise of their functions, to act with a view to enabling patient choice (for example, by commissioning so as to allow patients a choice of treatments, or a choice of providers, for a particular treatment).

- 317 *Duty to obtain appropriate advice.* New section 14Z38 requires integrated care boards to obtain appropriate advice from people who, collectively, have a broad range of professional expertise in relation to the prevention, diagnosis or treatment of illness, and the protection or improvement of public health to enable them to discharge their functions effectively. This could involve, for example, an integrated care board employing healthcare professionals to advise the integrated care board on commissioning decisions for certain services, or appointing professionals to any committee that the integrated care board may set up to support commissioning decisions. It could also involve consulting clinical networks and senates.
- 318 *Duty to promote innovation.* New section 14Z39 imposes a duty on integrated care boards, in the exercise of their functions, to promote innovation in the provision of health services and in making arrangements for the provision of health services.
- 319 *Duty in respect of research.* New section 14Z40 puts a duty on integrated care boards in respect of research. Each integrated care board must, in the exercise of its functions, have regard to the need to promote health research and the use of evidence obtained from such research. An integrated care board could, for example, use evidence obtained from health research to inform its commissioning plan.
- 320 *Duty to promote education and training* - New section 14Z41 puts a duty on integrated care boards in respect of education and training. Each integrated care board must, in exercising its functions, have regard to the need to promote education and training for persons who are employed, or who are considering becoming employed, in an activity related to the provision of services as part of the health service in England.
- 321 *Duty as to promoting integration.* Section 14Z42 requires integrated care boards to exercise their functions with a view to ensuring that health, social care and health-related services are provided in an integrated way where this would improve the quality of the services, reduce inequalities of access or reduce inequalities in outcomes; under this integration can be integration of health services with other health services or health services with health-related services (such as housing services), or health services with social care services.
- 322 *Duty to have regard to effect of decisions* – this provision, which is to be inserted in the NHS Act 2006 as the new section 14Z43, sets out a new duty, which also applies to the other ‘relevant bodies’. The ‘relevant bodies’ are NHS England, NHS Trusts in England and NHS Foundation Trusts, for integrated care boards.
- 323 This duty has been described by DHSC operationally as the ‘triple aim’ duty.
- 324 Subsection (1) provides that integrated care boards will be under a duty, in making a decision about the carrying out of their functions, to have regard to all likely effects of

their decisions on three areas: the health and well-being of the people of England (subsection (a)), the quality of services provided or arranged by relevant bodies (subsection (b)) and the efficiency and sustainability of resources used by the relevant bodies (subsection (c)).

325 The reference in the subsection to “all” likely effects means that the integrated care board will have to consider, under subsections (b) and (c), the effects of the decision both on its own quality of services and resource use and those of other relevant bodies.

326 Subsection (2) excludes decisions relating to services provided to a particular individual (e.g. Individual clinical decisions or highly specialist commissioning decisions concerning an individual patient) from this duty.

327 Subsection (3) provides that integrated care boards must have regard to guidance on the discharge of this duty published by NHS England under new section 13NB.

328 *Public involvement and consultation by integrated care boards.* New section 14Z44 sets out requirements for involving the public (whether by consultation or otherwise). Integrated care boards must make arrangements to involve individuals to whom services are being or may be provided in the commissioning process. Under 14Z44(2), individuals must be involved in planning commissioning arrangements; in developing and considering proposals for changes in the commissioning arrangements, where those proposals would have an impact on how services are provided or the range of health services available; and in decisions that would likewise have a significant impact. Under 14Z44(3), this duty does not apply in cases where a trust special administrator drafts a report concerning an NHS Trust or Foundation Trust and NHS England and the Secretary of State have already made decisions about actions to take.

329 *Joint exercise of functions with Local Health Boards.* Regulations may be made under new section 14Z45(1) to allow any prescribed functions of an integrated care board to be exercised jointly with a Local Health Board. Local Health Boards are the bodies responsible for commissioning and providing health services in Wales. Regulations may also make provision for any such functions to be exercised by a joint committee of the integrated care board and the Local Health Board. Subsection (3) makes it clear that these arrangements do not affect any liabilities of integrated care boards arising from the exercise of its functions under arrangements with a Local Health Board.

330 *Raising additional income.* New section 14Z46 allows integrated care boards to raise additional income for improving the health service, provided that this does not significantly interfere with the integrated care board’s ability to perform its functions.

331 *Power to make grants.* New section 14Z47 allows integrated care boards to make grants or loans, subject to such conditions as the integrated care board deems appropriate, to NHS

trusts, NHS foundation trusts, or voluntary organisations that provide or arrange for the provision of services similar to the services in respect of which an integrated care board has functions.

332 *Responsibility for payments to providers.* New section 14Z48(1) gives NHS England the power to publish a document specifying the circumstances in which an integrated care board is liable to make payments to a provider to pay for services provided under arrangements commissioned by another integrated care board. This provision would, for instance, enable NHS England to specify that, where a person uses an urgent care service commissioned by an integrated care board other than the integrated care board that is ordinarily responsible for that person's healthcare, the cost of that service is charged to the latter integrated care board. It could, for instance, decide that integrated care boards should be left to agree mutual arrangements for sharing costs where patients from a number of different integrated care boards use the same urgent care service. However, where NHS England publishes such a specification, an integrated care board will be required to make payments in accordance with that document (subsections (2) and (3)). In those circumstances, no other integrated care board will be liable for the payment. Any sums payable by virtue of subsection (2) may be recovered under subsection (5) as a civil debt. Where NHS England makes a specification, it may publish guidance for the purpose of assisting integrated care boards to understand, and apply, it (subsection (6)).

333 *Guidance by NHS England:* New section 14Z49 stipulates that NHS England must publish guidance for integrated care boards on the discharge of their functions. Integrated care boards must have regard to this guidance.

334 *Joint forward plans for integrated care board and its partners.* New section 14Z50 makes provision with regard to commissioning plans. Section 14Z50(1) stipulates that each integrated care board, and its partner NHS trusts and NHS foundation trusts, must prepare a plan before the start of each relevant period to set out how it will exercise its functions over the next 5 years. In practice, 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. Under 14Z50(2), the plan must, in particular, explain how the integrated care board proposes to discharge its duties to seek continuous improvement in the quality of services (under new section 14Z34), to reduce inequalities (section 14Z35), how it will fulfil its duty to have regard to the wider impact of decisions (section 14Z43), to ensure public involvement and consultation (section 14Z44) and its financial duties (under sections 223H to 223J). Under subsection 2b, it must also reference how the plan implements any relevant joint local health and wellbeing strategies to which the integrated care board is required to have regard.

- 335 Under 14Z50(4), this plan must be published and sent to NHS England, the relevant integrated care partnership and any relevant Health and Wellbeing Boards. NHS England may specify a date by when this must be done.
- 336 *Revision of forward plans.* Under new section 14Z51, the commissioning plan may be revised. Should the proposed revision be deemed ‘significant’, the integrated care board must publish the revised plan and give a copy to the integrated care partnership, NHS England and the relevant health and wellbeing board, having carried out consultation under new section 14Z52. Under subsection (3), where the integrated care board revises the plan and the changes are not significant, it must nonetheless publish the revised plan. A copy must also be provided to the integrated care partnership, each relevant health and wellbeing board and NHS England.
- 337 *Consultation about forward plans.* Under new section 14Z52, when preparing a commissioning plan, or making a change it deems significant, the integrated care board must consult individuals for whom it has responsibility for the purposes of section 3 of the NHS Act, for example the people to whom its members provide primary care services and those included within the integrated care board’s geographic area responsibilities.
- 338 Under 14Z52(3), the integrated care board must also provide relevant Health and Wellbeing Boards with a copy of the draft plan or revised plan (as the case may be) and consult on whether the plan adequately takes the latest joint health and wellbeing strategy into account.
- 339 Under 14Z52(5) and (6), the Health and Wellbeing Board is required to respond with its opinion on the forward plan and may also give its opinion to NHS England. Where a Health and Wellbeing board gives an opinion to NHS England, it must also give a copy to the integrated care board. Under subsection (7), if the integrated care board went on to make further changes to the forward plan, this process would have to be repeated. The revised plan would have to be published and a copy given the relevant Health and Wellbeing Board and NHS England.
- 340 Under subsection (8), all published forward plans must include:
- a summary of the views of individuals consulted;
 - an explanation of how those views were taken into account; and
 - a statement as to whether the relevant Health and Wellbeing Board(s) agreed that the plans have due regard to the joint health and well-being strategy or strategies.

- 341 *Opinion of Health and Wellbeing Boards on forward plan.* 14Z53 allows each Health and Wellbeing Board to provide NHS England with its opinion on whether an integrated care board's commissioning plan has taken proper account of the relevant joint health and wellbeing strategy. If it does so, it must provide a copy of this opinion to the integrated care board in question.
- 342 *Joint capital resource use plan for integrated care board and partners.* New section 14Z54 stipulates that before the start of each financial year, an integrated care board and its partner NHS trusts and NHS foundation trusts must prepare a plan setting out their planned capital resource use. Subsection (2) provides that the plan must relate to such a period as the Secretary of State may direct. Under subsection (5), they must give a copy of the plan to the integrated care partnership, each relevant Health and Wellbeing Board and NHS England. NHS England can publish guidance about the discharge of functions under this section under subsection (7).
- 343 Under subsection (9), NHS England may give directions, in relation to a financial year—
- specifying descriptions of resources which must, or must not, be treated as capital resources for the purposes of this section;
 - specifying uses of capital resources which must, or must not, be taken into account for the purposes of this section.
- 344 Under 14Z55, a plan published under section 14Z54 can be revised. Any revisions they consider significant must be published and a copy provided for NHS England and each relevant Health and Wellbeing Board. NHS England may publish guidance about the discharge by an integrated care board and its partner NHS trusts and NHS foundation trusts of their functions under this section. Under subsection (8), an integrated care board and its partner NHS trusts and NHS foundation trusts must have regard to any guidance published under this section.
- 345 Under subsection (10), NHS England may give directions, in relation to a financial year—
- specifying descriptions of resources which must, or must not, be treated as capital resources for the purposes of this section;
 - specifying uses of capital resources which must, or must not, be taken into account for the purposes of this section.
- 346 *Annual report.* New section 14Z56 stipulates that an integrated care board must, in each financial year, prepare a report on how it has discharged its functions in the previous financial year. Under subsection (2), an annual report must, in particular, explain how the integrated care board has discharged its duties in relation to the improvement in

quality of services (14Z34), reducing inequalities (14Z35), public involvement and consultation (14Z45) and the Triple Aim (14Z40). The report must also review to what extent the integrated care board has exercised its functions in accordance with its forward plan and capital resource plan, as well as to what extent it has implemented any relevant health and wellbeing strategies. Under subsection (3), in producing the report, the integrated care board must consult each relevant Health and Wellbeing Board. The integrated care board must also publish the annual report and give copies to NHS England by a date specified by NHS England (subsection (4)). NHS England may give directions to integrated care boards as to the form and content of the report.

347 *Performance assessment of integrated care boards.* New section 14Z57 stipulates that NHS England must conduct and publish a performance assessment of each integrated care board in respect of each financial year.

348 Under 14Z57(3), the assessment must, in particular, include an assessment of how well the integrated care board has discharged its duties concerning the improvement in quality of services (14Z34), reducing inequalities (14Z35), obtaining appropriate advice (14Z38), public involvement and consultation (14Z44), financial duties (223GB to 223O) and the duty to have regard to assessments and strategies (section 116B(1) of the Local Government and Public Involvement in Health Act 2007).

349 Under subsection (4), in producing the report, NHS England must consult each relevant Health and Wellbeing Board as to its views on the any steps that the board has taken to implement any relevant joint local health and wellbeing strategy. NHS England must also have regard to any guidance published under section 14Z49 or any document published by the Secretary of State.

350 *Power of NHS England to obtain information:* Under new section 14Z58, NHS England may require an integrated care board to provide NHS England with any necessary documents or other information.

351 *14Z59 Power to give directions to integrated care boards:* New section 14Z59(1) applies if NHS England considers an integrated care board to be failing or to have failed to discharge any of its functions, or that there is a significant risk that an integrated care board will fail to do so.

352 Under subsections (3), (4), (5) and (6), NHS England may:

- direct the integrated care board or chief executive of the integrated care board to discharge any of its functions.
- terminate the appointment of the chief executive and direct the chair and other members of the board to appoint a replacement of their direction.

- exercise any function on behalf of the board or direct another integrated care board to perform functions specified by NHS England.
- exercise any functions of the chief executive or direct a chief executive of another integrated care board to perform functions specified by NHS England.

353 Under subsection (8), the integrated care board is required to cooperate with any chief executive who is directed to exercise its functions.

354 *Permitted disclosures of information:* New section 14Z60 stipulates that integrated care boards are permitted to disclose information obtained in the exercise of its functions if it meets the lawful requirements.

355 *Interpretation:* New section 14Z61 defines the terms used in this chapter.

- “financial year”, in relation to an integrated care board, means the period beginning with the date on which the integrated care board is established and ending with the second 31 March following that date, and each successive period of twelve months;
- “the health service” means the health service in England;
- “health services” means services provided as part of the health service and, in section 14Z44, also includes services that are to be provided as part of the health service;
- “relevant Health and Wellbeing Board”, in relation to an integrated care board, has the meaning given by section 14Z50(7).
- Any reference to the functions of an integrated care board includes a reference to the functions of the Secretary of State that are exercisable by the board by virtue of arrangements under section 7A; the functions of NHS England that are exercisable by the board by virtue of arrangements under section 13Z.

Integrated Care Partnerships

Clause 20: Integrated care partnerships and strategies

356 This clause amends the Local Government and Public Involvement in Health Act 2007 to account for the transition from CCGs to integrated care boards and makes relevant amendments to provide for the Integrated Care Partnership (ICP) and its integrated care strategy.

357 Subsection (3) requires local authorities to share Joint Strategic Needs Assessments with the integrated care partnerships that overlap with the area of the local authority.

358 Subsection (4) inserts new sections into the Act on integrated care partnerships and their strategies.

359 116ZA subsection (1) requires the integrated care board and each local authority in the area of the integrated care board to establish an ‘integrated care partnership’, which is a joint committee of these bodies. Under subsection (2), the partnership must include members appointed by the integrated care board and each relevant local authority. Under subsection (3), the integrated care partnership may appoint other members and determine its own procedures.

360 116ZB subsection (1) requires the integrated care partnership to prepare an ‘integrated care strategy’. The strategy must detail how the needs of an area will be met by either the integrated care board, NHS England, or the local authorities. Under subsection (2) the strategy must consider how NHS bodies and local authorities could work together to meet these needs using section 75 of the NHS Act 2006 and the strategy may also state how health-related services could be more closely integrated (subsection (5)). In preparing this strategy the integrated care partnership must have regard to the NHS mandate and guidance published by the Secretary of State (subsection (3)) and involve the Local Healthwatch and people who live or work in the integrated care partnership’s area (subsection (4)).

361 Under 116ZB subsection (6), the integrated care partnership must consider revising its integrated care plan whenever it receives a new joint strategic needs assessment. Under 116ZB subsection (7), the integrated care strategy must be published and shared with each responsible local authority, and the relevant integrated care board in that area.

362 Subsection Clause 20(5) inserts into section 116A a requirement for local authorities and their partner integrated care boards, in response to an integrated care plan, to prepare a ‘joint local health and wellbeing strategy’ that sets out how the local authorities, integrated care board and NHS England will meet population needs in that area.

363 Subsection Clause 20(6) substitutes section 116B which places a requirement for local authorities and integrated care boards to have regard to the joint strategic needs assessment, the integrated care strategy, and the joint local health and wellbeing strategy when exercising their functions (subsection (1)), and for NHS England to have regard to the above when exercising their functions related to the provision of health services in the area (subsection (2)).

Integrated Care System: Financial Controls

Clause 21: NHS England’s financial responsibilities

364 This clause substitutes sections 223C to 223E of the NHS Act 2006.

365 *Financial duties of NHS England: expenditure.* New Section 223C sets out that NHS England must exercise its functions with a view to ensuring that total health expenditure

in respect of each financial year does not exceed the aggregate of any sums received in the year by NHS England and integrated care boards.

366 Under subsection (2), the Secretary of State may, by direction, specify descriptions of sums that are, or are not, to be treated for the purposes of this section as having been received by a body, or as having been received by it in a particular financial year; specify descriptions of expenditure that are, or are not, to be treated as part of total health expenditure or part of total expenditure for a particular year.

367 *NHS England: banking facilities.* New Section 223CA allows the Secretary of State to require NHS England to use banking facilities specified by them.

368 *Financial duties of NHS England: controls on total resource use.* New clause section 223D sets out that NHS England must exercise its functions with a view to ensuring that total capital resource use does not exceed the limit specified in a direction by the Secretary of State and that total revenue resource use does not exceed the limit specified in a direction by the Secretary of State. In this section total capital and revenue resource use are the resource use of NHS England, integrated care boards, NHS trusts and NHS foundation trusts taken together. Subsection (2) excludes transfers of resource between those bodies from the definition of resource use.

369 Under subsection (4), a direction specifying a limit in relation to a financial year may be varied by a subsequent direction only if—(a) NHS England agrees to the change, (b) a parliamentary general election takes place, or (c) the Secretary of State considers that there are exceptional circumstances which make the variation necessary.

370 Under subsection (5), the Secretary of State must publish and lay before Parliament any directions under this section.

371 *Financial duties of NHS England: additional controls on resource use.* Under new section 223E, the Secretary of State may direct NHS England to ensure— (a) that relevant capital resource in a financial year which is attributable to matters specified in the direction does not exceed an amount so specified; (b) that relevant revenue resource use in a financial year which is attributable to matters specified in the direction does not exceed an amount so specified. In this section “relevant capital resource use” and “relevant revenue resource use” refer to that resource use by NHS England and integrated care boards. Under subsection (3), the Secretary of State may direct NHS England to ensure that NHS England’s use of revenue resources in a financial year which is attributable to such matters relating to administration as are specified in the direction does not exceed an amount so specified.

Clause 22: Expansion of NHS England's duties in respect of expenditure

372 This clause enables new section 223C of the NHS Act 2006 (as substituted by clause 21 of this Act), to be expanded to add NHS trusts established under section 25 and NHS foundation trusts to the list of bodies contributing to the aggregate of any sums received in the year in respect to the financial duty on NHS England to ensuring that total health expenditure in respect of each financial year does not exceed the aggregate of any sums received in the year.

Clause 23: Financial Responsibilities of integrated care boards and their partners

373 *Power to impose financial requirements on integrated care boards.* This clause omits sections 223H to 223J and inserts a number of new sections. New section 223GB (inserted after section 223GA) allows NHS England to impose financial requirements on integrated care boards in relation to their management or use of financial or other resources. Under subsection (2), these requirements may include limits on expenditure or resource use. However, NHS England may not use this power to impose limits on the use of revenue resources by an integrated care board for the purposes of administration, unless the Secretary of State has ordered NHS England to do so. These requirements can be imposed on any integrated care boards specified, who must comply with them. Under subsection (3), NHS England must publish any requirements imposed by direction under this section.

374 *Financial duties of integrated care boards [etc]: expenditure limits.* Under new section 223GC, integrated care boards must operate with a view to ensure that the expenditure does not exceed the aggregate of any sums received by an integrated care board within that financial year. NHS England may specify descriptions of income and expenditure that should or should not be counted for the purposes of reaching financial balance, or the financial year in which they are counted.

375 *Integrated Care Boards: banking facilities.* New section 223GD allows the Secretary of State to specify the banking facilities that integrated care boards are required to use for any specified purpose.

376 *Joint financial objectives for integrated care boards.* Under new section 223L (substituting sections 223H to 223J), NHS England can set joint financial objectives for integrated care boards and their partner NHS trusts and NHS foundation trusts, who must operate with a view to achieving these objectives.

377 *Financial duties of integrated care boards: use of resources.* Under new section 223N, integrated care boards and their partner NHS trusts and NHS foundation trusts must operate with a view to ensuring that the local capital resource use and local revenue

resource use they use does not exceed the limits specified by direction from NHS England in that financial year. Under subsection (3), where an NHS trust or NHS foundation trust is partner to more than one integrated care board, NHS England can specify how resources should be apportioned to one or more different integrated care boards. Under subsection (4), NHS England can also specify what expenditure can or cannot be considered capital resources or revenue resources for the purpose of these provisions.

378 *Financial duties of integrated care boards: additional controls on resource use.* New section 223O allows NHS England, under direction of the Secretary of State, to give direction to an integrated care board and its partner NHS trusts and foundation trusts, in order to ensure that they do not spend more than a specified maximum amount of local capital resource or local revenue resource. Under subsection (2), NHS England can also specify what resources are or are not to be considered as capital resources or revenue resources for the purpose of these provisions.

379 *Resources etc relevant to section 223D, 223E, or 223N, or 223O* New section 223P allows the Secretary of State to specify which resources must, or must not, be treated or taken into account as capital resources or revenue resources for the purposes of section 223D, 223E, or 223N, or 223O.

Clause 24: Expansion of financial duties of integrated care boards and their partners

380 *Financial duties of integrated care boards etc: expenditure limits.* This clause, which it is intended may be commenced later once the sector is prepared to move to more system financial accountability, will omit section 223GC and insert new section 223LA to expand the scope of the expenditure financial duties. New section 223LA states that an integrated care board and its partner NHS trusts, and NHS foundation trusts must exercise their functions with a view to ensuring that local health expenditure does not exceed the aggregate of any sums received by them in the year.

381 Under subsection (3), NHS England may by direction specify descriptions of sums that are, or are not, to be treated for the purposes of this section as having been received by a body, or as having been received by it in a particular financial year and may specify descriptions of expenditure that are, or are not, to be treated as part of local health expenditure or part of local expenditure for a particular year.

Integrated care system: further amendments

Clause 25: Integrated Care System: further amendments

382 Clause 25 inserts schedule 4 which makes minor and consequential amendments relating to Integrated Care boards and Partnerships.

Schedule 4: Integrated Care system: minor and consequential amendments

383 This schedule makes minor and consequential amendments to do with integrated care systems.

Merger of NHS bodies etc.

Clause 26: Abolition of Monitor and transfer of functions to NHS England

384 Clause 26 abolishes Monitor under subsection (1). Subsection (2) explains that Schedule 5 contains consequential amendments that arise out of the transfer of Monitor's functions to NHS England, and related amendments. This clause fulfils the intention of DHSC to merge Monitor into NHS England to form a single body by transferring the appropriate functions of Monitor.

Schedule 5: Abolition of Monitor and transfer of its functions

385 This schedule contains consequential amendments relating to the abolition of Monitor and the transfer of its regulatory functions to NHS England.

Clause 27: Exercise by NHS England of new regulatory functions

386 Clause 27 inserts a new section 13SA, 'Minimising conflicts between regulatory and other functions', in the NHS Act 2006. Subsection (2) of this clause introduces this new section 13S, which in turn places a duty on NHS England to minimise the risk of conflict or manage any conflicts that arise between their regulatory functions, as set out in subsection (2) and (3), and its other functions. NHS England will be required to include in its annual report under section 13U of the NHS Act 2006, a statement explaining how it has complied with its section 13SA duty.

Clause 28: Modification of standard licence conditions

387 Clause 28 amends section 100 of the 2012 Act. Section 100 allows Monitor (in future, NHS England) to modify standard licence conditions in all providers' licences or in licences of a particular description. Before making such a modification, Monitor must comply with the notice requirements, giving providers affected the opportunity for those notified about the proposed modification to make representations.

388 Clause 28 requires that, before making what NHS England considers is a major change to the license conditions, they must carry out an assessment of the likely impact of the modification, or publish a statement setting out why such an assessment is not needed.

389 Subsection (3) makes consequential amendments to the section 100.

390 Subsection (4) requires NHS England to include this assessment in the notice given to providers and others.

Clause 29: Abolition of NHS Trust Development Authority

391 Clause 29 fulfils the intention of DHSC to merge the TDA into NHS England to form a single body by transferring the appropriate functions of the TDA. Subsection (1) abolishes the Special Health Authority called the National Health Service Trust Development Authority (the TDA) and subsection (2)(a) revokes the order establishing the TDA: The National Health Service Trust Development Authority (Establishment and Constitution) Order 2012 (SI 2012/901).

392 Subsections (2)(b) and (2)(c) also revoke the National Health Service Trust Development Authority Regulations 2012 (S.I. 2012/922); the National Health Service Trust Development Authority (Directions and Miscellaneous Amendments etc.) Regulations 2016 (S.I. 2016/214) and makes consequential amendments that arise as a result of the abolition of the TDA.

Clause 30: Merger of bodies: consequential amendment

393 Clause 30 makes consequential amendments to NHS England's general duties in the 2012 Act to reflect their new oversight role of NHS Trusts and Foundation Trusts.

Clause 31: Transfer schemes in connection with abolished bodies

394 Clause 31 gives the Secretary of State the power, under subsection (1) to make schemes to transfer the property, rights and liabilities (including criminal liabilities) from Monitor or the TDA to NHS England as a consequence of the abolishment of those bodies. Subsection (2) sets out the detail of what may be transferred as part of a transfer scheme and subsection (3) outlines the detail of transfer schemes.

Clause 32: Transfer schemes under section 31: taxation

395 Clause 32 provides that the Treasury may vary the way in which a relevant tax has effect in relation to anything transferred under a scheme under section 31, or anything done for the purposes of, or in relation to, a transfer under such a scheme.

396 The intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, the merger provisions need to include a power for the Treasury to vary any relevant tax.

Secretary of State's functions

Clause 33: Report on assessing and meeting workforce needs

397 Clause 33 inserts a new Section 1GA into the NHS Act 2006.

398 Subsection (1) sets out 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 is being taken forward.

399 Subsection (2) places a duty on HEE and NHS England to assist the Secretary of State in preparing the report, if asked by the Secretary of State to do so.

Clause 34: Arrangements for exercise of public health functions

400 Clause 34 replaces section 7A in the NHS Act 2006 and concerns the exercise of Secretary of State's public health functions. Subsections (1) and (2) allow for any of Secretary of State's public health functions to be exercised by NHS England, an integrated care board, a local authority that has duties to improve public health, a combined authority, or any other body that is specified in regulations. Under subsection (3), powers under this section may be exercised on such terms as may be agreed and agreements can be made as to the terms of payment as well as terms prohibiting or restricting the further onward delegation of the function in question or its joint exercise by a joint committee. Under subsection (5), any party that has been delegated a relevant public health function as part of these arrangements is liable for the exercise of that function. Similarly, only the body which exercises the function in question will be able to enforce any rights acquired in their exercise. The intention is to provide flexibility and efficiency in the way that public health services are delivered.

Clause 35: Power of direction: public health functions

401 Clause 35 introduces a new section 7B into the NHS Act 2006 and allows the Secretary of State for Health and Social Care to direct one or more relevant bodies to exercise any of the public health functions of the Secretary of State. "Public health functions" are functions under section 2A (duty to take steps to protect public health), section 2B (power to take steps to improve public health) or certain functions under Schedule 1. Subsection (2) defines relevant bodies as NHS England and Integrated Care Boards.

402 Subsection (3) of new section 7B provides that a direction may prohibit or restrict a relevant body from making arrangements under new sections 65Z5 (joint working and delegation arrangements) and 65Z6 (joint committees and pooled funds). This ensures that any functions that should not be capable of being delegated can be prescribed and any functions that may be delegated but that need to be more closely controlled can be subject to conditions.

403 Subsection (5) provides that the Secretary of State may provide funding to NHS England or an Integrated Care Board in relation to the functions to be exercised.

404 Subsection (6) enables the Secretary of State to give directions to an Integrated Care Board as to the exercise of any functions which it is directed to exercise by virtue of new

section 7B. In relation to NHS England, subsection (7) refers to section 13ZC for equivalent power to give directions to NHS England as to the exercise of such functions. This might be used, for example, to ensure compliance with nationally consistent standards for vaccination or screening services.

405 Subsection (8) provides that the Secretary of State must publish a direction given under subsection (1) or (6) as soon as reasonably practicable after giving the direction.

406 Subsection (9) of new section 7B provides that when NHS England and/ or an Integrated Care Board exercises the Secretary of State's public health functions under such a direction, any rights acquired or liabilities incurred will be enforceable against that body (and no other individual or body). Similarly, only the body which exercises the function in question will be able to enforce any rights acquired in their exercise.

407 New section 7B adds to existing powers whereby the Secretary of State for Health and Social Care can arrange for a range of other bodies to exercise public health functions (via section 7A of the National Health Service Act 2006). Specifically, in the case of NHS England and Integrated Care Boards, it additionally provides for the Secretary of State for Health and Social Care to achieve this result by direction.

Clause 36: Power of Direction: investigation functions

408 This clause introduces a new section 7C, section 7D and section 7E in the NHS Act 2006.

409 Subsection (2) inserts a new Section 7C Power of direction: investigation functions into the NHS Act 2006 this provides that the Secretary of State may direct NHS England, or any other public authority, to exercise any of the investigation functions which are specified in the direction.

410 Section 7C(5) provides that the Secretary of State may give directions to any person on whom those functions are conferred as to how those functions should be exercised. Section 7C(4) also provides that the Secretary of State may make payments to NHS England or any other public authority in respect of the exercise of those investigation functions.

411 Section 7C(9) clarifies that the investigation functions are the functions which were previously exercised by the Trust Development Authority in respect of:

- the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 made under sections 7 and 8 of the National Health Service Act 2006, (the HSIB directions 2016), or

- the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 made under sections 7 and 8 of the National Health Service Act 2006. (the HSIB maternity investigations 2018)

412 Section 2 also inserts a new section 7D transfer schemes in connection with a direction under section 7C. Subsection (7D)(1) and (2) provide that the Secretary of State may make one or more transfer schemes in connection with the transfer to NHS England and any other public body of any property, rights of liabilities relating to the discharge of functions pursuant to directions made under section 7C.

413 Subsection (7D)(3) clarifies that the transfer scheme can also be used to transfer property, rights and liabilities that could not otherwise be transferred; property acquired, and rights and liabilities arising after the making of the scheme and criminal liabilities.

414 Subsections (7D)(4) and (5) provide further details on what the transfer scheme may do or provide. This includes that, a transfer scheme may make provisions which are at the same or similar to those provided for by the Transfer of Undertakings (Protection of Employment) Regulations 2006. Therefore, a staff transfer scheme may be created to move staff from NHS England to the HSSIB, it would offer certain protections of employment rights for transferred staff.

415 Section 2 also inserts a new section 7E Transfer schemes under section 7D: into the NHS Act 2006. Subsection (7E)(1) provides that the Treasury may through regulations vary the way in which a relevant tax has effect in relation to anything transferred under a scheme under section 7D, or anything done for the purposes of, or in relation to, a transfer under such a scheme.

416 The Department's intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. In order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise, section 7E provisions need to include a power for the Treasury to vary any relevant tax.

417 The power to direct in sections 13ZC(7) and (8) is limited by other powers to make regulations and orders. In particular, the directions cannot be used to impose requirements which should be set out in regulations, and circumvent any Parliamentary scrutiny or control provided for in the regulation-making power.

Clause 37: General power to direct NHS England

418 Subsection (1) of clause 37 amends the NHS Act 2006 and inserts four new sections which provide the Secretary of State for Health and Social Care with powers to give directions to NHS England:

- 13ZC Secretary of State directions as to the exercise of NHS England functions;
- 13ZD Power to give directions: exceptions
- 13ZE Compliance with directions: significant failure
- 13ZF Secretary of State directions to provide information

419 New section 13ZC gives the Secretary of State the power to direct NHS England in relation to their functions. Any direction given to NHS England by the Secretary of State must be made in writing stating that it is in the public interest and be published.

420 Section 13ZC gives the Secretary of State the ability to direct NHS England to exercise or not exercise their functions; when or how a function is, or is not to be exercised; conditions that must be met before a function is exercised (relating to the provision of information, consultation or approval); and matters to be taken into account in exercising a function. The Secretary of State cannot use this power to direct NHS England not to perform a duty.

421 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 NHS England should be seeking to achieve. The Framework Agreement DHSC and NHS England will continue to set the parameters within which NHS England should operate and how DHSC and NHS England will interact with each other. The power of direction supplements these mechanisms.

422 The provision in clause 37 is designed to give the Secretary of State the ability, if required, to intervene and to set direction for NHS England, and ensure that NHS England is working effectively with other parts of the system including social care and public health, to support integration and tackle broader priorities such as health inequalities. For example, recognising the unique role the Secretary of State for Health and Social Care plays in the system, the Secretary of State could use the powers to request to see guidance developed by NHS England before it is published to ensure NHS England is working effectively with other parts of the system e.g. local authorities and that the views of local authorities are represented and align with priorities in social care.

423 Section 13ZD sets out the exceptions to this power. The Secretary of State cannot use the power in 13ZC to give directions to NHS England in relation to the appointment of individuals by NHS England (including NHS Trusts and Foundation Trusts); individual clinical decisions; or in relation to drugs or treatments that the National Institute for Health and Care Excellence (NICE) have not recommended or issued guidance on as to

its clinical and cost effectiveness.

424 The clause also removes section 13Z2 (failure to discharge functions) of the NHS Act 2006 and introduces new section 13ZE. This section continues (as in previous section 13Z2 of NHS Act 2006) to confer a power on the Secretary of State to intervene in cases of significant failure of NHS England to carry out any of its functions. This is in line with similar powers in the case of significant failure of the other arm's length bodies. The difference here is that it also applies to directions in 13ZC. If NHS England fails to comply with a direction in 13ZC, the Secretary of State may consider this a significant failure and will have to set out the reasons why this is the case. NHS England has a wide range of functions in relation to the health service. As a result, in the event of significant failure, it might be appropriate for the Secretary of State to intervene in a particular case, for example if NHS England failed to allocate funds to a particular ICB or if it failed to commission a service as required by the NHS Act. The Secretary of State may perform the functions themselves or direct another person to do so.

425 The clause also introduces section 13ZF which gives the Secretary of State powers to direct NHS England to provide information and removes paragraph 14 of Schedule A1 of the NHS Act 2006 (powers to require information). It gives the Secretary of State the power to direct NHS England to provide the Secretary of State with such information as they require, in such form and at such time or within such period, as the Secretary of State considers is necessary to deliver their functions in relation to the health service. A direction under this section also allows for a direction to NHS England to use any powers they hold to obtain this information from others (such as ICBs) if required.

Clause 38: Reconfiguration of services: intervention powers

426 Clause 38 amends the NHS Act 2006, to insert a new section, 68A. Section 68A provides for a new Schedule 10A to confers intervention powers on the Secretary of State in relation to the reconfiguration of NHS services.

427 Schedule 6 of this Bill inserts the new schedule 10A into the NHS Act 2006.

Schedule 6: Intervention powers over the reconfiguration of NHS services

428 In new Schedule 10A, paragraph 1 provides definitions to NHS commissioning body, NHS services, NHS trusts and the reconfiguration of NHS services.

- The NHS commissioning body is either NHS England or an Integrated Care Board.
- NHS services are services provided as part of the health service in England.

- NHS Trust is a trust established under section 25 of the NHS Act 2006, which gives the Secretary of State the power to establish bodies, called National Health Service trusts (“NHS trusts”), to provide goods and services for the purposes of the health service.
- The reconfiguration of NHS services is a change in service provision which has an impact on the point where the service is delivered to the user or the range of services available to individuals.

429 Paragraph 2 places a duty on the NHS commissioning body to notify the Secretary of State when there is a proposal to reconfigure services.

430 Paragraph 3 places a duty on the NHS commissioning body, NHS Trust or Foundation Trust to notify the Secretary of State when it is likely that a reconfiguration will be required. This is intended to capture situations where a temporary change to service provision is required to manage immediate operational issues.

431 Paragraph 4 sub-paragraph 1 gives the Secretary of State the power to give a direction to call in any proposal relating to a service reconfiguration. The direction is given to the NHS commissioning body.

432 Paragraph 4 sub-paragraph 2 allows the Secretary of State to take on the decision-making role of the NHS commissioning body. The Secretary of State must then inform the NHS commissioning body of their decision.

433 Paragraph 4 sub-paragraph 3 provides for the variety of decisions the Secretary of State may choose to take when giving a direction for the reconfiguration of NHS services. This includes power to decide whether a proposal should, or should not, proceed, or should proceed in a modified form; power to decide particular results to be achieved by the NHS commissioning bodies in taking decisions in relation to the proposal; power to decide the procedural or other steps that should, or should not, be taken in relation to the proposal; power to retake any decision previously taken by the NHS commissioning body.

434 Paragraph 4 sub-paragraph 4 refers to when the Secretary of State has made a decision, he must publish any decision made about a reconfiguration and notify the NHS commissioning body of the decision.

435 Paragraph 5 (subparagraph 1-3) refers to NHS commissioning bodies’ responsibility whilst awaiting and after being given direction from the Secretary of State. Whilst the Secretary of State is considering the proposal the NHS commissioning body must cease progressing on the proposal, unless explicitly permitted in the direction. Once the Secretary of State has issued a decision the NHS commissioning body must then act on that decision.

436 Paragraph 6 gives the Secretary of State the power to direct and NHS commissioning body to consider a reconfiguration of NHS services. NHS commissioning bodies are required to consider the proposals from the Secretary of State.

437 Paragraph 7 clarifies that during the Secretary of State's review and decision-making process, the relevant NHS commissioning body, NHS trust or NHS foundation trust must give the Secretary of State any information or other assistance that the Secretary of State requires for the purposes of carrying out any functions under this power.

438 Paragraph 8 subparagraph 1 states that the Secretary of State must publish guidance to outline the expectations NHS commissioning bodies, NHS Trusts and NHS foundation Trusts and how they will fulfil their duties to notify and respond when the Secretary of State calls in a reconfiguration. The guidance must also outline the process the Secretary of State will follow, including how he will adhere to his existing duties, including the Secretary of State's duty as to improvement in quality of services.

439 Paragraph 8 subparagraph 2 places a requirement on NHS commissioning bodies, NHS Trusts and NHS Foundation Trusts to have due regard to the guidance.

NHS Trusts

Clause 39: NHS trusts in England

440 Clause 39 repeals section 179 of the 2012 Act. Section 179 of the 2012 Act abolishes NHS Trusts in England. As not all NHS Trusts converted to NHS Foundation Trusts, NHS Trusts still exist, and this section has never been commenced.

Clause 40: Removal of power to appoint trust funds and trustees

441 Clause 40 repeals paragraph 10 of schedule 4 of the NHS Act 2006. This paragraph allows the Secretary of State to appoint trustees for an NHS Trust to hold property on Trust. This clause therefore removes the Secretary of States powers to appoint such Trustees.

Clause 41: Sections 39 and 40: consequential amendments

442 Clause 41 inserts schedule 7. Schedule 7 makes consequential amendments relating to NHS Trusts in England, and the removal of the Secretary of States powers to appoint Trustees.

Schedule 7: NHS trusts in England and removal of power to appoint trustees; consequential amendments

443 This schedule makes minor and consequential amendments in relation to NHS trusts and the removal of power to appoint trustees.

Clause 42: Licensing of NHS Trusts

444 Clause 42 removes the exemption on NHS trusts to hold a license from Monitor (in future NHS England).

445 Subsection (2) inserts a new clause into the 2012 Act, which requires Monitor (in future NHS England) to treat any new NHS Trusts as if they had applied for a license under section 85 of the 2012 Act, and had met the criteria for being granted a license set out under section 86.

446 Subsection (3) requires Monitor (in future NHS England) to treat existing NHS Trusts as if they had been established on the day of clause commencement for the purposes of granting them licenses under section 85.

Clause 43: NHS Trusts: effect of decisions

447 This provision, which is to be inserted in the NHS Act 2006 as the new section 26A, sets out a new duty, which also applies to the other 'relevant bodies'. The 'relevant bodies' are integrated care boards (new section 14Z43), NHS England (new section 13N) and NHS Foundation Trusts (new section 63A), for NHS trusts in England.

448 This duty has been described by DHSC operationally as the 'triple aim' duty.

449 The duty applies to NHS Trusts established under section 25 of the NHS Act 2006, the effect of which is that it only applies to NHS Trusts in England, and not Wales.

450 Subsection (1) provides that Trusts will be under a duty, in making a decision about the carrying out of their functions, to have regard to all likely effects of their decisions on three areas: the health and well-being of the people of England (subsection (a)), the quality of services provided or arranged by relevant bodies (subsection (b)) and the efficiency and sustainability of resources used by the relevant bodies (subsection (c)).

451 The reference in the subsection to "all" likely effects means that Trusts will have to consider, under subsections (b) and (c), the effects of the decision both on its own quality of services and resource use and those of other relevant bodies.

452 Subsection (2) excludes decisions relating to services provided to a particular individual (e.g. Individual clinical decisions or highly specialist commissioning decisions concerning an individual patient) from this duty.

453 Subsection (3) provides that Trusts must have regard to guidance on the discharge of this duty published by NHS England (13NB).

Clause 44: Oversight and support of NHS trusts

454 Under subsection (1), clause 44 amends the NHS Act 2006, and subsection (2) inserts new section 27A into the NHS Act 2006, which gives NHS England the power to

monitor NHS trusts established under section 25 of the NHS Act 2006 and to provide them with advice, guidance or other support. This carries across the function that the TDA was previously directed to carry out under the National Health Service Trust Development Authority Directions and Revocations and the Revocation of the Imperial College Healthcare National Health Service Trust Directions 2016 (the 2016 Directions).

Clause 45: Directions to NHS trusts

455 Clause 45 inserts a new section 27B which gives NHS England the power to give directions to NHS Trusts established under section 25 of the NHS Act 2006 on the exercise of their functions. The TDA previously had this power under direction from the Secretary of State as set out in the 2016 Directions and it has been carried across to NHS England.

456 Under subsection (2), this clause gives NHS England the equivalent power to direct NHS Trusts as is held by Secretary of State under section 8 of the NHS Act 2006. If an NHS England direction under this subsection conflicts with a Secretary of State direction under section 8 of the NHS Act 2006, NHS England's direction under this clause would have no effect.

457 The manner in which NHS England shall provide directions to NHS Trusts are included in the amended section 273(3) of the NHS Act 2006.

458 Subsection (3) of the clause amends section 73 of the NHS Act 2006 (directions and regulations under Part 2), at subsection (2), to reflect the insertion of new section 27B.

Clause 46: Recommendations about restructuring of NHS trusts

459 Clause 46 inserts a new section 27C in the NHS Act 2006 which gives NHS England the power to make recommendations to NHS Trusts and to take steps it considers appropriate, in relation to applications made by NHS trusts relating to mergers under section 56 of the NHS Act 2006; acquisitions under section 56A of the NHS Act 2006; transfer of property etc between NHS bodies under section 69A of the NHS Act 2006 and the dissolution of an NHS trust under paragraph 28 of Schedule 4 to the NHS Act 2006. The TDA was previously directed to exercise these functions under the 2016 Directions.

Clause 47: Intervention in NHS Trusts

460 Clause 47 inserts a new section 27D in the NHS Act 2006 which places a duty on NHS England to make recommendations to the Secretary of State if it consider that the Secretary of State ought to make an intervention order in relation to an NHS trust under section 66 of the NHS Act 2006 or a default order in relation to an NHS trust under section 68 of the NHS Act 2006. The NHS trusts are ones established under section 25 of NHS Act 2006. NHS England will also be required, under 27D(1)(b) and (c) to explain its

reasons for any recommendations and make any recommendations that are considered appropriate in relation to the contents of the order that the Secretary of State will make.

461 Previously the TDA was directed by the Secretary of State under the 2016 Directions, to make the recommendations that, through this clause, have been transferred to NHS England.

Clause 48: NHS Trusts: conversion to NHS foundation trusts and dissolution

462 Clause 48 amends the NHS Act 2006. Subsection (2) amends section 33 so that an application by NHS Trust to become a Foundation Trust, no longer requires the support of the Secretary of State. Subsection (3) amends section 35 so that authorisation may only be given for Foundation Trust status if the Secretary of State approves the authorisation and NHS England, having taken on the role of regulator, is satisfied of matters contained in section 35(2), which were matters that Monitor previously needed to be satisfied with before authorising an NHS trust to become a Foundation Trust.

463 Subsection (5) also amends paragraph 28, 29 and 30 of Schedule 4 to the NHS Act 2006. The amendment in paragraph 28 gives NHS England the power to dissolve an NHS trust on the approval of the Secretary of State and allows NHS England or the Secretary of State to make the order for dissolution if either consider it appropriate to do so. Neither the Secretary of State nor NHS England may make a dissolution order until after the completion of a consultation as may be prescribed, save for where it appears to either of them that the order needs to be made as a matter of urgency or where the order is made following the publication of a final report from a trust special administrator under section 65I(3) of the NHS Act 2006.

Clause 49: Appointment of chair of NHS trusts

464 Clause 49 amends paragraph 3(1)(a) of Schedule 4 (Appointment of chair of directors of NHS Trust) to the NHS Act 2006 to give NHS England the power to appoint the chair in the board of directors for an NHS trust. This replaces the Secretary of State's power to appoint the chair.

465 The TDA was previously directed by the Secretary of State to appoint the chair of NHS trusts under the 2016 Directions.

Clause 50: Financial Objectives for NHS trusts

466 Clause 50 inserts new paragraphs into schedule 5 of the NHS Act 2006.

467 Sub paragraph (2) allows NHS England to set financial objectives for Trusts.

468 Sub paragraph (3) requires NHS Trusts to meet any financial objectives set by NHS England.

469 Sub paragraph (4) allows NHS England to set objectives for all NHS Trusts, for specific types of NHS Trust (e.g. those providing mental health or community services) or for individual NHS Trusts.

NHS Foundation Trusts

Clause 51: Licensing of NHS Foundation Trusts

470 Clause 51 amends section 88 of the 2012 Act. Section 88 requires that Monitor must treat an NHS foundation trust in existence at commencement of this section, or an NHS trust which becomes a foundation trust at a later date, as having made an application and met the criteria for a licence. As a result of this, the foundation trusts will not have to make a licence application.

471 The new subsection (1) requires that Monitor (in future NHS England) will apply this provision both when a new Foundation Trust is established under section 36 of the *NHS Act 2006*, but also when a Foundation Trust is created as a result of a merger under section 56 or a separation under section 56B.

Clause 52: Capital Spending Limits for NHS Foundation Trusts

472 Clause 52 adds additional powers into the NHS Act 2006, to give NHS England the power to set a capital expenditure limit on an NHS Foundation Trust.

473 Subsection (2) of clause 52 inserts section 42B and section 42C into the NHS Act 2006.

474 Section 42B sets out how the limit to capital expenditure will be placed on a Foundation Trust, the process and defines "capital expenditure".

1. Subsections (1) and (2) gives NHS England the power to make an order to set a capital expenditure limit on an individually named NHS Foundation Trust for a defined period.
2. Subsection (3) and (4) places a duty on NHS England to consult with the Foundation Trust before the order is made and requires NHS England to publish the order so that is in the public domain.
3. Subsection (5) imposes a statutory duty on the NHS Foundation Trust not to exceed the capital expenditure limit as specified in the order.
4. Subsection (6) defined capital expenditure in line with how capital is reported in the Foundation Trusts annual accounts. Capital expenditure being that expenditure which falls to be capitalised in its annual accounts. This will cover assets with a life of greater than 1 year such as acquiring, or upgrading property, technology, or equipment.

475 Section 42C(1) requires NHS England to produce guidance on the use of its power to make orders, and subsection (2) requires NHS England to consult with the Secretary of State before publication of such guidance. The guidance will set out information about the circumstances in which NHS England is likely to make an order to set a capital expenditure limit for a Foundation Trust and how it will establish the limit.

476 Section 42C(3) requires NHS England to have regard to their own guidance when deciding whether to issue any orders to limit capital expenditure by Foundation Trusts.

477 Clause 52(3) provides that order made by NHS England under section 42B will not be a statutory instrument.

Clause 53: Accounts, annual reports, and forward plans

478 Clause 53 amends section 43 of and paragraph 27 of Schedule 7 to the NHS Act 2006 and sections 155 and 156 of the 2012 Act.

479 The amendments at subsection (1) and (2) means that Foundation Trusts will send their forward plans to NHS England, which have previously been sent to Monitor.

480 Section 155 of the 2012 Act contains a number of prospective amendments to paragraphs 24 and 25 of Schedule 7 to the NHS Act 2006. Those prospective amendments aim to substitute the regulator for the Secretary of State in relation to directions to Foundation Trust as to form and content of their accounts. To allow for greater flexibility on how accounts are to be prepared, those provisions are repealed through subsection (2)(a). As a consequence of the need for greater flexibility in the preparation of accounts, sections 43(3B) and (3C) of the NHS Act 2006, which contain provisions relating to the content of Foundations Trust's forward plan, and paragraphs 27(2) and (3) of Schedule 7 to the NHS Act 2006, which contains further provisions relating to a Foundation Trust's forward plan, are to be repealed through clause 53(1).

Clause 54: NHS foundation trusts: joint exercise of functions

481 Clause 54 adds in a new section 47A into the NHS Act 2006 and allows NHS foundation trusts to carry out its functions jointly with another person, should the NHS foundation trust consider such arrangements to be appropriate.

Clause 55: NHS foundation trusts: mergers, acquisitions and separations

482 Clause 55 amends Section 56 (mergers), 56A (Acquisitions) and 56B (Separations), of the NHS Act 2006.

483 Subsection (2) amends section 56(2) to remove the previous requirement that an application to merge a Foundation Trust with another Foundation Trust or an NHS

Trust established under section 25 of the NHS Act 2006, must be supported by the Secretary of State where one of the parties is an NHS Trust.

484 The amendment to section 56(4) places a duty on NHS England to grant the application if it is satisfied that necessary steps have been taken to prepare for dissolution and the establishment of the new trust and the Secretary of State approves the grant of the application.

485 Subsection (2) amends section 56A(3) is amended to remove the previous requirement that an application to acquire a Foundation Trust or an NHS Trust established under section 25 of the NHS Act 2006, must be supported by the Secretary of State where one of the parties to be acquired is an NHS Trust.

486 Subsection (3) amends section 56A(4) places a duty on NHS England to grant the application if it is satisfied that necessary steps have been taken to prepare for acquisition and the Secretary of State approves the grant of the application.

487 Subsection (4) amends section 56B(4) (separations) places a duty on NHS England to grant the application if it is satisfied that necessary steps have been taken to prepare for the dissolution of the trust and the establishment of each of the proposed new trusts and the Secretary of State approves the grant of the application.

Clause 56: Transfers on dissolution on NHS foundation trusts

488 Clause 56 amends subsection 57A (3) and (4) of the NHS Act 2006 and inserts a subsection (5). The amendment to subsection 57A (3) removes the requirement for the grant of an application made by a Foundation Trust for dissolution to be based on the trust having no liabilities.

489 The amendment to subsection 57A(4) requires the order made by NHS England once the application for dissolution has been granted, to transfer, or provide for the transfer of, the property and liabilities (including criminal liabilities) to another Foundation Trusts, an NHS Trust established under section 25 of the NHS Act 2006, or the Secretary of State.

490 The inclusion of subsection 57A(5) imposes a duty on NHS England to include in the order a provision for the transfer of any employees of the dissolved Foundation Trust.

Clause 57: NHS foundation trusts: wider effect of decisions

491 This provision, which is to be inserted in the National Health Service Act 2006 as the new section 63A, sets out a new duty, which also applies to the other 'relevant bodies'. The 'relevant bodies' are integrated care boards (new section 14Z43), NHS England (new section 13N) and NHS Trusts in England (new section 26A), for NHS foundation trusts.

492 This duty has been described by DHSC operationally as the ‘triple aim’ duty.

493 Subsection (1) provides that foundation trusts will be under a duty, in making a decision about the carrying out of their functions, to have regard to all likely effects of their decisions on three areas: the health and well-being of the people of England (subsection (a)), the quality of services provided or arranged by relevant bodies (subsection (b)) and the efficiency and sustainability of resources used by the relevant bodies (subsection (c)).

494 The reference in the subsection to “all” likely effects means that NHS foundation trusts will have to consider, under subsections (b) and (c), the effects of the decision both on its own quality of services and resource use and those of other relevant bodies.

495 Subsection (2) excludes decisions relating to services provided to a particular individual (e.g. Individual clinical decisions or highly specialist commissioning decisions concerning an individual patient) from this duty.

496 Subsection (3) provides that foundation trusts must have regard to guidance on the discharge of this duty published by NHS England (13NB).

NHS Trusts and NHS Foundation Trusts: transfer schemes

Clause 58: Transfer schemes between trusts

497 Clause 58 inserts section 69A after section 69 in the National Health Service Act 2006.

498 Section 69A, subsection 1 allows for NHS England to make one or more schemes to transfer property, rights and liabilities from a relevant NHS body to another relevant NHS body. A relevant body is defined in subsection 8.

499 Subsection (2) states that the application for a transfer scheme must be made jointly by the relevant NHS bodies, and state the property, rights and or liabilities which the NHS bodies wish to transfer.

500 Subsection (3) allows NHS England to grant an application for a transfer scheme when it is satisfied that any steps it considers necessary have been taken. This could include NHS England carrying out a review of the transfer and requiring the relevant NHS bodies to make a compelling case for such transfers (for example, patient benefits or value for money).

501 Subsection (4) sets out what may be included in a transfer scheme, such as property, rights, liabilities and criminal liabilities.

502 Subsection (5) sets out what can be provided to the transferee as part of the transfer scheme, any continued role of the transferor and the scope of the transfer scheme

generally (for example enabling the transfer scheme to make provisions for shared ownership or use of property).

503 Subsection (6) allows for a transfer scheme to be modified, and for those modifications to have effect from when the transfer scheme originally came into effect.

504 Subsection (7)(a) defines rights and liabilities to include rights and liabilities in relation to employment contracts.

505 Subsection (7)(b) defines property to include grant of a lease.

506 Subsection (8) defines a relevant NHS body as an NHS Trust or an NHS foundation trust. It also defines TUPE regulations as the Transfer of Undertakings (Protection of Employment) Regulations 2006.

Clause 59: Trust special administrators

507 Clause 59 introduces Schedule 8 of the Bill which amends Chapter 5A of the NHS Act 2006 (trust special administrators: NHS trusts and NHS foundation trusts). Schedule 8 outlines the changes to the process and authorisation for the appointment of Trust Special Administrators, including the reporting mechanisms.

Schedule 8: Trust special administrators: NHS trusts and NHS foundation trusts

508 Schedule 8 outlines the changes to the process and authorisation for the appointment of Trust Special Administrators, including the reporting mechanisms, amending the following sections of Chapter 5A, 'Trust Special Administrators: NHS Trusts and NHS Foundation Trusts' of the NHS Act 2006 as follows.

509 Paragraph 2 of the schedule amends section 65B – NHS trusts: appointment of trust special administrator to change the appointment process of a trust special administrator to exercise the functions of the chair and directors of an NHS trust. The duty had been on the Secretary of State to appoint a trust special administrator, who in turn directed the TDA to exercise that function under the 2016 Directions. The appointment of the trust special administrator is now to be done by NHS England (section 65B (1)).

510 Under subsection (2)(a) of the new 65B, NHS England must appoint a trusts special administrator if required to do so by the Care Quality Commission (CQC). Otherwise, under subsection 65B(2)(b), it can only make the order to appoint if it considers it to be in the interest of the health service and the Secretary of State has approved the order.

511 Under subsections (3) and (4) of the new 65B, the CQC may require NHS England to make an order under section 65B(1) if it is satisfied that there is a serious failure by the NHS trust to provide services that are of sufficient quality to be provided under the NHS Act 2006 but before doing so it must consult the Secretary of State and NHS

England and then the trust and any other person to which the trust provides goods or services under the NHS Act 2006 and anyone else the CQC considers it should consult.

512 Section 65B(1) and (2)(b) also allows for NHS England to make an order if it considers necessary in the interests of the Health Service, and this recommendation is approved by Secretary of State. In a case where NHS England is not required by the CQC to make an order to appoint a trust special administrator and it is considering making an order under section 65B(2)(b), before making the order NHS England must consult the trust, the CQC and any other person to which the trust provides goods or services under the NHS Act 2006 and which NHS England considers it appropriate to consult (section 65B(5)).

513 Subsection (6) and (7) of the new section 65B state that, in making an order to appoint a trust special administrator, NHS England must specify the date which the appointment is to take effect and must lay before Parliament a report stating the reasons for making an order.

514 Subsections (8), (9) and (10) of new section 65B outline the terms in which a trust special administrator appointment is made, and the conditions placed on the trust special administrator which are as follows.

- Subsections 8(a) and (b) – NHS England must appoint the person who is to be the trust special administrator from a day that is set out in the order.
- Subsection (9) – the appointed trust special administrator holds and vacates office in accordance with terms of appointment
- subsection (10) – NHS England may make provision as to pay remuneration and expenses.

515 Section 65BA - Care Quality Commission report on safety and quality of services places a duty on CQC to provide to NHS England and the Secretary of State a report on the safety and quality of the services provided by the NHS trust which is to be subject to the trust special administrator order that NHS England has been required by the CQC to make.

516 Paragraph 3 of the schedule amends Section 65D, 'NHS foundation trusts: appointment of trust special administrator' by replacing the name of the regulator, which was formerly Monitor, to NHS England who is now responsible for appointing a trust special administrator for Foundation Trusts and the actions involved in appointing a trust special administrator, which previously sat with Monitor. Other than changing the reference from "the regulator" to "NHS England", the only other amendments to section

65D is the removal of the requirement to indemnify a trust special administrator. This has been replaced with a provision allowing NHS England to pay remuneration and expenses, which replicates the provision in relation to NHS trusts.

517 Paragraph 4 of the schedule amends section 65DA, 'Objective of trust special administration'. The references to the regulator are amended and replaced with NHS England who now takes on that regulator role. No other amendments are made to this section.

518 Paragraph 5 of the schedule amends section 65F, 'Draft Report' replacing the requirement of the Trust Special Administrator to provide a draft report to the Secretary of State with one to provide a draft report to both the Secretary of State and NHS England if the report is in relation to an NHS trust. In the case of a foundation trust, the draft report is now to be provided to NHS England, having previously been provided to Monitor, the regulator. The draft report is to contain recommended action which, in the case of a NHS trust, is to be taken by NHS England or the Secretary of State and in the case of a foundation trust, is to be taken by NHS England and the draft is to be published (section 65F(1) and section 65F(1A)).

519 In a situation where the trust special administrator has:

- not obtained statements from each commissioner of NHS services (apart from NHS England),
- the draft report would achieve the trust special administrator objectives under section 65DA(1)(a) and would do so without harming essential services provided for the NHS by a trust that provides services under the NHS Act 2006,
- not obtained a statement from NHS England to that effect,

the trust special administrator may not provide the draft report in relation to a foundation trust (section 65(1B)(a) and (b)). The draft report also cannot be provided without having obtained a statement from the CQC that it considers that the recommendation would ensure that the service is of sufficient safety and quality to be provided under the NHS Act 2006 (section 65F(1C)).

520 When the trust special administrator is preparing the draft report it must consult those to whom the trust provides goods or services under the NHS Act 2006 and which NHS England direct the administrator should consult, and the CQC (section 65F(2)).

521 After NHS England has received the draft report in respect of an NHS trust or a foundation trust, it must lay the draft report before Parliament (section 65F(3)). It was previously for the Secretary of State to lay the draft before Parliament in respect of NHS

trusts and for Monitor as the regulator to lay the draft report before Parliament in relation to foundation trusts.

- 522 If NHS England decides not to provide the administrator with the statement under section 65F(1B)(b), it is required to give a notice of the reasons for its decision to the administrator, publish the notice and lay a copy of it before Parliament (section 65F(6)). Where the CQC decides not to provide the administrator with a statement to the effect mentioned in section 65F(1C), it must give a notice of the reasons for its decisions to the administrator and NHS England, publish the notice and lay a copy of it before Parliament (section 65F(6A)).
- 523 Paragraph 6 of schedule 8 makes amendments to Section 65G, 'Consultation Plan', replacing the references to the regulator to NHS England and including amended or new provisions for NHS England and CQC.
- 524 Section 65G(5) is replaced by the insertion of a new section which amends the name of 'The Board' to NHS England with the substance of that provision remaining unchanged.
- 525 A new section 5A is inserted which amends the requirements placed on the CQC where it decides not to provide a statement to the effect mentioned in subsection (4A) as the CQC is required to give notice of its reasons for that decision not only to the administrator, but now also to NHS England. That notice continues to be published and laid before Parliament.
- 526 Paragraph 7 of schedule 8 makes amendments to section 65H, 'Consultation requirements'.
- 527 Section 65H(7) and (8) which deal with persons to whom the trust special administrator must seek written responses from to the draft report, are now amalgamated in light of the earlier repeals of certain provisions. In addition, "the Board" is removed as a body from whom a written response should be sought, and NHS England may now direct the administrator to hold a meeting with any person and seek their responses (section 65H(9A)).
- 528 Section 65H(10) and (10A) has been replaced by a new section 65H(10) so that the Secretary of State may now direct NHS England as the new regulator, as to the persons from whom it should direct the administrator to request a written a response and seek a response.

- 529 As NHS England will be responsible for appointing a Trust Special Administrator for both NHS Trusts and Foundation Trust, section 65H (13) have been repealed as this is dealt with in new section 65H(10).
- 530 Paragraph 8 of schedule 8 makes amendments to section 65I, 'Final Report' to include a requirement of the Trust Special Administrator to report to NHS England as well as the Secretary of State with respect NHS Trusts.
- 531 The amendments require the trust special administrator to provide its final report with the recommended actions to NHS England and the Secretary of State in relation to an NHS trust, and to NHS England in the case of a foundation. The period for receipt of the report remains unchanged (section 65I(1) and (1A)).
- 532 Subsection (3) is amended to place a duty on NHS England rather than Secretary of State to lay the final report in parliament.
- 533 Paragraph 9 of schedule 8 makes amendments to section 65J, 'Power to extend times' to reflect the inclusion of new subsection 65I(1A) and the change in approval for an extension to be granted now resting with NHS England not the Secretary of State (section 65J(2)).
- 534 Section 65J(5) is repealed as NHS England regulates both NHS Trusts and Foundation Trusts.
- 535 Paragraphs 10 and 11 of schedule 8 substitutes a new section 65K, 'Decision of NHS England or Secretary of State in case of NHS trust'. In relation to NHS trusts, both NHS England and the Secretary of State are to receive the administrators final report which will state which action, if any, either are to take. The Secretary of State and NHS England are required to consult each other before taking any decision to take action in relation to a trust. After a decision has been taking to take action, that party taking the action must publish a notice of the decision and reason for it and lay a copy of the notice before Parliament as soon as reasonably practicable.
- 536 As a consequence, section 65K is replaced, placing a shared duty on NHS England and Secretary of State to consult on the recommendations of the report from the administrator and the action which it to be taken and publish a notice of the decision and lay this before Parliament.
- 537 This aligns to the provision that NHS England is now responsible for the appointment of Trust Special Administrator's.
- 538 Paragraph 12 of schedule 8 amends section 65KA by changing the name 'regulator' to 'NHS England'. Section 65KB - Secretary of State's response to regulator's decision
- 539 Paragraph 13 of schedule 8 amends section 65KB by replacing the reference to 'the regulator' to 'NHS England'.

- 540 Paragraph 14 of schedule 8 amends section 65KC by replacing reference to ‘the regulator’ with ‘NHS England’.
- 541 Paragraph 15 of schedule 8 amends section 65KD, Secretary of State’s response to resubmitted report’. If the Secretary of State is not satisfied with the final report and publishes a notice to say that an integrated care board has failed to discharge a function, the integrated care board is to be treated as having failed to discharge the function allowing the Secretary of State to exercise NHS England’s power of direction over integrated care board’s in section 14Z58 of the NHS Act 2006 whilst prohibiting NHS England from exercising that functions (section 65KD(5)).
- 542 The provision dealing with CCGs has been replaced by the integrated care board provision in section 65KD(5).
- 543 The provisions allowing the Secretary of State to exercise the Board’s functions if the notice stated that it was the Board who had failed to discharge its functions, has been repealed as the Secretary of State’s new power of direction over NHS England in clause 36 can achieve the same effect.
- 544 The provisions allowing the Secretary of State to exercise functions of Monitor if the notice stated that the trust special administrator or Monitor had failed to discharge their duties have been repealed now that NHS England replaces Monitor as the regulator and the Secretary of State’s new power of direction can achieve the same effect.
- 545 Paragraph 16 of schedule 8 makes amendments to section 65L, ‘Trusts coming out of administration’.
- 546 In relation to NHS trusts, if both the Secretary of State and NHS England decide not to dissolve a trust, NHS England must make an order specifying the date when the appointment of the trust special administrator and the suspension of the chair and directors of the trust come to an end (section 65L(1) and (2)).
- 547 In relation to an foundation trust, if the Secretary of State decides under section 65KD(9) not to dissolve the trust or decides they are satisfied under section 65KB(1) or 65KD(1) in respect of the matters stated within those provisions, and the action recommended in the final report is not to dissolve the trust, then the Secretary of State can make an order bringing the appointment of the trust special administrator and the suspension of the chair and directors of the trust, to an end (section 65L(2A) and (2B)).

548 Paragraph 17 of schedule 8 amends section 65LA 'Trusts to be dissolved', replacing in the reference to 'the regulator' to 'NHS England' at subsection (3).

549 Paragraph 18 of schedule 8 amends section 65M, 'Replacement of trust special administrator' to provide that NHS England, not the Secretary of State, is responsible for appointing a replacement administrator.

550 Section 65M(3) is repealed in light of the fact that NHS England is the regulator for both NHS Trusts and Foundation Trusts.

551 Paragraph 19 of schedule 8 amends section 65N 'Guidance' by placing the duty on NHS England, instead of the Secretary of State, to publish guidance for trust special administrators. Section 65N(4) is repealed in light of the fact that NHS England is the regulator for both NHS Trusts and Foundation Trusts.

552 Paragraph 20 of schedule 8 makes consequential amendments to section 65O, 'Interpretation of Chapter'.

553 Paragraph 21 makes consequential amendments to section 272 (orders, regulations, rules and directions).

Joint Working and Delegation of Functions

Clause 60: Joint working and delegation arrangements

554 This clause inserts new provisions into the NHS Act 2006.

555 *Section 65Z5 Joint working and delegation arrangements.* Under subsection (1), any of the bodies set out or prescribed under subsection (2) may arrange for one of its functions to be exercised by or jointly with one of the other bodies under subsection (2), or a local authority, or a combined authority. This includes functions that have already been delegated to a relevant body under this section. Regulations made under subsection (2)(e) may detail which other bodies can become a relevant body and be party to the arrangements under subsection (1) and (2). It will also be possible to state in regulations under subsection (3) which functions are not subject to the power at subsection (1) or where certain conditions should apply to the exercise of the power at subsection (1). Under subsection (4), powers under this section may be exercised on such terms as may be agreed, including terms of payment as well as terms prohibiting or restricting the further onward delegation of a function that has already been delegated. Under subsection (6), a body to which a function has been delegated will acquire the rights and

liabilities that arise or may arise from the exercise of that function, and these rights and liabilities are enforceable by or against that body only.

556 *Section 65Z6 Joint committees and pooled funds.* This clause applies where a body listed under section 65Z5(2) has agreed to jointly exercise a function with another body listed or prescribed under section 65Z5(2), or a local authority, or a combined authority. Under subsection (2), the parties jointly exercising the function may set up a joint committee in order to exercise the function. Under subsection (3), the parties jointly exercising the function may also establish and maintain a pooled fund in order to exercise the function. A pooled fund is defined as a fund to which the parties jointly exercising the function have contributed and out of which payments can be made in the exercise of functions under the arrangements. Under subsection (4), the parties jointly exercising the function may agree between themselves the terms of their respective liabilities in relation to the joint exercise of the function. The intention is to issue guidance under section 65Z7 about how joint committee arrangements could be administered and how liability arrangements could be decided. Regulations made under section 65Z5(3) may also impose conditions on what functions can be placed in a joint committee and how it should operate.

557 *Section 65Z7 Joint working and delegation: guidance by NHS England.* Under subsection (1), NHS England can issue guidance concerning the joint working and delegation arrangements set out under sections 65Z5 and 65Z6. Under subsection (2), all bodies listed under section 65Z5(2) must have regard to that guidance.

558 Under subsection (3), section 75 of the NHS Act 2006, which details arrangements between NHS bodies and local authorities, is amended so that where a combined authority is exercising an NHS function as part of the arrangements under section 65Z5 or 65Z6, it can be treated as an NHS body.

[Clause 61: References to functions: treatment delegation arrangements etc.](#)

559 This clause inserts a new section 275A into the NHS Act 2006. It is intended to produce a more consistent approach to the way in which functions are referred to in that Act.

560 The starting point is that a general reference to a person's functions is capable of covering functions delegated to the person, although there may be something about the legislative context to indicate that this is not the intention in relation to a particular reference.

561 The NHS Act 2006 does not take an entirely consistent approach in relation to delegated functions. In some places where a function can be delegated to another, express provision is made to the effect that a reference elsewhere to the recipient's functions includes a reference to the delegated function so far as exercisable by them (see, for

example, section 13Z4(2) and 14Z24(2)). In other places this is not spelt out. The contrast is potentially unhelpful and new section 275A seeks to address this issue.

562 There are some provisions within the NHS Act 2006 where the starting point explained above would not produce the desired policy result because (for example) a reference to the functions of NHS England should not, as a matter of policy include a reference to public health functions delegated to it by the Secretary of State under section 7A. To deal with this kind of case, new section 275A(2) confers a power to specify places where a reference to a person's functions do not include delegated functions. Given the need for a power to create exceptions, it seems helpful to articulate the starting point expressly for the purposes of the whole Act rather than leaving it to implication: see new section 275A(1).

563 It is not feasible to tackle these issues expressly across all health legislation and in any event they have arisen in the NHS Act 2006 primarily due to the inconsistent approach that has been taken in previous amendments to the Act. In relation to other legislation that, for example, refers to the functions of NHS England or an integrated care board it is still proposed to rely on the general starting point explained above, which one may expect to apply unless the context suggests otherwise.

564 However, there are a few places outside the NHS Act 2006 where it is thought that silence may give rise to genuine doubt as to what is intended, so those have been dealt with expressly. Examples are where express provision has been made previously (in section 13Z4(3) of the NHS Act 2006 or in other Acts) and it is considered necessary to continue that approach to avoid confusion. See, for example, the amendments to sections 197 and 250 of the Health and Social Care Act 2006.

[Schedule 9: References to functions: treatment of delegation arrangements etc](#)

565 This Schedule makes amendments to various enactments as a result of the insertion into the NHS Act 2006 of new section 7B (clause 35), new section 65Z5 (clause 60) and new section 275A (clause 61).

566 New sections 7B and 65Z5 create additional ways in which the functions of one person or body may be exercised by another. New section 7B enables the Secretary of State to direct NHS England or an integrated care board to exercise the Secretary of State's public health functions, and new section 65Z5 enables a variety of bodies to arrange for another body to exercise their functions either for them, or jointly with them. These new provisions add to the existing power for the Secretary of State to make arrangements under section 7A for NHS England, a CCG or a local authority to exercise the Secretary of State's public health functions ("section 7A arrangements"), and the existing power in section 75 for local authorities and NHS bodies to work jointly ("section 75 arrangements"). Finally, new section 275A makes express for the NHS Act 2006 the assumption that a general

reference in the Act to a person's functions is capable of covering functions delegated to the person.

567 This means that there is a need to revisit the provisions in the NHS Act 2006 and other primary legislation which state expressly that a reference to the functions of NHS England or an integrated care board include the exercise of public health functions of the Secretary of State delegated under section 7A arrangements. The new sections also affect provisions in the NHS Act 2006 and other legislation which include in a description of the public health functions of a local authority those functions which the local authority is exercising pursuant to section 7A arrangements.

568 The amendments to descriptions of the functions of NHS England and integrated care boards in the NHS Act 2006 therefore generally adopt a broader approach, in reliance on new section 275A. The amendments include references to arrangements made "by virtue of" the NHS Act 2006, as opposed to "under" it, to reflect the fact that functions may have been delegated in one or more of the ways described above. The amendments to sections 73A – 73C, which deal with local authority public health functions, ensure that the public health functions of the Secretary of State which are being exercised by an authority pursuant to the delegation or sharing arrangements in sections 65Z5 or 75 are captured.

569 The amendments to other primary legislation in this Schedule are generally intended to take a similarly broad approach to a description of the functions of NHS England or an integrated care board under the NHS Act 2006, or to services arranged pursuant to such functions. The substituted wording is intended to reflect the range of ways in which those bodies could be exercising functions on behalf of another. However, in certain cases it has been necessary or appropriate to make a specific reference to the routes by which functions may be delegated. See for example section 26 of the Local Government Act 1974, where the functions of the authority which may be subject to investigation by the local commissioner are expressed as including those public health functions of the Secretary of State which the authority may be exercising in pursuance of section 7A, 65Z5 or 75 arrangements.

570 The amendment made to the Local Government and Public Involvement in Health Act 2007 is driven by the repeal of sections 13Z4(2) and (3) and 14Z24(2) and (3), and the new approach to functions in section 275A of the NHS Act 2006. It applies section 275A to sections 116 to 116B of the 2007 Act. Those sections deal with joint strategic needs assessments, which can include health needs that could be met through the exercise of the functions of NHS ENGLAND and integrated care boards, and the amendment ensures that such functions would include delegated functions.

Collaborative Working

Clause 62: Repeal of duties to promote autonomy

571 Clause 62 amends the NHS Act 2006 by removing the Secretary of State and NHS England's duties to promote autonomy.

572 NHS England will continue to function as an arm's length body, but the removal of this duty is to allow for the introduction of clause 37 which gives the Secretary of State the ability to direct NHS England in regard to the exercise of their functions. The Secretary of State, when considering whether to place requirements on NHS England, will have to make a judgement as to whether these were in the interests of the public. The rationale for removing these duties is to 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.

Clause 63: Guidance about joint appointments

573 This clause inserts a new section 13UA into the NHS Act 2006. Subsections (1) and (2) give NHS England the ability to issue guidance concerning joint appointments between relevant NHS commissioners; relevant NHS commissioners and local authorities; and relevant NHS commissioners and Combined Authorities. In this section references to NHS bodies means NHS England, integrated care boards, NHS trusts and NHS foundation trusts. This will ensure that there is a clear set of criteria for organisations to consider when making joint appointments. Under subsection (3), NHS bodies are required to have regard to the guidance. Under subsection (4), ahead of publishing or revising any guidance, NHS England is required to consult with appropriate organisations.

Clause 64: Co-operation by NHS bodies etc

574 Clause 64 amends sections 72 and 82 of the NHS Act 2006 and section 96 of the 2012 Act.

575 Section 72 of the NHS Act 2006 is a duty imposed on NHS bodies, including some Welsh NHS bodies, to co-operate with each other. Clause 64 section (2) inserts a new power into section 72 of the NHS Act 2006 for the Secretary of State to make guidance on how this duty is discharged. It also imposes a duty on NHS bodies, except for Welsh NHS bodies, to have regard to this guidance.

576 Section 82 of the NHS Act 2006 is a duty imposed on NHS bodies and local authorities (including Welsh NHS bodies and Welsh local authorities) to co-operate with one another in order to advance the health and welfare of the people of England and Wales. Clause 64 section (3) inserts a new power for the Secretary of State to make guidance related to England. It also imposes a duty on NHS bodies and local authorities, except for Welsh NHS bodies and Welsh local authorities, to have regard to this guidance.

577 Section 96 of the 2012 Act specifies the purposes for which Monitor can set or modify licensing conditions of NHS health service providers. Section 96(2)(g) and section 96(3) of the 2012 Act allow the licence conditions to be modified if the purpose of modification is to enable co-operation between providers where that achieves one or more of the objectives of: (a) improving the quality of health care services for the NHS or the efficiency of their provision; (b) reducing inequalities in people's ability to access those services; and (c) reducing inequalities in the outcomes people achieve in the provision of those services.

578 Section (4)(a) amends section 96(2)(g) and section 96(3) so that the section 96(2)(g) purpose of enabling co-operation between providers of health care services no longer needs to be dependent upon achieving the objectives in (a), (b) or (c) before it can be considered as a basis for modifying the licence conditions. This does not mean that the licence cannot be modified to achieve the objectives set out in (a), (b), and (c), but means that modification of the licence under section 96(2)(g) is no longer conditional on achieving those objectives.

579 Section (4)(a) also expands section 96(2)(g) so that licence conditions can be modified to enable, promote and secure co-operation not just amongst NHS health service providers, but also between NHS bodies as defined in section 72 of the NHS Act 2006 and local authorities.

Clause 65: Wider Effect of decisions: licensing of health care providers

580 Section 96(2) of the 2012 Act specifies the purposes for which Monitor (which this Bill proposes to merge with NHS England) may set or modify the conditions contained in the licences which any provider of health care services for the purposes of the NHS must hold. In light of the creation of the 'triple aim' duty for NHS England, ICBs, NHS Foundation Trusts and NHS Trusts, a new purpose for which licence conditions may be set or modified is being created.

581 This provision will insert new subsection (da) into subsection 96(2). Subsection (da) creates a further purpose for which to NHS England may set conditions, namely that of ensuring that decisions are made with regard to all of their likely effects on the three factors which are included in the new "duty to have regard to the effect of decisions" new sections 14Z4, 13NA, 26A and 63A being inserted into the National Health Service Act 2006.

582 The new subsection (2A) provides the list of factors referred to at the new subsection (da), which are the same as the factors in the new sections 14Z4, 13NA, 26A and 63A being inserted into the NHS Act 2006. Subsection (2B) defines the reference to "relevant bodies" in subsection (2A).

NHS Payment Scheme

Clause 66: The NHS payment scheme

583 Clause 66 inserts schedule 10 and replaces the national tariff with the NHS payment scheme and makes provisions relating to the NHS payment scheme.

Schedule 10: The NHS payment scheme

584 Paragraph 1 of schedule 10 introduces the amendments made to the national tariff provisions in the 2012 Act as they relate to the NHS payment scheme.

585 Paragraph 2 of schedule 10 changes the name of the national tariff to the NHS payment scheme in section 97 of the 2012 Act which deals with conditions of licences for health care service providers.

586 Paragraph 3 of schedule 10 replaces part 3, chapter 4 with a new sections 114A to 114F to make provision about the NHS Payment Scheme.

587 New section 114A subsection (1) places a duty on NHS England to publish a document which contains rules for determining the price payable by a commissioner for health care services provided for the NHS and for the services that are provided through arrangements made by NHS England or an ICB under the Secretary of State's public health functions under section 7A or 7B NHS Act 2006.

588 Subsection (2) places duties on the commissioners and providers of services mentioned in subsection 1, to comply with rules made under that subsection.

589 Subsection (3) sets out what rules may do and what they may specify. For example, this could include specifying prices or formulae used to specify prices; or the rules may confer a discretion on the commissioner of a service or on NHS England.

590 Subsections (4) and (5) allow the rules to require prices to be agreed between commissioners and providers of a service, to set out how they are to be agreed and whether they are to be published.

591 Subsection (6) retains in substance the provision formerly in section 119(1) which seeks to secure that the prices payable for the provision of services within the scope of the NHS payment scheme result in a fair level of payment for providers of those services.

592 Subsection (7) retains in substance the provision formerly in section 116(4)(c), which allows the NHS payment scheme to make rules about making payments to providers in relation to the service being provided.

593 Subsection (8) allows the NHS payment scheme to contain guidance on the application

- of the rules and a commissioner is required to have regard to that guidance under subsection (9).
- 594 Subsection (10) in substance replicates what was formerly in section 116(12) with respect to the period when the NHS payment scheme has effect.
- 595 Section 114B retains in substance what was formerly in section 117(5) with NHS England now being the body to enforce compliance with the rules contained in the NHS payment scheme.
- 596 Section 114C sets out NHS England's duty to carry out an impact assessment or publish a statement if it concludes that is not needed, before publishing the NHS payment scheme. If NHS England does intend to publish the NHS payment scheme it must consult relevant integrated care boards, providers and other persons who NHS England considers appropriate, before publication. Section 114C(3) to (8) sets out the consultation process. This section draws on what was formerly section 69 (duty to carry out impact assessments) and section 118 (consultation on proposals for the national tariff).
- 597 Section 114D replaces what was formerly section 120 and deals with objections to the proposed NHS payment scheme during the consultation period. The objection process relates to integrated care boards as they have replaced CCGs. Whilst the criteria for the number of objections received before action is taken has not materially changed, (section 114D(1)(b)), the effect of the criteria being met has changed in that NHS England is required to consult persons who appear to be representatives of the integrated care boards or other relevant providers who objected. After that point, if NHS England decide to make significant amendments and consider it would be unfair to make the amendments without further consultation, NHS England must reconsult on the revised NHS payment scheme (section 114D(4)).
- 598 Should NHS England decide not to amend the NHS payment scheme following objections, it may publish the scheme but must publish a notice to explain their decision, and share it with integrated care boards and relevant providers who objected to the proposed scheme (section 114D(5)).
- 599 New section 114E subsection 1, allows NHS England to revise the payment scheme during the period for which it operates. NHS England must be satisfied that any revisions are not significant enough to require the publication of a new NHS payment scheme.
- 600 When deciding whether to revise the NHS payment scheme, or publish a new one, NHS England must have regard to: the proportion of integrated care boards or relevant

providers that would be affected; the impact of such revisions on integrated care boards and relevant providers; whether any integrated care boards or relevant providers would be disproportionately affected; and the amount of any increase or decrease in payments resulting from the revisions (section 114E(2)).

601 Subsection (3) places duties on NHS England to publish the NHS payment scheme as amended.

602 Subsection (4) requires NHS England to consult with integrated care boards, relevant providers and any other appropriate persons about amendments to the NHS payment scheme before making the amendments.

603 Subsection (5) requires NHS England to publish a notice specifying the proposed amendments and the period for which the consultation period will operate. The consultation period is defined in subsection 6 as 28 days from the day after which the notice is published. Under subsection 7, NHS England must share the notice with ICB's, relevant providers and any other appropriate persons.

Patient Choice and Provider Selection

Clause 67: Regulations as to patient choice

604 Clause 67 amends the NHS Act 2006 to insert provisions relating to patient choice.

605 Subsection (2) amends the existing section 6E in relation to standing rules. The existing power to issue regulations under this section is changed from a 'may' to a 'must'. This means that these regulations must contain provisions about how NHS England and integrated care boards will allow patients to make choices about their care. They also allow for provisions on steps NHS England and integrated care boards must take to protect and promote the rights of people to make choices where those rights arise from these regulations or are described in the NHS constitution. The existing subsection (2)(c) is removed as it has been replaced by these new provisions.

606 Subsection (3) inserts a new section 6F that provides an enforcement mechanism for NHS England to enforce the patient choice requirements made under 6E. Under 6F(1) NHS England may investigate an integrated care board on their compliance with the regulations in 6E and, under 6F(2) may issue directions to prevent, remedy, or mitigate the effects of failures. 6F(3) provides that, during, or following, an investigating, NHS England may accept an undertaking from the integrated care board for it to take actions regarding the actual or likely failure to comply. If NHS England accepts an undertaking it may, by virtue of 6F(4), not continue to investigate or issue directions relating to the area of the undertaking, unless the integrated care board fails to comply with the

undertaking. 6F(5) requires NHS England to take partial compliance into account. 6F(6) gives effect to Schedule 1ZA adds further detail on undertakings.

607 Subsection (3) inserts the new section 6G. 6G(1) requires NHS England to publish guidance on how it intends to exercise its power to investigate, direct on, and accept undertaking about patient choice from the new 6F and Schedule 1ZA. 6G(2) requires NHS England to consult people they feel it is appropriate to consult before publishing guidance or making significant revisions. 6G(3) requires NHS England to obtain Secretary of State approval before publishing this guidance. Guidance on how integrated care boards can comply with their requirements for patient choice can be issued by NHS England under the guidance making power contained in the new section 14Z49. Integrated care boards must have regard to this guidance.

608 Subsection (4) amends the existing provision on NHS England's annual report to include the patient choice regulations added by this section and the existing duty to enable patient choice.

609 Subsection (5) gives effect to the new Schedule 1ZA.

Schedule 11: Patient choice: undertakings by integrated care boards

610 This schedule contains further details about the procedure of undertakings under 6F.

611 Paragraph (2) outlines a requirement for NHS England to publish a procedure for entering undertakings and allowed to revise this and republish it. Both revision and initial publication require NHS England to consult those they think appropriate to consult.

612 Paragraph (3) describes that, on accepting an undertaking, NHS England must publish it but remove commercial information that would harm business interests or information related to a person's private affairs that would harm their interests.

613 Paragraph (4) allows the undertaking to be varied by mutual agreement.

614 Paragraph (5) relates to compliance certificates. When NHS England is satisfied that an undertaking has been complied with they must issue a 'compliance certificate'. An integrated care board that is given an undertaking may apply to NHS England at any time for a compliance certification with the information and in a manner that NHS England requires. NHS England must decide, and notify the applicant, within 14 days following after receiving the application.

615 Paragraph (6) outlines an appeal process. An integrated care board that has had an application refused can be appealed to the First-tier Tribunal on the grounds that the decision is based on an error of fact, is wrong in law, or is unfair or unreasonable. The Tribunal may confirm the decision or rule that it has no effect.

616 Paragraph (7) describes that, when NHS England considers that an integrated care board has supplied inaccurate, misleading, or incorrect information it can treat it as a failure to comply. If it does so, it must revoke any compliance certificates given to that integrated care board.

Clause 68: Procurement regulations

617 Clause 68 inserts a new section 12ZB into the NHS Act 2006, after section 12ZA.

618 Subsection 12ZB(1) enables the Secretary of State to make regulations which will apply to relevant authorities in relation to the procurement of health care services for the purposes of the health service in England and the procurement of health care services as part of mixed procurements e.g. with social care services. The term procurement relates to the overall process that commissioners must follow when arranging health care services, the selection of providers to provide those services.

619 Subsection 12ZB(2) specifies that the regulations may include requirements around the general aims of procurement, and the processes that must be followed.

620 Subsection 12ZB(3) outlines that the regulations may also include requirements relating to transparency and fairness, verifying compliance, and managing conflicts of interests.

621 Subsection 12ZB(4) permits NHS England to publish guidance that will set out how relevant authorities can comply with the requirements.

622 Subsection 12ZB(5) places a requirement on the relevant authorities to have regard to the published guidance.

623 Subsection 12ZB(6) requires NHS England to obtain the approval of the Secretary of State before publishing guidance.

624 Subsection 12ZB(7) specifies the meaning of “relevant authority” in this section (a combined authority, an Integrated Care Board, a local authority in England, NHS England, an NHS foundation trust, an NHS trust established under section 25); and the meaning of “health care service” as the definition given in Part 3 of the 2012 Act, which is as all forms of health care provided for individuals, whether relating to physical or mental health.

Clause 69: Procurement and patient choice: consequential amendments etc

625 Clause 69, subsection (1) removes the reference to the existing regulation making powers on procurement, patient choice and competition from section 12E of the NHS Act 2006 (Secretary of State’s duty as respects variation in provision of health services) and replaces this with the new procurement regulations (12ZB).

626 Clause 69, subsection (2) removes the existing regulation making powers on procurement, patient choice and competition from the 2012 Act.

627 Clause 69, subsection (3) omits paragraph b in subsection 7 of Section 40 in the Small Business, Enterprise and Employment Act 2015 (investigation of procurement functions), which references the current regulations.

628 Clause 69, subsection (4) revokes the current regulations on procurement, patient choice and competition.

Competition

Clause 70: Duty to provide assistance to the CMA

629 Clause 70 inserts section 13SD to the NHS Act 2006.

630 Section 13SD, subsection (1) places NHS England under a duty to share regulatory information that the CMA may require, or which NHS England considers would assist the CMA, in exercising the CMA's relevant functions. It also requires NHS England to provide any other assistance which the CMA may require in exercising its relevant functions.

631 Section 13SD, subsection (2) defines regulatory information as information held by NHS England in relation to its functions under section 13SA(2)(a) or (b) of the NHS Act 2006 (which is being inserted by this Bill, and lists NHS England's regulatory functions) or its functions under provisions being inserted into the NHS Act 2006 by this Bill in relation to the enforcement of patient choice and the oversight and restructuring of NHS Trusts (the proposed new sections 6F, 6G, 27A and 27C of the NHS Act 2006).

632 Section 13SD, subsection (2) also defines the CMA's relevant functions as their functions under the Competition Act 1998 and the Enterprise Act 2002, where those functions are carried out by the CMA Board or a CMA group (within the meaning of Schedule 4 to the Enterprise and Regulatory Reform Act 2013).

Clause 71: Mergers of providers: removal of CMA powers

633 Clause 71 amends the NHS Act 2006 to insert Section 72A after Section 72.

634 Section 72A, subsection (1) exempts the merger of two or more relevant NHS enterprises from the merger control regime under part 3 of the Enterprise Act 2002. Mergers between an NHS enterprise and an enterprise which is not a relevant NHS enterprise (e.g. a private healthcare provider) are still in scope of the merger control regime.

635 Section 72A, subsection (3) defines relevant NHS enterprise as the activities, or part of the activities, of an NHS trust or NHS foundation trust.

636 Section 72A, subsection (2) clarifies that the merger of two or more relevant enterprises

(e.g NHS foundation trusts) with an enterprise which is not a relevant NHS enterprise (e.g, a private healthcare provider) is still in scope of the merger control regime.

637 Clause 71 also repeals section 79 of the 2012 Act, which specifies that mergers involving NHS foundation trusts do fall within the scope of the merger regime in part 3 of the Enterprise Act 2002.

638 NHS England, as the national regulator, will continue to review proposed transactions, including mergers or acquisitions, to ensure there are clear patient benefits.

Clause 72: Removal of functions relating to competition etc.

639 Clause 72 amends the 2012 Act to remove sections 72 and 73 of that Act. Sections 72 and 73 of the 2012 Act provide for Monitor's concurrent competition functions with the CMA.

640 Clause 72 also provides for Schedule 12, which contains consequential amendments.

Schedule 12: Removal of CMA functions relating to competition etc

641 Schedule 12 contains consequential amendments relating to the removal of CMA functions relating to competition. It amends the:

- Company Directors Disqualification Act 1986
- Competition Act 1998
- Health and Social Care Act 2012
- Enterprise and Regulatory Reform Act 2013
- Care Act 2014

Clause 73: Removal of CMA's involvement in licensing etc.

642 Clause 73 amends the 2012 Act regarding NHS licencing. The licence contains conditions for providers of NHS services, including NHS foundation trusts and other providers. All NHS foundation trusts and most other providers of NHS services (but not NHS trusts) must hold a provider licence.

643 Subsection (2) removes the need for Monitor (which is being merged into NHS England as part of this Bill), to obtain the consent of the applicant to include a special condition in the licence, or to obtain the consent of a licence holder before modifying a special condition of a licence.

644 Subsection (3) repeals subsections 6 to 9 of section 100 of the 2012 Act. These sections allow for licence holders to object to amendments to the standard licence conditions and apply certain conditions to Monitor in relation to those objections. It also removes references to section 101 in subsection 11 of section 100.

- 645 Subsection (4) repeals section 101 of the 2012 Act, which allows Monitor to refer contested licence conditions to the CMA.
- 646 Subsection (5) amends section 103, subsection 3 in the 2012 Act to refer to licencing powers being transferred from Monitor to NHS England and to take account of the repeal of section 101 and Schedule 10 of the 2012 Act.
- 647 Subsection (6) removes references to section 142 from section 141 of the 2012 Act. Section 142 is repealed by subsection (7).
- 648 Subsection (8) removes paragraphs (d) and (j) of section 304(5) of the 2012 Act, which reference the regulation-making powers in the repealed sections 100(7) and 142 of the 2012 Act.
- 649 Subsection (9) repeals Schedule 10 of the 2012 Act, which sets out the process for Monitor’s referrals to the CMA in relation to contested licence conditions or a contested levy, as the ability to refer to the CMA in these cases is being removed via the repeal of sections 100(6) to (9) and 142 of that Act.

Miscellaneous

Clause 74: Special Health Authorities: removal of 3 year limit

- 650 Clause 74 disapplies the existing legislative provisions that currently impose the three-year time limit on any new Special Health Authority.
- 651 Subsection (1) sets out that section (28A) in Chapter 4 of the NHS Act 2006, which was a new section inserted by the 2012 Act (section 48), is to be removed.
- 652 Subsection (2) sets out changes to the 2017 Statutory Instrument used to create the NHS CFA, to reflect there is no longer an abolition date.
- 653 Subsection (3) sets out that section 48 of the 2012 Act is to be removed.

Clause 75: Tidying up etc provisions about accounts of certain NHS bodies

- 654 Clause 75 sets out requirements for Special Health Authorities in relation to their accounts and auditing.
- 655 Subsection 75(1) inserts a new section 29A after section 29 of the NHS Act 2006.
- 656 Section 29A Subsection (1) defines a Special Health Authority for the purposes of this section as a Special Health Authority that performs functions only or mainly in respect of England, or neither performs functions only or mainly in respect of England, nor performs functions only or mainly in respect of Wales.
- 657 Subsection (2) requires special Health Authorities to keep proper accounts and records.

658 Subsection (3) gives the Secretary of State powers, with the approval of the Treasury, to give a direction to Special Health Authorities direction about the form of its accounts.

659 Subsections (4), (5), (6) and (7) place requirements on Special Health Authorities with respect to the preparation of those annual accounts, including a requirement to send copies of accounts to the Secretary of State and the Comptroller and Auditor General for examination and report, and a requirement to lay before Parliament a copy of those accounts and the report of the Comptroller and Auditor General.

660 Subsection 75(2) inserts paragraph 11 A into Schedule 4 of the National Health Service Act 2006.

661 Paragraph 11A makes requirements for NHS Trusts to keep proper accounts and proper records in relation to the accounts.

662 Paragraph 11A Subparagraph (1) requires NHS Trusts to keep proper accounts and records.

663 Subparagraph (2) gives the Secretary of State powers, with the approval of the Treasury, to give a direction to NHS Trusts direction about the form of its accounts.

664 Subparagraph (3) places requirements on NHS Trusts to prepare annual accounts in such form as the Secretary of State may direct with the approval of the Treasury.

665 Subparagraph (5) sets out the role of the Comptroller and Auditor General in examining and reporting on those accounts.

666 Subparagraph (6) requires an NHS Trust to send audited annual accounts to NHS England by such date as NHS England may direct.

667 Subsection 75(3) makes consequential amendments to the National Audit Act 1983, the National Health Service Act 2006, and the Local Electoral Administration and Registration Services (Scotland) Act 2006.

Clause 76: Repeal of spent powers to make transfer schemes

668 Clause 76 subsection (1) repeals the powers of the Secretary of State in the 2012 Act 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.

669 Subsection (2) substitutes a new version of section 302 of the 2012 Act. Section 302 allows for a further transfer scheme in relation to any property, rights or liabilities that have been transferred under a scheme under section 300(1) of the 2012 Act (before its repeal) from a Primary Care Trust, Strategic Health Authority or the Secretary of State to a Special Health Authority or a qualifying company.

670 Subsection (3) consequentially amends Schedule 1 to the Public Records Act 1958

Clause 77: Abolition of Local Education and Training Boards

671 Clause 77 abolishes Local Education and Training Boards (LETBs). It repeals sections 103 to 107 and Schedule 6 and amends sections 100, 108, 119 of, and Schedule 5 to the Care Act 2014.

672 Subsection (4) repeals sections 103 to 107 which set out the local functions of HEE carried out by LETBs.

673 The amendments set out in subsections (3), (5), (6) and (7) to Sections 100, 108 and 119 of, and Schedule 5 to, the Care Act 2014 make consequential amendments to remove references to LETBs.

Clause 78: Hospital Patients with care and support needs: repeals etc

674 Subsection 78(1) revokes section 74 of the Care Act 2014 and Schedule 3 to the Care Act 2014 in its entirety.

675 Schedule 3 to the Care Act 2014 deals with the planning of discharge of patients in England from NHS hospital care to local authority care and support. In revoking Schedule 3 to the Care Act 2014 in its entirety, subsection 78(1) repeals the procedural requirements within that Schedule, which require social care needs assessments to be carried out by the relevant local authority before a patient is discharged from hospital.

676 Further, in revoking Schedule 3 of the Care Act 2014 in its entirety, subsection 78(1) revokes the provisions which enable the responsible NHS body to charge the relevant local authority via a penalty notice, where a patient's discharge from hospital has been delayed due to a failure of the local authority to arrange for a social care needs assessment, after having received an assessment and discharge notice for an individual from the relevant NHS body.

677 Subsection 78(2) repeals the Community Care (Delayed Discharges etc) Act 2003, as that Act is, in effect, identical to Schedule 3 to the Care Act 2014, and should subsequently also no longer have any application. The Community Care (Delayed Discharges etc) Act 2003 will therefore be repealed in its entirety, as it is no longer required in England or in Wales.

678 Subsection 78(3) makes relevant amendments that are required in consequence of this Bill repealing section 74 and Schedule 3 to the Care Act 2014.

679 Subsection 78(4) makes relevant amendments that are required in consequence of this Bill repealing the Community Care (Delayed Discharges etc) Act 2003.

Part 2: Health and Adult Social Care Information

Clause 79: Information standards

- 680 Clause 79 amends section 250 (powers to publish information standards) of the 2012 Act.
- 681 It inserts a new subsection (2A) which provides that an information standard must specify who the information standard applies to. It also inserts new subsections (2B) and (6A) to (6D) and substitutes subsections (2) and (6).
- 682 The substituted subsection (2) defines “an information standard” as a standard in relation to the processing of information (as opposed to as a document containing such standards).
- 683 New subsection (2B) describes the persons who an information standard may apply to, being the Secretary of State, NHS England, any public body which exercises functions in connection with the provision of health services or adult social care in England and any person other than a public body who is required to be registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008 in respect of the carrying on of a regulated activity (within the meaning of Part 1)
- 684 Subsection (5), which specifies that an information standard must include guidance about implementation of the standard, is omitted.
- 685 The substituted subsection (6) requires the Secretary of State to have regard to any information standard published by NHS England and which applies to the Secretary of State and to comply with any information standard published by the Secretary of State and which applies to the Secretary of State.
- 686 New subsection (6A) provides that any other person to whom an information standard applies must comply with the standard.
- 687 New subsection (6B) enables regulations to empower a person publishing an information standard to waive the requirement to comply (wholly, partially, generally or for a specific period of time).
- 688 New subsection (6C) enables those regulations to limit the circumstances when a waiver may be granted, to set out a procedure for waivers, and to require specific information about waivers to be included in an information standard.
- 689 New subsection (6D) signposts to section 277E for enforcement of information standards against persons other than public bodies.
- 690 The substituted section 251 requires regulations to set out the procedure to be followed in connection with preparing and publishing information standards and enables regulations to require information standards to be reviewed from time to time. It requires the Secretary of State to consult appropriate persons before laying draft

regulations in Parliament and allows the Secretary of State and NHS England to adopt any information standard prepared or published by another person.

691 Section 251ZA (information standards: compliance) enables the Secretary of State to require information from a person to enable the Secretary of State to monitor that person's compliance with information standards. The Secretary of State must set out any requirement in writing and the requirement may set out how and when the person must provide the information. Subsection (4) signposts to section 277E in respect of enforcement.

Clause 80: Sharing anonymous health and social care information

692 Clause 80 amends Chapter 1A of Part 9 of the 2012 Act. It inserts, after existing section 251C, a new section 251D relating to the sharing of anonymous information for purposes related to the functions of health or adult social care bodies in England.

693 Subsection (1) specifies that a public body which exercises functions in connection with the provision of health services or adult social care in England may require information, other than personal information, from another such public body or from another person who provides health services or adult social care in England, pursuant to arrangements made with such a public body. The power applies only in relation to information that relates to the activities of the relevant public body or private provider in connection with the provision of health services or adult social care in England (in pursuance of arrangements made with a public body in the case of a private provider).

694 Subsection (2) specifies that a health or social care body may only impose a requirement to provide information under subsection (1) for purposes relating to that body's functions in connection with the provision of health services or adult social care in England.

695 Subsection (3) sets out that regulations may be made to create exceptions to the power to require information. Exceptions could apply to specific, named bodies, descriptions of bodies, descriptions of information, or other exceptions (such as where information is commercially sensitive).

696 Subsection (4) sets out that a body on whom a requirement may be imposed under subsection (1) is not required to process information so as to render it into a form in which it must be provided. They are only required to share information if they already hold it in a form that does not identify an individual, or enable the identity of an individual to be ascertained. The effect of subsection (4) is also that they would not be required to process information that would otherwise be subject to an exception introduced by regulations, for example, by redacting information that is subject to an exception.

697 Subsection (5) signposts to section 277E in respect of enforcement against private health or social care providers.

698 Subsection (6) sets out the definitions of certain terms for the purposes of this section.

Clause 81: General duties of the Health and Social Care Information Centre etc

699 Clause 81 amends section 253(1) (general duties of the Information Centre) of the 2012 Act which sets out the matters which the Information Centre must have regard to when exercising functions. It inserts a new paragraph requiring the Information Centre 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. The clause also requires that NHS Digital balances the need to have regard to the matters set out in section 253(1) so far as they compete. The effect of this is to place consideration of benefit to the health and care system at the centre of NHS Digital's duties.

700 Clause 81 also amends section 261 (dissemination of information) of the 2012 Act so 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 (It is intended that this amendment will put beyond doubt NHS Digital's power to share data in connection with health care or adult social care. This could include for example commissioning, planning, policy analysis and development, population health management,, 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.

Clause 82: Collection of information from private health care providers

701 Clause 82 amends section 259(1) of the 2012 Act which sets out the Information Centre's powers to require and request the provision of information. The effect of the amendment is to additionally enable the Information Centre to require private providers of health services to provide to the Information Centre any information it requires in order to comply with a direction from the Secretary of State under section 254 of the 2012 Act to establish an information system. This does not include information which the Information Centre requires in order to comply with requests under section 255 of the 2012 Act.

702 Subsections (c) to (g) of clause 82 make consequential amendments to section 259.

703 Subsection (h) of clause 82 signposts to new section 277E for enforcement of requirements against persons other than public bodies and defines "health care providers".

Clause 83: Collection of information about adult social care

- 704 Clause 83 inserts into Part 9 of the 2012 Act a new Chapter 3 which contains sections 277A, 277B, 277C and 277D concerning information about adult social care.
- 705 Section 277A(1) enables the Secretary of State to require certain providers of adult social care services to provide to the Secretary of State information relating to themselves, their activities in connection with providing adult social care in England, or individuals they have provided adult social care to England or, where those services are commissioned by a Local Authority in England, outside England.
- 706 Subsection (2) stipulates that the Secretary of State can only require information if it is for purposes connected with the adult social care system in England.
- 707 Subsection (3) enables the Secretary of State to specify the form and manner of information, and when the information must be provided.
- 708 Subsection (4) states that the requirement to provide information must be in writing.
- 709 Subsection (5) provides that providing information under this section does not breach any obligation of confidence (which would include the common law duty of confidentiality) but is subject to any other express restrictions on disclosing information that may be imposed by any enactment. This would include restrictions under the Data Protection Act 2018 and the UK GDPR.
- 710 Subsection (6) signposts to section 277E in respect of enforcement.
- 711 Subsection (7) defines “adult social care”, “English local authority”, and “relevant provider of adult social care services”.
- 712 Section 277B imposes restrictions on the disclosure of information provided under section 277A. The disclosure of that information would additionally be subject to restrictions under the Data Protection Act 2018, the UK GDPR and the common law duty of confidentiality.
- 713 Subsection (1) restricts the disclosure of information provided under section 277A so that it may only be disclosed for purposes connected with the health service system or adult social care system.
- 714 Subsection (2) further restricts the disclosure of that information so that commercially sensitive information may not be disclosed unless the Secretary of State considers disclosure to be appropriate, having taken into account the public interest as well as the interests of the person to whom that information relates.
- 715 Subsection (3) sets out that subsections (1) and (2) do not restrict the disclosure of information where: consent has been given, the information has previously been lawfully disclosed to the public or where the disclosure is in accordance with any court

order, is for the purposes of protecting the welfare of any individual, is for the purposes of a persons' exercise of functions under any Act, is in connection with the investigation of a criminal offence within or outside the United Kingdom or is for the purpose of criminal proceedings within or outside the United Kingdom.

716 Subsection (4) defines the term "commercially sensitive information".

717 Section 277C(1) empowers the Secretary of State to direct the Health and Social Care Information Centre to exercise the functions of the Secretary of State under section 277A and provides that the restrictions on disclosure of information set out in section 277B apply in such a case.

718 Subsection (2) empowers the Secretary of State to direct a Special Health Authority performing functions in respect of England to exercise the functions of the Secretary of State under section 277A and provides that the restrictions on disclosure of information set out in section 277B apply in such a case..

719 Subsection (3) empowers the Secretary of State to direct the Information Centre or the Special Health Authority in question about the exercise of any functions that it is directed to exercise under subsection (1) or (2). This includes directions as to the processing of information that the body obtains in exercising those functions.

720 Section 277D(1) enables the Secretary of State to make arrangements for a person (prescribed by regulations) to exercise the functions of the Secretary of State under section 277A and provides that the restrictions on disclosure of information set out in section 277B apply in such a case

721 Subsection (2) enables those arrangements to provide for the Secretary of State to make payments to the person as well as to set out circumstances where the payments must be repaid.

722 Subsection (3) enables those arrangements to make provision of a kind which may be made in directions under the 2012 Act such as provision for the person in question to exercise the Secretary of State's functions wholly or to a limited extent and in specific cases or circumstances or more generally.

Clause 84: Enforcement of duties against private providers

723 Clause 84 inserts into Part 9 of the 2012 Act a new Chapter 4 containing section 277E which concerns enforcement and section 277F which concerns directions to a Special Health Authority to exercise the enforcement functions under regulations under section 277E

724 Section 277E(1) provides a power for regulations to enable the Secretary of State to impose a financial penalty on various persons. Those persons are a person other than a

public body (i.e. a private provider) who fails to comply with an information standard without reasonable excuse (subsection (1)(a)); a person who, without reasonable excuse, fails to comply with a requirement to provide information imposed under section 251ZA(1), 251D(1), 259(1)(a) or (aa) or 277A(1) or who, without reasonable excuse, provides false or misleading information (subsection (1)(c)).

725 Subsection (2) states that the amount of the financial penalty is to be specified in, or determined in accordance with, the regulations.

726 Subsection (3) requires the regulations to include provision requiring the Secretary of State to give a person written notice of intention to impose a financial penalty before it is imposed; ensuring a person is given an opportunity to make representations; requiring the Secretary of State, following representations, to decide whether to impose the financial penalty and to give a final notice in writing imposing the penalty; enabling a person to appeal to the First-tier Tribunal; and setting out the powers of the Tribunal on such an appeal.

727 Subsection (4) states that the regulations may include provision: enabling amendment or withdrawal of a notice of intent or final notice; requiring the Secretary of State to withdraw a final notice in circumstances specified in the regulations; for a financial penalty to be increased if paid late; and for recovery of financial penalties in the county court.

728 Subsection (5) sets out the definition of “public body”.

729 Section 277F enables the Secretary of State to direct a Special Health Authority performing functions only or mainly in respect of England to exercise the enforcement functions under regulations under section 277E and to give directions to the Special Health Authority about the exercise of those functions.

Clause 85: Medicine Information Systems

730 Clause 85(1) provides that the following provisions amend the Medicines and Medical Devices Act 2021.

731 Clause 85(2) substitutes “REGULATIONS: GENERAL” in Part 2, for the heading of Chapter 1.

732 Clause 85(3) inserts a new section 7A (Information Systems) after Chapter 1 of Part 2 of the Medicines and Medical Devices Act 2021. This new section 7A confers a delegated power on the appropriate authority to make regulations providing for a system of information in relation to medicines to be established and operated by the Health and Social Care Information Centre (“the Information Centre”), and specifies the type of provision which can be included in the regulations. In relation to England, Scotland and Wales, the “appropriate authority” is the Secretary of State. In relation to Northern

Ireland, the “appropriate authority” is the Department of Health in Northern Ireland acting alone, or the Secretary of State and the Department of Health in Northern Ireland acting jointly. “Appropriate authority” is defined in section 2 (Human medicines) of the Medicines and Medical Devices Act 2021. The definition reflects the position whereby key functions under the Human Medicines Regulations are carried out by the Licensing Authority, which consists of both Secretary of State and Northern Ireland Minister.

733 Section 7A(1) provides that regulations may be made about the establishment and operation by the Information Centre of one or more information systems. The power is restricted to purposes relating to the safety, quality and efficacy of human medicines and the improvement of clinical decision-making in relation to human medicines. Such purposes may include the generation of high-quality evidence regarding the use, benefits and risks of these medicines to inform regulatory decision making, supporting local clinical practice and providing patients and prescribers with the evidence they need to make better informed decisions.

734 Subsections (1)(a) and (c) of section 19 of the Medicines and Medical Devices Act 2012 make specific provisions relating to devices that are placed on the market, and about the improvement of medical device safety and performance through advances in technology. It was necessary for these subsections to be worded in this way to distinguish between devices on the market and those that are not, and to make specific provision about technological developments in relation to the latter. However, when it comes to subsection 7A(1), this wording was not necessary given the differences in the regulation of medicines and medical devices.

735 Section 7A(2) describes the type of provision that the regulations may make. This is a non-exhaustive list. Provision may be about the type of information that could be gathered, for example this may be information relating to a particular medicine, patients who are prescribed the medicine or prescriber information. Regulations may also impose requirements to provide that information to the Information Centre and make provision about the use or disclosure of that information and requirements that may be placed on the Information Centre in exercising its functions under the regulations. These provisions would ensure that the Information Centre would be able to mandate the provision of specific information to be included in the information system and that the Information Centre would be able to use and disclose such information, for example in circumstances where the MHRA requires such information for the purpose of establishing a medicines registry.

736 Section 7A(3) sets out additional information about the kind of provision which may be made pursuant to section 7A(2)(a) and (b). It provides that regulations concerning the information which is to be collected and entered into any medicines information system

may relate to information for specified purposes, information that the Information Centre needs to carry out its functions under the regulations, information which is of a specified description that may relate to individuals and information described in a written direction given by the appropriate authority, which may also relate to individuals. Relying on these powers, regulations can specify the type of information required so that for example, details of patients, and their prescribers can be recorded and monitored to improve pharmacovigilance. It also ensures that the appropriate authority can set out in a direction the details of what information must be collected. Directions will be used as a means to enable the appropriate authority to specify what information needs to be collected by the Information Centre for each registry. This will enable the appropriate authority to promptly amend what information is collected by the Information Centre, as public health needs change or develop, and the need for new or different information emerges. It also ensures that the appropriate authority can set out in a direction the details of what information must be collected.

737 Section 7A(4) goes on to specify the kind of provision which can be included in the regulations pursuant to section 7A(2)(b).

738 Section 7A(4)(a) provides that the regulations may specify the persons, or categories of persons who may be required to provide information to the Information Centre. Those persons or categories must fall within section 7A(5). For example, the regulations would be able to set out the types of healthcare providers who are required to submit information to the Information Centre, including private providers and providers in devolved administrations. This would enable the collection of comprehensive, UK-wide information.

739 Section 7A(4)(b) provides that regulations may specify the time and manner in which the information required must be provided or for those matters to be determined by the Information Centre. This provision can be used to ensure the Information Centre receives the most up-to-date information in a way that can be easily analysed by requiring providers to send information by a specific time and in a specific format.

740 Section 7A(4)(c) provides that regulations may describe any procedural steps the Information Centre must follow when requiring a person to provide information. This ensures secondary legislation can set out the way in which the Information Centre would need to request information from providers, for example taking into account that the process for collecting information may vary in devolved territories.

741 Section 7A(4)(d) provides that regulations may specify that required information is recorded or retained. Regulations can for example set out what information must be recorded and stored and the duration of storage of such information.

742 Section 7A(4)(e) provides that regulations may include provision about the enforcement of requirements imposed by regulations made under section 7A(1). This provides a mechanism to set out in secondary legislation how the collection of information would be enforced. The intention is that the provisions in the regulations would act as a robust tool to ensure compliance by providers to share information for purposes set out in 7A(1) and provide for appropriate repercussions in an event of non-compliance.

743 Section 7A(5) sets out who may be required to store information and/or provide it to the Information Centre. This is limited to any person who provides services, or exercises any powers or duties, relating to human medicines, health or education. This means that information can be collected from providers such as healthcare providers, private providers and providers of education services. For example, data relating to education and child development may be required in a registry to understand the potential for neurodevelopment disorders in those exposed to medicines in utero or transgenerational effects on the children of people who were exposed to the medicine.

744 Section 7A(6) provides non-exhaustive examples of the possible provisions that may be included in the regulations on the use and disclosure of information held within the information system (section 7A(2)(c)). These include the analysis of that information (whether alone or linked with other information), the publication of that information (or of information that has been analysed in combination with it), the disclosure of that information to specified persons or descriptions of persons or for specified purposes, and the use or further disclosure of that information by any person to whom information has been disclosed under the regulations. This means that the Information Centre would be able to link non-information system data such as data already collected by the Information Centre, with information system data and share this with the MHRA for the purpose of establishing registries. The combination of different types of data could not only improve data quality on a specific medicine which would further help support the safe use of the medicine, but it would help reduce the burden on healthcare providers by avoiding the need for multiple requests for the same information.

745 Section 7A(7) provides that where regulations confer a power on the appropriate authority to give a direction under section 7A(3)(d), they must provide that the power includes a power to vary or revoke the directions by a subsequent direction. This means previous directions can be changed or replaced if there are circumstances where a new direction was needed. For example, if further information was required to be collected for an existing medicines registry.

746 Section 7A(8) enables regulations made pursuant to section 7A(1) to provide that disclosure of information for the purposes of medicines information systems does not contravene an obligation of confidence owed by the person making the disclosure or any

other restriction on the disclosure of information, other than a restriction imposed by data protection legislation. These provisions will allow regulations to include provision setting aside duties of confidence as well as other restrictions on disclosure of information. No disclosure would be able to contravene data protection legislation. This provision would ensure that the Information Centre can disclose information, including information that has been lawfully linked under this clause, onwards, for example to the MHRA for the purposes of establishing a registry. This will ensure that all necessary information can be included in a medicines registry where there was concern about risk or safety of a medicine or to ensure patient safety.

747 Section 7A(9) defines terms used in section 7A.

748 Section 7B creates a new offence related to information disclosure.

749 Section 7B(1) provides that a person commits an offence if they receive information under regulations made under section 7A(1) and then use or disclose that information in contravention of those regulations. This is to ensure information included in the information system is used and disclosed appropriately and is consistent with the provision made for disclosure of information contained in medical devices information systems.

750 Section 7B(2) outlines the maximum penalties for these offences. These are:

- As a result of a summary conviction in England and Wales, which is an offence that is triable in a magistrates' court, a person can be imprisoned for up to 51 weeks, receive a fine, or both.
- As a result of a summary conviction in Scotland or Northern Ireland, a person can be imprisoned for up to 6 months, or receive a fine not exceeding £5,000 (level 5 on the standard scale), or both. A level 5 on the standard scale references the scale of fines for summary offences as outlined in the Criminal Justice Act 1982.

751 Section 7B(3) outlines that the maximum 51 weeks imprisonment outlined in section 7B(2)(a) is to be read as 6 months if the offence is committed before section 281(5) of the Criminal Justice Act 2003 is commenced.

752 Clause 85(4) amends section 19 (medical devices: information systems) as described below.

753 Clause 85(4)(a) amends subsection (6) of section 19 to provide for publication and other disclosure of information that has been analysed in combination with information contained in a medical device information system.

754 Clause 85(4)(b) inserts a new subsection after section 19(7) that inserts the same

provision as section 7A(8) into section 19.

755 Clause 85(5) amends section 43 (power to make consequential etc provision). Where regulations made under sections 7A or 19 make consequential provision by virtue of section 43(2)(a), the new section 43(3) will ensure that those regulations may change the territorial extent of provisions of Chapter 2 of Part 9 of the 2012 Act (constitution and functions etc of the Health and Social Care Information Centre), or otherwise amend that Chapter. In establishing and operating the medicines and medical devices information systems the Information Centre will have more substantial functions in relation to Scotland and Northern Ireland than it had prior to the Medicines and Medical Devices Act 2021 as amended by the Bill. To ensure effective functioning and operation of the information systems it is therefore appropriate to ensure that certain provisions of the 2012 Act which relate to NHS Digital's functions under the Medicines and Medical Devices Act, could form part of the law of the whole of the UK, rather than just England and Wales, if deemed necessary.

756 Clause 85(6) amends section 44 (scope of Northern Ireland departments) to require that regulations under section 7A(1) cannot be made by a Northern Ireland Department acting alone unless the provision would fall within the legislative competence of the Northern Ireland Assembly and would not require the consent of the Secretary of State.

757 Clause 85(7) amends section 45 (consultation) to include 7A(1) in the list of sections in subsection (6)(a). This provides that consultation on regulations made pursuant to section 7A(1) is to be carried out by the appropriate authority.

758 Clause 85(8) amends section 46 (reporting requirements) so that regulations made under section 7A(1) are subject to the same reporting requirements as medicines regulations made under section 2.

759 Clause 85(9) amends section 47 (procedure for regulations) to ensure the procedure for making regulations under section 7A(1) is the same as that for medicines regulations made under section 2 of the Medicines and Medical Devices Act 2021.

760 Clause 85(10) amends section 253 of the 2012 Act (general duties of Information Centre), to provide that subsections (1) and (2) of that section do not apply in relation to the functions of the Information Centre by virtue of the Medicines and Medical Devices Act 2021. This is considered necessary because the duties in section 253 are England-specific and therefore not appropriate to the UK-wide functions conferred on the Information Centre by the Medicines and Medical Devices Act 2021.

Part 3: Secretary of State's Powers to Transfer or Delegate Functions

Clause 86: Relevant bodies

761 Clause 86 sets out the “relevant bodies” to which the clause applies. These are all health Non-Departmental Public Bodies and are as follows:

- Health Education England.
- The Health and Social Care Information Centre,
- The Health Research Authority
- The Human Fertilisation and Embryology Authority.
- The Human Tissue Authority
- NHS England

762 The Health and Social Care Information Centre is the legal name of NHS Digital.

Clause 87: Power to transfer functions between bodies

763 Subsection (1) of Clause 87 confers a power on the Secretary of State, through regulations, to transfer functions between the relevant bodies as outlined above.

764 Subsection (2) sets out the conditions which need to be met in order for these regulations to be made. 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

765 Subsection (3) sets out an exemption to the transfer of functions of NHS England, to prevent the Secretary of State from using the new power to make NHS England redundant and abolish it.

766 Subsection (4) sets out that through secondary legislation, the Secretary of State can modify the functions, constitution or funding of either body, and abolish the relevant body if it has become redundant as a consequence of the transfer of functions. This regulation power is by virtue of subsection(1)(a) of clause 131 which provides that a power to make regulations under any provision of the Act includes the power to make consequential, supplementary, incidental, transitional or saving provision.

767 Subsection (5) sets out that where: any regulations made under this provision relate to a function that is exercisable in relation to Scotland, Wales or Northern Ireland and where there is a pre-existing requirement in the constitution of the body from which the

function is transferred for the representation of the interests of one of the devolved nations, the Secretary of State must make provision for maintaining such representation by way of modifying, if necessary, the constitutional arrangements of the body receiving the function.

768 Subsection (6) sets out that “Minister” means a Minister of the Crown as defined by the Ministers of the Crown Act. This defines ‘Ministers of the Crown’ as follows: “Minister of the Crown” means the holder of an office in Her Majesty’s Government in the United Kingdom, and includes the Treasury, the Board of Trade and the Defence Council.

Clause 88: Power to provide for exercise of functions of Secretary of State

769 Subsection (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.

770 Subsection (2) provides that the functions that may be specified are of the Secretary of State’s functions which relate to the health service in England or which they may provide for a Special Health Authority to exercise.

771 Subsection (3) sets out that the regulations made as part of this clause may make provision modifying the functions, constitutional or funding arrangements of the relevant bodies.

772 Subsection(4) sets out that the Secretary of State must make provision by way of modifying the relevant bodies constitutional arrangements for maintaining any existing provision for the body to include a member whose experience, functions or appointment are connected with that part of the UK (analogous to the provision in subsection (5) of clause 87.

773 Subsection (5) sets out that regulations under this section may make provision for determining whether and in what circumstances the Secretary of State or a relevant body is liable for the exercise of the specified functions by the relevant body.

774 Subsection (6) sets out that the use of this power does not preclude the Secretary of State from exercising the function.

775 Subsection (7) states that “the health service” has the same meaning as in the National Health Act 2006. This defines ‘the health service’ as follows:

‘the health service continued under section 1(1) of the National Health Act 2006 and under section 1(1) of the National Health Service (Wales) Act 2006’

Clause 89: Scope of powers

776 Subsection (1) sets out what references to modifying the functions of a body includes.

- 777 Subsection (2) sets out what references to the constitutional arrangements of a body includes.
- 778 Subsection (3) sets out what references to modifying the funding arrangements of a body includes.
- 779 Subsection (4) sets out certain types of powers that regulations under clauses 87 and 88 may repeal and re-enact (but may not create), and provides that regulations under clauses 87 and 88 may repeal and re-enact (but not create) a criminal offence.
- 780 Subsection (5) sets out that provision made by regulations may be made by repealing, revoking or amending provision made by or under an Act of Parliament.
- 781 Subsection (6) sets out that this includes those provisions made by the Devolved Administration legislatures.
- 782 Subsection (7) sets out that “Minister” means a Minister of the Crown as defined by the Ministers of the Crown Act. This defines ‘Ministers of the Crown’ as follows:
- “Minister of the Crown” means the holder of an office in Her Majesty’s Government in the United Kingdom, and includes the Treasury, the Board of Trade and the Defence Council.

Clause 90: Transfer schemes in connection with regulations

- 783 Subsection (1) sets out that the Secretary of State may make one or more schemes for the transfer of property, rights or liabilities.
- 784 Subsection (2) sets out that, where regulations provide for the transfer of functions between relevant bodies, the transfer scheme may make provision for the transfer of property, rights or liabilities to any appropriate person from the relevant body from which functions are being transferred.
- 785 Subsection (3) sets out that, where regulations provide for the delegation of a function of the Secretary of State to a relevant body, the transfer scheme may make provision for the transfer of property, rights or liabilities from any of the list of persons or bodies set out at subsections (a) to (c) to an appropriate person.
- 786 Subsection (4) sets out a non-exhaustive list of certain types of assets, rights and liabilities that may be included in a transfer.
- 787 Subsection (5) sets out a non-exhaustive list of types of provision that the transfer scheme may make.
- 788 Subsection (6) sets out that a transfer scheme may provide for modifications by agreement and that they are to have effect from the date of the original scheme coming into effect.

789 Subsection (7) clarifies what "TUPE regulations" means: the Transfer of Undertakings (Protection of Employment) Regulations 2006 (S.I. 2006/246).

790 Subsection (8) states that references to rights and liabilities includes those relating to contracts of employment and the transfer of property includes the grant of a lease.

791 Subsection (9) states the inclusion of civil servants of the State in the contract of employment in subsection (8).

792 Subsection (10) lists those included in the term "appropriate person".

Clause 91: Transfer schemes: taxation

793 Subsections (1), (2) and (3) set out that the Treasury may make provision to vary of the way in which a relevant tax has effect in relation to assets and liabilities that are transferred under a scheme made under clause 90, and anything done for the purpose of, or in relation to a transfers. This includes tax exemption, or a modification of a tax provision, and will be specified in the scheme with Treasury consent.

794 Subsection (4) sets out that regulations under this section are subject to annulment in pursuance of a resolution of the House of Commons

795 Subsections (5) states that references to the transfer of property includes the grant of a lease

796 Subsection (6) sets out what the relevant taxes are and the meaning of tax provision for the purpose of this clause.

Clause 92: Consultation on draft regulations

797 Subsection (1) sets out that the Secretary of State must consult:

- i.* any body to which draft regulations relate,
- ii.* the relevant devolved administration(s) if regulations would apply in a devolved nation, and either would make provision that would be within the legislative competence of the devolved legislature, or make provision for any mater in relation to which functions are exercised by the devolved executive and
- iii.* any other persons that the Secretary of State considers appropriate.

798 Subsection (2) makes further provision clarifying the circumstances in which the relevant Northern Ireland department must be consulted under subsection (1).

Consultation will not be required in relation to a matter which (a) would only be within the legislative competence of the Northern Ireland Assembly if the Assembly obtained the consent of the Secretary of State under section 8 of the Northern Ireland Act 1998 to legislate in respect of it, and (b) does not affect, other than incidentally, a transferred matter (within the meaning of the Northern Ireland Act 1998).

799 Subsection (3) sets out the requirement for the Secretary of State to carry out a further consultation should a change to the draft regulations appear appropriate to the Secretary of State, following the initial consultation.

800 Subsection (4) states that for the purposes of this section whether the consultation is carried out before or after the commencement of this section is immaterial.

Part 4: The Health Services Safety Investigations Body

Introductory

Clause 93: Establishment of the HSSIB

801 Clause 93 establishes the Health Services Safety Investigations Body (“the HSSIB”) as a body corporate. It also gives effect to Schedule 13.

Schedule 13: The Health Service Safety Investigations Body

Part 1 – Constitution

802 The Schedule provides for the HSSIB’s governance arrangements. It includes details of the membership of the HSSIB and the process for appointments, including the appointment of the chief executive, and sets out the HSSIB’s financial and reporting obligations.

Status

803 The HSSIB’s status is confirmed as a non-Crown organisation, in line with the status of other non-Departmental Public Bodies. The HSSIB is not to be regarded as a servant or agent of the Crown and will not enjoy any status, immunity or privilege of the Crown. The HSSIB’s property will not be regarded as property of, or property held on behalf of, the Crown.

Membership

804 The HSSIB is to consist of executive members including a Chief Investigator, and non-executive members consisting of a chair and at least four other members who will form the HSSIB’s Board.

805 The HSSIB must have more non-executive than executive members.

The Chief Investigator: appointment and status

806 The chief executive is also known as the Chief Investigator. The Chief Investigator is appointed by the non-executive members, with the consent of the Secretary of State. They are to be an employee of HSSIB.

Other executive members: appointment and status

807 The executive members are to be appointed by the non-executive members of the HSSIB and no more than five executive members (in addition to the Chief Investigator) can be appointed without the consent of the Secretary of State. This is intended to ensure that the HSSIB's board remains at an appropriate size and composition and to ensure that the appointment of any additional members is justified. The executive members are to be employees of the HSSIB.

Non-executive members: tenure

808 The schedule makes provision for the terms and conditions of appointment and tenure of office for the HSSIB's non-executive members. The maximum term of office for non-executive members is six years (the initial appointment can be for three years plus possible reappointment for a further three). The Secretary of State may suspend or remove a non-executive member from office, on the grounds of incapacity, misbehaviour, or failure to carry out duties properly.

Non-executive members: suspension from office

809 The Secretary of State must provide the individual with notice of the suspension. The initial period of suspension must not exceed six months, and the Secretary of State may review the suspension at any time. In addition, the Secretary of State must review the suspension if requested to by the person in writing. However, there is no requirement to review the suspension before three months have passed following the start of the suspension.

810 After a review during a period of suspension, the Secretary of State may confirm the suspension, revoke the suspension, or suspend the person for another period of not more than six months. This period would begin once the current period of suspension expires.

811 The Secretary of State must revoke the suspension if the Secretary of State decides that there are no grounds to remove the person from office under paragraph 5(3) or decides that there are grounds to remove the person from office, but does not remove the person from office under that provision.

812 If the chair is suspended from office under paragraph 5(4), the Secretary of State may appoint a non-executive member as interim chair to exercise the chair's functions. This appointment is for a term not exceeding the shorter of the remainder of the interim chair's term as a non-executive member, the period ending with the appointment of a new chair of the period ending with the revocation or expiry of the existing chair's suspension.

813 If a person's initial term as interim chair ends as a result of the expiry of their term as a non-executive member and they are to be re-appointed as a non-executive member, they

may be re-appointed as interim chair for a further term in compliance with paragraph 7(2). The further term must be behind at the end of their initial term as interim chair.

Non-executive members: payment

814 It is required that the HSSIB must pay to non-executive members such remuneration and allowances as the Secretary of State may decide. The HSSIB can make arrangements for pensions, allowances and gratuities to be paid to non-executive members or former non-executive members. These arrangements would be for the HSSIB to determine with the approval of the Secretary of State.

Staff

815 The HSSIB is provided with powers to employ staff on such pay, terms and conditions as it may determine, following Secretary of State's approval of its policy on the remuneration, pensions etc. of employees.

Procedure

816 The HSSIB has the power to regulate its own procedure and any vacancy amongst the members does not affect the validity of its actions.

Committees

817 The HSSIB may appoint committees and sub-committees and pay remuneration and allowances to committee members if they are not members or employees of the HSSIB.

Exercise of functions

818 The HSSIB must exercise the functions conferred on it by this Part effectively, efficiently and economically, as with other public bodies in the health service. The provision places the HSSIB under the same duty of economy and efficiency as other public bodies in the health service

819 The HSSIB can delegate authority to carry out its functions to any non-executive member, any employee or a committee or sub-committee.

Assistance in exercise of functions

820 The HSSIB can obtain assistance from other persons, for example experts, in exercising its functions.

Funding

821 The Secretary of State may fund the HSSIB's activities to the extent that the Secretary of State considers appropriate.

Supplementary powers

822 The HSSIB can carry out the corporate activities that are likely to be necessary in order for it to carry out its statutory work and function as an organisation. This includes powers to enter into agreements, buy or sell property, supply goods and services and develop, own and exploit intellectual property. The HSSIB holds the power to temporarily borrow money by overdraft with the consent of the Secretary of State.

Use of income from charges

823 Any income that the HSSIB generates in connection with the exercise of its functions must be re-invested in carrying out those functions.

Losses and liabilities etc

824 The HSSIB is included in the list of authorities covered by section 265 of the Public Health Act 1875. The effect of this is to protect members and officers of the HSSIB from personal liability in certain circumstances.

Accounts

825 As a non-Departmental Public Body, the HSSIB is required to keep proper accounts and prepare a set of accounts in each financial year. The HSSIB is required to prepare these accounts in the form, and with the content, and using methods and principles determined by the Secretary of State. The HSSIB must send its annual accounts to the Secretary of State and the Comptroller and Auditor General who is responsible for examining, certifying and reporting on the accounts and for laying copies of the audited accounts (and his report on them) before Parliament.

Reports and other information

826 The HSSIB must publish an annual report on how it has exercised its functions. The annual report must be sent to the Secretary of State and laid before Parliament. The HSSIB is also required to provide further reports and information about its own functions to the Secretary of State as required in so far as they relate to the exercise of their functions in the round, but not the details of specific investigations.

827 Examples of the information that might be requested are:

- Information about salaries for auditing;
- Performance data for parliamentary scrutiny;
- Costing data for budget setting;
- Employee data for equalities monitoring.

Seal and signature

828 The HSSIB's seal must be signed by any member of the HSSIB or any other person authorised for that purpose for it to be authenticated.

Part 2: Transfer Schemes

829 The Secretary of State may make one or more transfer schemes in connection with the transfer of the Investigation Branch's functions following the abolition of the Trust Development Authority (TDA) pending the establishment of the HSSIB by this Act.

Investigations

Clause 94: Investigation of incidents with safety implication

830 Clause 94 gives the HSSIB the function of investigating "qualifying incidents". These are incidents that occur in England during the provision of health care services and have, or may have, implications for the safety of patients. The purpose of the investigation is to identify the risks to the safety of patients and address those risks by facilitating the improvement of systems and practices in the provision of health care services in England (under clause 94(2)).

831 Clause 94(1) sets out that the HSSIB could investigate a qualifying incident that occurred during the provision of health care services in any setting in England, including in the NHS or in the independent sector. The purpose of its investigations is to identify risks to the safety of patients and to address them by facilitating improvements in the health care system.

832 Where an investigation relates to an incident that did not occur during the provision of NHS services, the HSSIB must consider whether, in relation to any risks identified, the systems and practices in the provision of NHS services could be improved (under clause 94(3)). NHS services means health care services provided in England for the purposes of the health service continued under section 1(1) of the National Health Services Act 2006. The HSSIB will determine and publish the criteria it will use to determine which qualifying incident it will investigate (under clause 96(1)(a)).

833 The aim is that the HSSIB will gather general lessons from investigating patient safety incidents and share these to prevent a recurrence of a similar incident. The HSSIB will make recommendations in its report on an investigation and will require the relevant body to respond within a specified period, setting out the action they intend to take in response to that recommendation. Clause 94(4) provides that the HSSIB's investigative function is not for the purposes of assessing or determining blame, civil or criminal liability, or action to be taken by a professional regulator in respect of an individual.

Clause 95: Deciding which incidents to investigate

834 Clause 95 outlines how the HSSIB determines which qualifying incidents it should investigate as part of its function under clause 94. Clause 95(2) also gives the Secretary of State a power to direct the HSSIB to carry out an investigation of a particular qualifying incident that has occurred, or group of qualifying incidents that have occurred and are of a particular description, and to specify the date by which the HSSIB must publish its final report. The Secretary of State may also issue a further direction specifying a later date (for example, to grant an extension).

835 Once the HSSIB has begun an investigation, it must publish a statement reporting that it has begun the investigation. This must include a brief description of the incident(s) under investigation, and set out, in general terms, the issues that the HSSIB expects to consider in the investigation. The HSSIB may give advance notice of such a statement to any person the HSSIB considers may be affected by the investigation. This may include, but is not limited to, patients, families, any individual who has referred the incident to the HSSIB, or a Trust or other healthcare provider.

836 Where the HSSIB discontinues an investigation, it must publish a statement reporting that it has discontinued the investigation, and its reasons for doing so.

837 If the HSSIB determines not to investigate a qualifying incident, it may give notice of this to any person the HSSIB considers to have an interest in the determination. This may include, but is not limited to, patients, families, any individual who has referred the incident to the HSSIB, or a Trust or other healthcare provider. In doing so, the HSSIB may include a brief description of the incident and explain its reasons for not investigating.

Clause 96: Criteria, principles and processes

838 Clause 96(1) outlines that the HSSIB must determine and publish the criteria it will use to determine the incidents it will investigate, the principles that will govern investigations, the processes that will be followed in carrying out investigations, and the processes for ensuring that, so far as reasonable and practicable, patients and their families are involved in investigations. It is expected that this will include the process that will be used to determine how interested parties (e.g. patients, families, and staff in both the NHS and independent sector, as well as staff in other health bodies such as NHS England,) will be involved in the investigations. The processes must include the procedures and methods to be used in investigations, including the interviewing of persons, and the time periods within which the HSSIB will aim to complete investigations (under clause 96(2)). Different types of investigation may have different processes in carrying out investigations and involving patients and families. Anything which is published concerning the processes for patient and family involvement in investigations must be easily accessible by patients and families and capable of being

understood by them (under clause 96(4)). The intention is that the HSSIB will make all necessary efforts to involve patients and families in investigations, as far as is reasonable practicably possible. However, where individuals cannot be reached, despite efforts made by the HSSIB, or where they refuse to participate, this should not prevent the HSSIB from proceeding with its investigation.

839 Clause 96(7) sets out that in developing these criteria, principles and processes, the HSSIB must consult the Secretary of State and any other persons as they think appropriate.

840 The HSSIB must review the criteria, principles and processes once in the first three years after publication and at least once every five years after the first review (under clause 96(5)), and if revising following review must consult the Secretary of State or other persons the HSSIB considers appropriate. The aim of these provisions is to encourage the HSSIB to change and improve its methods as it becomes more experienced in conducting safety investigations within the health service.

Reports

Clause 97: Final reports

841 Clause 97(1) outlines that the HSSIB must publish a “final report” on the outcome of its investigations. The report must include a statement of findings of fact and an analysis of the investigation’s findings together with any recommendations as to the action to be taken by any person that the HSSIB considers is appropriate. If the investigation relates to an incident that did not occur during the provision of NHS services, the report must also set out the HSSIB’s conclusions on the matters it considered with regard to clause 94(3). This clause outlines that in these circumstances the HSSIB must consider whether, in relation to any risks identified, the systems and practices in the provision of NHS services could be improved.

842 In making recommendations, the HSSIB must focus on addressing risks to the safety of patients, rather than on the activities of individuals involved in the incident. In particular, the final report may not include any assessment or determination of blame, civil or criminal liability, or whether action needs to be taken in respect of an individual by a regulatory body (under clause 97(3)).

843 Set out by clause 97(5), protected information may be disclosed in the final report if the HSSIB determines that the benefits to patient’s safety served by the disclosure outweigh any adverse impact on current or future investigations by deterring people from providing information to the HSSIB, and any adverse impact on securing the improvement of the safety of health care services provided to patients in England.

844 Names of individuals who provided information to the HSSIB for the purposes of the investigation, or who were involved in the incident under investigation, must not be included in the report, unless they have given their express permission to the HSSIB to do so.

845 Where an investigation is carried out following a direction from the Secretary of State under clause 95, the HSSIB must send a copy of the final report to the Secretary of State.

Clause 98: Interim reports

846 The HSSIB may publish an “interim report” during an investigation. The interim report may contain findings of fact and an analysis of the investigation’s findings together with any recommendations as to the action to be taken by any person that the HSSIB considers is appropriate. If the investigation relates to an incident that did not occur during the provision of NHS services, for example, in an independent hospital, the report may also set out the HSSIB’s conclusions with regard to clause 94(3). The aim is to address urgent risks to the safety of patients quickly, or issues that are known early in an investigation, so that swift action can be taken and lessons learned across health care systems.

847 Interim reports are subject to the same conditions as final reports, as set out in clause 97(3) to (7).

Clause 99: Draft reports

848 Before publishing a final or interim report, the HSSIB:

- i. must circulate a draft of the report to any person who the HSSIB reasonably believes could be adversely affected by the report, or where that person has died to the person who the HSSIB believes represents their best interest (if any) (under clause 99(1)(a));
- ii. may send a draft report to any other person who the HSSIB believes should be provided with a draft (under clause 99(1)(b));
- iii. must notify every person to whom a draft report has been sent that they have the opportunity to comment before a specified deadline. If a person’s comments are not taken into account, the HSSIB must explain to the person why this is (under clauses 99(3) and 99(4)).

Clause 100: Response to reports

849 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 who is in receipt of recommendations, in a manner the HSSIB thinks is appropriate. As outlined in clause 100(4), the addressees of the report must, by the HSSIB’s deadline,

provide a written response to the HSSIB setting out the action it will take in relation to the recommendations. The HSSIB may publish the response.

850 A response to a recommendation is not required where the recommendation could be required by an Act of Senedd Cymru, made without the consent of a Minister of the Crown (under clause 100(6)). This means that the duty to respond would not apply to any body that is, or could be established by the Welsh Parliament such as health service bodies. The HSSIB may make recommendations to persons in Wales who would be required to respond.

Clause 101: Admissibility of reports

851 Unless the High Court makes an order to the contrary, final and interim reports prepared by the HSSIB following an investigation (including drafts of those reports) are not admissible in certain types of proceedings, including:

- i. proceedings to determine civil or criminal liability;
- ii. proceedings before any employment tribunal;
- iii. proceedings before a regulatory body (including proceedings for the purposes of investigating an allegation);
- iv. proceedings to determine an appeal against a decision made in any of the above types of proceedings.

852 Set out by clause 101(3), the High Court may order that a final or interim report is admissible in the above proceedings in response to an application to the Court by a person who is a party to proceedings or otherwise entitled to appear in them. The HSSIB would be able to make representations to the Court about any application, for example to explain its reasons for not wanting the report to be considered as evidence in the proceedings.

853 Clause 101(5) outlines that the High Court may only make an order that a report of the HSSIB is admissible if it determines that the interests of justice served by admitting the report outweigh:

- i. any adverse impact on current or future investigations by the HSSIB by deterring persons from providing information, and,
- ii. any adverse impact on securing the improvement of the safety of health care services provided to patients in England.

Investigatory Powers etc

Clause 102: Powers of entry, inspection and seizure

- 854 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.
- 855 These are similar powers to investigatory bodies in other safety-critical industries, such as the Air Accident Investigations Branch (AAIB).
- 856 If the HSSIB considers it necessary for the purpose of furthering the investigation, an HSSIB investigator may enter and inspect premises in England; inspect and take copies of documents at the premises, or capable of being viewed using equipment at the premises, for example if the document is stored in the cloud; inspect any equipment or other item; and seize and remove any documents, equipment or items (unless doing so would put a patient's safety at risk).
- 857 Where any document, equipment or other item is seized by an investigator (including where a copy is taken), the HSSIB may retain it for as long as is necessary for the purposes of investigation (under clause 102(3)).
- 858 The power of entry does not apply to premises which are used wholly or mainly as a "private dwelling". An investigator can therefore only enter a private dwelling with consent. This could apply, for example, where domiciliary care is provided to a patient and would mean that an investigator would need to obtain consent from the resident before entering their home.
- 859 If asked an investigator must show evidence that he or she is acting on behalf of the HSSIB. This will normally be a letter of authority from the Chief Investigator.
- 860 There are specific provisions which apply where the HSSIB wishes to enter premises in which there is a Crown interest. This may be for example, in prisons, other secure institutions and premises occupied by armed forces personnel, where health care is provided.
- 861 Clause 102(5) provides that the HSSIB must give reasonable notice to the occupier of the premises before exercising its powers of entry. This will allow arrangements to be made to ensure the safety of the HSSIB investigators and to maintain security at the premises being inspected
- 862 If the Secretary of State believes that it is appropriate and in the interests of national security, the powers conferred by 102(1) can be limited. In summary these are powers of entry, inspection and seizure. This limitation can include restricting the exercise of the powers in which there is a Crown interest (which are specified in the certificate), or

restricting the powers so they are not exercisable in relation to premises which are specified, except in the circumstances outlined in the certificate. The definition of “Crown interest” is set out at clause 102(7).

Clause 103: Powers to require information etc.

863 Clause 103(1) makes provision for an investigator to obtain information, documents, equipment or other items. An investigator may give a notice asking someone to attend at a specified time and place to answer questions or to provide information, documents, equipment or other items as specified or of a description specified in the notice by a specified date.

864 An investigator may only give a notice in certain circumstances, specified in 103(2). A notice must outline the grounds the investigator has for believing they have fulfilled the circumstances in which a notice may be given and attach evidence of the investigator’s authority from the HSSIB to exercise the powers conferred in this section. It must also give a timescale for responding and an explanation of the consequences of failing to comply with the notice i.e. it could be a criminal offence, as set out in clause 105. A person who commits this offence is liable on summary conviction to a fine.

865 Information held in an electronic form, may be required in a form in which it is legible, and this should be made clear in the notice.

866 Clause 103 sets out the safeguards that apply where a notice is served. A person is not required by virtue of the notice to provide any information, document, equipment or other item where its provision would risk the safety of any patient, its provision might incriminate the person, or in the case of the information of document, the person would be entitled to refuse to provide it in any legal proceedings in any court on the grounds it is subject to legal professional privilege.

867 An investigator may withdraw a notice issued under clause 103.

868 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.

869 A person attending to answer questions pursuant to a notice must be reimbursed by the HSSIB for any reasonable costs incurred in attending. The HSSIB may record, by any means, such as in writing or electronically, the answers given by a person for the purposes of an investigation.

Clause 104: Voluntary provision of information etc

870 Clause 104 allows a person to disclose information, documents, equipment or other items to the HSSIB if he or she reasonably believes that disclosure is necessary to enable the HSSIB to carry out its functions, set out in clause 94.

Clause 105: Offences relating to investigations

871 Clause 105 creates new criminal offences for intentionally obstructing an investigator in the performance of functions conferred under clause 102 (power of entry, inspection and seizure), or failing to comply with a notice under clause 103 without a reasonable excuse. For example, if an individual intentionally obstructed an inspector from entering and inspecting a premises in England, this would be an offence. If a notice under clause 103 required a person to attend an interview at a given time and place, and they did not do so (without reasonable excuse), this would be an offence.

872 It is also a criminal offence to knowingly (or suspectingly) provide false or misleading information to the HSSIB, for the purposes of its investigation function, under clause 105(1). This could include providing information to an investigator as part of the investigation of a qualifying incident. But if a person discovers falsified or misleading information which they want to disclose to the HSSIB, they can do so, provided that they explain that they think the information is false. They would also need to demonstrate that they reasonably believed the information would help the HSSIB in carrying out its investigation function. If so, this would constitute a defence.

873 If a person relies on this defence, and there is evidence which causes issues with the defence, the court must presume that the defence is satisfied, until the prosecution proves beyond reasonable doubt that it is not.

874 Clause 105(4) sets out that a person who commits any of the offences will be subject to a summary conviction and a fine set by the courts. Persons in the public service of the Crown are not exempt from the offence of intentionally obstructing an investigator in the performance of their functions under clause 102 or being held liable upon summary conviction to a fine.

Protection of Material Held by the HSSIB

Clause 106: Prohibition on disclosure of HSSIB material

875 Clause 106(1) prevents the HSSIB, or any individual connected with the HSSIB from disclosing “protected material” to any person. In this context, protected material includes any information, document, equipment or other item which is held by the HSSIB (or a connected individual) for the purposes of the HSSIB’s investigation function, relates to a qualifying incident (regardless of whether it is being investigated) and has not already been lawfully made available to the public.

876 Clause 106(2) sets out that any information, documents, equipment or other item which is not held by the HSSIB (or a connected individual) for the purposes of the HSSIB's investigation function, does not relate to a qualifying incident (whether or not investigated by the HSSIB), or which has previously and lawfully been made available to the public, is not to be regarded as "protected material" in this context. The aim is to create a 'safe space' within which participants can provide information for the purposes of an investigation in confidence and therefore feel able to speak openly and candidly with the HSSIB.

877 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.

878 Clause 106(3) to (5) define who the main prohibition on disclosure applies to. These include past and present members of the HSSIB, including committee and sub-committee members, investigators and administrators or other workers of the HSSIB including apprentices and agency workers.

Schedule 14: Prohibition on disclosure of HSSIB material: exceptions

Disclosures for purposes of investigations

879 The HSSIB, or an individual connected with the HSSIB, may disclose protected material to an individual connected with the HSSIB if either the person making the disclosure, or an authorized person reasonably believes that the disclosure is necessary for the purposes of carrying out the HSSIB's investigation function.

880 In this context, "authorised person" means an individual who is connected with the HSSIB and authorized by the HSSIB for this purpose. The HSSIB, or a connected individual, may disclose protected material to a person who is not connected to the HSSIB if the Chief Investigator reasonably believes that the disclosure is necessary to carry out the HSSIB's investigation function.

Disclosures relating to prosecution or investigation of offences

881 Either the HSSIB or a connected individual may disclose protected material to a person if the Chief Investigator reasonably believes that the disclosure is necessary for the prosecution or investigation of an offence under clause (105) (offences relating to investigations) or (108) (offences of unlawful disclosure).

Disclosures relating to safety risks

882 The HSSIB, or a connected individual, may disclose protected material to an individual where the Chief Investigator reasonably believes that disclosure is necessary to address a serious and continuing risk to the safety of any patient or to the public.

883 However, the HSSIB may disclose no more than is necessary, to enable the person in receipt of the protected material to take steps to address the risk. The protected material may only be disclosed to an individual who the Chief Investigator reasonably believes is in a position to address that risk. For example, where the HSSIB have evidence of negligent behaviour by a medical professional, which may risk the safety of patients and wish to disclose that information to their employer, they should only disclose sufficient information to enable the employer to carry out their own investigation.

Disclosure by order of the High Court

884 A person may apply to the High Court for access to protected material for specified purposes. This may include onward disclosure to a person specified in the application.

885 The HSSIB may make representation to the High Court if an application for disclosure is made.

886 The Court may only make an order to allow the protected material to be disclosed if it determines that the interests of justice served by disclosing the protected material in question outweigh:

- any adverse impact on current and future investigations by the HSSIB by deterring persons from providing information for investigations, and
- any adverse impact on securing the improvement the safety of health care services provided to patients in England.

Coroners

887 A coroner must conduct an inquest into a death that he or she suspects was violent or unnatural, where for example, the deceased might have been murdered or taken his or her own life, if the cause of death is unknown or if the person dies in custody or otherwise in state detention. Coroners have powers under the Coroners and Justice Act 2009 to compel the production of evidence for the purposes of an investigation.

888 Notwithstanding clause 106 (prohibition on disclosure of HSSIB material), a senior coroner may require the disclosure of protected material by the HSSIB pursuant to paragraph 1(1)(b) or (c) or (2) of Schedule 5 to the Coroners and Justice Act 2009. For these purposes, a senior coroner is a person appointed as a senior coroner under paragraph 1 of Schedule 3 to the Coroners and Justice Act 2009.

889 The HSSIB may disclose protected information to a senior coroner for the purpose of complying with a notice issued in accordance with Schedule 5 of the Coroners and Justice Act 2009. The HSSIB may also disclose information to a senior coroner if the Chief Investigator reasonably believes that the senior coroner could require the HSSIB to

disclose the material if they issued a notice pursuant to Schedule 5 (where a notice is not in fact issued).

890 A senior coroner who receives protected material from the HSSIB will not be able to disclose the protected material to any other person, including using it during an inquest, unless the senior coroner successfully applies to the High Court for an order permitting disclosure.

891 A senior coroner may apply to the High Court for an order that protected material disclosed to them pursuant to this section, may be disclosed in the course of an investigation under Part 1 of the Coroners and Justice Act 2009, which may include at an inquest, which is held in public. The protected material may also be disclosed in reports about action to prevent deaths, or otherwise to another person.

892 In these circumstances, the High Court may only allow the protected material to be disclosed if it determines that the interests of justice served by disclosing the protected material in question outweigh: any adverse impact on current and future investigations by the HSSIB by deterring persons from providing information for investigation, and any adverse impact on securing the improvement of the safety of health care services provided to patients in England.

Exercise of Chief Investigator's functions

893 This provision gives the Chief Investigator the power to delegate functions under any provision of Schedule 14 to an HSSIB investigator. The delegation of such functions may relate to all cases, a particular case, or certain type of cases.

Guidance

894 The HSSIB must publish guidance and any revisions to the guidance, setting out the circumstances in which the HSSIB may exercise its power to disclose under paragraphs 2, 3 or 4 of Schedule 14, the types of protected material it might be appropriate to disclose under such a provision, and the processes it should follow when disclosing protected material.

Clause 107: Exceptions of prohibition on disclosure

895 Clause 107 specifies that the prohibition on disclosure set out in clause 106(1) does not apply to a disclosure authorised or required by schedule 14 (which lists exceptions to the prohibition on disclosure), any other provision of this Part, or regulations made by the Secretary of State.

896 Clause 107(1)(c) also provides for a regulation-making power for the Secretary of State. This allows for regulations to be made authorising the disclosure of particular protected

materials. However, a regulation may not be made which would authorise the disclosure of all protected material by reference to the incident to which it relates.

Clause 108: Offences of unlawful disclosure

897 A person commits an offence if they breach the prohibition on disclosure of protected material held by the HSSIB (clause 106(1)) by knowingly or recklessly disclosing protected material to another person, and they know or suspect that disclosure is prohibited. This applies to the persons who fall within the definition of the HSSIB in clause 106(3).

898 A person formerly connected with the HSSIB commits an offence if they breach the prohibition on disclosure under clause 106(5) by knowingly or recklessly disclosing protected material to another person, and they know or suspect that disclosure is prohibited.

899 A person who is not connected with the HSSIB, but who receives protected material from the HSSIB in accordance with paragraphs 2-4 of schedule 14, or a draft report, or under any regulations made under 107(1)(c), commits an offence if they knowingly or recklessly disclose protected material to another person without reasonable excuse, and they know or suspect that the material in question is protected material.

900 A person who commits an offence under this clause is liable on summary conviction to a fine.

Clause 109: Restriction of statutory powers requiring disclosure

901 Clause 109 prevents a power in any other legislation being used to require disclosure of, or to seize, any protected material from the HSSIB. This clause does not apply to coroners in some circumstances (see paragraph 6 of Schedule 14). Clause 109(3) ensures that the clause will not impact on any provision that is within the competence of a devolved legislature.

Relationship with other bodies

Clause 110: Co-operation

902 Clause 110 recognises that other health bodies may be investigating the same or a related incident to that being investigated by the HSSIB which could raise logistical issues. Both the HSSIB and the listed health bodies must co-operate with each other in respect of practical arrangements for co-ordinating those investigations such as appropriately sequencing investigations. The listed health bodies are:

- a) an NHS foundation trust, an NHS trust or any other person providing NHS services;

- b) NHS England;
- c) an integrated care board;
- d) a Special Health Authority;
- e) the Care Quality Commission;
- f) the Health Research Authority;
- g) the Human Tissue Authority;
- h) the Human Fertilisation and Embryology Authority;
- i) Health Education England;
- j) the Health Service Commissioner for England;
- k) the Parliamentary Commissioner for Administration;
- l) any regulatory body;
- m) the Health and Safety Executive
- n) the Commissioner for Patient Safety

Clause 110(4) and (5) requires the HSSIB to publish guidance clarifying when incidents should be regarded as related and must publish any revisions to the guidance.

Clause 111: Assistance of NHS bodies

903 In addition to its core investigatory functions, the HSSIB may disseminate information about best practice in carrying out investigations, developing standards to be adopted in carrying out investigations and providing advice, guidance or training. Where requested to do so, the HSSIB must give assistance to the following NHS bodies relating to the carrying out of investigations into incidents occurring during the provision of NHS services or occurring at premises at which NHS services are provided: NHS trusts, NHS foundation trusts, and the NHS England and integrated care boards. The Secretary of State, NHS England or the body itself may request the assistance. If the assistance sought is the provision of advice, guidance or training, the HSSIB would not be bound to provide this assistance if it decided it was impracticable for it to do so.

904 The HSSIB may also give assistance to other persons not listed in this clause, including independent providers of healthcare services. The HSSIB may only give assistance to such persons where the assistance is connected to a matter related to the carrying out of investigations and they are requested to do so by the person themselves. The HSSIB may only provide assistance in these circumstances where the assistance does not significantly interfere with the HSSIB's investigation function. The activities which the

HSSIB may carry out in order to give this assistance is not restricted to activities carried out in the United Kingdom.

905 Except in the case of the listed NHS bodies in England, the HSSIB may charge a fee for sharing its expertise on a commercial basis.

Clause 112: Investigations relating to Wales and Northern Ireland

906 The HSSIB may enter into agreements to carry out certain investigations, outlined by 112(2), These investigations include those which are into one or more incidents that have occurred, or is occurring, in the United Kingdom:

- During the provision of services provided for the purposes of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006 and/or health care, within the meaning of the Health and Social Care (Reform) Act (Northern Ireland) 2009, provided for the purposes of the system promoted under section 2(1) of that Act. Alternatively, the incident(s) occur at premises at which any of those services are or have been provided.

And where:

- The incident(s) have or may have implications for the safety of persons for whom those services are provided.
- The investigation is carried out for the purpose of identifying risks to the safety of such persons and addressing those risks by facilitating the improvement of systems and practices in the provision of any:
 - services provided for the purposes of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006, or,
 - health care within the meaning of the Health and Social Care (Reform) Act (Northern Ireland) 2009, provided for the purposes of the system promoted under section 2(1) of the Act, and
- The investigation does not involve the assessment or determination of blame or civil or criminal liability.

907 The HSSIB may impose charges for providing services under an agreement to carry out these investigations. These investigations may only be entered into by the HSSIB if it considers that the provision of services under the agreement will not, to any significant extent, interfere with the exercise by the HSSIB of its investigation function.

908 The HSSIB cannot contract to provide such investigations in respect of Scottish Health care but bodies in Scotland may request expertise from HSSIB under clause 111 during the course of its own investigation.

Oversight of functions

Clause 113: Failure to exercise functions

909 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. In that event, the clause confers on the Secretary of State a power to direct the HSSIB as to how to exercise its functions, setting a time frame if appropriate. In the event that the HSSIB failed to comply with such directions, the Secretary of State may exercise the functions in question or arrange for another party to do so. The Secretary of State, when giving a direction, cannot direct the HSSIB about the outcome of a particular investigation.

Clause 114: Review

910 Clause 114 confers a duty on the Secretary of State to review the effectiveness of the HSSIB in exercising its investigation function, prepare and publish a report of that review, and lay the report before Parliament. This must be done before the end of four years of clause 94 coming into force.

Offences: supplementary

Clause 115: Offences by bodies corporate

911 Clause 115 deals with corporate liability. If an offence under Part 4 of the Bill is proved to have been committed with the consent or connivance of an officer of a body corporate or is attributable to any neglect on the part of an officer, then the individual officer as well as the body corporate, commits the offence and is liable to be proceeded against and punished accordingly. An officer of a body corporate means a director, manager, secretary or other similar officer or anyone purporting to act in any such capacity.

Clause 116: Offences by partnerships

912 Clause 116 provides for when an offence has been committed by a partnership, such as a GP partnership, and allows proceedings to be brought in the name of the partnerships as well as the individual partners.

913 If an offence under Part 4 of the Bill is proved to have been committed with the consent or connivance of a partner or is attributable to any neglect on the part of a partner, then the individual partner (which includes a person purporting to act as a partner), as well as the partnership commits the offence and is liable to be proceeded against and punished accordingly.

914 A fine imposed on a partnership must be paid out of the partnership assets. If an individual partner is convicted of an offence the fine would be paid by the partner as an individual.

915 For the purposes of proceedings such as Schedule 3 of the Magistrates' Courts Act 1980, and rules of the court relating to the service of documents, partnerships should be treated as if they are a body corporate.

Supplementary

Clause 117: Obligations of confidence etc

916 Any disclosure of information, document, equipment, or other item which is required or authorised by clause 103, clause 104 or schedule 14 does not breach any obligation of confidence owed by the person making the disclosure or any other restriction on disclosure.

917 Nothing within Part 4 of the Bill requires or authorises a disclosure of information which would contravene data protection legislation. When considering whether a disclosure would breach data protection legislation, it should be taken into account that the Bill requires or authorises disclosure.

Clause 118: Consequential amendments relating to Part 4

918 Clause 118 inserts schedule 15, which makes consequential amendments in relation to the establishment of the HSSIB.

Schedule 15: Consequential Amendments relating to Part 4

919 This schedule makes consequential amendments to the following Acts to include references to the HSSIB where appropriate:

- Public Records Act 1958
- Public Bodies (Admission to Meetings) Act 1960
- Parliamentary Commissioner Act 1967
- House of Commons Disqualification Act 1975
- Copyright, Designs and Patents Act 1988
- Employment Rights Act 1996
- Freedom of Information Act 2000
- National Health Service Act 2006
- Health Act 2009
- Equality Act 2010.

Clause 119: Interpretation of Part 4

920 Clause 119 provides definitions that apply throughout Part 4 of the Bill.

Part 5: Miscellaneous

International Healthcare

Clause 120: International Healthcare arrangements

- 921 This clause amends the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 (“HEEASAA”) to enable the Government to implement comprehensive reciprocal healthcare agreements with countries outside the EEA and Switzerland.
- 922 Subsections (1) and (6) renames the short title of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 so it is clear that the legal framework for implementing comprehensive healthcare arrangements in the Act is no longer restricted to arrangements with the European Economic Area and Switzerland.
- 923 Subsection (3) and (4) removes the wide power to make healthcare payments in section 1 HEEASAA and the power to make regulations in relation to healthcare and healthcare agreements in section 2 HEEASAA and replaces it with a healthcare agreements and payments regulation power. The effect of this substitution is that the Secretary of State will be able to make regulations to pay for healthcare provided outside the United Kingdom where the payments give effect to a healthcare agreement (new section 2(1) HEEASAA). The exact arrangements which will be provided for under any future reciprocal healthcare agreements is a matter for negotiations.
- 924 The Secretary of State will also be able to make regulations for the payment of healthcare provided in another country where the healthcare is outside the scope of a healthcare agreement but only if the Secretary of State thinks the payment is justified by exceptional circumstances and the healthcare is provided in a country with which the UK has a healthcare agreement (new section 2(2) HEEASAA). This discretionary power, could, for example, be exercised to pay for a specific treatment which falls outside the scope of an agreed healthcare agreement.
- 925 The amendments in new section 2(1) - (7) HEEASAA provide the Secretary of State with a discretionary power to make regulations (negative) that make provision for the purpose of giving effect to a healthcare agreement and for discretionary payments outside the scope of a healthcare agreement.
- 926 Among other things, regulations made under section 2 are capable of being used to confer or delegate functions to a public authority.
- 927 The substituted section 2 effectively removes the existing section 2 power to make regulations to establish detailed unilateral healthcare arrangements. This power was created to support people to access healthcare in the EEA and Switzerland in the event

of a no deal EU Exit. As we have now agreed social security coordination provisions covering healthcare in the EU in the Withdrawal Agreement and the Trade and Cooperation Agreement, this measure is no longer needed.

928 Subsection (5) amends the definition of “healthcare agreement” so that it is clear it includes any agreement regarding healthcare provided in another country, whether payments are included in the agreement or not.

929 The amendments will also extend the existing data sharing provisions in section 4 HEEASAA to ROW countries to provide a legal basis for facilitating data processing to support the making of payments and the giving effect to healthcare agreements. This data sharing will be fully in line with the UK GDPR as section 4 provides that it does not authorise the processing of personal data which “contravenes the data protection legislation”.

930 The territorial extent and application of this clause is England and Wales, Scotland and Northern Ireland.

Social Care: Regulation and Financial Assistance

Clause 121: Regulation of local authority functions relating to adult social care

931 Clause 121 amends Chapter 3 of Part 1 of the Health and Social Care Act 2008.

Subsection (3) inserts section 46A to the Health and Social Care Act 2008 to introduce a new duty for the CQC to review and make an assessment of the performance of English local authorities in their delivery of their adult social care functions under Part 1 of the Care Act 2014.

932 Section 46A(1) will require the CQC to review local authorities undertaking of ‘regulated care functions’ (adult social care functions under Part 1 of the Care Act 2014), assess their performance following such a review and then publish a report of its assessment.

933 Section 46A(2) and (3) provide that the ‘regulated care functions’ to be reviewed are to be set out in secondary legislation and may include all or an aspect of a function.

934 The reviews undertaken by the CQC under new section 46A will be by reference to objectives and priorities set for the CQC by the Secretary of State under section 46A(4). Review by the CQC will be by reference to a set of quality indicators determined by the CQC and subject to the subsequent approval of the Secretary of State. Under section 46A(8) the CQC must devise a methodology for assessing and evaluating local authorities’ performance , and the frequency by which it will undertake its performance

reviews, which it must then set out in a statement to be approved by the Secretary of State. The methodology can be varied according to the circumstances of the review.

935 Upon approval by the Secretary of State, in accordance with section 46A(11) the CQC must then publish this statement. The CQC must also publish the objectives and priorities against which it is undertaking its reviews as set by the Secretary of State, and the quality indicators against which performance is to be assessed.

936 Under section 46A(12) the new review and performance assessment duty of the CQC will apply to “relevant English local authorities” who have duties and responsibilities to undertake adult social care functions, namely: county councils, district councils where there is no county council, London borough councils or the Common Council of the City of London. For the purposes of this section it is also specified that the Council of the Isles of Scilly is included in this definition of ‘English local authority’ only so far as references to local authority in Part 1 of the Care Act 2014 include references to the Council of the Isles of Scilly.

937 Subsection (4) amends section 48 so that a special review is a review other than a review under section 46A.

938 Subsection (5) amends section 50 of the Health and Social Care Act 2008, such that following a review of a local authority under Section 46A, there will be certain steps that the CQC may or must take when a local authority is considered by the CQC to be failing in the discharge of its adult social services functions. In accordance with the provisions in section 50, these steps are determined by whether the CQC considers failings to be substantial or not.

939 Under section 50 of the Health and Social Care Act 2008, if the CQC considers that a local authority is failing to discharge of any of its adult social services functions to an acceptable standard, it is obliged to inform the Secretary of State and recommend any special measures that it considers that the Secretary of State should take. Following a recommendation by the CQC of special measures, the CQC must, if asked to do so by the Secretary of State, undertake a further review of the local authority concerned and prepare a further report, covering any particular issues the Secretary of State might specify. Where the failing is deemed as not substantial by the CQC, it may instead give notice to the local authority setting out the details of failure; the action that the CQC thinks the local authority should take to remedy the failing; and the time by which the CQC considers that this should be done, and inform the Secretary of State of the giving of the notice.

940 Subsection (6) amends section 60 of the Health and Social Care Act 2008, so that the CQC may carry out inspections of relevant English local authorities in relation to the exercise of their regulatory functions.

Clause 122: Provision of social care services: financial assistance

941 The Health and Social Care Act 2008 allows the Secretary of State to provide financial assistance to ‘qualifying bodies’ who are providing health and social care services, or to those providing related services to providers of health and social care services.

942 Section 150 of the Health and Social Care Act 2008 and the Health and Social Care (Financial Assistance) Regulations 2009 prescribe conditions for a ‘qualifying body’, and this excludes providers who operate for profit. Social care in England is largely delivered by private providers operating on a profit-making basis as an ordinary business. As such, the Secretary of State is unable to make direct payments under this existing statutory power to much of the social care provider sector. Regular funding for social care is delivered funded via CCGs (soon to be Integrated Care Boards) or local authorities.

943 Clause 122 seeks to address this by making changes to sections 149-156 of the Health and Social Care Act 2008, expanding existing powers so that payments can be made to providers delivering social care services or delivering services relating to that provision of social care.

944 These proposals do not amend the powers in these sections regarding the ability of the Secretary of State to make payments to health service providers. The type of payment that can be made and any terms on which a payment is made, to health service providers will also not be changed.

Professional Regulation

Clause 123: Regulation of health care and associated professions

945 Clause 123 amends section 60 and schedule 3 of the Health Act 1999 and enables further changes to be made through secondary legislation to the professional regulation system.

946 Subsections 2(a) and (b) of clause (123) amends section 60 by inserting new subsections (1)(bza) & (1)(be) and permits a profession currently regulated to be removed from statutory regulation when the profession no longer requires regulation for the purpose of the protection of the public. This power extends to the regulation of social care workers in England, for whom the power to regulate in legislation is not currently enacted.

- 947 Subsection 2(c) substitutes a new section (2) which provides an updated list of the legislation that regulates the professions and subsection 2(d) inserts a new subsection (2ZZA) which clarifies that a healthcare profession within the scope of section 60 includes any group of workers, whether or not they are generally regarded as a profession, which may include senior managers and leaders. Subsection 2(e) amends section 2ZB to make clear the new power to take professions out of regulation includes the currently un enacted provisions concerning social care workers in England.
- 948 Subsection 3(a) and (b) amends Schedule 3 of the Health Act 1999 (by inserting a new para 1C and removing sub-paragraphs 7(1) & (1A) to permit the abolition of an individual health and care professional regulatory body, where the profession(s) it regulates continues to be regulated by another regulatory body or where the profession(s) has been removed from regulation. This power includes the regulation of social care workers in England for which the power to regulate in legislation is not currently enacted.
- 949 The current restrictions on the power for health and care regulatory bodies to delegate their functions in schedule 3 para 8 through legislation will be amended by subsection 3(c) to enable the delegation of certain functions to another regulatory body. These functions are the keeping of a register; determining standards of education and training for admission to practice and providing advice about standards of conduct and performance; and carrying out the fitness to practise function. This will also apply to the regulation of social care workers in England, if the provision concerning them are enacted. The intention is that the delegating regulator will retain responsibility for the delegated function in relation to the professions it continues to regulate.

Medical Examiners

Clause 124: Medical Examiners

- 950 Clause 124 amends sections 19 and 20 of the Coroners and Justice Act 2009 in England.
- 951 Subsection (2) amends section 19 of the Coroners and Justice Act 2009 to insert three new subsections ((A1)-(A3)).
- 952 Subsection (2) ((A1)) introduces a power for English NHS bodies to appoint Medical Examiners.
- 953 Subsection (2) ((A2)) introduces a duty on the Secretary of State for Health and Social Care 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 to identify and deter poor practice, and to ensure that their performance is monitored.

954 Subsection (2) ((A3)) introduces a power for the Secretary of State for Health and Social Care to give a direction to an English NHS body in order to: require the body to appoint one or more medical examiners; set out the funds or resources that should be made available to such employed medical examiner; set out the means and methods that may be employed to monitor performance of medical examiners.

955 Subsections (3) and (4) amend section (19)(1) and (19)(2) to remove references to local authorities in England but leave or clarify the references to Local Health Boards in Wales

956 Subsection (5) amends section 19(5) to replace the reference to a local authority with an English NHS body. The effect of this subsection is to make clear that this section and any regulations made under it does not give such English NHS body any role in relation to the way in which medical examiners exercise their professional judgment as medical practitioners.

957 Subsection (6) amends section 19 to insert a new subsection (5A), which defines English NHS body for the purposes of section 19 as:

- a. NHS England
- b. An Integrated Care Board
- c. An NHS Trust
- d. A Special Health Authority
- e. An NHS Foundation Trust.

958 Subsection (8) amends section 20(5) of the Coroners and Justice Act 2009, which provides a power to make regulations requiring a fee to be payable in respect of the medical examiner's confirmation of cause of death. The amendment will require any such fee to be payable to an English NHS body rather than a local authority. The introduction of regulations will be dependent on wider reforms around existing requirements for cremations and will be subject to further parliamentary scrutiny.

959 Subsection (9) amends section 20(7) to provide that, for the purposes of section 20, 'English NHS body' has the same meaning as in Section 19.

960 Subsection (10) amends the 2012 Act removing the provision which inserted references to English local authorities initially into the Coroners and Justice Act 2009.

Food and Drink

Clause 125: Advertising of less healthy food and drink

961 Clause 125 inserts schedule 16.

962 Schedule 16 is attached to clause 125 which amends the Communications Act 2003 to

restrict the advertising of certain food and drink products. This schedule is divided into four paragraphs:

- Paragraph 1: the watershed prohibition as it applies to Television
- Paragraph 2: the watershed prohibition as it applies to ODPS under UK jurisdiction
- Paragraph 3: the paid-for prohibition as it applies online
- Paragraph 4: consequential amendments needed to the Communications Act 2003

Schedule 16: Advertising of less healthy food and drink

Part 1: Programme services: Watershed

Paragraph 1: Television programme services

963 Paragraph 1 of Schedule 16 to clause 125 of the Bill inserts new section 321A into the Communications act 2003.

964 Subsection (1) of the new section 321A requires OFCOM to set standards to prohibit the advertising of identifiable less healthy food and drink on television programmes between 0530-2100.

965 Subsection (2) confirms that the prohibition will not apply to advertisements by food or drink small and medium sized enterprises (“SMEs”); and any advertisements prescribed in any regulations made by the Secretary of State. Subsection (3) confirms before the Secretary of State can make any regulations for additional exemptions under subsection (2) they are under a duty to consult.

966 Subsection (4) confirms that “advertisements” include those under sponsorship agreement. Products are “identifiable” if a person could reasonably be expected to identify the advertisements as being for that product. Products are determined to be “less healthy” via a two stage approach. They first need to be included in one of the product categories that will be set out in regulations, then the ‘relevant guidance’- the “Nutrient Profiling Technical Guidance¹²” will need to be applied. Subsection (6) confirms that the Secretary of State may amend the definition of ‘relevant guidance’. However, subsection (7) confirms that changes must first be laid before and approved by the both Houses of Parliament. Subsection (4) also defines “food or drink SME” as meaning a small or medium enterprise as defined in regulations and subsection (5) allows that definition to include staff of another person.

¹² "Nutrient Profiling Technical Guidance - Gov.uk." 1 Jan. 2011, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf. Accessed 18 Jun. 2021.

Paragraph 2: On-demand programme services

967 Paragraph 2 of Schedule 16 to the Bill inserts a new section 368FA in the Communications Act 2003.

968 Subsection (1) of new clause 368FA introduces a restriction on the advertising of less healthy food and drink on on-demand programme services between 0530-2100.

969 Subsection (2) confirms that the prohibition will not apply to advertisements by food or drink SMEs.

970 Subsection (3) confirms that further exemptions to the prohibition may be made by regulation by the Secretary of State. Subsection (4) confirms that before the Secretary of State can make any regulations under subsection (3) they are under a duty to consult.

971 Subsection (5) confirms that “advertisements” include those under sponsorship agreement. Products are “identifiable” if a person could reasonably be expected to identify the advertisements as being for that product. Products are determined to be “less healthy” via a two stage approach. They first need to be included in one of the product categories that will be set out in regulations, then the ‘relevant guidance’ - the “Nutrient Profiling Technical Guidance¹³” will need to be applied. Subsection (7) confirms that the Secretary of State may amend the definition of ‘relevant guidance’. However, subsection (8) confirms that this cannot be done without first being laid before and approved by both Houses of Parliament. Subsection (5) also defines “food or drink SME” as meaning a small or medium enterprise as defined in regulations and subsection (6) allows that definition to include staff of another person.

Part 2: Online Services: Prohibition

972 Paragraph 3 of Schedule 16 to the Bill inserts Part C Online advertising of less healthy food and drink in the Communications Act 2003, after Part 4B. Part C comprises Sections 368Z14 through to 368Z20.

368Z14 Prohibition of paid-for advertising of less healthy food and drink

973 Subsection (1) prohibits paid-for advertising of identifiable less healthy food and drink online.

974 Subsection (2) confirms that the prohibition will not apply to advertisements by food or drink SMEs. Subsection (3) confirms that the prohibition does not apply to business-to-business advertisements where business activity and commerce is not conducted with

¹³ "Nutrient Profiling Technical Guidance - Gov.uk." 1 Jan. 2011, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf. Accessed 18 Jun. 2021.

the purpose of encouraging children's consumption of less healthy food or drink. This subsection also exempts: advertisements that are included in UK regulated on-demand programme services as these fall into the watershed prohibition, advertisements in regulated radio services, advertisements paid for by a person / parties that do not carry on business in the UK and are not intended to be accessed by a UK audience.

975 Subsection (4) provides; and that further exemptions to the prohibition may be made by regulation by the Secretary of State in order to keep up with developments in technology and changes in the industry to this policy as it develops. Subsection (5) confirms that before the Secretary of State can make any regulations under subsection (4) the Secretary of State is under a duty to consult.

976 Subsection (6) confirms that "payment" includes monetary or non-monetary exchange when in reference to placing advertisements on the internet. "Placed" includes continued to be placed. "Advertisements" include those under sponsorship agreement. Products are "identifiable" if a person could reasonably be expected to identify the advertisements as being for that product. Products are determined to be "less healthy" via a two stage approach. They first need to be included in one of the product categories that will be set out in regulations, then the 'relevant guidance'- the "Nutrient Profiling Technical Guidance"¹⁴ will need to be applied. Subsection (8) confirms that the Secretary of State may amend the definition of 'relevant guidance'. However, subsection (9) confirms that changes must first be laid before and approved by the both Houses of Parliament. Subsection (6) also defines "food or drink SME" as meaning a small or medium enterprise as defined in regulations and subsection (7) allows that definition to include staff of another person. Likewise, Subsection (6) states that regulated radio services will be given meaning by regulations.

977 Subsection (10) confirms that from 1 August 2021 any paid online advertising of less healthy food or drink placed online on or after 1 January 2023 amounts to a breach of the prohibition. Subsection (11) confirms that subsection (10) does not apply if arrangements and reasonable action is taken to remove the advert before 1 January 2023.

368Z15 Enforcement

978 Subsection (1) details that when the Appropriate Regulatory Authority considers a person is/ has contravened the prohibition of paid-for advertising on the internet (section 368Z14), they may either give the person an enforcement notification and/or impose a financial penalty on them in accordance with the financial penalties detailed in

¹⁴ "Nutrient Profiling Technical Guidance - Gov.uk." 1 Jan. 2011, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf. Accessed 18 Jun. 2021.

section 368Z16.

979 Subsection (2) confirms that action outlined in subsection (1) cannot occur unless there are reasonable grounds for believing that a breach of the prohibition is occurring/occurred and that the Appropriate Regulatory Authority has allowed the person considered in breach an opportunity to make representations.

980 Subsection (3) confirms that enforcement notifications should specify how a person has breached the prohibition, and impose requirements on the person to take steps to remedy the breach, provides a reasonable amount of time for a person to remedy and sets out the reasons for the Appropriate Regulatory Authority's decision to issue the enforcement notification.

981 Subsection (4) confirms that remedial actions dictated by the Appropriate Regulatory Authority include instructing or requesting that specified persons remove advertisements from the internet and/or arrange for advertisements to be modified in specific ways.

982 Subsection (5) states that a person in receipt of an enforcement notification must comply with it. Subsection (6) outlines that compliance is enforceable in civil proceedings (i.e. through the civil court) by the Appropriate Regulatory Authority. Subsection (7) confirms that in circumstances of non-compliance with enforcement notifications, the Appropriate Regulatory Authority can impose financial penalties.

368Z16 Financial penalties

983 Subsection (1) outlines the financial penalty imposed on a person is as the Appropriate Regulatory Authority determines to be appropriate and proportionate to the scale of the breach. The maximum penalty on a relevant business is such amount not exceeding the greater of 5% of the turnover of the relevant business for the relevant period or £250,000. In any other case it is £250,000.

984 Subsection (3) confirms that a person's "relevant business" is any business which is involved or associated with the manufacture or sale of less healthy food or drink. "Relevant period", means the period of one year ending the 31 March before the time at which the penalty is imposed. However in the case that the business has been carrying for less than a year the relevant period is the time during which the business has been carried out, and if a business has ceased to operate when the penalty is imposed, then the relevant period is one year ending with the time the business ceased to operate. This subsection also outlines that the turnover of a relevant business should be calculated in accordance with UK accounting practices. If the relevant business consists of two or more undertakings, then the turnover for each is combined.

985 Subsection (4) confirms that to determine the applicable financial penalty of subsection (1) the Appropriate Regulatory Authority must have regard to statements published by OFCOM under section 392 CA (the guidelines to be followed in determining the amount of penalties).

986 Subsection (5) outlines that the financial penalty imposed under this section, if not paid within the relevant period, can be recoverable by the Appropriate Regulatory Authority as a debt from the person obliged to pay it. Subsection (6) details that if a financial penalty is imposed under this section that has a connection with Northern Ireland and no connection with the rest of the United Kingdom, the penalty must be paid into the Consolidated Fund of Northern Ireland, but in any other case, a financial penalty imposed under this section is to be paid into the Consolidated Fund of the United Kingdom as described in subsection (7).

368Z17 Power to demand information

987 Subsection (1) allows the Appropriate Regulatory Authority to give a person a notice demanding information, for the purpose of carrying out their functions. Subsection (2) confirms that they may demand any information that the person appears to have or be able to generate. Under subsection (3) notices must describe the required information, fix a reasonable period for the information to be provided and set out the appropriate regulatory authority's reasons for requiring it. Subsection (4) details that a notice under this section may specify the manner in which the information is to be provided.

988 Subsection (5) states that the Appropriate Regulatory Authority may not request information under this section unless they have given the person from whom it is required an opportunity to challenge the grounds for the request. Subsection (6) outlines that the enforcement mechanisms outlined in Section 368Z15 apply in relation to a failure to comply with a demand for information. Subsection (7) confirms that "information" includes copies of advertisements.

368Z18 Guidance

989 Subsection (1) confirms that the Appropriate Regulatory Authority must draw up and, from time to time, review and revise, guidance relating to the online advertising prohibition. Subsection (2) places a requirement for them to consult the Secretary of State before drawing up or revising the guidance, and in subsection (3) they must ensure any guidance is brought to the attention of those who will be affected by it.

368Z19 The Appropriate Regulatory Authority

990 Subsection (1) allows OFCOM to designate their function as the Appropriate Regulatory Authority to a body for the purposes of any provision in respect of the online advertising prohibition. "Designation" means the act of specifying an Appropriate

Regulatory Authority- Subsection (12). Subsection (9) outlines the requirements for a body to be designated.

991 Subsection (2) confirms that if OFCOM do not designate, that they (OFCOM) will be the Appropriate Regulatory Authority. However, if a body is designated then subsection (3) allows OFCOM to act as the Appropriate Regulatory Authority for that purpose concurrently with or in place of that body. Subsection (4) allows OFCOM to provide a designated body with assistance (including financial assistance) in connection with any of the functions of the body under this Part.

992 Subsection (5) and (6) outlines the designation framework to appoint a body as the Appropriate Regulatory Authority. Subsection (7) states that a designation is effective for a period specified by OFCOM and may be revoked by OFCOM at any time. Subsection (8) says OFCOM must publish any designation so that it is brought to the attention of people who are likely to be affected by it. Subsection (10) allows OFCOM to provide and share information to a designated body if it relates to their functions as the Appropriate Regulatory Authority and vice versa. Subsection (11) allows the appropriate regulatory body to carry out, commission or support (financially or otherwise) research where related to their functions.

368Z20 Power to amend this Part to extend prohibition

993 Subsection (1) gives the Secretary of State the power to amend this Part for the purpose of broadening the scope of restrictions to prohibiting persons from placing on the internet advertisements for an identifiable less healthy food or drink product and/or making arrangements for advertisements for an identifiable less healthy food or drink product to be placed on the internet. Subsection (2) defined “placing” as including leaving in place and “placed” as including continuing to be placed.

994 Subsection (2) allows the power detailed in subsection (1) to repeal, revoke or amend a provision made by or under any of the following whenever passed or made—

- an Act;
- an Act of the Scottish Parliament;
- a Measure or Act of Senedd Cymru;
- Northern Ireland legislation.

995 Subsection (4) sets a requirement to consult before making regulations under subsection (1) and subsection (5) sets a requirement for a statutory instrument containing regulations under subsection (1) to be laid before and approved by each House of Parliament.

368Z21 Interpretation

996 This Part outlines that the “Appropriate Regulatory Authority” is to be construed in accordance with section 368Z19 i.e. OFCOM; and that “less healthy”, in relation to a food or drink product, has the meaning given by section 368Z14(6)(d). Products are determined to be “less healthy” via a two stage approach. They first need to be included in one of the product categories that will be set out in regulations, then if they meet the description set out in regulations and in accordance with the ‘relevant guidance’ - the “Nutrient Profiling Technical Guidance¹⁵” will need to be applied.

Part 3: Consequential Amendments

997 This paragraph outlines the amendments that need to be made to the Communications Act 2003 to ensure that the new parts detailed in this Bill are in line with the rest of the 2003 Act.

998 It requires section 368C of the Communications Act 2003 to be updated to include a requirement on the Appropriate Regulatory Authority to draw up, review and revise guidance on section 368FA (the restriction for On-demand programme services) and for there to be a requirement to consult the Secretary of State before drawing up this guidance.

Clause 126: Hospital Food Standards

999 Section 20 of the Health and Social Care Act 2008 provides the Secretary of State with a general power to make regulations imposing any requirements to be met by providers and managers of regulated activities that he sees fit in relation to regulated activities. The regulations made may, in particular, include provision intended to safeguard the health, safety and welfare of people who receive regulated health care, and to ensure that those services are of the necessary quality.

1000 Clause 126 of the Bill introduces new section 20 (3)(da) to the Health and Social Care Act 2008 and allows the Secretary of State to make regulations as he sees appropriate to impose requirements in connection with food or drink provided or made available to any person on hospital premises in England that are used in connection with the carrying on of a regulated activity. 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.

1001 Subsection (a) amends subsection (3)(d) of section 20 of the Health and Social Care Act 2008 to introduce a new subsection (3)(da) which gives the Secretary of State a power to

¹⁵ "Nutrient Profiling Technical Guidance - Gov.uk." 1 Jan. 2011, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf. Accessed 18 Jun. 2021.

impose requirements in relation to food or drink provided or made available to any person on hospital premises in England.

1002 Subsection (b) amends subsection (4)(a) of section 20 of the Health and Social Care Act 2008 to specify that regulations made in relation to food and drink under the new subsection (3)(da) may be in relation to specific nutritional standards or other nutritional requirements.

1003 The proposed definition of hospital for the purposes of this clause is defined in section 275 of the National Health Service Act 2006 which states:

- “hospital” means:
- any institution for the reception and treatment of persons suffering from illness,
- any maternity home, and
- any institution for the reception and treatment of persons during convalescence or persons requiring medical rehabilitation,
- and includes clinics, dispensaries and out-patient departments maintained in connection with any such home or institution, and “hospital accommodation” must be construed accordingly,

1004 The Secretary of State is obliged to consult on any regulations made or any significant changes to existing regulations as required under subsection (8) of section 20.

1005 Section 162 of the Health and Social Care Act 2008 sets out the Parliamentary scrutiny for regulations made under section 20. Any regulations made under subsection 20 (3) (da) of Clause 126 will be subject to those requirements.

Clause 127: Food information for consumers: power to amend retained EU law

1006 Clause 127 introduces new section 16 (3A) and section 16 (3B) to the Food Safety Act 1990 and allows the Secretary of State (in relation to England) and Ministers in Scotland (in relation to Scotland) and Ministers in Wales (in relation to Wales) to amend by regulations pursuant to section 16 (1)(e) requirements set out in retained direct principal EU legislation, Regulation (EU) No. 1169/2011 relating to food information and labelling. Section 16 (1)(e) outlines which matters the regulations made under the power in this subsection may concern. For example, regulating, labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food.

1007 The Provision will apply to Wales and Scotland, where this Act will legislate for similar powers to be exercised by Ministers in those territories.

1008 Subsection 2 of the clause amends section 48 of the Food Safety Act 1990 and relates to Parliamentary scrutiny for regulations made under section 16 (1)(e) and 16(3A) of the Food Safety Act 1990. Subsection 48 is amended to state that any regulations made in reliance of section 16(3A), (3B) and (3C) which amend existing primary legislation will be subject to the affirmative procedure. Where the Secretary of State (in relation to England), Ministers in Wales (in relation to Wales) and Ministers in Scotland (in relation to Scotland), exercise the power under subsection 3A, 3B and 3C, the Regulations must be approved by their respective chamber (either both Houses of Parliament, Senedd Cymru or Scottish Parliament).

Fluoridation of Water Supplies

Clause 128: Fluoridation of water supplies

- 1009 Clause 128 amends certain provisions of the Water Industry Act 1991 to remove the power of local authorities to initiate new water fluoridation schemes or make variations or to terminate to existing schemes in England, and to confer that power instead to the Secretary of State for Health and Social Care.
- 1010 Clause 128(2) amends section 87 of the Water Industry Act 1991. It inserts a new enabling power (s.87(6A)) allowing the Secretary of State to disapply, through regulations, the existing provisions in section 87(6) which require the Secretary of State to reimburse water undertakers for capital and operating costs for operating fluoridation schemes. As provided by the new section 87(12), the affirmative resolution procedure must be used to make such regulations. New section 87(6B) enables the Secretary of State to make regulations (subject to the negative procedure) requiring public sector bodies to make payments to the Secretary of State to meet water fluoridation costs. New section 87(7G) imposes on the Secretary of State a duty to consult before making regulations under either new section 87(6A) or section 87(6B).
- 1011 Clause 128(2) also amends 87(11) of the Water Industry Act 1991 so as to require the Secretary of State to consult water undertakers (water companies who provide water and sewerage services for general domestic use to UK homes) on whether any fluoridation scheme, or variation or termination to an existing scheme is operable and efficient, prior to undertaking any consultation required by section 89 of the Act.
- 1012 Clause 128(5) makes changes to section 89 of the Water Industry Act 1991 so that it applies to both England and Wales (rather than just Wales, as currently). The effect of these amendments is to require the Secretary of State to consult on any proposals for new fluoridation schemes or proposals to vary/terminate existing schemes. There is an existing regulation making power in section 89 which, as applied to England, will enable

the Secretary of State to make regulations to provide further detail on the process and requirements of any consultation (including circumstances where consultation is not required).

Clause 129: Fluoridation of water supplies: transitional provision

1013 Clause 129 inserts new transitional provisions into the Water Industry Act 1991 in relation to England. They provide to the Secretary of State for Health and Social care the power to require water undertakers to enter into updated water fluoridation arrangements where the Secretary of State considers it necessary to render the arrangements fit for purpose. Clause 129 also amends section 91 of the Water Industry Act 1991 so that it applies only to Wales, maintaining the current position for transitional provisions in relation to Wales and any Welsh fluoridation arrangements.

Part 6: General

Clause 130: Power to make consequential provision

1014 This clause provides a power which allows the Secretary of State, by regulations, to make provision that is consequential on this Bill.

1015 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.

1016 Where regulations modify primary legislation, the affirmative procedure must be used. Otherwise, the regulations can be made under the negative procedure. This provision may be used to amend primary legislation passed in any part of the United Kingdom.

Clause 131: Regulations

1017 Subsection (1) provides that where regulations are made under this Act, those regulations may make consequential, supplementary, incidental, transitional or saving provision. Subsection (1)(b) also allows regulations to make different provision for different purposes.

1018 Subsection (2) clarifies that regulations under this Act are to be made by statutory instrument.

1019 Subsection (3) specifies that regulations made under the following powers in the Act 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 HSSIB's prohibition on disclosure.
- Clause 130 if any regulations are laid using this power to amend Primary legislation.

1020 Subsection (5) provides that this clause does not apply to commencement regulations.

Clause 132: Financial provision

1021 Clause 132 deals with the further financial provision necessary as a result of the Bill.

Clause 133: Extent

1022 Clause 133 sets out the territorial extent of the Bill, that is the jurisdictions within which the Bill forms part of the law.

1023 Subsection (1) provides that the Bill extends to England and Wales only with the exception of a few clauses specified in subsections (2) and (3).

1024 Subsection (2) sets out that the following sections and subsections of the Bill 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);

1025 Subsection (3) clarifies that any amendment made by the Bill has the same extent as the provision that is amended.

Clause 134: Commencement

1026 This clause provides that Part 6 of the Bill come into force on the day that this Act is passed. These are the general provisions (dealing with consequential amendments, regulations, extent, commencement and the Act's title). Clause 125 and Schedule 16 (advertising of less healthy food and drink) come into force on 1 January 2023. The remaining provisions of the Act 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.

Clause 135: Short title

1027 This clause states the Bill's short title as 'The Health and Care Act 2021'

Commencement

1028 Clause 134 sets out commencement. All the provisions of the Bill will come into force on the day or days specified by the Secretary of State in regulations other than Part 6 (dealing with consequential amendments, regulations, extent, commencement and the Act's title) which will come into force on the day this Act is passed and clause 125 and Schedule 16 (advertising of less healthy food and drink) which will come into force on 1 January 2023.

Financial implications of the Bill

1029 The measures in this Bill are, in the most part, enabling and as a result most of the proposals will not place direct costs on health and care organisations purely by their enactment.

1030 In most cases where provisions in the Bill create new bodies or to transfer functions between bodies these will not incur additional costs, because these functions are already being performed in the system. Indeed, we would expect the Bill to deliver savings as a result of more efficient exercise of those functions.

1031 Where costs are incurred, many will only materialise at a later stage depending on how organisations choose to deploy the provisions. Where some of the proposals trigger costs – such as with the creation of statutory ICBs, or mandatory data collection from social care providers – these are expected to be limited and will be funded from existing settlements, with benefits to the organisation's wider activities.

1032 As such, it is difficult to monetise any costs at this stage. The measures in the Bill that may result in cost include, but are not limited to:

- The establishment and running of Integrated Care Systems (comprising of the Integrated Care Board and the Integrated Care Partnership);
- The merger of NHS England and NHS Improvement and additional activities for that body (including supporting ICSs);
- The establishment of the Health Services Safety Investigations Body;
- The establishment of international healthcare arrangements;
- Medicine information systems;
- Regulation and financial assistance relating to social care; and
- Establishment of fluoridation of water schemes.

Parliamentary approval for financial costs or for charges imposed

1033 A money resolution is required for this Bill. A money resolution is required where a Bill authorises new charges on the public revenue (broadly speaking, new public expenditure). In relation to Parts 1 and 2 of the Bill, the potential for increases in public expenditure is mainly attributable to new or expanded functions conferred on public authorities. This includes expenditure on the newly created integrated care boards under clause 13 and on information systems relating to human medicines under clause 85. Part 3 of the Bill confers powers for the Secretary of State to transfer functions between, and delegate functions to, public authorities, which gives rise to the potential for increases in sums paid by the Secretary of State to those authorities. Part 4 of the Bill sets up the Health Services Safety Investigations Body, which is to be grant funded by the Secretary of State under paragraph 14 of Schedule 13 to the Bill. In Part 5 the potential for increased public expenditure is mainly attributable to clause 120 (which expands powers in respect of international healthcare agreements, including powers to make payments), clause 122 (which expands a powers to give financial assistance in respect of social care services) and clause 125 and Schedule 16 (which impose prohibitions on advertising of certain less health food and drink, which will be enforced by OFCOM).

1034 A ways and means resolution is also required for this Bill. A ways and means resolution is required where a Bill authorises new charges upon the people. The resolution is needed to cover the powers in clauses 32 and 91 and Part 2 of Schedule 13 to make tax changes in relation to transfer schemes. The resolution also covers the payment of sums into the Consolidated Fund, which is needed because new section 368Z16(7) of the Communications Act 2003 (inserted by Schedule 16 to the Bill) makes express provision for payments in.

Compatibility with the European Convention on Human Rights

1035 The Secretary of State for Health and Social Care has made a statement under section 19(1)(a) of the Human Rights Act 1998 that, in his view, the provisions of the Bill are compatible with the Convention rights.

1036 The imposition of a financial penalty under regulations made in exercise of the power in clause 84 on private providers of health or adult social care services engages the right to a fair trial in Article 6(1) ECHR. The limits set out on this power, including the

requirement for an independent appeal procedure, ensure it is compatible with Article 6 ECHR.

1037 The power conferred on the Health Services Safety Investigations Body in clause 103 to require individuals to provide information or answer questions potentially engages the right not to incriminate oneself, guaranteed by Article 6 ECHR. Therefore, clause 103(3) ensures that individuals are not required to provide information which may incriminate them. The HSSIB's function of investigating is expressly not exercisable to determine civil or criminal liability and so the engagement of participants in the HSSIB investigations does not engage Article 6.

1038 The power of entry conferred on the Health Services Safety Investigations Body in clause 102 may be exercised to enter business premises to obtain information for the purpose of an investigation, and therefore engages the right to respect for private and family life guaranteed by Article 8 ECHR and Article 1 of Protocol 1 (right to peaceful enjoyment of property and possession). The purpose of the provisions is to facilitate high quality investigations which aim to facilitate improvement of systems and practices in the provision of NHS Services. There are also adequate safeguards, for example, the HSSIB will hold and process confidential information in accordance with the law including data protection legislation and clause 102 provides that the power may not be used to enter premises that are wholly or mainly used as a private dwelling.

1039 Clause 125 introduces restrictions on advertising for less healthy food and drink products on (1) television programme services, (2) on-demand programme services and (3) the internet, which engage Article 10 ECHR (freedom of expression). These measures are necessary for the protection of health, which is one of the listed aims under Article 10, and are proportionate to this aim.

1040 The provisions of Parts 1, 2, 4 and 5 permit to a very limited extent the sharing of personal data with bodies for the purposes of certain functions conferred by the Bill, engaging the right to respect for private and family life guaranteed by Article 8 ECHR. This limited sharing of personal data is justified by the interests of operating an effective system of health and social care. Any impact on an individual's rights is clearly prescribed in the Bill and any information must be held and shared by the bodies concerned in compliance with the requirements of the Data Protection Act 2018 and the retained UK version of the General Data Protection Regulation (EU) 2016/679.

1041 The restrictions on advertising for less healthy food and drink products contained in clause 125 engage the right to freedom of expression guaranteed by Article 10 ECHR. The restrictions on advertising on television programme services, on-demand programme services and the internet are justified by the legitimate aim of protecting public health in

respect of childhood obesity. They do no more than is necessary to achieve this aim, and are therefore proportionate. The Government will publish an ECHR memorandum which explains in detail its assessment of the compatibility of the Bill's provisions with the Convention rights.

Related documents

The following documents are relevant to the Bill and can be read at the stated locations:

- *Integration and Innovation Working together to Improve Health and Social Care for All White Paper*: Integration and innovation: working together to improve health and social care for all (HTML version) - GOV.UK (www.gov.uk)
- *NHS Recommendations to Government and Parliament for an NHS Bill*: Microsoft Word - NHS's recommendations to Government and Parliament - Final.docx (England.nhs.uk)
- *NHS Long Term Plan*: NHS Long Term Plan » Online version of the NHS Long Term Plan
- *Integrating Care : Next Steps to Building Strong and Effective Integrated Care Systems across England*: Report template - NHSI website (England.nhs.uk)
- *Regulating healthcare professionals, protecting the public*: Regulating healthcare professionals, protecting the public
- *Reducing Bureaucracy in the Health and Social Care System*: **Error! Hyperlink reference not valid.**
- *A review of the Fit and Proper Person's Test*: A review of the Fit and Proper Person Test
- *Promoting Professionalism, reforming regulation: Government Response to Consultation*: Promoting professionalism, reforming regulation consultation response
- *Promoting Professionalism, reforming regulation*: Promoting professionalism, reforming regulation
- *Regulation of Health and Social Care Professionals*: Regulation of Health and Social Care Professionals | Law Commission
- *Learning not blaming: response to 3 reports on patient safety: Learning not blaming: the Government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS' and the Morecambe Bay Investigation*
- *Independent Review of NHS Hospital Food*: Report of the Independent Review of NHS Hospital Food (publishing.service.gov.uk)
- *Introducing further advertising restrictions on TV and online for products high in fat, sugar and salt (HFSS)*: [2019 Consultation](#)
- *Introducing a total online advertising restriction for products high in fat, sugar and salt (HFSS)*: [2020 Consultation](#)

- *Tackling obesity: empowering adults and children to live healthier lives*: [Tackling Obesity: empowering adults and children to live healthier lives](#)
- *Restricting promotions of food and drink that is high in fat, sugar and salt*: <https://www.gov.uk/government/consultations/restricting-promotions-of-food-and-drink-that-is-high-in-fat-sugar-and-salt#history>
- *Department of Health and Social Care Nutrient Profiling Technical Guidance*: [Nutrient Profiling Technical Guidance](#)
- *Data saves lives: reshaping health and social care with data (draft)*: Data saves lives: reshaping health and social care with data (draft) - GOV.UK (www.gov.uk)

Annex - Territorial extent and application in the United Kingdom

Healthcare is a devolved matter. The provisions in the Bill primarily extend to England and Wales and apply in England only. However, a number of measures do relate to devolved areas of competence.¹⁶

Applies to England only: Clauses 2-98, 102, 108, 110-119, 121, 122, 124, 126, 128, 129; and Schedules 1-13 and 15

Applies to England and Wales in part: Clauses 1, 78, 101, 107; and Schedule 14

Applies to England and Wales: Clauses 99, 100, 103-106, 111, 112

Applies to England, Wales and Scotland: Clause 127

Applies to all territories: Clauses 85-92, 109, 120, 123, 125, 130-135; and Schedule 16

Provision	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Would corresponding provision be within the competence of Senedd Cymru?	Would corresponding provision be within the competence of the Scottish Parliament?	Would corresponding provision be within the competence of the Northern Ireland Assembly?	Legislative Consent Motion needed?
PART 1								
Health Service in England: Integration, Collaboration and Reform								
Clause 1	Yes	In part	No	No	Yes	Yes	Yes	No
Schedule 1	Yes	No	No	No	Yes	Yes	Yes	No
Clauses 2-11	Yes	No	No	No	Yes	Yes	Yes	No
<i>Integrated care system</i>								
Clause 13	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 2	Yes	No	No	No	Yes	Yes	Yes	No
<i>Integrated care boards: functions</i>								
Clauses 12-19	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 3	Yes	No	No	No	Yes	Yes	Yes	No
<i>Integrated care partnerships</i>								
Clauses 20-25	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 4	Yes	No	No	No	Yes	Yes	Yes	No

¹⁶ References in this Annex to a provision being within the legislative competence of the Scottish Parliament, Senedd Cymru or the Northern Ireland Assembly are to the provision being within the legislative competence of the relevant devolved legislature for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.

<i>Merger of NHS bodies etc</i>								
Clauses 26-31	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 5	Yes	No	No	No	Yes	Yes	Yes	No
<i>Secretary of State's functions</i>								
Clauses 32-50	Yes	No	No	No	Yes	Yes	Yes	No
Schedules 6-7	Yes	No	No	No	Yes	Yes	Yes	No
<i>NHS foundation trusts</i>								
Clauses 51-57	Yes	No	No	No	Yes	Yes	Yes	No
<i>NHS trusts and NHS foundation trusts: transfer schemes</i>								
Clauses 58-59	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 8	Yes	No	No	No	Yes	Yes	Yes	No
<i>Joint working and delegation of functions</i>								
Clauses 60-61	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 9	Yes	No	No	No	Yes	Yes	Yes	No
<i>Collaborative working</i>								
Clauses 62-65	Yes	No	No	No	Yes	Yes	Yes	No
<i>NHS payment scheme</i>								
Clause 66	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 10	Yes	No	No	No	Yes	Yes	Yes	No
<i>Patient choice and provider selection</i>								
Clauses 67-69	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 11	Yes	No	No	No	Yes	Yes	Yes	No
<i>Competition</i>								
Clauses 70-73	Yes	No	No	No	Yes	Yes	Yes	No
<i>Miscellaneous</i>								
Clauses 74-77	Yes	No	No	No	Yes	Yes	Yes	No
Clause 78	Yes	In part	No	No	Yes	Yes	Yes	Yes (W)
PART 2 HEALTH AND ADULT SOCIAL CARE: INFORMATION								
Clauses 79-84	Yes	No	No	No	Yes	Yes	Yes	No
Clause 85	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (S, NI, W)
PART 3 SECRETARY OF STATE'S POWERS TO TRANSFER OR DELEGATE FUNCTIONS								
Clauses 86-92	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (S, NI, W)
PART 4 THE HEALTH SERVICES SAFETY INVESTIGATIONS BRANCH								
<i>Introductory</i>								
Clause 93	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 13	Yes	No	No	No	Yes	Yes	Yes	No
<i>Investigations</i>								
Clauses 94-96	Yes	No	No	No	Yes	Yes	Yes	No
<i>Reports</i>								
Clauses 97-101	Yes	No	No	No	Yes	Yes	Yes	No
<i>Investigatory powers etc</i>								
Clause 102-105	Yes	No	No	No	Yes	Yes	Yes	No
<i>Protection of material held by the HSSIB</i>								
Clause 106	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 14	Yes	In part	No	No	Yes	Yes	Yes	No
Clause 107	Yes	In part	No	No	Yes	Yes	Yes	No
Clause 108	Yes	No	No	No	Yes	Yes	Yes	No

Clause 109	Yes	Yes	Yes	Yes	N/A	N/A	N/A	No
<i>Relationship with other bodies</i>								
Clause 110 Co-operation	Yes	No	No	No	Yes	Yes	Yes	No
Clauses 111-112	Yes	Yes	No	No	Yes	Yes	Yes	No
<i>Oversight of functions</i>								
Clause 113-114	Yes	No	No	No	Yes	Yes	Yes	No
<i>Offences: supplementary</i>								
Clauses 115-116	Yes	No	No	No	Yes	Yes	Yes	No
<i>Supplementary</i>								
Clauses 117-119	Yes	No	No	No	Yes	Yes	Yes	No
Schedule 15	Yes	No	No	No	Yes	Yes	Yes	No
PART 5: MISCELLANEOUS								
<i>International healthcare arrangements</i>								
Clause 120	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (S, W and NI)
<i>Social care : regulation and financial assistance</i>								
Clauses 121-122	Yes	No	No	No	Yes	Yes	Yes	No
<i>Professional regulation</i>								
Clause 123	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (S and NI)
<i>Medical Examiners</i>								
Clause 124	Yes	No	No	No	Yes	Yes	Yes	No
<i>Food and drink</i>								
Clause 125	Yes	Yes	Yes	Yes	N/A	N/A	N/As	No
Schedule 16	Yes	Yes	Yes	Yes	N/A	N/A	N/A	No
Clause 126	Yes	No	No	No	Yes	Yes	Yes	No
Clause 127	Yes	Yes	Yes	No	N/A	N/A	N/A	Yes (S and W)
<i>Fluoridation of water supplies</i>								
Clauses 128 and 129	Yes	No	No	No	Yes	Yes	Yes	No
PART 6								
GENERAL								
Clauses 130-135	Yes	In part	In part	In part	N/A	N/A	N/A	No

Subject matter and legislative competence of devolved legislatures

In the opinion of the UK Government, the subject matter of the Bill is within the devolved competence of the Welsh, Scottish and Northern Irish legislatures because it relates to health. Health policy and funding is controlled by the respective Devolved Administrations.

Health is within the competence of Senedd Cymru because it is not a reserved matter under Schedule 7A of the Government of Wales Act 2006. It is within the competence of the Scottish Parliament because it is not a reserved matter under Schedule 5 of the Scotland Act 1998. It is within the competence of the Northern Ireland Executive because it is neither reserved under Schedule 3 to the Northern Ireland Act 1998 nor excepted under Schedule 2 to that Act.

The exceptions are:

- Clause 123: Regulation of healthcare and associated professions. Professional Regulation is reserved under the Scotland Act 1998 with the exception of professions brought into regulation since the Scotland Act 1998 including any professions brought into regulation in the future. Professional regulation is an entirely reserved matter under the Wales Act 2006.
- Clause 109. Restriction of statutory powers requiring disclosure. This clause prevents a UK wide power relating to reserved areas being used to require disclosure of, or to seize, any protected material from the HSSIB and therefore would be outside the legislative competence of the devolved legislatures.
- Clauses 111 and 112. These could have some practical effect in Wales as a result of a request for assistance or agreement in relation to clauses 111 or 112, but this wouldn't involve any devolved legislation being affected.
- Clause 125 and Schedule 16: Advertising of less healthy food and drink. Whilst food and health are within devolved competence in all three settlements, Internet services and broadcasting matters are reserved in all three devolution settlements (sections C10 and K1 of Schedule 5 to the Scotland Act 1998, sections C9 and K1 of Schedule 7A to the Government of Wales Act 2006 and Paragraph 29 of Schedule 3 to the Northern Ireland Act 1998).

HEALTH AND CARE BILL

EXPLANATORY NOTES

These Explanatory Notes relate to the Health and Care Bill as introduced in the House of Commons on 6 July 2021 (Bill 140).

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